UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW HAMPSHIRE, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF WASHINGTON, AND STATE OF WISCONSIN,
***EX REL.* ALLISON KELLY, FRANK GARCIA, AND STEPHEN FAUCI,**

Plaintiffs/Relators,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS AG,
NOVARTIS CORPORATION,
GENENTECH, INC.,
ROCHE HOLDINGS, INC.,
AND THE ROCHE GROUP,

Defendants.

CIVIL ACTION NO. 12-CV-10962-JLT

FILED UNDER SEAL

CONSOLIDATED FIRST AMENDED COMPLAINT FOR DAMAGES, CIVIL PENALTIES, AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FEDERAL CIVIL FALSE CLAIMS ACT AND SIMILAR STATE STATUTES

I. INTRODUCTION: SUMMARY OF FALSE CLAIMS AND DAMAGES TO GOVERNMENTS

1. This is an action brought on behalf of the United States of America, twenty-nine (29) States, and the District of Columbia, by Relators Allison Kelly, Frank Garcia, and Stephen Fauci, under the federal Civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, twenty-nine (29) comparable State False Claims Acts, and the District of Columbia's False Claims Act. Ms. Kelly, Mr. Garcia, and Mr. Fauci are whistleblowers—or "relators" in FCA parlance—who allege that all Defendants, collectively comprising two of the largest pharmaceutical conglomerates in the world, have worked hand in hand, from 2001 forward,[1] to conspire and cause other health care providers ("HCPs")—principally specialty pharmacies, pulmonologists, allergists/immunologists, pediatricians, internists (internal medicine physicians), general practitioners, and family doctors—to overbill federal and State health insurance programs—including Medicare and especially Medicaid[2] (which Defendants have treated as a soft target or "low-hanging fruit"). As explained in detail herein, Defendants have done so by engaging in at least six schemes (some of which overlap to some degree): by (1) illegally off-label marketing and misbranding the asthma drug, Xolair® (generic name Omalizumab), for unapproved indications and dosages; (2) offering, and actually providing, an egregious, vast array of illegal kickbacks to HCPs in their co-promotion of Xolair (the "kickbacks scheme"); (3) falsifying

[1] Although Defendants' "launch" of Xolair formally began in June 2003, their business plans to illegally market Xolair began in 2001—before both the launch and the FDA's limited approval of Xolair in June 2003.

[2] While Medicare is completely funded or almost completely funded by the federal government, Medicaid is heavily funded by both the States and the federal government.

Statements of Medical Necessity ("SMNs") for Xolair, which are effectively prescriptions, and encouraging, aiding, abetting, and causing HCPs and their staffs to falsify them; (4) illegally and misleadingly instructing HCPs to upcode for the administration of Xolair; (5) failing to accurately report and provide the "Best Price" for Xolair to the U.S.A. and States by failing to factor in rebates on Xolair that were inherent in the kickbacks provided to HCPs, and particularly by failing to report that free Xolair is provided to HCPs through Defendants' Wastage Program—all intentionally causing vastly increased reimbursement for Xolair from federal and State health insurance programs.

2. Sixth, one part of kickbacks scheme, the American Express Travelers Cheque Program, has been a Novartis company-wide "pattern or practice." That is, it has not been limited to Novartis' sales of Xolair. There is no conceivable legitimate purpose for distributing these travelers checks to HCPs, their nurses, and other staff. They have been distributed by Novartis in amounts typically ranging from $50.00 to $500.00, and have been used by Novartis sales managers and sales representatives to ingratiate HCPs to Novartis and its sales forces, and thereby achieve access to doctors' offices and boost sales on their expansive line of prescription drugs, including blockbuster drugs and near-blockbuster drugs, like Diovan, Gleevec/Glivec, Neoral/Sandimmune, Lamisil, Zometa, and the many others described herein. A September 2006 Novartis memorandum confirms that it has been a Novartis company-wide program. Hence, this egregious kickback has been utilized by Novartis on a massive scale in all of their billions of dollars in annual drug sales, tainting and rendering void as a matter of law all claims for reimbursement of those drugs that have been submitted to government healthcare programs.

3. Defendants' actions and omissions have caused HCPs around the United States to prescribe and administer Xolair to their patients for illegitimate, off-label purposes that are

invalid for reimbursement; for legitimate purposes that are invalid for reimbursement because they have been tainted by kickbacks; and to inaccurately represent its medical necessity and eligibility for government healthcare program reimbursement, thereby causing improper and illegal reimbursements by federal and State governments. In so doing, all Defendants have violated the FCA, State False Claims Acts, the District of Columbia False Claims Act, Medicare and Medicaid rules, the Anti-Kickback Statute, the Federal Food, Drug, and Cosmetic Act, and other laws and regulations.

4. This action has been brought against Defendants Novartis, AG; Novartis Corporation; its subsidiary Novartis Pharmaceuticals Corporation (the three of which are referred to collectively as "Novartis" because they are interrelated entities that worked in concert and, hence, are common enterprises); Genentech, Inc.; the Roche Group (which acquired Genentech in 2009); and Roche Holdings, Inc. (Genentech, Inc. and The Roche Group's parent company) (the three of which are referred to collectively as "Genentech" because they are interrelated entities that worked in concert and, hence, are common enterprises). Novartis and Genentech have co-marketed Xolair from 2001 forward,[3] and are jointly responsible for the illegal acts regarding Xolair described herein. Thus, they are very frequently referred to herein collectively as "Defendants." In other words, "Defendants," when used herein, refers to all Defendants. In contrast, liability is sought only against Novartis for the American Express Travelers Cheque Program—except insofar as it involved Xolair.

5. The Food and Drug Administration ("FDA") approved Xolair in June 2003 for the treatment of only moderate to severe, persistent asthma in individuals aged 12 and older—if and

[3] As set forth above in footnote 1, Defendants' marketing of Xolair actually began in 2001 prior to the FDA's limited approval of Xolair in 2003 and prior to the formal launch of Xolair in June 2003. Further, as described in detail herein, prior to 2003, Genentech submitted a Biologics License Application ("BLA") to the FDA, which the FDA completely rejected.

only if certain criteria were met: in short, that the patient have a positive skin test or in vitro reactivity to a perennial allergen, and whose symptoms are inadequately controlled with inhaled corticosteroids ("ICSs"). Defendants had hoped that the FDA would approve Xolair for much wider use, including the treatment of mild asthma. That potentially would have allowed for Xolair to become a "blockbuster" drug, i.e., an extremely high-selling drug. But the FDA was very concerned about the lack of scientific evidence of Xolair's efficacy in the treatment of mild asthma. Moreover, the FDA was also concerned about Xolair's many potential serious side effects, including the life-threatening risk of anaphylaxis. Hence, the FDA rejected the broad indication that Defendants had sought.[4]

6. When the Xolair marketing launch began in 2003, which was actually prior to FDA approval later that year, many sales representatives who had been hired or assigned to sell it had been told by managers that "Medicare and Medicaid approvals" were in place. However, it was soon learned that Medicaid approvals had not yet been obtained in most States and the lack thereof would adversely impact the companies' ability to meet revenue targets. (Medicaid approvals were later promptly secured in all or virtually all States—including the States named herein as Plaintiffs. Medicare approval was also later promptly secured.)

7. In 2007, the FDA required that Xolair's label/Product Insert ("PI") carry a "black box" warning. A black box warning is required by the FDA for only a small percentage of drugs that have been FDA-approved, and is the strongest and most serious warning that the FDA may require when a drug is marketed. A black box warning can be just one step short of the removal of a drug from the market. It is a recognition of how harmful the drug can be if given to patients, who are at risk of very serious side-effects. The black box warning was intended to place HCPs

[4] Although both Novartis and Genentech had hoped for a broad indication for Xolair, only Genentech actually submitted the BLA for Xolair.

and patients on more conspicuous notice of the fact that Xolair carries a risk of serious injury or death due to anaphylactic shock. Another Xolair PI warning required by the FDA, but not required to be contained in the "black box," was that a marked increase in the risks of certain kinds of solid tumor cancers can occur after only one year of use of Xolair. More recently, in July 2009, the FDA announced that it is monitoring Xolair's safety data because of interim findings that Xolair also increases the risk of various adverse cardiac events, including arrhythmia, ischemic heart disease, and cardiac arrest. Hence, Xolair carries a host of potential serious side effects, including four life-threatening diseases or events: anaphylaxis, cancers, heart attacks, and heart disease.

8. Independent of the FDA, numerous HCPs have had their serious concerns about Xolair, too. They have been concerned with Xolair's potential dangerous side effects; the limited usefulness of Xolair; and the time commitment, labor commitment, and high costs of administering Xolair—because it is a biologic product that is injected subcutaneously—in contrast to competing, FDA-approved ICSs, like Advair, as well as other drugs, like Singulair (a pill; not a steroid like Advair). Advair and Singulair cost a small fraction of what Xolair costs, and have been proven to be highly effective to treat mild, moderate, and severe asthma. With an annual cost per patient averaging approximately $10,000 to $24,000 per year, Xolair is extremely expensive. (Xolair costs about $548 per vial, and with a recommended dosage of 1-3 vials every 2 weeks for a maximum of 6 vials, treatment can cost as much as about $6,576 every 4 weeks.)

9. For the above reasons, many health insurance companies and managed care organizations ("MCOs") have been cautious about approving the use of Xolair. Anticipation and appreciation of that fact has prompted Defendants to focus a lot of their sales forces

(and customers/HCPs) upon seeking reimbursement from government healthcare programs, like Medicare and especially Medicaid. (However, many MCOs are also largely funded by Medicare and/or Medicaid.)

10. As suggested above, some doctors also have been reluctant to prescribe Xolair because they have been reasonably concerned that it would harm their bottom line—i.e., by increasing office/administrative costs and interfering with doctors' "bread and butter"—for example, for allergists/immunologists, immunotherapy (allergy shots) and, more recently, rush immunotherapy (allergy shots concentrated over a short amount of time). Xolair sales managers and representatives have been instructed to counter this hesitancy with every marketing tool at their disposal—including the off-label marketing scheme and kickbacks scheme set forth herein.[5]

11. Faced with these major obstacles to high sales—all stemming from the high expense, questionable efficacy, and high-risk side effects of Xolair—Defendants responded not by accepting the legal limitations of the drug, but rather by disregarding patient safety, the wisdom of the FDA, and the concerns of numerous medical practitioners, by aggressively and illegally marketing Xolair to HCPs for use by patients with mild or "active" asthma, by patients with moderate to severe asthma who did not meet all FDA criteria, by patients who merely suffer from seasonal allergies or the "allergic cascade" that could culminate with an asthma attack, and

[5] As used throughout this Complaint, "Xolair sales managers and representatives" usually means "the Xolair sales representative and, less frequently but to no small extent, the Xolair sales manager," because the vast majority of oral and written Xolair sales and marketing communications between Defendants and HCPs are conducted through Xolair sales representatives. However, at times Xolair sales representatives are accompanied by Xolair sales managers on sales calls to HCPs; at other times Xolair sales managers conduct their own sales calls on HCPs; and very frequently Xolair sales managers have gone through sales training that includes (but is often more extensive than) substantially the same sales training that Xolair sales representatives undergo. Furthermore, "Xolair sales managers and representatives" is frequently stated because Xolair sales representatives largely act under the direction and control of Xolair sales managers.

by patients who were required to be administered either less or no Xolair because of their serum total immunoglobulin ("IgE") level and/or body weights.

12. From 2003 forward,[6] Defendants have aggressively marketed the term and concept of "active asthma." As used by Defendants, "active asthma" intentionally, loosely refers to asthma in patients who either have been diagnosed with any degree of asthma, or who have experienced asthma symptoms to any extent within the past year. Defendants also have aggressively marketed the term and concept of an "allergic cascade," to refer generally to the build-up of allergy symptoms that may precede an asthma attack in patients suffering from "allergic asthma." In addition, the "allergic cascade" can be involved in other allergic conditions that are not associated with asthma (like allergic reactions to peanut, latex, milk, eggs, nuts, shellfish, strawberry and tomatoes). Defendants have instructed their Xolair sales managers and sales representatives to speak with HCPs about "active asthma," allergies, and the "allergic cascade"—instead of the FDA criteria for diagnosis of moderate to severe, persistent asthma, and the requirement that the asthma symptoms be inadequately controlled with inhaled steroids—to redirect HCPs' focus from the FDA's limited indication for Xolair, to a much larger Xolair patient population that would fall under these broad and vague terms. This means of promotion necessarily (a) has encompassed a far larger patient population pool than those with moderate to severe, persistent asthma; (b) has meant that Xolair has been promoted to patients with mild asthma; (c) has meant that Xolair has been promoted to patients with allergies, but not necessarily asthma; and (d) has run directly contrary to the limited indication approved by the FDA for Xolair. Allergies are, of course, distinct medical conditions from the disease of asthma. Moreover, Xolair has never been FDA-approved to preempt the specific allergic reactions that

[6] Unless otherwise specified herein, all of Defendants' illegal activities are alleged to have occurred from 2003 forward.

could contribute to asthma attacks. Defendants have even boldly and illegally off-label marketed Xolair to HCPs for the treatment of asthmatics under the age of 12—frequently targeting pediatricians for this purpose, even though the FDA also rejected Xolair for the treatment of any form of asthma in children under age 12.

13. Furthermore, in the course of promoting Xolair for uses that the FDA has never approved, Defendants' Xolair sales forces—under the direction and pressure of supervisors—have failed to disclose to HCPs, or have concealed and deemphasized to HCPs, the critical facts that: (a) the evidence from the very studies upon which Defendants had relied to obtain FDA approval of Xolair, fail to show any benefit for patients with mild asthma; (b) Xolair's safety and efficacy has not been established as to any other condition besides that for which it has been expressly indicated; (c) the FDA has required that the previous two facts be included in Xolair's labeling; and (d) Defendants never have completed a study of Xolair's efficacy and safety for treating mild cases of asthma, despite the fact that the companies had committed to undertaking and completing such a study by November 30, 2005, as a condition for receiving FDA approval in June 2003.

14. In short, Defendants determined as early as 2003 that they would never succeed in transforming Xolair into a blockbuster or near-blockbuster drug unless they broke the law. And that is exactly what they have knowingly done, by aggressively and illegally marketing Xolair, on a national basis, to induce HCPs to prescribe Xolair for wide-ranging use—despite the drug's very limited efficacy and proven threats to patient safety.

15. Defendants' national campaign to aggressively off-label market and misbrand Xolair, induce HCPs to prescribe Xolair, and boost Xolair sales, has been extremely successful. A FDA report concerning Xolair, dated July 9, 2009, shows that FDA scientists analyzed data

provided by Wolters Kluwer (a healthcare data collection service) and found evidence of widespread off-label use of Xolair. To quote the FDA report in most relevant part:

> According to Wolters Kluwer nation-wide estimate, 18,000 patients received a medical or prescription claim for [Xolair] in 2008, and approximately 89% of these patients were 18 years or older. The co-dispensing analysis revealed that during 2008 29% of patients did not receive another asthma medication and only 13% of asthmatics received a single class of medication along with their [Xolair] prescription. Based on this drug use data, about 1/3 of asthmatics are using [Xolair] as single treatment product, and in about 43% of asthmatics in the database, [Xolair] is possibly utilized by patients with mild asthma. This data raises two intriguing observations: 1) [Xolair] is being utilized outside its approved indication and outside the recommendations of national and international guidelines, and 2) the primary patient population that receives the drug (i.e., those with mild intermittent asthma) failed to show efficacy. This suggestion of mis-use or inappropriate use of [Xolair] is of concern.
>
> Risk/Benefit of Omalizumab, July 9, 2009, Dept. of Health & Human Services, Public Health Service, Food & Drug Administration, Center for Drug Evaluation & Research, Office of Surveillance & Epidemiology, at 35 (emphasis in underlining added).

16. In 2011, the FDA again found evidence of off-label use of Xolair—this time regarding the treatment of children under age 12: "The labeled indication for Xolair is moderate to severe persistent asthma in patients aged 12 years and older. Although the use appears to be low, the analyses in this review suggest that Xolair is used in patient aged less than 12 years old for asthma as well as for off-labeled indications other than asthma." Xolair Drug Use Review, Dec. 5, 2011, Dept. of Health & Human Services, Public Health Service, Food & Drug Administration, Center for Drug Evaluation & Research, Office of Surveillance & Epidemiology, at 7.

17. Thus, this is that extremely rare FCA lawsuit, in which FDA scientists, through their own analyses, have observed that off-label use of a drug is widespread and troubling (without even knowing that Relators previously, in 2006, had formally blown the whistle on

Defendants' off-label marketing of Xolair).[7] As shown above, in 2009 FDA researchers expressly found that about one-third of asthmatics receiving Xolair were apparently using it as a single treatment product—a fact only consistent with use of the drug for the mildest form of the condition: mild intermittent asthma. FDA researchers estimated that, overall, 43% of Xolair prescriptions written during the 2008 sample year were for mild asthma and were, thus, off-label.

18. Because Defendants have routinely marketed and promoted Xolair through oral and written off-label statements that mild asthma is one of the possible uses of Xolair—a use which was not FDA-approved and as to which the drug's safety and efficacy has never been established—the drug's labeling does not bear adequate directions for the "purposes for which it is intended." Defendants therefore have misbranded Xolair, making it ineligible for reimbursement under government healthcare programs.

19. Defendants have illegally induced HCPs to prescribe Xolair by coaching them, through incorrect and misleading information—provided by Defendants themselves and through its retained independent contractor, the LASH Group—that they can submit claims for reimbursement for the administration of Xolair at improper rates: by advising HCPs to bill for patient levels 4-5 when only patient levels 1-2 were normally proper, and by advising HCPs to use improper medical current procedural terminology ("CPT") and diagnosis codes ("ICD-9s"), to ensure coverage and reimbursement at higher rates.

20. From 2003 forward, Defendants have aggressively and illegally marketed Xolair by providing a panoply of valuable kickbacks to HCPs (doctors, nurses, and doctors' additional staff), to induce them to overlook the drug's very troubling profile. These kickbacks, which have

[7] The FDA report does not constitute a "public disclosure" of prohibited off-label marketing; it only discusses off-label use.

targeted HCPs who have prescribed Xolair or have been in a good position to prescribe Xolair, are clearly "over the top":

I. Free Cash Equivalents and Expensive Gifts

> *American Express travelers checks (the equivalent of cash gifts)—The American Express Travelers Cheque Program has been a Novartis company-wide "pattern or practice." That is, it has not been limited to Novartis' Xolair sales franchise. There is no conceivable legitimate purpose for distributing these travelers checks to HCPs, their nurses, and other staff. They are like cash, because they can be redeemed for cash or used to purchase items at virtually any store, restaurant, or other retail establishment that accepts them. They have been distributed by Novartis in amounts typically ranging from $50.00 to $500.00, and have been used by Novartis sales managers and sales representatives to ingratiate HCPs to the Xolair and other Novartis drug sales forces and achieve access to doctors' offices. Co-Relator Allison Kelly used and observed this program not only as a Xolair sales representative from July 1, 2003 through March 22, 2007, but also previously as a Novartis Diovan and Lotrel sales representative from April 1, 2001 through June 30, 2003. A September 2006 Novartis memorandum (which is attached to this Complaint) confirms that it is a company-wide program. Hence, this most egregious of kickbacks has been utilized by Novartis on a massive scale in all of their billions of dollars in annual drug sales. It extends to Novartis' many blockbuster drugs, near-blockbuster drugs, and other drugs, invalidating government healthcare program reimbursement for all of those drugs' sales. (A summary of the extent of those many billions of dollars of drug sales is set forth herein.);

> Expensive tickets to sports and entertainment events (e.g., prime seats to New York Yankees and Boston Red Sox games);

> High–value celebrity and sports memorabilia (including celebrity autographed items);

> Underwriting HCPs' "open houses" (payments for expensive parties when doctors open new offices or relocate and seek to demonstrate or advertise their relocation or growth);

> Payments for advertising (print advertisements, flyers, and even billboards) for HCPs who prescribe Xolair;

> Opulent meals and expensive drinks for HCPs, nurses, and other staff, with honoraria of $1,000.00 to $3,000.00 paid to speakers (comprising a

nationwide "speakers bureau") who frequently do not even speak about asthma, or make limited remarks about it;

> $500.00 payments to physicians for "preceptorships" (allowing sales representatives and/or managers to tag along for alleged educational purposes, when asthma patients are purportedly being seen by the physicians; in actual practice, these preceptorships are frequently no more than payments for access to HCPs, with Xolair sales representatives frequently visiting HCPs at times when the HCPs are not even seeing Xolair asthma patients—or even asthma patients in general);

> Other valuable items (If a HCP enjoys a particular delicacy or hobby, sales representatives and/or managers may target—and of have targeted—that HCP with gifts of that delicacy or hobby (e.g., fine wines, cheeses, golf clothes or equipment));

> Unrestricted grants to HCPs to allow HCPs to pay for a broad array of valuable items, including some of the above-described items;

> Patient Experience Program ("PEP") payments and co-payment waivers:

Under one part of Defendants' PEP, Defendants forgive the co-payments of patients who agree to speak favorably about asthma treatment with Xolair. This helps ensure that the patients continue with treatment by the HCP, because the expensive co-payments constitute a reason that the patient might discontinue taking Xolair. But it is frequently the sales representatives themselves who call into Defendants or go online to register the patients' "experience" with Xolair, in lieu of the patients themselves, creating false and unreliable data that is fed into the Xolair TENOR study—i.e., to "pad" the study. Defendants have been fully aware of this fact—even encouraging it. (The TENOR study is a Novartis- and Genentech-sponsored "scientific" study on the quality-of-life scores of patients taking Xolair—with patients taking Xolair who, it is previously determined, will state that they have had a positive experience with the drug. This removes the random, scientific nature that is expected of such a study.) Under another part of the PEP, patients are paid cash or reimbursed to speak favorably about Xolair. For example, many patients were flown to Arizona, with all expenses paid and payment of a stipend, for Defendants to train these patients to speak favorably about their Xolair experiences at future patient speaker events, and to study how to further maximize their experiences for marketing purposes. The patient speakers are then also paid for their future speaking events (speaking to HCPs and prospective Xolair patients), with the speakers' travel, hotel, food, and other expenses paid by Defendants—as well as that of many of the HCPs in attendance.

> One of the highest prescribers of Xolair in the country, Dr. Mridula Gupta Noori, was given the exorbitant kickback of being treated to the "President's Club" in the Bahamas (an opulent, all-expense paid trip to a Bahamas resort, which is normally only provided to the most successful sales representatives, sales managers, and select company executives);

> Gift certificates to opulent restaurants;

> Expensive pens, often engraved with HCPs' names;

> "Premium" gifts, including expensive medical books (e.g., sought-after anatomy books with color drawings);

> HCP speaker training events in which Defendants pay for the HCPs' lavish travel expenses, hotel, meals, and drinks;

> Opulent "roundtable" meals and expensive alcoholic drinks;

> Speaker programs at country clubs and casinos, with lodging, meals and drinks paid for;

> Office parties for HCPs, their staffs, and guests (e.g., birthday parties, holiday parties, pizza parties);

> "Happy hours" at bars and restaurants for HCPs, their staffs, and guests;

> Expensive gourmet food and wine gift baskets/bottles of wine;

> Bogus/fake studies led by physician key opinion leaders ("KOLs") /"thought leaders," with payments by Defendants to the KOLs (e.g., the TENOR study);

> Lucrative payments to "advisory ('ad') board" members—both physician ad boards and nurse ad boards—with the main purpose being payments to the physicians and nurses "serving on them," to ensure the prescribing of Xolair, as opposed to a bona fide program of paying HCPs for advice about asthma and/or patients' experience with Xolair; and

> Wastage Program (a Xolair replacement/reimbursement program that ensures that HCPs will not be out of pocket, for example, for any vials of Xolair that are not used because of a patient "no-show" or because one or more vials is spilled, lost, or broken).

II. Free Medical & Office Equipment: Defendants have provided a variety of

expensive equipment to HCPs to induce them to administer Xolair because these free items are calculated to ingratiate HCPs to Defendants and their Xolair sales forces, and because storing and mixing/reconstituting Xolair, testing IgE levels, and tracking asthma patients are all expensive, time-consuming propositions for the many HCPs, who, in contrast, do not incur these major expenses in prescribing FDA-approved competitor drugs like Advair and Singulair. However, these expenses are overhead/expenses required to be borne by the HCP, and are not unique medical expenses only associated with prescribing Xolair.

> Free swirlers/spinners (for mixing Xolair);

> Free pulmonary function machines (to test for asthma);

> Free refrigerators (to store Xolair);

> Free IgE test kits (to test for asthma);

> Free computers (to register and track asthma patients); and

> Free 10cc diluent (preservative-free sterile water for injection), 3cc syringes, 18-gauge large-bore needles for reconstitution, 25-gauge needle for administration, alcohol swabs, and Sharps containers.

Many of the above-listed pieces of equipment each cost hundreds of dollars, as detailed below.

III. Free Services: Defendants have provided a variety of free services to HCPs, which are normally overhead/expenses to be borne by the HCP, because of Defendants' calculation that providing these free services ingratiate HCPs to Defendants and their Xolair sales forces, and because of Defendants' deep concern that prospective prescribers of Xolair would not prescribe the drug because of the administrative hassles and expenses of doing so.

> Sales representatives and managers have singled out asthma patients by sorting through and tabbing HCPs' patient charts and/or HCP computer records—a task to be performed, if at all, by the HCPs and/or their staff;

> Sales representatives and managers have filled out Statements of Medical Necessity ("SMNs") for HCPs and their staffs, have obtained physicians' signatures, and have sent them to specialty pharmacies, health insurers, MCOs, and/or government healthcare programs, to ensure that HCPs actually prescribe Xolair (SMNs are, effectively, prescriptions.);

> Sales representatives and managers have filled out appeals letters for HCPs when health insurers, MCOs, and/or government healthcare

programs deny approval for Xolair;

> Defendants have provided for delivery of Xolair to patients in their homes, to reduce the costs to HCPs of administering Xolair, despite the fact that the FDA-approved indication for Xolair requires administration of the drug in a medical office or hospital because of the serious risk of anaphylaxis and other serious side effects; and

> As noted above, Defendants have systematically provided coding and reimbursement assistance to HCPs—both directly and by hiring the LASH Group to provide such assistance (to relieve HCPs of customary overhead, to advise HCPs to bill for patient levels 4-5 when patient levels 1-2 were proper, and to advise HCPs to use improper CPT codes and/or ICD-9s to ensure coverage and higher reimbursement).

21. Because several components of this kickbacks scheme have been "national programs"—i.e., systematically conducted by Defendants on a nationwide basis, with the requirement that Xolair sales representatives carry out their directives—all of Defendants' Xolair sales that were funded to any extent by a government healthcare program are tainted and illegal as a matter of law.

22. In addition, Defendants' off-label marketing of Xolair was so widespread and integral to their marketing and sales practices—a veritable job requirement for Xolair sales representatives to meet sales quotas and keep their jobs—that all of Defendants' Xolair sales from 2003 forward that were funded to any extent by a government healthcare program are also illegal as a matter of law for this reason.

23. Many of the above-summarized free services to HCPs involve violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, insofar as patients do not give informed consent to allow Defendants to access their private health records for Defendants' improper purposes.

24. Because Defendants' illegal schemes to boost sales of Xolair have been successful, the drug actually has achieved "blockbuster" or "near-blockbuster" status. In 2003,

the year in which Xolair was launched, the revenue was only about $25 million. Since then, sales of Xolair have far exceeded goals, and have increased steadily and dramatically (e.g., $187 million in 2004, $320 million in 2005). The Defendants' goal for 2006 was initially $410 million, but at the "kickoff" meeting for 2006, sales representatives were asked by managers to bring in $500 million. This was referred to by company officials as the "half a billion dollar challenge."

25. From 2003 through 2011, approximately $4.2 billion of Xolair was sold in the U.S.A.[8] From 2003 through 2008 alone, there were approximately $1.9 billion in Xolair sales in the United States. After 2008, Xolair sales increased greatly, despite the FDA's addition of a "black box" warning to Xolair's label in 2007. Conservatively, twelve percent (12%) of these $4.2 billion in U.S. Xolair sales have been financed through public funds—taxpayer money. Defendants have been fully aware, at all relevant times, of the huge contributions that government healthcare programs have made towards the drug's sales and profitability. According to public records from the federal government, from 2003 through 2011 alone, the States reimbursed claims for 293,465.29 Xolair units through the Medicaid Program, with total State/Medicaid reimbursement for Xolair equaling approximately $292 million during that time period, as detailed herein. From February 1, 2008 through January 31, 2011 alone, under Medicare Part B alone (i.e., excluding Medicare Part D), Medicare Part B processed 157,580 claims for Xolair using procedure code J2357, allowed 8,178,511 units, and paid out $119,981,029. Thus, from 2004 through 2011 alone, Defendants illegally obtained

[8] Sources: gene.com (Genentech's website), Roche and Genentech's annual reports from 2004 through 2012, Novartis 6-Ks filed with the SEC from 2004 through 2012, Bloomberg.com, pdl.com, and drugs.com. These sales are broken down as follows, by year: $25.1M in 2003, $187.6M in 2004, $320.6M in 2005, $425M in 2006, $472M in 2007, $517M in 2008, $571M in 2009, $985M in 2010, and $705M in 2011.

approximately $412 million in federal and State funds—without even including all Medicare Part D reimbursement.

26. Pursuant to 31 U.S.C. § 3730(b)(2), and comparable provisions in State False Claims Acts, this action has been brought *in camera* and filed under seal. The U.S.A. and various States declined to intervene in the 2006 action initiated by co-Relators Allison Kelly and Frank Garcia, and joined by co-Relator Stephen Fauci, but have expressly allowed Relators to pursue this case for their benefit under the FCA and State False Claims Acts—as permitted by these statutes.

27. It is well settled that government "declinations"—i.e., decisions not to intervene—are not reflections of the merits of a case; the U.S.A. and the States do not have endless resources to combat fraud and false claims. A declination only means that the government is not intervening at this time. In any event, one or more governments could still decide to intervene in the future—for example, at the close of discovery or shortly before trial.[9]

[9] As the U.S.A. recently wrote in a Statement of Interest in *U.S.A. ex rel. Spay v. CVS Caremark Corp.*, Case No. 09-4672 (E.D. Pa. Sept. 10, 2012): "The Government's decision whether or not to intervene is based on many factors, including questions of resource allocation and judgments as to which types of cases it chooses to pursue at a given time. Moreover, the FCA expressly gives the United States the right to reconsider its decision not to intervene at later stages of the case (for example, after discovery)….Courts 'do not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrongdoing insufficient or the qui tam relator's allegations for fraud to be without merit. In any given case, the government may have a host of reasons for not pursuing a claim.' *U.S.A. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) (The United States' 'absence from the fray' does not mean that the relator's claims lack merit). 'Non-intervention does not necessarily signal government disinterest in an action,' *U.S.A. ex rel. DeCarlo v Kiewet/AFC Enters.*, 937 F. Supp. 1039, 1047 (S.D.N.Y. 1996). It signals that the United States is not intervening – no more, no less." In further support, the U.S.A. cited the following cases: *U.S.A. ex rel. Chandler v. Cook Cty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003); *U.S.A. ex rel. Al-Amin v. George Washington Univ.*, 533 F. Supp.2d 12, 21-22 (D.D.C. 2008); *Anderson v. McTish, Kunkle & Assocs.*, No. 4:CV-04-754, 2006 WL 1985762, at *1 n.1 (M.D. Pa. July 13, 2006).

28. Ms. Kelly is a former employee of Novartis. Her allegations arise from her first-hand, inside knowledge of Defendants' practices, learned throughout the course of her full-time employment by Novartis from May 1, 1999 through March 23, 2007—a period of almost eight years. She was employed as a Xolair sales representative for nearly four years—during approximately the second half of her employment. Like so many other employees of Defendants', she carried out very many of these practices, at the direction of Defendants—the architects of the fraud. Defendants frequently have misled their sales forces about Defendants' activities, creating a false impression that they are legal, and hiding from them a substantial amount of information about Xolair's side effects. Defendants' sales representatives and sales managers also have acted under extremely high pressure by Defendants to meet sales objectives—at risk of losing their jobs. In short, the focus of this lawsuit's allegations is against the Defendants.

29. The same points made in the preceding paragraph are also true for co-Relators Frank Garcia and Stephen Fauci, during their respective periods of employment by Genentech. Genentech employed Mr. Fauci as a pharmaceutical sales representative for approximately five years, with approximately the last two years spent as a Xolair sales representative. Genentech employed Mr. Garcia as a Xolair sales representative for approximately one year. Collectively, Relators spent approximately six-and-a-half years selling Xolair; interacting with sales managers, other Xolair sales representatives, and HCPs; and obtaining inside information concerning the schemes detailed herein.

30. Relators do not allege any legal violations by the overwhelming majority of HCPs that Defendants caused to submit false claims to government healthcare programs, through the Center for Medicare and Medicaid Services ("CMS"). Had the Defendants not distributed a vast

array of kickbacks, engaged in extensive off-label marketing, misled HCPs into using improper billing codes, and mischaracterized the safety and efficacy of Xolair, the United States Treasury and the treasuries of the 29 States and the District of Columbia, would not have been overbilled.

31. Through all of these actions, which are further detailed below, and corroborated by and memorialized in numerous attachments to this Complaint which are incorporated herein by reference, Defendants have caused the submission of false claims to government entities; have made, used, or caused to be made, false records or statements to get false or fraudulent claims to be paid by Medicare, Medicaid, and other government health care programs; and have conspired to do so—all in violation of the federal FCA and State False Claims Acts. From 2001 through the present, and continuing, Defendants marketing plan, devised at a senior executive level, has been to exploit government healthcare programs, including Medicare and Medicaid, with the direct and intended effect of causing the submission of false claims to such programs. Numerous top-level executives with Defendants, as well as high-level and mid-level managers, have not only been aware of Defendants' off-label marketing scheme, kickbacks scheme, and the other schemes detailed herein, but have played an active role in supporting and promoting the schemes.

32. As a result of Defendants' actions, they are jointly liable for treble damages, civil penalties of $5,500.00 to $11,000.00 per false claim, and all other damages in the premises, to the United States Treasury, as well as the treasuries of the 29 States and the District of Columbia, in an amount conservatively estimated to exceed $1.5 billion in treble damages, and many billions more in civil penalties.

33. All of the above-summarized allegations are described below in great detail.

II. JURISDICTION AND VENUE

34. These claims arise under the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), as amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, as well as 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 & 3730.

35. Under the FCA, this Complaint has been filed *in camera* and under seal.

36. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a), which provides: "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants any one defendant, can be found, resides, transacts business or in which any act proscribed by § 3729 occurred." All Defendants have transacted business in the District of Massachusetts.

37. This Court also has supplemental jurisdiction over the claims brought pursuant to the California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin False Claims Acts, pursuant to 28 U.S.C. § 1367, which provides that "in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

38. The above-listed States have enacted their own FCAs, which very closely track the federal FCA, including, but not limited to: the California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; the Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-305 *et seq.*; the

Connecticut False Claims Act, Conn. § 17b-301 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*; the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*; the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; the Georgia False Medicaid Claims Act, O.C.G.A. § 49-1-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, IC § 5-11-5.5; the Iowa False Claims Act, § 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, § 437.1 *et seq.*; the Maryland False Claims Act, Md. Health-General Code Ann. § 2-601 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*; the Michigan Medicaid False Claims Act, MI ST Ch. 400 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Montana Code § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. RSA § 167:61-b *et seq.*; the New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468); the New York False Claims Act, N.Y. C.L.S. St. Fin. § 187 *et seq.*; the North Carolina False Claims Act, N.C. Art. 52, § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. Title 63, § 5053.1 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws, § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01- 216.1 *et seq.*; the Washington Medicaid Fraud False Claims Act, R.C.W. § 74.09.201 *et seq.*, and the Wisconsin False Claims Act, Wisc. Stat. § 20.931 *et seq.* These State False Claims Acts and the District of Columbia Procurement Reform Amendment Act apply, *inter alia*, to the state portion of Medicaid fraud

losses caused by false Medicaid claims submitted to the jointly federal-state funded Medicaid Program.

III. PARTIES

39. *Qui tam* Relator **Allison Kelly** ("Relator") is a person of the full age of majority and a resident of Scarsdale, New York. She is a former employee/pharmaceutical sales representative of Novartis. She first started working for Novartis on May 3, 1999 as a sales representative, selling Novartis products within the Ciba Sales Division (cardiovascular sales: Diovan, Lotrel, Famvir, and Lescol) in the Bronx/Westchester, New York area. She was then promoted to the respiratory dermatology division (selling Elidel, Ritalin, Focalin, and Lamisil). In June 2003, as Xolair was about to be launched, she was promoted again, this time to the Xolair sales force under the respiratory dermatology division. In that role, she reported first to Frank Garay, then to William Stewart, then to acting manager Daniel Giunta, and finally to Martin Clark. The Regional Director for the "Xolair franchise" is Elizabeth Johnson, who has held that position since August 2005, taking over for her predecessor, Norbert Stone. Ms. Kelly was employed as a Xolair sales representative from July 1, 2003 through March 23, 2007—a period of nearly four years.

40. Ms. Kelly was assigned by Novartis to market and sell Xolair to HCPs in the Bronx/Westchester area of New York, under a co-marketing arrangement between Novartis and Genentech. Through this assignment, Ms. Kelly worked closely with co-Relator Frank Garcia.

41. *Qui tam* Relator **Frank Garcia** ("Relator") is a person of the full age of majority and a resident of New York City, New York. He is a former employee/pharmaceutical sales representative of Genentech.

42. Mr. Garcia was also paid to market and sell Xolair in the Bronx/Westchester area of New York. He worked as a pharmaceutical representative in Genentech's Respiratory Division from June 2003 through May 2004. During that time period, he reported to a Genentech District Manager, Jerry Kelly, who was responsible for Xolair sales for the New York Metropolitan District. During that time period, Genentech's Xolair Regional Manager—for the full Northeast Region—was Kelli Wilson, who was based in the Boston area.

43. Ms. Kelly and Mr. Garcia frequently attended staff meetings, conferences, briefings, and debriefings together, and often received instructions together as part of the joint Novartis-Genentech sales force for the co-marketing of Xolair. As part of their assignment to work together, they also had direct communications with physicians—including pulmonologists, allergists, internists, pediatricians, general practitioners, and family doctors—to whom Defendants' Xolair marketing was directed.

44. *Qui tam* Relator **Stephen Fauci** ("Relator") is a person of the full age of majority and a resident of the Commonwealth of Massachusetts, specifically residing at 4 Kelley Lane, Middleton, Massachusetts. Like Mr. Garcia, he is also a former employee/pharmaceutical sales representative of Genentech.

45. Genentech employed Mr. Fauci as a pharmaceutical sales representative for approximately five years—first as a clinical specialist and then, after promotion in October 2004, as a senior clinical specialist. In or about March 2003, Mr. Fauci was moved to Genentech's Xolair franchise. Mr. Fauci was selected in 2004 to serve on Genentech's National Xolair [Sales] Representative Panel. His employment ended in April 2005, after spending approximately two years as a Xolair sales representative.

46. All three Relators received recognition from their employers for achievements as sales representatives. For example, Mr. Fauci was voted Northeast ("Patriot" division) MVP by his peers in December 2004, and Ms. Kelly ranked third in the nation in Novartis' "PEP Blitz" from September through October 2006 and won the East Area Xolair award in February 2005.

47. Relators bring this action on behalf of themselves and, much more importantly, on behalf of the United States of America, as well as the twenty-nine (29) States and District of Columbia named herein as Plaintiffs.

48. Relators have standing to bring this action on behalf of the United States pursuant to 31 U.S.C. § 3730(b)(1).

49. Relators bring this action based on their direct and independent knowledge, from first-hand experience and from examination of many thousands of pages of documents from the Defendants during their employment.

50. None of the allegations set forth in this Complaint are based on a "public disclosure" as set forth in 31 U.S.C. § 3730(e)(4).

51. Notwithstanding same, Relators are "original sources" of the facts alleged in this Complaint.

52. As former employees, Relators have direct and independent knowledge of the allegations in this Complaint.

53. As pharmaceutical sales representatives, Relators attended meetings and were privy to numerous internal communications and discussions (including e-mails) regarding the marketing of the Xolair (and for Ms. Kelly, Xolair and all of the other Novartis drugs described herein).

54. Relators have both personal and inside knowledge of Defendants' purposeful, nationwide schemes of illegally (1) off-label marketing/misbranding of Xolair; (2) offering and actually providing kickbacks to HCPs to promote both off-label and on-label sales of Xolair; (3) causing their own sales forces and others to falsify SMNs for Xolair; (4) instructing and inducing HCPs to bill for patient levels 4-5 when patient levels 1-2 were proper, and advising HCPs to use improper CPT Codes and ICD-9s to ensure coverage and reimbursement at higher rates; (5) failing to accurately report the "best price" for Xolair; and (6) all other illegal conduct concerning Xolair described herein.

55. Ms. Kelly also has both personal and inside, direct and independent knowledge of Novartis' nationwide scheme with respect to the other Novartis drugs described herein.

56. Like other employees of Defendants, Relators bent under great pressure from managers and executives, and financial pressures, to engage in many of the acts that are detailed herein—including off-label marketing and distribution of kickbacks.

57. For example, Mr. Fauci dispensed kickbacks for the benefit of Defendants.

58. Similarly, Ms. Kelly followed supervisors' instructions to fill out SMNs, off-label market, and provided a wide array of kickbacks to HCPs. Mr. Garcia also off-label marketed Xolair and distributed kickbacks to HCPs.

59. Prior to filing this Complaint, Relators have provided to the Attorney General of the United States, the United States Attorney for the District of Massachusetts, and the State Attorneys General of the States identified in the Complaint, a confidential statement of material evidence and information related to this Complaint.

60. Defendant **Novartis Pharmaceuticals Corporation** is a New Jersey-based pharmaceutical subsidiary of Novartis Corporation. It is headquartered at One Health Plaza,

East Hanover, New Jersey, and is incorporated under the laws of the State of Delaware. Novartis Pharmaceuticals Corporation has locations in New York, New Jersey, and California. As the pharmaceuticals unit of Novartis Corporation and Novartis AG, Novartis Pharmaceuticals Corporation develops, manufactures, sells, and markets Novartis Corporation and Novartis AG's drugs in the United States.

61. Defendant **Novartis Corporation** (traded on the NYSE as "NVS") is a New York corporation, formed in 1966, with locations in New York, New Jersey, and the District of Columbia. Its corporate headquarters is located at 608 5th Avenue, New York, New York 10020. Novartis Corporation is essentially the U.S. headquarters of Switzerland-based Novartis AG. Novartis Corporation handles the administration, sales, and marketing of a wide variety of prescription drugs, vaccines, consumer medicines, and veterinary products. It is the parent corporation of Novartis Pharmaceuticals Corporation—its and Novartis AG's pharmaceuticals unit.

62. Defendant **Novartis AG** is a publicly traded, diversified pharmaceutical conglomerate with operations throughout much of the world, including the United States. It is headquartered in Basel, Switzerland, specifically at Lichtstrasse 35, Basel CH 4056, Switzerland. It is the parent company of U.S.-based and incorporated Novartis Corporation and Novartis Pharmaceuticals Corporation.

63. **Defendants Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG are referred to herein collectively as "Novartis"** because they have worked in concert and as a joint or common enterprise in marketing and selling Xolair, and the other drugs described herein, and have engaged collectively in the acts set forth in this Complaint.

64. At all times relevant hereto, Novartis has acted through its agents and employees, and the acts of its agents and employees have been within the scope of their agency and employment. The policies and practices alleged in this Complaint have been established and/or ratified at the highest corporate levels of Novartis.

65. Defendant **Genentech, Inc.** (traded on the NYSE as "DNA") is a United States pharmaceutical subsidiary, with its headquarters at One DNA Way, South San Francisco, California, and is incorporated under the laws of the State of Delaware.

66. In March of 2009, Genentech, Inc. was acquired by, merged into, and became a member of Defendant, the **Roche Group**, through a merger agreement. With that merger, Roche and Genentech, Inc. combined their pharmaceutical operations in the United States. The Roche Group is responsible for the acts and liabilities of Genentech, Inc. after the merger in March 2009 and through the present. It is not presently known whether the Roche Group is a U.S. corporation, or is organized under the laws of a foreign nation. It is possibly merely a trade name of Roche Holdings, Inc., a U.S. corporation.

67. Defendant **Roche Holdings Inc.** is a pharmaceutical corporation, headquartered at 340 Kingsland Street, Nutley, New Jersey 07110-1150, and is incorporated under the laws of Delaware.

68. **Defendants Genentech, Inc., the Roche Group, and Roche Holdings Inc. are referred to herein collectively as "Genentech"** because they have worked in concert and as a joint or common enterprise that have marketed and sold Xolair and have engaged collectively in the acts described in this Complaint.

69. Genentech is a biotechnology company that discovers, develops, manufactures, markets, and sells pharmaceuticals/drugs.

70. At all times relevant hereto, Genentech has acted through its agents and employees, and the acts of its agents and employees have been within the scope of their agency and employment. The policies and practices alleged in this Complaint have been established and/or ratified at the highest corporate levels of Genentech.

71. Further, Novartis and Genentech have worked in concert, jointly marketing and selling Xolair, and engaging collectively in, and conspiring in, the acts described in this Complaint.

72. The **United States of America** is a plaintiff in this action. The United States brings this action on behalf of HHS, CMS, and the United States Treasury.

73. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been prescribed by HCPs and provided to Medicare, Medicaid, and other government healthcare program recipients/beneficiaries, and normally have been covered benefits under these programs.

74. The **State of California** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients in California and have been a covered Medicaid benefit under its Medi-Cal Program.

75. The **State of Colorado** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair**,** and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

76. The **State of Connecticut** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to

Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

77. The **State of Delaware** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

78. The **District of Columbia** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

79. The **State of Florida** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

80. The **State of Georgia** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

81. The **State of Hawaii** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

82. The **State of Illinois** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

83. The **State of Indiana** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

84. The **State of Iowa** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

85. The **State of Louisiana** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

86. The **State of Maryland** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

87. The **State of Massachusetts** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been

provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

88. The **State of Michigan** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

89. The **State of Minnesota** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

90. The **State of Montana** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

91. The **State of Nevada** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

92. The **State of New Hampshire** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

93. The **State of New Jersey** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

94. The **State of New Mexico** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

95. The **State of New York** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

96. The **State of North Carolina** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

97. The **State of Oklahoma** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

98. The **State of Rhode Island** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been

provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

99. The **State of Tennessee** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

100. The **State of Texas** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

101. The **State of Virginia** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

102. The **State of Washington** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

103. The **State of Wisconsin** is a Plaintiff in this action. At all relevant times herein, Defendants' drug, Xolair, and the other Novartis drugs described herein, have been provided to Medicaid recipients there and have been a covered Medicaid benefit under its Medicaid Program.

IV. THE MEDICARE AND MEDICAID PROGRAMS

104. This is an action to recover treble damages, civil penalties of $5,500.00 to $11,000.00 per false claim, attorneys' fees, costs and expenses, on behalf of the United States of America, twenty-nine (29) States, and the District of Columbia, arising from Defendants' conduct in deliberately or recklessly causing the false claims to be presented under the Medicare, Medicaid, TRICARE and other federally- and State-funded government healthcare programs (collectively "government healthcare programs").

105. The **Medicare Program** is a government financial health insurance program administered by the Social Security Administration of the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment, and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of certain individual healthcare patients pursuant to federal regulations.

106. **Medicare Part B** generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (42 C.F.R. § 410.26) (e.g., certain oncology drugs); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. 42 C.F.R. §§ 405.517, 414.701.

107. Xolair is an injectable drug which has been at all relevant times a Medicare Part B covered drug. The other Novartis drugs described herein have been, at all relevant times, covered under Medicare Part A and/or B.

108. During the relevant time period, CMS contracted with private insurance carriers ("Contractors") to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § l395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b).

109. Contractors receive, process and pay claims under Medicare Part B for drugs from various Medicare providers and suppliers. Typically, once a contractor approves a claim, the contractor then submits a payment request to a Medicare bank account funded by federal funds.

110. Coverage under Part B is limited to items and services which are "reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § l395y(a)(1)(A).

111. At all relevant times, the cost of providing Defendants' drugs, including Xolair, for on-label uses, have been covered by Medicare Part B. However, because Xolair has been misbranded, no prescription for Xolair has been properly reimbursable by Medicare Part B. Further, at all relevant times, the cost of providing Xolair for mild asthma has not been properly covered by Medicare Part B because use of the drug to treat mild asthma has been neither reasonable nor necessary. In addition, all Xolair and other drug prescriptions at issue that have been tainted in any way by the offering or provision of a kickback have not been properly reimbursable.

112. On January 1, 2006, the **Medicare Part D** prescription drug benefit went into effect. Medicare Part D subsidizes the cost of prescription drugs for Medicare beneficiaries. *See* Title XVIII of the Social Security Act, 42 U.S.C. §§ l395 *et seq.*

113. Part D covers the cost of FDA-approved prescription drugs used for "a medically accepted indication." *See* 42 U.S.C. §§ 1395w-102(e)(1), 1395w-151(a)(2). Just as in the Medicaid Program, for Medicare Part D reimbursement, a "medically accepted indication" means any use or indication which is approved by the FDA or which is supported by one or more citations in certain drug compendia. *See* 42 U.S.C. § 1396r-8(k)(6) & (g)(1)(B)(i). The relevant drug compendia are the same as those for Medicaid: AHFS Drug Information and USP DI (or its

successor publications). *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i). In sum, Part D drug coverage excludes drugs not approved by the FDA, and those not for use for a medically accepted indication. Because Xolair has been off-label marketed for uses not allowed by the FDA-approved indication, and not allowed by any approved compendia, all claims reimbursements under Part D have been improper. In addition, all Xolair and other drug prescriptions at issue tainted in any way by the offering or provision of a kickback have not been properly reimbursable.

114. The Medicare Part D prescription drug benefit is offered by private prescription drug plans and Medicare prescription drug plans. Medicare beneficiaries have a choice among many different plans in each State. Medicare reimburses the private plans for its coverage of Medicare beneficiaries.

115. From January 1, 2006 forward, Xolair for on-label uses has been a covered drug under Medicare Part D. However, because Xolair has been misbranded, no prescription for Xolair has been properly reimbursable by Medicare Part D. Further, at all relevant times, the cost of providing Xolair for mild asthma has not been properly covered by Medicare Part D because mild asthma has been neither a medically accepted indication for which the drug was approved by the FDA nor one supported by any citations included in any of the specified drug compendia.

116. Many low-income patients are "dual eligible"—those who qualify for both Medicare and Medicaid. In the case of dual eligibles, Medicare is the primary source of drug coverage.

117. The federal government enacted the **Medicaid program** in 1965 as a cooperative undertaking between the federal and State governments to help the States provide health care to

low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. *See* 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(l), 1903(a)(1). The federal government then pays each State a statutorily established share of "the total amount expended ... as medical assistance under the State plan ..." *See* 42 U.S.C. § 1396b(a)(l). This federal-to-State payment is known as federal financial participation ("FFP"). In sum, Medicaid drug coverage excludes drugs not approved by the FDA, and those not for use for a medically accepted indication. In addition, all Xolair and other drug prescriptions at issue tainted in any way by the offering or provision of a kickback have not been properly reimbursable.

V. TRICARE AND OTHER FEDERAL PROGRAMS

118. **Tricare**, formerly known as the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), is the component agency of the U.S. Department of Defense that administers and supervises the health care program for certain military personnel and their dependents. Tricare contracts with a fiscal intermediary that receives, adjudicates, processes, and pays health care claims submitted to it by Tricare beneficiaries or providers. The funds used to pay the Tricare claims are federal government funds. In addition to Medicare, Medicaid, and Tricare, the federal government also reimburses for the cost of prescription drugs under several other government healthcare programs, including the Railroad Retirement Medicare Program, the Federal Employee Health Benefit Plans, the Veterans Administration, the Indian Health Service and State Legal Immigrant Assistance Grants.

119. Tricare categorically excludes coverage for "[u]nproven drugs." 32 C.F.R. § 199.4(g)(15). Tricare defines "unproven" as lacking necessary FDA approval. 32 C.F.R. § 199.4(g)(15)(i)(A)-(B). Thus, under Tricare, benefits may not be extended for drugs not approved by the FDA. At all relevant times herein, because Xolair has been misbranded, no prescription for Xolair has been properly reimbursable by Tricare. Further, at all relevant times herein, the cost of providing Xolair for mild asthma has not been properly covered by Tricare because it has been an "unproven" use of the drug in this regard. Finally, all prescriptions for Xolair and the other Novartis drugs described herein have been tainted, and have rendered void as a matter of law all claims for reimbursement of those drugs that have been submitted to Tricare.

VI. VETERANS HEALTH ADMINISTRATION

120. The **Veteran Health Administration** is the component of the U.S. Department of Veterans Affairs ("VA") that implements the medical assistance program of the VA through the administration and operation of numerous VA outpatient clinics, hospitals, medical centers, and long-term healthcare facilities. The VA provides numerous prescription drugs in connection with VA programs and obtains funds from the federal government.

121. With respect to the VA, the federal reimbursement scheme provides that prescription drugs are only reimbursable if they are FDA-approved or otherwise medically accepted to treat the particular diagnosis for which the drug is prescribed. *See* 38 U.S.C. § 8126. A "medically accepted indication" means any use or indication which has been approved by the FDA or which is supported by one or more citations in certain drug compendia. *See* 42 U.S.C. §§ 1396r-8(k)(6), (g)(1)(B)(i). The relevant drug compendia are the same as those for Medicaid: AHFS Drug Information and USP DI (or its successor publications). *See* 42 U.S.C. §

1396r-8(g)(1)(B)(i). In sum, VA drug coverage excludes drugs not approved by the FDA, and those not used for a medically accepted indication.

122. At all relevant times herein, Xolair for on-label uses has been a covered drug under the VA. But because Xolair has been misbranded, no prescription for Xolair has been properly reimbursable by the VA. Further, at all relevant times herein, the cost of providing Xolair for mild asthma has not been properly covered by the VA because mild asthma has been neither a medically accepted indication for which the drug was approved by the VA nor one that has been supported by any citations included in any of the specified drug compendia. Finally, all prescriptions for Xolair and the other Novartis drugs described herein have been tainted, and have rendered void as a matter of law, all claims for reimbursement of those drugs that have been submitted to the VA.

123. Under all federal and State government healthcare programs, medical costs are not reimbursable when one or more kickbacks have been offered or provided to a HCP.

VII. THE ANTIKICKBACK STATUTE

124. Congress enacted the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7(b)(2), to prevent improper financial considerations from influencing the amount, type, cost, and/or selection of health care services financed to any extent by the U.S. Treasury.

125. It is remuneration, or merely the offering of it, to induce payments by Medicare or Medicaid, that transforms an ordinary, lawful transaction into one that violates the AKS.

126. Kickbacks can take a wide variety of forms, including cash, gifts, supplies, long-term credit arrangements, equipment, and services.

127. The AKS broadly defines a kickback or inducement to mean "any money, fee, commission, credit, gift, gratuity, thing of value, or compensation of any kind which is

provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor or subcontractor employee, for the purpose of improperly obtaining or rewarding favorable treatment in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52-53.

128. The AKS provides both civil and criminal penalties for offering or paying any remuneration to induce someone to refer patients to or for, or to purchase, lease, or order, any item, service or facility for which payment may be made by a federally funded health care program. 42 U.S.C. § 1320(a)-7(b). This prohibition applies whether the financial benefit is provided directly or indirectly, "in cash or in kind."

129. Compliance with the AKS is a prerequisite for receiving payment from the Medicare, Medicaid, and other federal health programs.

130. In 2010, Congress amended the AKS when it enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). The amendment makes clearer than ever that Medicare or Medicaid claims that are influenced in any way by kickbacks are, by definition, false claims under the FCA. PPACA, 124 Stat. 119, § 6402(g) (amending Section 1128B of Social Security Act, 42 U.S.C. § 1320a-7(b)(g)).

131. Another PPACA amendment of the AKS clarified that specific intent to violate the AKS or actual knowledge of a kickback violation is not required under the FCA. PPACA, § 6402(f)(1).

132. The PPACA provides in relevant part as follows:

> Sec. 6402. ENHANCED MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.
>
> * * *
>
> (f) HEALTH CARE FRAUD.—

(1) KICKBACKS.—Section 1128B of the Social Security Act (42 U.S.C. §1320a-7b) is amended by adding at the end the following new subsection:

"(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.."

(2) REVISING THE INTENT REQUIREMENT.—SECTION 1128B of the Social Security Act (42 U.S.C. §1320a-7b), as amended by paragraph (1), is amended by adding at the end the following new subsection:

"(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.."

PPACA, Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (2010) (AKS Amendments).

133. When a pharmaceutical company pays a kickback to a HCP, or offers to pay a kickback to a HCP, the kickback taints the entire prescription and all related services, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship, and creates a conflict of interest, potentially putting the patient's health at risk.[10]

134. A kickback is material if it has a natural tendency to influence, or is capable of influencing, the decisionmaker to which it was addressed. All of Defendants' kickbacks, and offers thereof, have been material.

135. The Government is not required to pay for services tainted by kickbacks because,

[10] Novartis itself has at least partially acknowledged that the presence of a kickback can taint a prescription and trigger FCA liability. To quote Novartis' own website (as of March 12, 2006): "[f]iling or facilitating the filing of 'false claims' against the Government is a violation of [the False Claims Act] and can lead to huge fines and penalties. Claims submitted for reimbursement from Federal health care programs tainted by any number of problems, including prescriptions written where a kickback has been found to be present, are alleged by the Government to be 'false claims.'" This description of FCA liability for kickbacks is partially accurate.

in such circumstances, the Government has no assurance that the medical services were provided in the best interests of the patient, instead of the financial interests of the HCP or the party that induced the HCP.

136. Kickback-tainted reimbursements are deemed to be false claims. All of Defendants' kickbacks have "tainted."

137. Alternatively, kickbacks render false the claims submissions of HCPs under either an express or an implied certification theory.

138. Under the "implied certification" theory, "where the government pays funds to a party, and would not have paid those funds had it known a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent."

139. Under the "express certification" theory, claims submissions are false where the providers at issue expressly certified that they would comply with all relevant laws, or a specific law like the AKS.

140. As set forth herein, Defendants have engaged in a nationwide system of kickbacks to promote and sell Xolair, and Novartis has engaged in the American Express Travelers Cheque program as a kickback to promote and sell Xolair and the other drugs described herein.

141. Defendants' wide array of kickbacks was designed to alter physicians' objectivity in deciding on therapies for the treatment of the disease states involved, including asthma and allergies. Specifically, with respect to Xolair, they were designed to cause physicians to be less concerned about the dangerous side effects and expenses associated with the drug, as compared to the FDA-approved uses of competitor drugs, like ICSs.

142. It is important to note that Relators have not alleged that the myriad HCPs that Defendants have caused to submit false claims, are liable in the case at bar. Rather, liability is only sought to be imposed against Defendants—the architects, or cause, of the false claims submissions.

143. Notably, Defendants have engaged in many aggressive marketing activities that were not AKS violations—like providing lucrative commissions to their marketing forces. Those rich incentives were sufficient to effectively market Xolair without running afoul of the AKS. But that was not enough for Defendants, which have knowingly and intentionally gone into prohibited AKS territory to ensure that key decision-makers—the HCPs who could purchase Xolair and seek reimbursement from government healthcare programs—would be induced to buy Xolair (instead of competitors' FDA-approved drugs, which were the logical and comparatively safe alternative). The same is also true for Novartis with respect to the other drugs involved.

144. At all relevant times herein, Defendants not only have been aware that they were violating—or at serious risk of violating—the AKS, FDA off-label marketing laws, and the other laws set forth herein, but they also have been aware that AKS-based FCA cases have formed the basis of some of the largest FCA lawsuits brought by relators and the Government. Despite the known risks—both to patient safety and of legal liability—Defendants have doled out kickbacks, and offered kickbacks, to boost Xolair sales for nearly a decade, to date. With respect to the other drugs described herein, Novartis also has offered and provided American Express Travelers Checks as kickbacks for over a decade.

VIII. THE STRICT REQUIREMENT OF FDA APPROVAL OF PRESCRIPTION DRUGS

145. The FDA regulates human use of pharmaceutical drugs and biologics like Xolair. Companies seeking to introduce new drugs for human use into interstate commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

146. Notably, the FDCA prohibits companies from distributing in interstate commerce any drugs that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a), (b).

147. In order for a company to gain FDA approval of a drug, the company must first submit and receive approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. The company is required to include in the NDA all intended uses proposed for a new drug's labeling and to prove that the new drug is safe and effective for those uses. 21 U.S.C. § 355(b).

148. To prove that the drug is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new drug unless, on the basis of all information reviewed, it is demonstrated that a drug can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the drug for this purpose. 21 U.S.C. § 355(d).

IX. THE STRICT REQUIREMENT OF FDA APPROVAL OF BIOLOGICS

149. With respect to biological products—also known as "biologics"—like Xolair, the process is substantially the same or very similar to the FDA process for approval of prescription drugs.

150. The FDA regulates human use of pharmaceutical drugs, medical devices and biologics. Companies seeking to introduce new products for human use into interstate commerce

must comply with FDA statutes and regulations, including the FDCA. *See* 21 U.S.C. § 301 *et seq.*

151. As it specifically relates to biologics, such as viruses, therapeutic serums, toxins, antitoxins, vaccines, blood components, allergenic products, proteins, and analogous products (*see* 42 U.S.C. § 262(i)(1)), while the FDCA regulates the on- and off-label uses of such products, the FDA-approval process for biologics is governed by a separate statute, 42 U.S.C. § 262, under the Public Health Service Act ("PHSA").

152. Notwithstanding this separate classification, the PHSA's governance of the approval process for biologics is expressly not intended to supersede the FDA's right to regulate the use and labeling of medical products under the FDCA. *See* 42 U.S.C. § 262(g).

153. Notably, the PHSA prohibits companies from distributing in interstate commerce any biologics that the FDA has not approved as safe and effective. *See* 42 U.S.C. § 262(a).

154. In order for a company to gain FDA approval of a biologic, the company must first submit and receive approval of a Biologic License Application ("BLA") pursuant to 42 U.S.C. § 262. The company is required to include in the BLA: data derived from non-clinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency; a full description of manufacturing methods; data establishing the stability of the product through the dating period; a sample representative of the product; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); the address of each location involved in the manufacture of the biologic; and specimens of the labels, enclosures, and, if applicable, the Medication Guide, proposed to be used for the product. *See* 21 C.F.R. § 601.2(a).

155. As it specifically relates to labeling, all biologics subject to a BLA are to include labeling that "must contain a summary of the essential scientific information needed for the safe and effective use of the drug," "must be informative and accurate and neither promotional in tone nor false or misleading in any particular," and "must be based whenever possible on data derived from human experience." *See* 21 C.F.R. § 201.56(a).

156. The label must also contain specified subheadings, *see* 21 C.F.R. § 201.56(d)(1), and must contain various specific information as it relates to prescribing information (such as dosage information, indications and usage, warnings and precautions, adverse reactions, pediatric and geriatric use, use by pregnant and expectant mothers, and a limitation statement). *See* 21 C.F.R. § 201.57.

157. As to biologics, "all indications listed in [the Indications and Usage section of the labeling] must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section." *See* 21 C.F.R. § 201.57(c)(2)(v).

158. The FDA's regulatory requirement that the biologic's manufacturer must provide data from scientifically sound clinical trials is intended to ensure the product's safety and effectiveness. If the FDA determines that the product does not meet the regulatory requirements—namely the insurance of safety, purity, and potency; a proper methodology of laboratory and clinical studies used to test the biologic's safety and efficacy; and the contents of the product's label and associated informational materials—then the BLA "shall be denied and the applicant shall be informed of the grounds for...the decision." *See* 21 C.F.R. § 601.4(b). Furthermore, if a biologic license is issued to the manufacturer for a product and it is

subsequently discovered that "[t]he licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use," the biologic license shall be revoked. *See* 21 C.F.R. § 601.5(a)(2012); 21 C.F.R. § 601.5(b)(1)(vi).

159. Pursuant to the FDA's statement dated March 16, 2000 and published in the Federal Register, any use for a product that was not proposed in the BLA and approved for the label by the FDA is "unapproved" or "off-label." *See* Fed. Reg. 14286, 14286 (Mar. 16, 2000). The FDA includes in its definition of "drug or medical device" biological products regulated under the PHSA. *See* Fed. Reg. 14286, 14286 n.1 (Mar. 16, 2000).

160. Although physicians may traditionally prescribe a product for an off-label use so long as the product has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from promoting or marketing a product for an off-label use.

161. Any use for a drug that was not proposed in the BLA and approved for the label by the FDA is "unapproved" or "off-label." 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000).

162. Although physicians may traditionally prescribe a drug for an off-label use so long as the drug has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from marketing a drug for an off-label use.

163. Furthermore, a drug's "labeling"—and materials or oral statements are considered part of a drug's labeling if they are distributed by the manufacturer or stated by a sponsor's representative for the purpose of explaining the uses of the drug, even if they are not packaged with the drug—must be consistent with its FDA indications. 21 U.S.C. §§ 321(m) and (n), 331.

X. THE FDA'S STRICT PROHIBITION AGAINST MISBRANDING

164. The FDCA prohibits the distribution in interstate commerce of any drug or biologic that is misbranded. 21 U.S.C. §§ 331(a), 331(k), & 333(a). Specifically, 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any...drug...that is...misbranded." 21 U.S.C. § 331(k) prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

165. A drug or biologic is misbranded if the labeling does not contain adequate directions for use and adequate warnings against its use where such use can be dangerous to the user's health. *See* 21 U.S.C. § 352. "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended." *See* 21 C.F.R. § 201.5.

166. A drug or biologic's "intended use" is determined by considering the "objective intent of the persons legally responsible for the labeling of the drugs[,]" as evidenced by the "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128 (emphasis added).

167. A drug or biologic's labeling must not be inaccurate or otherwise misleading in any way. *See* 21 C.F.R. § 201.56(a)(2); *see also* 21 U.S.C. § 321(m), (n). Furthermore, if a manufacturer or its representatives makes oral or written statements regarding medical indications or uses for which the drug or biologic has not been approved by the FDA, then the drug or biologic's labeling will not be considered to be not bearing adequate directions, and the drug will be considered misbranded.

168. Misbranded drugs are not approved by the FDA and therefore are ineligible for reimbursement under public health plans.

169. Any approved drug must be accompanied by a package insert ("PI") or product manual specifically setting forth the approved uses for the product, also known as "on-label" uses. *See* 62 Fed. Reg. 64074, 64075 (Dec. 3, 1997). Conversely, any use or indication not contained within such material is considered "off-label."

170. Use of an approved drug or biologic for any purpose other than those indications specifically approved by the FDA is referred to as an "off-label" use. Off-label uses include treating a condition not indicated on the label, treating the indicated condition at a different dosage or dosage frequency, or treating a different patient population than those approved by the FDA.

171. Once a drug or biologic is approved as safe and effective for one indication, the FDA does not prohibit doctors from prescribing the drug for off-label uses. This is consistent with the FDA's mission to regulate drugs without interfering with the practice of medicine and doctors' discretion in treating their patients.

172. Under public health plans like Medicare Part D, Medicaid, and the Veteran's Health Administration, reimbursement is available only for covered outpatient drugs, which pursuant to 42 U.S.C. § 1396r-8(k)(3), only includes drugs that are used for "a medically accepted indication," defined in 42 U.S.C. § 1396r-8(k)(6) to be a use "which is approved under" the FDCA or included in certain drug compendia identified in 42 U.S.C. § 1396r-8(g)(1)(B)(i). Similarly, under Medicare Part B, only drugs which are reasonable or necessary can be reimbursed. *See* 42 U.S.C. § 1395y(a)(i)(A).

173. In sum, at all relevant times, the regulatory scheme set up by Congress has aimed to protect patients and consumers by ensuring that drug and biologic companies do not try to promote drugs and biologics for uses other than those found to be safe and effective by the FDA, and do not make materially misleading statements, while allowing doctors the freedom to treat patients as they see fit.

174. The key issue in analyzing whether a drug or biologic manufacturer has illegally promoted an off-label use of a product is whether the manufacturer promoted an "intended use" for the product that has not been approved by the FDA. *See* 21 U.S.C. § 321(k)-(n)(2012).

175. In assessing whether a marketed or promoted use of a product is in fact the "intended use" of the product, one should consider not only the product's labeling itself, but other information disseminated by the drug or biologic manufacturer during scientific and educational meetings, symposia, continuing medical education ("CME") courses, and the reprinting of medical journal articles. *See* 21 C.F.R. § 201.128 (2012); 21 C.F.R. § 801.4(2012); l62 Fed. Reg. 64074, 64075 (Dec. 3, 1997).

XI. XOLAIR: A PROFILE OF THE BIOLOGIC/DRUG

176. As set forth above, the drug at issue is Omalizumab, which Defendants have jointly marketed as "Xolair."

177. The National Drug Code ("NDC") number for Xolair is 50242-0040-62. Previously, the 10-digit version was 50242-040-62.

178. Xolair is a sterile, white, preservative-free, lyophilized powder contained in a single-use vial that is reconstituted with sterile water for injection ("SWFI") United States Pharmacopeia ("USP"), and administered as a subcutaneous ("SC") injection.

179. A Xolair vial contains 202.5 milligrams (mg) of Omalizumab, 145.5 mg of sucrose, 2.8 mg of L-histidine hydrochloride monohydrate, 1.8 mg of L-histidine, and 0.5 mg of polysorbate 20, and is designed to deliver 150 mg of Omalizumab in 1.2 milliliters (mL) after reconstitution with 1.4 mL SWFI, USP.

180. When the FDA approved Xolair in June 2003, the FDA limited its indication, as follows: "Xolair is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids ("ICSs"). Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions."

181. Thus, an appropriate patient/candidate for Xolair is someone who is:

> at least 12 years old; and

> has moderate to severe asthma; and

> which is persistent; and

> who has a positive skin test or *in vitro* reactivity to a perennial aeroallergen; and

> whose perennial aeroallergen symptoms are inadequately controlled with ICSs.

182. Accordingly, Xolair is not indicated for a patient/candidate who:

> is under the age of 12; or

> has mild asthma; or

> has no asthma or less-than-mild asthma; or

> has any form of asthma that is not moderate to severe; or

> has any form of asthma that is not persistent; or

> either has not had a positive skin test or *in vitro* reactivity to a perennial aeroallergen;

or

> does not have perennial aeroallergen symptoms; or

> has perennial aeroallergen symptoms that are adequately controlled, as by ICSs;[11] or

> has not undergone treatment for perennial aeroallergen symptoms by treatment with ICSs.

XII. DEFENDANTS' "HOW–TO" GUIDE FOR HEALTHCARE PROVIDERS

183. In 2005, Defendants distributed a CD-ROM to HCPs entitled "Prescribing Xolair: The how-to guide for healthcare providers."

184. According to the guide, in June 2003 the FDA approved Xolair, which is "indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids." The Guide elaborated that Xolair "is a prescription medicine for people who:

• Are 12 years of age and above

• Have moderate to severe persistent asthma. This means they have 1 or more of the following:

- Asthma symptoms every day

- Daily need for a rescue inhaler

- 2 or more asthma attacks a week

[11] Indeed, the 2003 PI for Xolair makes clear that it should be a common event that the Xolair patient is undergoing *concomitant* treatment by corticosteroids: "**Corticosteroid Reduction** Systemic or inhaled corticosteroids should not be abruptly discontinued upon initiation of Xolair therapy. Decreases in corticosteroids should be performed under the direct supervision of a physician and may need to be performed gradually." (emphasis in boldface in original)

- 1 or more nights a week waking up with asthma symptoms

- A below-normal reading (less than 80%) from a toll called a peak flow meter, which measures how well the lungs work.

• Have asthma that is triggered by year-round allergens in the air, which is confirmed by a doctor using a simple skin or blood test. This is known as allergic asthma.

• Continue to have asthma symptoms even though they are taking inhaled steroids.

Adding Xolair injections to treatment with inhaled steroids has been clinically proven to help reduce the number of asthma attacks. Xolair has not been proven to work in other allergic conditions."

185. The guide specifies the five (5) "specialty pharmacies" ("SPs") from whom HCPs should purchase the drug. HCPs also have been directed to fax the Patient Authorization and Notice of Release ("PAN") and Statement-of-Medical-Necessity ("SMN") forms to these five (5) SPs:

• Priority Healthcare Corporation, Ph: 866-757-3929, fax: 866: 269-3113, www.priorityheathcare.com.

• Option Care, Inc., Ph: 888-282-5166, fax: 888-570-4700, www.optioncare.com

• Nova Factor, Inc., Ph: 866-839-2162, fax: 866-531-1025, www.accredohealth.net/nova

• CuraScript Pharmacy, Inc., Ph: 888-281-5464, fax: 888-773-7386, www.curascript.com

• Caremark Rx, Inc., Ph: 800-237-2767, fax: 800-323-2445, www.caremark.com.[12]

[12] As set forth below, the names of some of these SPs have changed through the years, as a result of mergers and acquisitions. Additional contact information and details about these SPs is set forth herein, in the sections about claims submissions and Defendants' training modules.

186. SPs—like the five approved to handle shipments of Xolair to patients or their physicians—provide special handling and packaging of medicines, as well as support services for determining whether the patient's health insurance covers a drug. In general, the treating physician or patient normally chooses the SP, but the choice may be affected by the patient's health plan and/or which SP already has a working relationship with the treating physician. However, with respect to Xolair (like many biologics and specialty drugs), the manufacturer, seller, and/or marketer—here Defendants—have routinely directed HCPs and patients to use their five (5) preferred SPs which, from 2003 forward, have enjoyed exclusive contracts with Defendants to serve as SPs for Xolair.

187. The guide also has instructed HCPs to "contact [Defendants'] Single Point of Contact (SPOC) at 800-704-6610 for assistance with authorization for patients outside the Specialty Pharmacy Network or for appeal, buy-and-bill support, alternative coverage assistance, and co-pay resource referral." SPOC's website has been at www.spoconline.com.

188. The guide also has instructed office-based, non-institutional HCPs and suppliers on filling out CMS-1500 forms for Xolair reimbursement and services.

189. The guide also has instructed institutional HCPs on filling out CMS-1450 (UB-92) forms for Xolair reimbursement and services.

190. The guide also has instructed HCPs that the following ICD-9 diagnosis codes are proper: 493 for "asthma," and 493.0__* for "extrinsic asthma."

191. The guide also has instructed HCPs that the following Current Procedural Terminology ("CPT") codes are proper for billing of professional services by physicians: 86003, 82785, 95004, 95024, 95027, 95028, 90782, G 0351, 95115, 95117, and 95199.

192. The guide also has instructed HCPs that the following Evaluation and Management ("E/M") codes are proper for level-of-service billing of professional services by physicians: 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, and 99215.

193. The guide also has instructed HCPs that the following CPT modifiers are proper for use by physicians: -25 and -76.

194. The guide also has instructed HCPs that the following additional reference codes are proper for use by physicians: S 0107 for "omalizumab, injection, 25 mg"; J 2357 for "omalizumab, injection, 5 mg"; and NDC 50242-00460-62 for the "Xolair national drug code."

XIII. THE EXTENT OF THE FRAUD

195. Defendants' off-label marketing of Xolair, furnishing of illegal kickbacks relating to its purchase and use, and other illegal acts, render false and invalidate the claims that have been submitted by HCPs to government healthcare programs, concerning the purchase and administration of Xolair, and the hospital, outpatient, physician, and other related services rendered along with the administration of Xolair, for which Defendants are liable under the FCA and the State False Claims Acts described herein.

196. Through their positions as pharmaceutical sales representatives with Defendants for a combined total of approximately fourteen (14) years (with a combined approximately six-and-a-half (6.5) of those years spent selling Xolair), Relators have attained and possess very extensive and intricate personal and inside knowledge of the unlawful acts that are detailed herein, including, but not limited to, the identities of the SPs and many customers/HCPs that submitted claims for reimbursement to Medicare and/or Medicaid.[13]

[13] While all three Relators are former insiders with extensive, direct and independent knowledge of Defendants' schemes, Mr. Fauci acquired a particularly high level of reliable, inside information because he served on the Xolair National Sales Representative Panel in 2004. In

197. Notwithstanding this fact, Defendants have closely guarded numerous details concerning the fraud schemes and clients' billing of Xolair and related services, in order to conceal the fraudulent nature of Defendants' activities. Numerous details concerning the frauds and their consequences are within the exclusive, collective knowledge of Defendants and the HCPs that submitted claims for reimbursement, and may only be utilized in this litigation through the taking of discovery.

198. Defendants' fraudulent acts have been committed on a nationwide basis. Many of the written and oral communications from Defendants that are featured herein show that Defendants' off-label marketing, kickbacks, and other schemes have been endorsed by Defendants' executives, senior-level managers, and mid-level managers, and have been implemented through several mandatory programs that rendered systematic both the off-label marketing and many components of the kickbacks scheme.

199. Relators also know that the fraudulent acts detailed herein have caused HCPs who were customers of Defendants to submit false claims, because the off-label marketing, kickback, and other illegal acts set forth herein have been conducted nationally and systematically—as confirmed by Relators throughout the course of their employment—having been learned from local, regional, and national training, sales, and strategy meetings and sessions, as well as various phone calls with sales managers, and with other sales representatives, who repeatedly acknowledged the off-label marketing and kickbacks, and other fraudulent acts detailed herein.

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carrying out this position/duty, Mr. Fauci spent many weeks preparing for the National Sales Meeting in San Francisco in November 2004, gathering information from Genentech sales managers and especially sales representatives about which sales techniques—including which off-label marketing and kickback techniques—were proving most effective in the field.

200. All known facts point to the endemic nature of these violations by Defendants. Relators know that all policies and procedures concerning Xolair have emanated from or have been approved by Defendants' respective corporate headquarters. Likewise, Novartis' American Express Travelers Cheque Program, which also concerned the additional Novartis drugs described herein, also has emanated from and/or has been approved by Novartis' corporate headquarters.

201. It is impossible to state, at this early stage of the proceedings, the exact number and full identification of each and every HCP affected by Defendants' actions because—as set forth above—Defendants have closely guarded information concerning HCPs' purchase of the drug and billing of drug therapies and related services, in order to conceal the fraudulent nature of Defendants' activities, and because of the extremely widespread nature of the fraud. Precious few individuals, or more likely, no individuals, who have worked for Defendants would ever be in a position to specifically identify, at the pleadings stage of a lawsuit, every single HCP that Defendants have caused to submit false claims. Moreover, those individuals normally would be very high-ranking officers within the companies—persons highly unlikely to ever expose fraud to which they contributed so heavily. Nonetheless, this Complaint details the sources of the overwhelming majority of Xolair claims submitted to government healthcare programs—particularly insofar as Relators have identified the five (5) SPs responsible for the vast majority of claims submissions.

202. Relators have learned from multiple managers, sales representatives, and/or analysts who have worked for Defendants—that HCPs routinely "billed" (i.e., submitted requests for reimbursement to) Medicare, Medicaid, and other government healthcare programs,

for the purchase and administration of Xolair. Hence, there can be no question that false claims were submitted to such programs as a result of Defendants' actions.

XIV. BACKGROUND ON ASTHMA

203. As explained by the National Institutes of Health ("NIH"), asthma is a common yet complex chronic disorder of the airways that is characterized by variable and recurring symptoms, including airflow obstruction, bronchial hyper-responsiveness, and an underlying inflammation. The interaction of these features of asthma determines the clinical manifestations and severity of asthma and the response to treatment.

204. In the United States, asthma affects more than 22 million persons. It is one of the most common chronic diseases of childhood, affecting more than 6 million children ("Current Asthma Prevalence," National Health Interview Survey ("NHIS"), National Center for Health Statistics, Centers for Disease Control and Prevention, 2005) (NHIS 2005).

205. Overall, there are two broad groups of asthma: allergic asthma and idiosyncratic asthma. Only allergic asthma is associated with an immunoglobulin ("IgE") response. Because Xolair is only designed for treatment of allergic asthma, it is not useful for treatment of the various types of idiosyncratic asthma, which include: drug-induced (aspirin, etc.) asthma, exercise-induced asthma, stress-induced asthma, asthma induced by a viral upper respiratory tract infection; asthma induced by wide changes in temperature; and occupational-exposure-induced asthma.

206. The allergy-induced form of asthma accounts for approximately one-third of asthma cases, with idiosyncratic asthma accounting for approximately the remaining two-thirds.

207. The subjective measures used to grade asthma generally include ability to sleep through the night, ability to participate in daily activities without breathlessness, the occurrence

of acute worsenings called exacerbations, and exercise tolerance. Peak expiratory flow rate ("PEFR") may be used for home monitoring of obstruction of breathing. In the clinic or hospital, expiratory volume in the first second of a forced expiration ("FEV1") is determined to assess severity; the FEV1 is measured using equipment found in a clinic or hospital that can be calibrated so that individuals may be compared rigorously to reference populations. Decrements in either measure signify a worsening in the ability to exhale rapidly and completely, due in asthma to reversible obstruction of the airways.[14]

208. The NIH guidelines have categorized asthma as mild intermittent, mild persistent, moderate persistent, and severe persistent, based upon pretreatment symptoms and measurements, as follows (These NIH guidelines do not supersede or affect the FDA's limited indication for Xolair, and do not constitute an approved drug compendium. Further, these guidelines are intended for use by doctors—not by pharmaceutical or biologics manufacturers, marketers, and sellers.):

> • A patient is diagnosed with "mild intermittent asthma" if: the patient experiences symptoms less than once a week; the patient experiences brief exacerbations; the frequency of nighttime awakenings with asthma symptoms is less than or equal to twice/month; and the patient's FEV1 or PEF readings are greater than or equal to 80% with variability less than 20%.
>
> • A patient is diagnosed with "mild persistent asthma" if: the patient experiences symptoms over once a week but less than once a day; the patient's exacerbations possibly affect the patient's activity and sleep; the frequency of nighttime awakenings with asthma symptoms is more than twice/month; and the patient's FEV1 or PEF readings are greater than or equal to 80% with variability between 20%- 30%.

[14] Thus, FEV1 means "forced expiratory volume in 1 second;" i.e., the volume exhaled during the first second of a forced expiratory maneuver started from the level of total lung capacity. FEV1 is by far the most frequently used index for assessing airway obstruction, bronchoconstriction, or bronchodilatation. FEV1 is expressed as a percentage of the vital capacity ("VC")—the standard index for assessing and quantifying airflow limitation. VC is volume of the lungs between a full inspiration and a full expiration.

> • A patient is diagnosed with "moderate persistent asthma" if: the patient's asthma interferes with daily activities; the patient's exacerbations possibly affect the patient's activity and sleep; the frequency of nighttime awakenings with asthma symptoms is more than once/week, but not nightly; the patient uses a quick-relief inhaler daily; and the patient's FEV1 or PEF readings are 60 to 80% with variability less than 30%.
>
> • A patient is diagnosed with "severe persistent asthma" if: the patient's asthma interferes with daily activities; the patient experiences frequent exacerbations; the patient experiences frequent nighttime awakenings with asthma symptoms; the patient's daily activities are limited; and the patient's FEV1 or PEF readings are less than 60% with variability greater than 30%.

209. The FDA has approved many drugs for treating asthma, depending on which severity category applies to the specific type of asthma and whether long-term relief or short-term relief is needed. The NIH states that there are two basic kinds of medication for treating asthma: long-term control medications used to achieve and maintain control of persistent asthma, and quick-relief (i.e., "rescue") medications used to treat acute symptoms and exacerbations.

XV. XOLAIR'S DERIVATION AND DOSING

210. Xolair, which was produced by Genentech and marketed by Genentech and Novartis, is a recombinant Chinese Hamster Ovary cell-derived humanized IgE lk monoclonal antibody. Because it derives from living matter, it is considered a biologic. According to Defendants, Xolair acts to capture IgE (the molecule in the human body that can play a major role in asthma) to help stop asthma attacks and symptoms before they start. The human body produces IgE in response to certain allergens. For 6 in 10 people with asthma, IgE triggers the release of chemicals, which may lead to an attack. Xolair captures most of the IgE related to asthma.

211. Xolair is administered subcutaneously every 4 weeks at 150 mg or 300 mg per dose, or every 2 weeks at 225 mg, 300 mg, or 375 mg per dose. Because the solution is quite

viscous, the injection takes at least 5 to 10 seconds to administer—and often much longer. For the patient, receiving a Xolair injection is a very unpleasant experience as compared to taking Advair and/or Singulair.

212. According to the Xolair label/PI, Xolair's safety and efficacy were evaluated in three randomized, double-blind, placebo-controlled, multi-centered trials. The trials enrolled patients aged 12 to 76 years old, with moderate to severe persistent asthma (according to criteria of the National Heart Lung and Blood Institute ("NHLBI") for at least one year, and a positive skin test reaction to a perennial aeroallergen. All patients were already being treated with ICSs and short-acting beta-antagonists. Xolair dosing was based on body weight and baseline serum total IgE concentration.

XVI. SUMMARY OF XOLAIR'S FDA REGULATORY HISTORY

213. Although the FDA partially approved Xolair for marketing in 2003, the drug's FDA regulatory history actually began a few years earlier.

214. As set forth above, biologics are approved for marketing under provisions of the PHSA, which requires a firm that manufactures a biologic for sale in interstate commerce to hold a license for the product. A BLA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and medical effects of the biologic. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.

A. 2000 BLA

215. Genentech and Novartis jointly submitted a BLA on June 2, 2000 (received by the FDA on June 5, 2000) to license and sell Xolair.

216. At that time, Defendants' management placed a great deal of importance on Xolair, and were optimistic that it would prove to be a breakthrough, blockbuster drug.

217. In Defendants' original BLA submission on June 2, 2000, the companies sought licensure for the broad use of Xolair in the prophylaxis and treatment of: 1) adult/adolescent allergic asthma (including mild asthma); 2) pediatric allergic asthma (including mild asthma); 3) adult/adolescent seasonal allergic rhinitis ("SAR") and 4) pediatric SAR.

B. 2001 FDA COMPLETE REVIEW LETTER

218. In response to their June 2000 BLA submission, the FDA sent Defendants its Complete Review Letter on July 5, 2001, in which the FDA completely rejected the drug for approval. The July 5, 2001 Complete Review Letter from the FDA highlighted a number of limitations within the original submission, including the limited size of the clinical safety database and the inability to meaningfully assess certain safety signals. The letter noted that substantially greater safety information was necessary in order to assess the risks and benefits related to the proposed asthma indication, and even greater amounts of clinical safety information were necessary for the proposed SAR indication.

C. 2002 BLA AMENDMENT

219. In response to the FDA's Complete Review Letter dated July 5, 2001, Genentech filed a December 18, 2002 BLA amendment (Complete Response to Complete Review Letter) that significantly narrowed the proposed indications for Xolair: it excluded both adult and pediatric SAR, as well as pediatric allergic asthma.

220. The December 18, 2002 Complete Response also included clinical data from approximately three times more subjects exposed to Xolair than were originally submitted in June 2000.

D. 2003 LIMITED FDA APPROVAL

221. The FDA approved Xolair on June 20, 2003 for a far smaller patient pool than Defendants had originally sought. Specifically, as the FDA-approved labeling/PI states, the FDA approved the drug: "for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions."

222. As stated in the 2002 BLA submission, the safety and efficacy of Xolair were evaluated in three clinical studies. As the PI notes, the studies showed that there is an increased rate of various kinds of cancer among Xolair users that surfaced after only a year of use of the drug, and there is also an increased risk of anaphylaxis—which may occur at any time that the drug is administered (i.e., not necessarily the first time it is administered; even over a year after first administration of Xolair).

223. Anaphylaxis is a severe, whole-body allergic reaction to a chemical that has become an allergen. It is a life-threatening condition and requires immediate, professional medical attention. In all three studies, Xolair did not relieve asthmatic incidents in the case of mild asthma, a fact which was required to be included in the FDA-approved labeling.

224. As a condition for the June 20, 2003 approval of Xolair, Defendants agreed to conduct a post-marketing study specifically designed to evaluate the efficacy of Xolair in patients with mild asthma (the "EXACT" study). The study was due for submission to the FDA on November 30, 2005. Sometime in 2009, five years after the study was due to the FDA, Defendants began to conduct the post-marketing EXACT study that Genentech had agreed to

conduct when Xolair was approved in June 2003. According to the FDA, as of October 21, 2009, only 77 of the 300 planned patients were enrolled, and just 54 had completed the study. To date, more than six years after the study was due for submission to the FDA, the study is still not complete.

E. 2003 PRODUCT INSERT

225. The original 2003 PI for Xolair warned of many possible, serious side effects.

226. First, the PI warned that anaphylaxis is a contraindication of the drug. Specifically, the PI warned: "**CONTRAINDICATIONS** Xolair should not be administered to patients who have experienced a severe hypersensitivity reaction to Xolair (see WARNINGS: Anaphylaxis)." (emphasis in boldface in original)

227. The 2003 PI also warned: "Anaphylaxis has occurred within 2 hours of the first or subsequent administration of Xolair in 3 (<0.1%) patients without other identifiable allergic triggers. These events included urticarial and throat and/or tongue edema….Patients should be observed after injection of Xolair, and medications for the treatment of severe hypersensitivity reactions including anaphylaxis should be available…."

228. The 2003 PI also specified that Xolair is therefore to be administered in a medical office or hospital setting.

229. Given that anaphylaxis was recognized at the outset as a serious potential side effect of Xolair use, it is dumbfounding that Defendants, in part, marketed and advocated Xolair administration at home—i.e., outside of the watchful eye of a HCP that could monitor the patient for an anaphylactic reaction.

F. 2007 BLACK BOX WARNING

230. On February 21, 2007, the FDA announced that it would require Genentech to strengthen the label warning for Xolair by requiring inclusion of a "black box" warning regarding Xolair's anaphylaxis risk, which was found to be double what it appeared to be when the drug was originally approved in 2003. A copy of this announcement appears at www.fda.gov.bbs/topics/NEWS/2007/NEW01567.html [also attached hereto and incorporated herein by reference as **Exhibit "A"**]. The announcement also spelled out other serious potential side effects of the drug, and stated that the "FDA has asked Genentech to revise the Xolair label and provide a Medication Guide for patients to strengthen the existing warning for anaphylaxis."

231. On July 2, 2007, the FDA followed through, issuing a "black box" warning regarding Xolair due to anaphylaxis risk, which was double what it appeared to be when the drug was originally approved in 2003, stating:

> Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, patients should be closely observed for an appropriate period of time after Xolair administration, and health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur (see WARNINGS, and PRECAUTIONS, Information for Patients).

232. According to the FDA, black box warnings on a drug's labeling are added when a drug has "special problems, particularly ones that may lead to death or serious injury."

G. 2008 BLA SUPPLEMENT

233. Despite the foregoing negative turn of events, on December 5, 2008, Defendants jointly submitted a supplement to their BLA, again actually seeking to expand the asthma indication for Xolair to children 6 to 11 years of age. They submitted this supplement despite the fact that they had yet to conduct the clinical study on the efficacy of Xolair in mild cases of

asthma, which they had committed to conducting and completing as a condition of approval back in June 2003. This supplement to the BLA triggered another examination of Xolair by the FDA.

H. 2009 FDA NOTICE OF VIOLATION

234. In a Notice of Violation letter from the FDA to Genentech dated March 26, 2009, the FDA stated that Genentech's sponsored link regarding Xolair was misleading because it made representations and/or suggestions about the efficacy of Xolair, but failed to communicate any risk information associated with the drug; it inadequately communicated the drug's indications; and it failed to use the required established name. Thus, the FDA concluded, the sponsored links misbranded the drugs in violation of the FDCA and FDA-implementing regulations. *See* 21 U.S.C. §§ 352(a) & (n), 321(n); 21 C.F.R. 201.10(g)(1), 202.l(b)(1), (e)(3)(i), (ii) & (e)(6)(i). Specifically, the Notice of Violation letter states:

> The sponsored link for Xolair misleadingly broadens the indication for Xolair by implying that all patients with allergic asthma are candidates for Xolair therapy ("Are you suffering from allergic asthma? The cause might be IgE"; presented along with the name of the drug), when this is not the case. Rather, as stated in its PI, Xolair is only indicated for patients 12 years and older with moderate to severe persistent asthma "who have a positive skin test or in vitro reactivity to a perennial aero allergen and whose symptoms are inadequately controlled with inhaled corticosteroids." Additionally, the sponsored link fails to convey that the safety and efficacy of Xolair has not been established in other allergic conditions.

I. 2009 FDA ANALYSIS OF WIDESPREAD OFF-LABEL USE

235. The FDA's Division of Pulmonary and Allergy Products completed an analysis dated July 9, 2009, which concluded that in roughly 43% of cases Xolair may well have been prescribed off-label for mild cases of asthma. The Division concluded this was cause for concern not only because Xolair was being used off-label to such a large extent, but also because studies showed that Xolair was of no use to mild asthmatics. In particular, Xolair was the sole asthma drug the patient was using in one-third of the cases overall—a fact which is only

consistent with Xolair prescriptions being written for the mildest form of asthma: mild intermittent asthma. This fact was also of concern because Xolair was FDA-approved as an add-on drug, not as a drug to be used alone. The FDA analysis specifically states:

> According to Wolters Kluwer nation-wide estimate, 18,000 patients received a medical or prescription claim for omalizumab in 2008, and approximately 89% of these patients were 18 years or older. The co-dispensing analysis revealed that during 2008 29% of patients did not receive another asthma medication and only 13% of asthmatics received a single class of medication along with their omalizumab prescription. Based on this drug use data, about 1/3 of asthmatics are using omalizumab as single treatment product, and in about 43% of asthmatics in the database, omalizumab is possibly utilized by patients with mild asthma. This data raises two intriguing observations: 1) omalizumab is being utilized outside its approved indication and outside the recommendations of national and international guidelines, and 2) the primary patient population that receives the drug (i.e., those with mild intermittent asthma) failed to show efficacy. This suggestion of mis-use or inappropriate use of omalizumab is of concern.
>
> Risk/Benefit of Omalizumab, July 9, 2009, Dept. of Health & Human Services, Public Health Service, Food & Drug Administration, Center for Drug Evaluation & Research, Office of Surveillance & Epidemiology, at 35 (emphasis in underlining added).

J. 2009 FDA INTERIM SAFETY FINDINGS AND RENEWED REJECTION OF USE IN CHILDREN AGED 6-11

236. On July 16, 2009, the FDA publicly announced that it was evaluating interim safety findings from yet another study of Xolair which Defendants had agreed to conduct as a condition to the June 2003 approval. According to the FDA, these interim findings suggested a disproportionate increase in ischemic heart disease, arrhythmias, cardiac failure and other cardiac events among patients taking Xolair.

237. On November 18, 2009, the FDA advisory panel voted 10-4 against approval of Xolair for use in children aged 6-11.

K. 2011 FDA FINDINGS OF OFF-LABEL USE IN CHILDREN AGED 6-11

238. In 2011, the FDA again found evidence of Defendants' off-label marketing of

Xolair—this time regarding the treatment of children under age 12: "The labeled indication for Xolair is moderate to severe persistent asthma in patients aged 12 years and older. Although the use appears to be low, the analyses in this review suggest that Xolair is used in patient aged less than 12 years old for asthma as well as for off-labeled indications other than asthma." Xolair Drug Use Review, Dec. 5, 2011, Dept. of Health & Human Services, Public Health Service, Food & Drug Administration, Center for Drug Evaluation & Research, Office of Surveillance & Epidemiology, at 7.

XVII. OFF-LABEL MARKETING AND MISBRANDING OF XOLAIR

239. At the time Xolair entered the market in June 2003, many different asthma drugs were already on the market which were FDA-approved for the long-term treatment of asthma--including Advair and Singulair. Singulair is an asthma medication taken once daily in a pill form which was FDA-approved in 1998 for allergic asthma (mild, moderate, and severe), and also for SAR.

240. At all relevant times, Defendants' sales representatives and sales managers have co-marketed Xolair pursuant to a co-marketing agreement. (Xolair is listed as a Novartis drug on the Novartis website, and as a Genentech drug on Genentech's website, or as drugs from both companies.) Indeed, sales representatives from both Novartis and Genentech have attended, in the normal course of business, many of the same sales calls made on physicians.

241. Defendants' Xolair sales forces have been at a major disadvantage. Xolair is an extremely expensive medication. With an annual cost per patient of approximately $10,000 to $24,000 per year, its price has been substantially more than that of the drugs that Defendants' sales representatives and managers have been directed to compete against. The drug's indications are very limited: (1) It can only be used for patients aged 12 and over, with moderate to severe

persistent asthma—not mild asthma and not SAR; (2) a detailed SMN has to be completed and signed by the treating physician, providing justification for the use of the drug before insurers, including government healthcare programs, would reimburse for it; (3) the patient's pre-treatment serum IgE level has to be tested; and (4) the drug must be administered by needle in the doctor's office (or a clinic or hospital), and the patient is required to remain in the office (or clinic or hospital) for at least two hours to be monitored for the risk of an anaphylactic response.

242. Initially, Defendants' sales representatives were positioned to promote Xolair in a manner consistent with its label. But even as early as at the launch of the drug in 2003, sales managers instructed sales representatives to downplay anaphylaxis and malignancy data and to provide off-label information (e.g., on mild asthma use, pediatric use, rush immunotherapy, and SAR). Further, Defendants recognized as early as late 2003 that sales were not on pace to approach the companies' optimistic sales forecasts, so management began to implement and approve of new, more aggressive promotional methods.

243. After Xolair received FDA approval in June 2003 for a narrow indication, Defendants also quickly acknowledged that the barriers to the level of Xolair sales that they sought would be much greater than hoped. In the summer of 2003, Defendants decided to meet the challenge and clear these obstacles by off-label marketing and engaging in kickbacks. This decision was made by Defendants' national (senior) Xolair sales team—i.e., the highest-level of Defendants' sales managers—with the support of Defendants' executive leadership.

A. KEY OPINION LEADERS AND THE XOLAIR SPEAKERS' BUREAU

244. Defendants have routinely paid physicians to serve as key opinion leaders ("KOLs"), a.k.a. "thought leaders," to off-label market Xolair, serve on sham and/or superficial

advisory boards ("ad boards"), lead roundtables, speak at other Xolair events, and engage in preceptorships.

245. There have been basically two types of KOLs: a small, core group of national KOLs; and a much larger group of local KOLs.

246. The fees that Defendants paid to physicians to serve as KOLs, serve on ad boards, lead roundtables, speak at other Xolair events, and engage in preceptorships, have been premium (high) fees in relation to the services actually rendered or, in many cases, not actually rendered (as where a doctor was paid an honorarium to speak at a "Xolair" dinner, but did not even bring up the drug).

247. From 2003 forward, Defendants have created an expanding Xolair "speakers' bureau" consisting of KOLs. The plan, which has been carried out, was to enlist doctors to serve as KOLs, promote Xolair to other doctors, and expand the speakers' bureau beyond the originally recruited KOLs. By handsomely paying honoraria to the doctors on the speakers' bureau, and buying lavish lunches and dinners for them and other attendees, Defendants' intent has been to influence the doctors' Xolair-prescribing habits, i.e., to boost Xolair sales—both on-label and off-label.

248. These kickbacks have also been a means used by Defendants to reward the highest Xolair prescribers and as a means of incentivizing doctors to increase their writing of Xolair prescriptions.

249. Based on the number of paid speakers in Relators' sales territories, and statements made by Relators' managers and other sales representatives, Relators conservatively estimate that, from 2003 forward, 1,000 doctors across the country—including allergists/immunologists, pulmonologists, and pediatricians—have served on Defendants' Xolair speakers bureau.

250. Some of these doctors on the Xolair speakers' bureau were paid additional sums of money—thousands of dollars per year—to serve as national speakers/KOLs/thought leaders—a designation that also brought with it additional kickbacks: more free meals, flights, resort stays, etc., as more fully set forth herein.

B. DETAILING

251. Aware from extensive experience and studies that doctor visits by sales representatives (called "detailing" in the pharmaceutical industry) results in increased drugs sales, Defendants engaged in a nationwide campaign to detail doctors on Xolair, requiring their Xolair sales representatives to do so regularly—at risk of job termination if this job requirement were not fulfilled.

252. During many of these "sales calls" or "details," off-label marketing was undertaken by Xolair sales representatives—under instructions from their sales managers, who took their marching orders from higher-level managers and executives.

253. From 2003 forward, approximately 200 of Defendants' Xolair sales representatives have engaged in such detailing, and have frequently used these sales visits to distribute kickbacks.

254. Relators routinely made such detailing/sales calls during their respective dates of employment.

255. The sales calls were made not only to doctors in their medical offices, but also to doctors, pharmacists and other persons with decision-making influence in hospitals, clinics, and pharmacies (including managers and pharmacists).

256. When Xolair sales representatives could not access doctors during these visits, Xolair sales representatives, including the Relators, when possible, have frequently detailed

doctors' nurses, office managers, and other persons, per Defendants' instructions and advice that such assistants often prove the most effective means of ultimately gaining access to the doctors.

C. OFF-LABEL MESSAGING AVENUES

257. From 2003 forward, Defendants intentionally, systematically, and effectively circumvented the FDCA's strict rules against off-label marketing by distributing to HCPs off-label medical literature (including journal articles, journal abstracts, editorials, and other ostensibly peer-reviewed pieces)—during the detailing process, at meals, via e-mails, and by phone calls. In short, multiple avenues of off-label messaging have been routinely employed.

258. Again, by law, only FDA-approved marketing pieces are to be used by Defendants. Although the pieces, e-mails, and/or cover sheets accompanying them have often been accompanied by statements like "Not for distribution," "Not for promotional use," "For internal purposes only," "For educational use only," and/or or similar statements, the reality is that Defendants have instructed their sales managers to instruct their sales representatives to proactively distribute them to HCPs, and told the sales representatives that doing so was a key to boosting sales and the sales representatives' earning higher compensation.

259. With some pieces, Defendants have instructed Xolair sales representatives to show the piece, or some key language in the piece, and not to leave the piece with the HCP.

260. Further, although at first glance some of the pieces appear to have been only intended for distribution to a HCP upon the HCP's unsolicited request for the information, Defendants have impressed upon their Xolair sales forces to make the record appear that it was the HCPs—not the sales representatives—who raised the off-label discussion.

261. Defendants previously and regularly had instructed Xolair sales representatives on how to conduct the detailing, move the doctor towards discussion of one or more off-label uses

(e.g., treatment of mild asthmatics by speaking about the "allergic cascade" or "uncontrolled asthma"), and by closing with a request for business.

D. OFF-LABEL MARKETING REPORTS

262. For example, Defendants have required their Xolair sales forces to complete "contact reports," "detail reports," or "detailing reports" following sales calls on doctors.

263. These reports usually identified the applicable doctor's name, the date, a summary of the discussion during the sales call, a brief plan for follow-up, and a description of any samples given to the doctor.

264. Defendants instructed their Xolair sales representatives to be careful not to allude to off-label marketing or items that could be considered kickbacks. Further, they were instructed to mischaracterize any off-label discussions, when necessary, as a physician-initiated inquiry into an off-label use, to disguise the fact that Defendants were utilizing a large sales force to proactively off-label market.

265. Many of the promotional pieces utilized by Defendants were not independent studies. Far from that, many of the studies were drafted by Defendants' own employees and/or non-employee authors who were heavily compensated by Defendants.

E. IMMUNOTHERAPY

266. In the later summer of 2003, Defendants' national Xolair sales team—i.e., the highest-level of Defendants' sales managers, which included Leslie Flynn from Genentech (Director of Xolair Sales), Bill Huff from Genentech ("FDSO"), Eddie Williams from Novartis (Vice President of Xolair Sales), Charlene Furwa from Novartis (Executive Director of Xolair Sales), Norbert Stone (East Director of Xolair Sales)—decided to use Thomas Casale, M.D.'s off-label study on rush immunotherapy as the lead, initial springboard to boost sales by

"injecting" Xolair into the lucrative market of immunotherapy, including rush immunotherapy. The basic concept was to market to allergists—who treat patients suffering from SAR-- the message that a 6-month regimen of Xolair, in tandem with immunotherapy (allergy shots), would help prevent asthma; i.e., that immunotherapy could be enhanced with Xolair treatment—even though Xolair was not FDA-approved for this purpose.

267. "Immunotherapy"—popularly known simply as "allergy shots"—is a form of treatment for many types of allergies, including SAR. Unlike medications that are used to treat the symptoms of allergies, immunotherapy treats how one's body deals with allergies.

268. "Rush immunotherapy" is a type of immunotherapy involving giving the patient multiple allergy shots over a period of many hours to days, achieving a maintenance dose (or near-maintenance dose) in a very short amount of time. Unlike traditional, long-term immunotherapy, which can last several years, "rush immunotherapy" involves giving a patient a larger dose of antigen in one injection. A person undergoing rush immunotherapy often spends at least a couple of days in the allergist's office, receiving numerous allergy shots over this initial, concentrated period of time. After the initial period of rush immunotherapy, a person is able to come into the allergist's office typically only once a week for the next many weeks—then even less often. The goal—besides less frequent visits to the allergist--is for the patient to benefit from allergy shots more quickly, usually within a few weeks. Rush immunotherapy frequently results in allergic reactions, so various medications (including antihistamines and corticosteroids) are often administered to prevent or minimize these reactions. "Rush immunotherapy" carries a higher risk of anaphylactic shock, but Defendants promoted Xolair to be given in conjunction with rush immunotherapy because, Defendants claimed, it would reduce the risk of anaphylactic shock.

269. From 2003 forward, Defendants have off-label marketed Xolair for use in both immunotherapy in general and rush immunotherapy in particular. Xolair has never been FDA approved for these uses, or approved by any drug compendia for these uses.

270. Defendants have targeted allergists throughout the United States to prescribe Xolair with immunotherapy. Defendants' sales and marketing managers strategized that, because rush immunotherapy was frequently practiced by allergists, Xolair sales would be rocket-boosted if allergists could be persuaded to prescribe Xolair as part of rush immunotherapy treatments.

271. To this end, Defendants' management instructed their sales forces to disseminate to allergists the study by Thomas Casale, M.D., described above.

F. 2004 NATIONAL SALES REPRESENTATIVE PANEL MEETING & MINUTES

272. The fact that Defendants had an expanded, aggressive definition of the patient population in mind very early in the marketing campaign is also shown by part of co-Relator Stephen Fauci's experience when was participated in the National Sales Representative Panel Meeting in San Francisco in 2004. (As detailed later herein, Mr. Fauci's experiences leading up to this panel meeting also show Defendants' off-label marketing and kickbacks schemes.) At the meeting, specially designated Xolair sales representatives from all over the country, including Mr. Fauci, gathered to discuss Xolair sales tactics and feedback they had received from other Xolair sales representatives. Leslie Flynn, the Director of Genentech's Xolair sales franchise, told the sales representatives, "Do not use moderate to severe asthma; use the phrase 'active asthma.'" This statement appears in typewritten notes of the meeting sent to the entire Genentech and Novartis sales organization. At the National Sales Representative Panel Meeting, Defendants also provided Xolair sales representatives with a reprint entitled, "The Anti-IgE

Antibody Omalizumab Reduces Exacerbations and Steroid Requirement in Allergic Asthmatics," by M. Soler, Pulmonary Division, University Hospital, Basel, Switzerland. A reprint summary provided by Genentech's marketing department told Xolair sales representatives how to best use the article with doctors: "Use the first paragraph of the study to help describe the ideal Xolair patient 'Patients with mild…[asthma]....This paragraph is also helpful because it describes the non-compliant patient, as well as the sub-optimally controlled patient...."

273. But Defendants' national marketing strategy, described immediately above, had more than this purpose: it was also simply a strategy for getting their Xolair sales forces through the door that stood between allergists' waiting rooms and their inner offices. Once inside, other off-label marketing avenues also would be pitched. For example, in anticipation of the allergy season, it was pitched from late 2003 forward to market to allergists that Xolair would help protect against the severity of asthma (to "nip in the bud" asthma attacks for patients who merely have SAR), and to also market Xolair for use in patients suffering from mild asthma, and moderate or severe asthma that did not meet the FDA prerequisites for treatment of patients with moderate to severe asthma.

274. Defendants' national Xolair sales team strategized that allergists see more asthma patients than pulmonologists, and are a softer target because pulmonologists, as a group, are less convinced that immunotherapy is effective in treating asthma. Further, they strategized that pulmonologists are more involved in treating moderate to severe cases of asthma, which are much fewer in number than mild cases of asthma.

275. Defendants' resolute off-label marketing of Xolair to HCPs for use in treating mild asthmatics reflects Defendants' total disregard for the fact that Defendants lacked any clinical studies that showed that Xolair was safe and effective for mild asthmatics—a patient

group that composes roughly one-third (1/3) of the total number of asthma patients in the U.S.A. every year.

276. Defendants have instructed their Xolair sales forces on how to overcome HCPs' reluctance or objections to prescribing Xolair for the huge patient population of mild asthmatics. From 2004 forward, sales managers and trainers have provided role-paying strategies and other advice on consummating Xolair sales with reluctant HCPs. Often times these tips included working in off-label messages and studies, as well as minimization of the risks of prescribing Xolair to a patient population outside of the FDA indication (as by downplaying the FDA warnings about anaphylaxis).

277. Defendants also have paid KOLs to promote the notion that HCPs should take a closer look at their mild asthma patients—lest they overlook that they in fact suffered from moderate to severe, persistent asthma, or uncontrolled asthma. Common strategies that Defendants have used with KOLs—which they often used with Xolair sale representatives themselves—have been to urge them to: (1) "talk up" the fact that a child asthma patient who is missing school may actually be a moderate or severe case because of the negative effect on a child that is missing school days because of the disease; (2) "talk up" how Xolair can nip a serious asthma attack in the bud, before the "mild" asthmatic experiences an aggravation or higher stage of allergic asthma reaction; (3) "talk up" how a patient can suffer from moderate to severe, persistent asthma even if ICSs have not been used, in part or in full, to treat the patient; (4) etc.

278. Once Defendants' national Xolair sales team created this initial off-label marketing strategy in mid-2003, it was promptly, systematically implemented nationwide, and expanded after 2003 with the addition of more off-label studies, also detailed in this

Complaint—to further boost Xolair sales**. Exhibit "B"** lists the names of many members of Defendants' sales forces who—almost without any exception—participated heavily in the off-label marketing campaign (and the other schemes detailed in this Complaint).

279. The Senior Leadership Team for Genentech and Novartis—including Leslie Flynn, Uli Beran, and Kelli Wilson—have also purposely off-label marketed and branded IgE-mediated disease as a sub-category of asthma. With the implementation of this strategy by their Xolair sales forces, Defendants Xolair inherently shifted the conversation with HCPs from the FDA-indicated uses of Xolair, to prescribing Xolair for any airway restriction, inflammation, or lung remodeling disease that is stimulated by the enhanced production of IgE. Defendants hired and trained physicians to serve as "Key Opinion Leaders" ("KOLs"), including Henry Milgrom, M.D. (Director, Ambulatory Pediatric Allergy Program, Dept. of Pediatrics, National Jewish Health, Denver, CO), Russell Settitpane, M.D. (affiliated with Brown Univ. in Rhode Island), and Williams Busse, M.D. (Allergy, Asthma & Immunology Clinic, Adult & Pediatric, Univ. of Wisconsin School of Medicine & Public Health), who made presentations across the country, from late 2003 or early 2004 forward, in which they argued that the IgE-mediated disease, and the "allergic cascade," could be clinically addressed only by Xolair. This off-label marketing/misbranding campaign was reinforced by the collateral materials used by virtually everyone in Defendants' sales forces. It was also carried out by the 5 specialty pharmacy companies, named above, that were hired/contracted by Defendants, to provide their own, additional outside and inside sales forces to engage in the off-label/misbranding campaign. Defendants' nationwide speaker programs used the title, or some variation of the title, "IgE-Mediated Disease and Allergic Cascade," in furtherance of this campaign. As noted above, 43% of Xolair users were patients with mild cases of asthma (off-label), Defendants' initial studies for

FDA approval showed no efficacy in mild asthma, and 33% of those patients were only receiving Xolair and no other asthma therapy (also off-label).

280. Defendants' national Xolair sales team soon began to view Advair and Singulair (and other drugs) as being directly in competition with Xolair. However, Advair and Singulair are FDA indicated for a significantly larger pool of patients—those with mild to severe asthma and SAR—while Xolair is only indicated for patients with moderate to severe, persistent asthma.

281. Many sales representatives—including Ken Clifford, a Genentech sales representative based in Albany, New York—complained to management—including John Mastrianni, Jim Sullivan, Leslie Flynn, Kelly Wilson, Rob Rindini, and others—and objected to management's marketing position that Advair and Singulair were direct competitors to Xolair, stating that Advair and Singulair are approved for a wider patient population than Xolair. But these sales managers rejected the sales representatives' objections, and encouraged sales representatives to engage in aggressive "best practices" and "pull through" methods to maximize sales. Defendants' use of the terms "pull through" and "best practices" were often "code," or euphemisms, for implementation of many of the aggressive, illegal activities highlighted by this lawsuit.

282. Defendants have regularly instructed their sales representatives to promote illegal uses of Xolair to their prescribing physician customers by marketing Xolair for treatment of all types of asthma, not just moderate to severe asthma, as the approved indication stated.

283. More specifically, Defendants instructed the sales representatives, when speaking to physicians, to use the term "active asthma" in place of "moderate to severe persistent asthma." The term "active asthma" generally means asthma that has been diagnosed by a physician, or

asthma in which symptoms have been experienced within the last year. Thus, most any patient that sees a doctor for asthma will have "active asthma."

284. Defendants' practice of using the term "active asthma" began in the Northeast in early 2004. Because its use was met with success, spurring more sales, it was formally embraced and adopted nationwide, no later than November 2004. Specifically, instructions are contained in the minutes to a November 5, 2004 National Xolair Sales Representative Panel Meeting, attended by certain Xolair sales personnel from across the United States to reflect the opinions of the wider Xolair sales force. This document reflects many of Defendants' illegal marketing tactics. These minutes were distributed to all of Genentech's Xolair sales representatives and treated as sales directives from management by the sales force nationwide. Marketing by using the term "active asthma," in place of moderate to severe persistent asthma, greatly expanded Xolair sales representatives' patient pool.

285. Leslie Flynn, Genentech's Director of Sales for Xolair, distributed these minutes from the November 2004 National Sales Representative Meeting in San Francisco, which Stephen Fauci attended, to the entire Genentech-Novartis Xolair sales organization. Because Defendants perceived that pulmonologists thought that IgE tests were of questionable usefulness for assessing the propriety of Xolair treatment for asthmatics, Leslie Flynn advised all Xolair sales representatives to pitch to "PUDs" (a term that Defendants have used to refer to pulmonologists) IgE as a dosing metric. IgE is not for dosing purposes only; it is a significant serum marker for a physician's clinical impression, evaluation of appropriate treatment, and overall medical evaluation. IgE, body mass index ("BMI") and asthma control all play a significant clinical role in whether Xolair is appropriate and necessary. The cost-effectiveness of a treatment like Xolair has to be taken into consideration when it is vastly more expensive than

other treatment modalities. Indeed, the FDA's position in this regard is that a drug is not recommended when it is much more expensive and has not been shown to work as well as, or better than, current treatment modalities.

286. These minutes kept by Leslie Flynn, which show both the Genentech and Novartis names/logos at the top of the first page, are dated November 5, 2004. The minutes' "Subject" is "Recap of the National Rep Panel meeting." Attendees of that meeting are listed as Ms. Flynn, Dwayne Blackwell, [co-Relator] Stephen Fauci, Barb Dreiling, Stacey Stames, Lora Eberhardt, Greg Tutko, Dave Tyson and Thomas Woods—all Genentech and Novartis sales managers and representatives. It states that the "Meeting Objectives" were to "[s]olicit feedback on High Impact ideas to grow SMNs and other topics of interest to the [sales] field." Among the "High Impact Ideas" listed and memorialized by Ms. Flynn were to "[u]se term 'Active Asthma' vs mod / severe;" "[u]se TENOR data – filed of PELS" (TENOR was a bogus, off-label study, financed by Defendants, in which physicians were paid to provide patient quality-of-life data to Defendants); "[m]easure impact of LASH programs on B&B [buy and bill] for Medicare with 'other Report;'" "Offices used [off-label] Juniper [study] for QOL [quality of life] follow up, can we put link on Xolair.com to juniper site?" [a reference to utilizing this off-label study of the quality of life of Xolair users], and "[c]apitalize on RN [registered nurse], NP [nurse practitioner] and Resp[iratory] Therapist in pt [patient] identification."

287. These minutes reflect decisions, and directives, to off-label market to HCPs by encouraging them to prescribe Xolair to any patient experiencing asthma symptoms, with a focus on using physicians' nurses and respiratory therapists to influence doctors, and even bypass doctors to achieve Xolair sales. In other words, physicians' assistants could be targeted for identifying new Xolair patients. *Id.* at 1.

288. These minutes also reflect some of the barriers that the Xolair sales forces frequently encountered, and ways that Defendants devised to try to surmount them. To get pulmonologists and other physicians to prescribe Xolair, despite their long-term concerns with Xolair's efficacy and safety, and preference for safer, more effective ICSs for the treatment of asthma, it was written: "Access to PUDs-Work with hosp[ital]…case managers to recommend Xolair to MDs that are no see, every territory has no see PUDs and MDs that will never write on their [sales representatives'] target list." Similarly, Ms. Flynn wrote that "20% of target list will never write [a Xolair prescription] – sleep PUDs or Intensivists." *Id.* That reflects the fact that the Xolair sales force encountered strong resistance from about 20% of physicians on sales representatives' target lists because of the drug's safety and efficacy issues. To the question, "What steps should we take in 2005 to be sure that our customers see us as highly valued?," one of the answers written by Ms. Flynn was "preceptorships for all [sales] reps." "Preceptorships," as noted above and described in detail below in the "Kickbacks Scheme" section of this Complaint, are payments from Defendants to physicians for allowing sales representatives into their offices, purportedly to witness physician interactions with asthma patients. Training initiatives in 2005 for other types of kickbacks and off-label marketing were listed, as well, including: training for "pulm[onary] function tests" (which were distributed to HCPs as a kickback), "spin selling" (which referred to selling Xolair by putting a spin on the appropriate use of the drug), and "[d]ivisional journal clubs," which were sales force sub-groups for exchanging off-label promotional literature for more effective off-label marketing. Defendants' push to get the Xolair sales force to "pull through" in getting SMNs was reflected by the notation that some sales representatives expressed that they "[d]on't need constant mentioning of SMNs, but need strategies, pilots and how to's, like more divisional contests" to obtain SMNs. The

minutes also reflect the Defendants' goal in 2004 to "grow [Xolair] from $1-3 billion." *Id.* at 3. "Clinicals" (clinical studies) are also, by their very nature, off-label studies—unless they formed part of the FDA approval process (which these did not).

289. Although Xolair's FDA-approval required administration of the drug in doctor's offices, clinics, or hospitals, because of the risk of anaphylactic shock and other side effects, these November 5, 2004 minutes clearly reflect that Defendants have blissfully ignored that safety requirement. In answer to the questions, "Do you have any MDs implementing home infusion [at-home administration of the drug]? How is it working?," Ms. Flynn wrote: "Yes, it is being done and is spreading[.] One office does the first 4 injections then moves to the home[.] Sporadic, relatives who are medical personnel request it[.] Sent home with epi pens, Done selectively based upon geography or insurance requirements[.] ALs don't want this[.] Uli- new SMN includes box for home administration, this will cause a lot of issues with Allergists, remove and leave office and other boxes only." "Epi pens" are epinephrine "pen" devices that allergy patients theoretically may use to inject themselves in case of an emergency—like an anaphylactic reaction.

290. The concluding notation in the minutes reflect the fact that physicians continued to have concerns about safety and efficacy: "One year safety data, safety concerns still exist, laggards want more date [data]." A "laggard" is, of course, a person who makes slow progress and follows behind the pack.

G. NATIONAL, REGIONAL, AND LOCAL SALES MEETINGS

291. While employed by Novartis, Relators attended national, regional, local, and "breakout" sales meetings during which attendees were shown PowerPoint slides directing sales representatives to employ the phrase "active asthma" rather than "moderate to severe persistent

asthma" when discussing Xolair's potential uses with physicians. That phrase was also contained in flip-charts as a directive to the sales force. These flip charts were also used at national, regional and/or breakout sales meetings.

292. Defendants never directed the Xolair sales force to draw any distinction between "mild" or "active" asthma and "moderate to severe asthma." To the contrary, from late 2004 forward, the sales forces were being directed nationwide to avoid the term "moderate to severe" and "moderate to severe, persistent," and instead to employ and market the terms "active asthma," "allergic asthma," and "allergic cascade," so that the drug would not be pigeon-holed to its FDA label/approved indication, which would greatly limit sales by reminding HCPs of its limited indication because of safety and efficacy issues.

293. Furthermore, in the course of promoting Xolair for uses the FDA had never approved, Defendants' sales forces were instructed by sales managers and trainers to fail to disclose to HCPs, and indeed failed to disclose to HCPs, the critical facts that: (a) the evidence from the very studies upon which Genentech and Novartis had relied to obtain FDA approval of the drug to treat a subset of patients with moderate to severe asthma, failed to show any benefit to patients with mild asthma; (b) Xolair's safety and efficacy had not been established as to any other allergic conditions besides that for which it was expressly indicated; (c) the FDA had required that the previous two facts be included in Xolair's labeling; and (d) starting December 1, 2005, Defendants had never completed a study of Xolair's efficacy and safety for treating mild cases of asthma, despite the fact the companies had committed to undertaking and completing such a study by November 30, 2005, as a condition to receiving FDA approval in June 2003.

294. Defendants' Xolair sales forces—including over 20 Regional and Divisional Sales

Managers as well as sales representatives from both Novartis and Genentech—have promoted Xolair for "active asthma." These include Genentech's head of sales for the Northeastern United States (Kelli Wilson), its head of sales for New England (John Mastrianni), its head of sales for New York State (Jerry Kelly), and its head of sales for Washington D.C., Pennsylvania, and Maryland (Ryan Diaz).

295. The marketing of Xolair for mild asthma, contrary to the indication and use approved by the FDA, constituted misbranding of the drug.

296. Relators and the rest of the Xolair sales force knew that the drug was not efficacious for mild asthma. Pre-launch Xolair materials made clear the drug has no benefit for mild cases of asthma.

297. Defendants' management repeatedly and forcefully instructed sales representatives to falsely advise physicians that IgE levels are only relevant to a determination of the dosage of Xolair to be administered, and that physicians should therefore focus on making extremely strong clinical impressions of symptomatic "active asthma," regardless of the IgE level in prescribing Xolair. In this manner, as well as the other methods discussed herein, Defendants have promoted Xolair for the treatment of asthmatic conditions other than moderate to severe, persistent allergic asthma. The manner of improperly increasing Xolair sales was expressed in the minutes of the same November 2004 National Xolair Sales Representatives Panel Meeting during which the "active asthma" phraseology was used, as well.

298. The sales practices that Defendants' management directed sales representatives to utilize, which actually have been utilized by sales representatives, illegally promoted the "off-label" use of Xolair.

299. As of Relators' last dates of employment, there were no signs whatsoever that Defendants intended to comply with the Medicare, Medicaid, FDA, and other requirements discussed.

300. Indeed, through their investigations, Relators have learned that the vast majority of the illegal sales practices employed by Defendants to sell Xolair, described herein, have continued past the ends of their employment, and into the present, as sales people have continued to feel pressure from management to push these schemes to meet their sales goals. When Mr. Garcia and Ms. Kelly's original lawsuit was filed, the Government subpoenaed Defendants for records relating to their allegations. When the Government allowed them access to some of those documents, which were electronically produced by Defendants, Mr. Garcia and Ms. Kelly saw evidence that the off-label marketing continued past their dates of employment, and that the Defendants had redacted portions of the electronically produced documents to hide potential evidence. (One scheme that Relator Allison Kelly believes that Novartis discontinued in 2006 or 2007 was the scheme of preceptorships. However, she believes that Genentech continued with that component of the kickbacks scheme, based on information available to her.)

301. Indeed, additional evidence of Defendants' off-label marketing of Xolair is evident from after their employments. Among other things, off-label marketing statements have appeared in both Defendants' websites during 2012. Further, since 2006, Defendants have fired employees, including Genentech's firing of Xolair district sales manager Jason Reich in 2008 or 2009, for having complained about off-label marketing of Xolair.

302. In contrast, Xolair's FDA-approved label states:

> Xolair is indicated for adults and adolescents (12 years of age and above) with <u>moderate to severe persistent asthma</u> who have a positive skin test or in vitro reactivity to a perennial aero allergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations

in these patients. Safety and efficacy have not been established in other allergic conditions.

(emphases in underlining added).

303. As explained above, Tricare does not extend benefits for drugs not approved by the FDA, Medicaid, and Medicare Part D, and the Veteran's Health Administration will only reimburse for a drug used for a "medically accepted indication," which means an FDA-approved indication or one which is supported by one or more citations in certain drug compendia, including USP DI and AHFS Drug Information. Mild asthma is not supported by any citations in the relevant drug compendia:

> • USP DI 2007 (last available edition): Xolair "is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skim test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids."
>
> Xolair "is not indicated to treat acute asthma exacerbations and should not be used for treatment of acute bronchospasm of status asthmatics."
>
> • AHFS Drug Information 2009: "[Xolair] is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skim test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids."
>
> "Safety and efficacy of [Xolair] in the management of other allergic conditions have not been established."

304. Faced with competition, and a limited, moderate to severe, persistent asthma FDA indication, Defendants have marketed and distributed misbranded Xolair in interstate commerce, and have promoted Xolair for mild asthma, an off-label indication, in order to increase sales, revenues, and market share.

305. At all relevant times herein, Xolair sales representatives have made oral statements regarding the drug being indicated for use in patients with mild asthma, an indication for which the drug was not approved by the FDA; thus, the drug did not bear adequate directions

for use and under the FDCA the drug was misbranded. Misbranded drugs are not approved by the FDA.

306. At all relevant times herein, Defendants have promoted and sold misbranded Xolair to prescribing physicians. Because such prescribing physicians and specialty pharmacies have sought reimbursements from government healthcare programs for non-FDA approved, misbranded Xolair, Defendants have caused false claims to be submitted to the government.

307. In addition to the instances listed elsewhere herein, Defendants have illegally promoted and marketed Xolair off-label to prescribing physicians by promoting Xolair to patients experiencing mild asthma, contrary to its indications and labeling; by failing to mention to prescribing physicians that the evidence does not support Xolair's efficacy for mild asthma and that the FDA has specifically concluded that Xolair is not effective for mild asthma; and by either filling out SMN forms, or instructing physicians to fill out SMN forms, to reflect that the patient had "moderate to severe" asthma, thereby supporting the prescribing of Xolair. Defendants also have made material affirmative misstatements and omitted material facts in the course of engaging in this off-label promotion.

H. OFF-LABEL PUBLICATIONS

308. Defendants have regularly instructed their Xolair forces to market the off-label uses of Xolair, and to disseminate medical literature which, in part or in full, described the usefulness or potential usefulness in treating asthma patients who were outside of the FDA-approved indication.

309. Defendants' sales representatives have followed a national sales policy and procedure to promote Xolair off-label by providing non-approved clinical studies and "homemade" marketing materials not approved by the FDA, which were designed to show the

supposed but unproven efficacy of Xolair for off-label conditions. Defendants' sales forces utilized these unreliable and unapproved clinical studies to promote off-label use of Xolair. Defendants directed their sales forces to intentionally misstate or overstate the findings of these unreliable studies to support specific claims of Xolair's off-label efficacy. Defendants intended that these unapproved clinical studies and marketing materials would cause HCPs/customers to prescribe Xolair for off-label use and would result in the presentation or submission of false and/or fraudulent claims to government healthcare programs.

310. Defendants have deliberately detailed physicians on "off-label" uses of Xolair, often orally and sometimes in the form of unpublished abstracts (often financed by the companies themselves), and have encouraged their sales forces to get this information before doctors, in order to increase sales. (As noted above, while physicians are allowed to prescribe medications "off label," it is a violation of the FDCA for drug companies to market their products "off label," except in narrowly prescribed categories not present here.)

311. Defendants' senior marketing groups developed collateral materials that were distributed nationally and warehoused for their Xolair sales forces to order. These materials have been distributed by sales representatives to HCPs because they used ambiguous terms—like "allergic cascade," "active asthma," and "IgE-mediated disease"—that sales representatives were instructed to use to blur the line between Xolair's FDA-approved, limited indication, and a broader, off-label spectrum of conceivable uses. Defendants' Xolair sales forces have routinely followed through with this directive: doing so was a veritable job requirement for Xolair sales representatives, to meet sales quotas and keep their jobs.

312. On a routine basis, throughout the course of their employments, Defendants' sales

representatives—including co-Relators Ms. Kelly, Mr. Garcia, and Mr. Fauci—received promotional literature on, and were informed about, Xolair's unapproved uses, and were encouraged and instructed to get this information before physicians. The literature and discussions dealt with such potential, but unapproved, uses of Xolair as: sinusitis, SAR, peanut allergy, use in conjunction with immunotherapy and rush immunotherapy, and pediatric applications.

313. Xolair is not approved for and/or lacks sufficient efficacy data for: steroid reduction; atopic dermatitis; other IgE-mediated diseases, e.g., multiple sclerosis, lupus; sinusitis; SAR; food allergies; latex allergies; peanut allergies; mild asthma; pediatric patients; patients with IgE levels below 30 or above 700; patients who weigh more than 150 kilograms ("KG") or less than 30 KG; patients who do not test positive to a perennial allergy; patients who are currently controlled on ICSs; improving quality of life; and reducing emergency room visits.

314. Although the FDA did not approve Xolair for use by children under the age of 12, Defendants have aggressively marketed the drug to pediatricians, who care for patients who are predominantly under that age. While it is true that pediatricians also care for youths who are age 12 or over, Defendants' intent has also been to capture as much of the pediatric market as possible, regardless of age. Defendants' sales managers and trainers made this clear to the Xolair sales forces in sales meetings, conference calls, and sales conferences.

315. The off-label studies were not peer-reviewed, often were scientifically questionable due to the small sample size of patients, and failed to meet the criteria of the FDCA for dissemination of "off-label" data to physicians. For example, in 2003 and 2004, Mr. Garcia's manager, Jerry Kelly, stressed the importance of noting to allergists the "rush immunotherapy" educational literature because they would be most hesitant to write prescriptions for Xolair if

traditional allergy shots (immunotherapy) or rush immunotherapy was eliminated or reduced. He also stressed the importance of the steroid reduction studies to pulmonologists, allergists, pediatric pulmonologists, pediatric allergists, and pediatricians.

316. At all relevant times, Defendants' sales managers also have given the Relators and other sales representatives "target lists" of hospitals, other medical facilities, physicians, and other HCPs to contact in their territories, and have instructed them to sell Xolair to them. These target lists have been approved by Defendants' senior management, who distributed them to sales managers, who redistributed them to sales representatives. For example, Novartis managers (including Frank Garay, William Stewart, Dan Giunta, and Martin Clark) gave Ms. Kelly a target list of doctors in the Bronx/Westchester, New York area that included pediatricians, internists, family practice doctors, pediatric pulmonologists, and pediatric allergists. When Xolair was launched, the Defendants openly discussed pediatric studies and that there had been children as young as six in the studies. These practices were company-wide, and nationwide, in scope. Again, Relators frequently attended sales meetings on a local, regional, and national basis in which these practices were openly discussed among managers and sales representatives from all parts of the country, and encouraged. Examples include the Xolair Launch meeting in Orlando, July 2003, the Las Vegas Xolair meeting in September 2003, the San Diego Xolair "T1" (Trimester 1 covering January-April of the year) meeting in January 2004, the Dallas T1 meeting in February 2004, and the Xolair Teleconference Nationwide in February 2005.

317. At these and other meetings, sales representatives, including co-Relators Ms. Kelly, Mr. Garcia, and Mr. Fauci, were told to fully absorb this data on unapproved uses fully, in order to be able to detail physicians with the information and show the "success" Xolair was

having in these unapproved uses. At several points, there were open discussions about the fact that the majority of patients on Xolair did not meet the approved indications and eligibility criteria. This detailing of HCPs has routinely taken place, as suggested above.

318. Co-Relators Kelly and Gacia routinely off-label marketed to HCPs through the means discussed in this Complaint. For example, for most of his employment in 2003 and 2004, Mr. Garcia off-label marketed to as many physicians in his sales territory as he could, including, but not limited to, Drs. Alan Kaufman, Allen Dozor, Joseph Casino, Michael Mandell, Craig S. Osleeb, James Pollowitz, Anne Maitland, Jeffrey S. Sugar, Noreen Linn, and Richard B. Frimer. Likewise, during most of her period of employment as a Xolair sales representative, Ms. Kelly off-label marketed to as many physicians in his sales territory as she could, including, but not limited to, Drs. Ahuja, Lehach, Pollowitz, Rosenzweig, Linn, Maitland, Sugar, and Kaufman.

319. E-mails clearly show that Xolair sales managers have distributed off-label studies to sales representatives. For example, on September 20, 2006, Martin Clark, Novartis' Xolair New York Area Sales Manager, e-mailed "3" off-label "reprints to Xolair sales representatives, specifically off-label reprints from Mary K. Miller and the TENOR Study Group, Dr. De Marco, and Dr. Stuart W. Stoloff. Novartis and Genentech intended and instructed their sales managers and representatives to utilize such off-label studies to "change the conversation" from the FDA's approved indication for Xolair, to alternative off-label approaches for determining which patients are candidates for receiving the drug. For example, while the FDA indication required that specific criteria be met for prescribing Xolair, including "severity" (moderate to severe persistent asthma), the Stoloff study also discussed "control." Xolair sales representatives have often used the Stoloff study to shift HCPs to thinking about prescribing Xolair for patients having any

problems with asthma control—as opposed to the FDA restriction to "moderate to severe persistent asthma." Asthma that is not under perfect control is not, of course, necessarily "moderate to severe persistent asthma." The Miller/TENOR concluded in part, in the opening synopsis of the study, that "[c]lassification of asthma severity on the basis of current asthma symptoms and lung function may be useful but not completely reflective of a patient's true asthma condition." This study also has been used by the Xolair sales forces to convey a clear message to HCPs that the FCA indication was an incomplete way of targeting the appropriate Xolair patient population.

320. Defendants' Xolair sales forces have been specifically instructed by superiors to fight the FDA label with the off-label studies that Defendants provided to them. It was another one of Defendants' "best practices" to achieve "pull through."

321. Defendants not only have instructed their sales managers and representatives to off-label market, provide kickbacks, and engage in other unlawful actions to boost sales, Defendants have regularly reminded them of the importance of doing so, and have even made the sales managers and representatives write out plans for aggressively achieving sales objectives that incorporated these "tools." This has been done on a nationwide basis by Defendants, during national, regional and local sales meetings/conferences, in e-mails, in conference calls, and in sales manager "ride-alongs" with sales representatives during their visits to HCPs. For example, in planning for most Xolair National Sales Meetings, sales representatives have been asked to complete "Account Planning Workshop Pre-Work" papers. In these papers, sales representatives were to identify their physicians into three categories: high-prescribing physicians, low-prescribing physicians, and non-prescribing physicians. They were then required to "[l]ist the barriers you think are preventing your low- and non-prescribing physicians from prescribing

Xolair for more patients" and "[l]ist the strategies and tactics you plan to use to advance high-prescribing physicians along the sales continuum and increase the prescribing habits of low-and non-prescribing physicians."

I. EXAMPLES OF OFF-LABEL PUBLICATIONS

322. The following publications are among the off-label studies that Defendants' sales representatives (including Relators) have been instructed to share with and/or disseminate to HCPs, and in fact have shared with and provided to HCPs, throughout the country:

> Donald Y.M. Leung, M.D., Ph.D., Hugh A. Sampson, M.D., John W. Yunginger, M.D., A. Wesley Burks, Jr., M.D., Lynda C. Schneider, M.D., Cornelis H. Wortel, M.D., Ph.D., Frances M. Davis, Ph.D., John D. Hyun, B.S., & William R. Shanahan, Jr., M.D., for the TNX-901 Peanut Allergy Study Group, "Original Article": *Effect of Anti-IgE Therapy in Patients with Peanut Allergy*, The New England Journal of Medicine (Vol. 348, No. 11; Mar. 13, 2003, at 986-993). This study, which involved 84 participants who were administered either TNX-901 [omalizumab] or a placebo, notes at the outset that "peanut allergy is characterized by symptoms and signs after ingestion that may include nausea, vomiting, diarrhea, abdominal pain, urticarial, angioedema, bronchospasm, hypotension, loss of consciousness, and death." The article concludes: "A 450-mg dose of TNX-901 [omalizumab] significantly and substantially increased the threshold of sensitivity to peanut on oral food challenge from a level equal to approximately half a peanut (178 mg) to one equal to almost nine peanuts (2805 mg), an effect that should translate into protection against most unintended ingestions of peanuts." Thus, this article touts the possible efficacy of omalizumab for treatment of peanut allergies. The FDA did not approve Xolair (omalizumab) for treatment of peanut allergies, or any allergies. Although Defendants

were prohibited from off-label marketing through the use of this article, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Henry Metzger, M.D., "Editorial": *Two Approaches to Peanut Allergy*, The New England Journal of Medicine (Vol. 348, No. 11; Mar. 13, 2003, at 1046-1048). This editorial summarizes the study conducted by Donald Leung, M.D., Ph.D., *et al*, *Effect of Anti-IgE Therapy in Patients with Peanut Allergy*, The New England Journal of Medicine (Vol. 348, No. 11; Mar. 13, 2003, at 986-993). Dr. Metzger notes the "efficacy of the treatment" that was provided with TNX-901 [omalizumab], and that "this approach has been under investigation for about 15 years and has been used in clinical trials to treat allergic rhinitis and allergic asthma." (Allergic rhinitis is a collection of symptoms, mostly in the nose and eyes, which occur when one breathes in something to which he is allergic, such as dust, dander, insect venom, or pollen.) Xolair [omalizumab] was not FDA-approved for treatment of allergic rhinitis, peanut allergies, or other allergies. Although Defendants were prohibited from off-label marketing through the use of this editorial, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Beverly Merz, "Behind the Research": *Studying Peanut Anaphylaxis*, The New England Journal of Medicine (Vol. 348, No. 11; Mar. 13, 2003, at 975-976). This commentary also summarizes the study conducted by Donald Leung, M.D., Ph.D., *et al*, *Effect of Anti-IgE Therapy in Patients with Peanut Allergy*, The New England Journal of Medicine (Vol. 348, No. 11; Mar. 13, 2003, at 986-993). Ms. Merz states that "In this issue of the *Journal*, Leung et al (pages 986-993), report results with a new drug [TNX-901/omalizumab] to reduce the risk of anaphylactic reactions to food. In a multi-center, phase 2 study, TNX-901, a monoclonal antibody to IgE, increased the threshold of sensitivity to peanut antigen to a level that should

afford protection from unintended ingestions….The study brings new information at a time when the prevalence of food allergy is rising….For children and adults with peanut allergy, hyper-vigilance has become a way of life: food-label scrutiny is second nature, and sampling dishes of unknown provenance is verboten." This commentator also quotes one of the study's authors as saying that some of the study's participants even reported to have seemingly developed a greater tolerance to foods other than peanuts. Ms. Merz subsequently noted: "In September 2002, the [FDA] granted TNX-901 fast-track status, a designation designed to expedite review for approval. Even so, further investigation has come to a halt. Phase 3 studies, which would establish dosage and indications, are on hold pending the resolution of litigation among Tanox, Genentech, and Novartis—the companies that were partners in developing the drug." Xolair [omalizumab] was not FDA-approved for treatment of peanut allergies or any other allergies. Although Defendants were prohibited from off-label marketing through the use of this commentary, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Thomas B. Casale, M.D., William W. Busse, M.D., Joel N. Kline, M.D., Zuhair K. Ballas, M.D., Mark H. Moss, M.D., Robert G. Townley, M.D., Masoud Mokhtarani, M.D., Vicki Seyfert-Margolis, Ph.D., Adam Asare, Ph.D., Kirk Bateman, M.S., Yamo Deniz, M.D., and the Immune Tolerance Network Group, *Omalizumab pretreatment decreases acute reactions after rush immunotherapy for ragweed-induced seasonal allergic rhinitis*, Journal of Allergy & Clinical Immunology 2006 (Vol. 117, at 134-140): The authors of this study wrote that rush immunotherapy ("RIT") "presents an attractive alternative to standard immunotherapy. However, RIT carries a much greater risk of acute allergic reactions, including anaphylaxis." The authors "hypothesized that omalizumab [Xolair], a humanized monoclonal antiIgE antibody,

would be effective in enhancing both safety and efficacy of RIT." A 123-patient study was conducted. The authors reported: "Patients receiving omalizumab plus immunotherapy had fewer adverse events than those receiving immunotherapy alone. Post hoc analysis of groups receiving immunotherapy demonstrated that addition of omalizumab resulted in a 5-fold decrease in risk of anaphylaxis caused by RIT…." The authors concluded: "Omalizumab pretreatment enhances the safety of RIT for ragweed allergic rhinitis. Furthermore, combined therapy with omalizumab and allergen immunotherapy may be an effective strategy to permit more rapid and higher doses of allergen immunotherapy to be given more safely and with greater efficacy to patients with allergic diseases." Other notable statements included: (1) "Omalizumab (Xolair…) is a humanized monoclonal anti-IgE antibody with established efficacy for moderate-to-severe allergic asthma and intermittent (seasonal) and persistent (perennial) allergic rhinitis"; (2) "This study has demonstrated the potential utility of omalizumab pretreatment in allergen-specific immunotherapy of ragweed-induced allergy rhinitis. It is unique in showing that omalizumab pretreatment can provide substantial protection against acute allergic reactions, including anaphylaxis, during a RIT protocol. Pretreatment of patients with omalizumab for 9 weeks reduced the rate of anaphylactic events during RIT by almost 80%."; (3) "A previous study in children showed that concomitant treatment with omalizumab and allergen-specific (tree or grass) immunotherapy was more effective than immunotherapy alone"; (4) "In summary, omalizumab pretreatment appears to offer substantial protection from serious allergic reactions after RIT. With further investigation, omalizumab pretreatment appropriately dosed and timed could ultimately lead to the safer and more effective use of allergen-specific immunotherapy for a variety of patients and disorders." Several of the study's authors disclosed significant conflicts of interest: including six authors who disclosed that they have either worked

at, owned stock in, served a consultant with, served on the speakers bureau of, or have received grants from, the Defendants or a parent company thereof. The FDA did not approve Xolair (omalizumab) for treatment of ragweed-induced SAR, or any allergies. Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Thomas B. Casale, M.D., *Omalizumab and Immunotherapy* (undated, at 83-87): In this paper/presentation, Dr. Casale made numerous off-label statements that are pertinent because Defendants' sales representatives were directed to distribute it to HCPs. These statements included the following: "Allergic rhinitis effects 20 to 40 million Americans annually, including 10 to 30% of adults and up to 40% of children. Symptoms can range from mild to seriously debilitating and can affect quality of life resulting in loss of work and school days. Effective management of seasonal allergic rhinitis may be an important component of the treatment of co-existing or complicating respiratory conditions such as asthma, sinusitis and otitis media….Omalizumab…has been approved for the treatment of moderate to severe persistent allergic asthma in the United States. Omalizumab has been shown to be safe and effective for the treatment of children and adults with seasonal and perennial allergic rhinitis as well as allergic asthma….there is a need for safer and more effective therapies capable of inducing an immune tolerant state. The combination of anti-IgE and allergen immunotherapy holds promise for such therapy….The rationale for combining omalizumab plus allergen immunotherapy includes the prospects of improved clinical benefits and immunotolerogenic effects. Furthermore, by decreasing serum IgE levels and FceR1 expression, omalizumab should make immunotherapy safer. In a study conducted by the Omalizumab Rhinitis Study Group, the effects of adding omalizumab to immunotherapy were examined in children….The combination

of immunotherapy plus omalizumab was more effective than either therapy alone or placebo….In this presentation, I will also review the results of a NIH/Immune Tolerance Network sponsored study examining the effects of pre-treatment of ragweed allergic rhinitis patients with omalizumab prior to immunotherapy. Our hypothesis was that pre-treatment of ragweed allergic patients with omalizumab will condition the recipient so that subsequent administration of ragweed allergen immunotherapy is safer, clinically more effective and immunologically more efficient at inducing a long-lasting immune tolerance to ragweed….159 total subjects were randomized. At the time of preparation of this handout, we are still analyzing the data for statistical differences between the 4 treatment groups. However, preliminary analyses indicate that the average daily allergy severity scores were significantly better in the omalizumab plus immunotherapy group versus the immunotherapy alone group. Furthermore, in protocol correct patients, the combination of omalizumab plus immunotherapy was better than omalizumab alone, immunotherapy alone or placebo alone. Omalizumab had a protective effect on allergic-type reactions to both rush immunotherapy and maintenance immunotherapy. This effect was manifested by a reduction in serious adverse events, anaphylactic reactions, and the use of epinephrine and prednisone to treat reactions. The data suggest that omalizumab pre-treatment may be an effective strategy to permit more rapid and high doses of allergen immunotherapy to be used. However, the exact dosing and timing warrants further study. The mechanisms involved in improved efficacy and safety of omalizumab and immunotherapy are still under investigation. Further analyses of these data will likely provide important information on how best to use these therapies in combination. It is anticipated at the time of this meeting the final results from the primary efficacy and safety trial will be available." The FDA did not approve Xolair (omalizumab) for treatment of allergic rhinitis, or any allergies. The FDA also

did not approve Xolair for use with children. Hence, Defendants were prohibited from off-label marketing through the use of this article. However, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> "Abstract": *The Epidemiology and Natural History of Asthma: Outcomes and Treatment* Regimens (TENOR) Study (American College of Allergy, Asthma and Immunology (ACAA) Meeting, Nov. 12, 2003), concerning "the natural history, including medication use, of patients with severe or difficult-to-treat asthma." This analysis described the outcomes of TENOR patients who reported single-unit combination asthma therapy use (fluticasone propionate and almeterol xinafoate) at baseline and Month 12 visits compared to patients who reported never using combination asthma therapy." The analysis concluded that "patients taking single-unit combination asthma therapy do not appear to differ from patients taking multiple asthma medications in terms of asthma-related healthcare utilization in this population of patients with severe or difficult-to-treat asthma." The distribution of this study by Defendants' sales force was unlawful because the spectrum of patients with "difficult-to-treat asthma" is much broader than the approved indication of Xolair. Further, the study focused on patients that were 13 years or older, which includes children who were not within Xolair's indicated age restriction. Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> "Abstract": *Latex Allergy and Omalizumab* (undated). This study concerned latex allergy, which is "common among healthcare workers (prevalence estimated at 3-21%), who are regularly exposed to latex gloves or other latex-containing medical supplies. Symptoms can be local and/or systemic and include conjunctivitis, rhinitis, urticaria, bronchospasm and

anaphylaxis." The study noted that "omalizumab…stops the allergic cascade by binding to free IgE…[and] is effective in the treatment of patients with allergic asthma and rhinitis." The study's purpose was "to evaluate the efficacy of omalizumab in healthcare workers with occupational latex allergy." The study concluded that "omalizumab had statistically and clinically relevant ocular anti-allergic activity (assessed by the conjunctival challenge test); had skin anti-allergic activity (assessed by the latex glove challenge test and the quantitative skin prick test); [and] was well tolerated." The promotion by Defendants of this abstract—and study—was off-label because Xolair was not FDA-approved for occupational latex allergy, or any other allergies. Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> S.T. Holgate, *et al*, on behalf of the Omalizumab 011 International Study *Group, Efficacy and safety of a recombinant anti-immunoglobulin E antibody (omalizumab) in severe allergic asthma*, Clinical & Experimental Allergy 2004; Vol. 34, at 632-638: This study "was supported by a grant from Novartis Pharma AG, Basel, Switzerland and Genentech, South San Francisco, California, USA." The study was conducted because "patients with severe asthma are often inadequately controlled on existing anti-asthma therapy, constituting an unmet clinical need," and concluded that "[o]malizumab treatment improves asthma control in severely allergic asthmatics, reducing inhaled corticosteroid requirements without worsening of symptoms control or increase in rescue medication use." The more detailed conclusion of the study was: "In conclusion, the present study in patients with severe allergic asthma shows that omalizumab is not only well tolerated when added to optimized therapy with inhaled corticosteroids but also enables the underlying disease to be controlled (and in most cases improved) with a significantly

lower dose of such therapy. These findings build upon earlier studies showing that omalizumab represents a novel therapeutic approach for allergic asthma over a range of severities in adults and children." The promotion by Defendants of this study was off-label because Xolair was not FDA-approved for treatment of any allergies, or for use with children. Hence, Defendants were prohibited from off-label marketing through the use of this article. However, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> *Can Guideline-defined Asthma Control Be Achieved? The Gaining Optimal Asthma Control Study*, American Journal of Respiratory Critical Care Medicine, Vol. 170, No. 8, Oct. 2004, at 836-844: This study involved a patient population of 3,421 people between the ages of 12 and 80 with at least a 6-month history of asthma. The promotion by Defendants of this study was off-label because, among other things, Xolair was not FDA-approved for use in children, and only for moderate and severe cases of asthma, and only then after preconditions were satisfied. This study included mild cases and children, and the promotion of this study was intended to highlight Xolair's efficacy in such off-label cases. The study concluded: "In summary, this study has shown that guideline-defined control of asthma can be achieved in the majority of patients with uncontrolled asthma with combination salmeterol/fluticasone treatment. This approach should be the preferred treatment selection for patients whose asthma is uncontrolled, regardless of their previous inhaled corticosteroid regimen. Salmeterol/fluticasone achieves sustained control of asthma as defined by a composite of relevant clinical goals of treatment in more patients, more rapidly and at a lower dose of inhaled corticosteroids than fluticasone alone. In addition, the approach of aiming for total control and maintaining treatment resulted in the virtual elimination of exacerbations and near-normal quality of life in the majority of patients and brought substantial benefit even to those who failed to achieve this high level of

control." The study disclosed that one of the authors, William W. Busse, received consultancy fees from "Genentech/Novartis ($100,000 for 2002 and 2003)" and other companies. Although Defendants were prohibited from off-label marketing through the use of this article, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Stanley J. Szefler, M.D., *et al*, for the Asthma Clinical Research Network of the National Heart, Lung, and Blood Institute, *Significant Variability in Response to Inhaled Corticosteroids for Persistent Asthma*, Journal of Allergy & Clinical Immunology (Vol. 109, No. 3, Mar. 2002): The promotion by Defendants of this study was off-label because, among other things, Xolair was only FDA-approved for moderate and severe cases of asthma, and only then after preconditions were satisfied—not for broader "persistent" asthma. Indeed, the conclusion of the study stated in part: "In summary, our findings show that in this study population of individuals with mild to moderate persistent asthma, low-to-medium-dose FP-MDI and BDP-MDI was sufficient to attain a maximal increase in…" (emphasis in underlining added) Although Defendants were prohibited from off-label marketing through the use of this article, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> *J.K. Peat, et al, Serum IgE levels, atopy, and asthma in young adults: results from a longitudinal cohort study*, Allergy, Vol. 51 (1996), at 804-810: The promotion by Defendants of this study was off-label because, among other things, Xolair was not FDA-approved for use in children, and only for moderate and severe cases of asthma, and only then after preconditions were satisfied. This study included mild cases and children, and the promotion of this study was intended to highlight Xolair's efficacy in such off-label cases. To quote the study in part: "In this paper, we examine the relation between sensitization to common allergens, respiratory

symptoms, and AHR in childhood and levels of total serum IgE in a cohort of young adults aged 18-19 years who had been studied up to five times at 2-year intervals during their childhood ….718 children were studied. Each second year thereafter until 1992, every effort was made to contact and study each subject….A total of 407 of 718 subjects who attended the initial study in 1982 were also subjects at the final study in 1992…" At the end of the study, the authors stated: "Because allergic history influences the presence of symptoms and AHR which continue into adulthood, further research is needed to determine the mechanisms which protect some sensitized children from developing sensitization and high serum IgE levels in response to the inhalation of common allergens." Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Larry Borish, M.D., *et al*, for the TENOR Study Group, *Total serum IgE levels in a large cohort of patients with severe or difficult-to-treat asthma,* Annals of Allergy, Asthma & Immunology (Vol. 95, No. 3, Sept. 2005), at 247-253: This study was performed, in part, due to the existence of "limited data being available on levels of IgE in large cohorts of patients with severe or difficult-to–treat asthma." The study's objective was "[to] examine IgE levels and disease in patients from The Epidemiology and Natural History of Asthma: Outcomes ad Treatment Regimens (TENOR) study. The study found, among other things that "[c]hildren (6-12 years old) and adolescents (13-17 years old) have higher mean IgE levels than adults.…Among children, patients with severe asthma have a higher mean IgE level…than patients with moderate…or mild…asthma…." The study concluded that "[i]n patients with severe or difficult-to-treat asthma from the TENOR study, higher total IgE levels were observed in males, children, smokers, nonwhite/racial ethnic groups, and adults with childhood-onset

disease. In addition, IgE levels are associated with asthma severity among younger patients." 10.4% of the study group was adolescent, and 16.2% was pediatric. The authors noted that "[o]verall, TENOR's pediatric patients with severe asthma have higher IgE levels compared with children with moderate or mild asthma." The study touted "TENOR [as] the largest observational study conducted of patients with severe or difficult to treat asthma with measured IgE levels. Although TENOR is not a population-based study, the cohort represents children, adolescents, and adults of diverse racial and ethnic backgrounds from widely distributed areas across the United States. With more than 4,500 participants with a measured IgE level at baseline, TENOR provides the largest database available to examine the relationships between demographic and clinical characteristics and IgE patients with severe or difficult-to-treat asthma." One of the authors of this study, Chantal Dolan, Ph.D., was specifically identified as working on behalf of Genentech. Further, it was specified that "[t]he TENOR Study is funded by Genentech Inc and Novartis Pharmaceuticals Corp." The promotion by Defendants of this study was off-label because Xolair was not FDA-approved for treatment of "difficult-to-treat asthma," mild asthma, or asthma in children or adolescents. Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

> Chantal M. Dolan, Ph.D., *et al*, for the TENOR Study Group, *Design & baseline characteristics of The Epidemiology and Natural History of Asthma: Outcomes & Treatment Regimens (TENOR) study: a large cohort of patients with severe or difficult-to-treat asthma,* Annals of Allergy, Asthma & Immunology (Vol. 92, Jan. 2004), at 32-39: This study began by stating that "[p]atients with severe and difficult-to-treat asthma represent a small percentage of asthma patients, yet they account for much of the morbidity, mortality, and cost of disease. The

goal of The Epidemiology and Natural History of Asthma: Outcomes ad Treatment Regimens (TENOR) study is to better understand the natural history of asthma in these patients." The study's objective was described as being "[t]o describe the methods and baseline characteristics of the TENOR study cohort." To this end, "[f]rom January through October 2001, more than 400 U.S. pulmonologists and allergists enrolled patients," including "patients 6 years or older who were considered to have severe or difficult-to-treat asthma by their physicians were eligible." 10% of the study participants were adolescents (13-17 years), and 16% were children (6-12 years). The authors observed that "[a]n economic analysis of asthma costs in 1992 reported that the largest single contributor to the indirect costs of asthma was days of school missed, with more than 10 million days of school missed each year." The study's conclusions were: "The TENOR study is the largest cohort of patients with severe or difficult-to-treat asthma. Although patients are equally divided into moderate or severe asthma categories, most are considered difficult-to-treat. The TENOR study highlights the lack of control in moderate-to-severe asthma and provides a unique opportunity to examine factors related to health outcomes in this understudied population." The authors also concluded: "Despite more mild disease, both children and adolescents reported high levels of health care utilization. In particular, unscheduled office visits and the use of steroid bursts in the previous 3 months were equally high among adults, adolescents, and children. A greater proportion of children and adolescents had a history of intubation compared with adults. These data suggest that even patients considered to have mild or moderate asthma have symptom control problems." The first-listed author of this study, Chantal Dolan, Ph.D., was specifically identified as working for Genentech in South San Francisco. Further, it was specified that "[t]he TENOR Study is sponsored by Genentech Inc and Novartis Pharmaceuticals Corp." The promotion by

Defendants of this study was off-label because Xolair was not FDA-approved for treatment of "difficult-to-treat asthma," mild asthma, or asthma in children or adolescents. Although Defendants were prohibited from off-label marketing through the use of this study, Defendants have required their Xolair sales forces to do the opposite, and the directive has been carried out.

323. The above is not an all-inclusive list and/or summary of off-label literature and messages that Defendants have required their Xolair sales forces to utilize to illegally promote Xolair sales.

J. JOURNAL CLUBS/"HOME-MADE" OFF-LABEL LITERATURE

324. As reflected by Leslie Flynn's minutes from the National Xolair Sales Representative Panel Meeting dated November 5, 2004, numerous Xolair sales managers have required Xolair sales represenatives in their divisions to participate in "journal clubs," which were sales force sub-groups for finding and exchanging off-label promotional literature for more effective off-label marketing.

325. Defendants' sales managers have lauded Xolair sales representatives, like co-Relator Stephen Fauci, when they have found any medical literature, through these clubs or on their own, that could be used for off-label marketing. Within Genentech and Novartis, these pieces were sometimes referred to as "home-made" off-label literature, because they were located by the sales representatives, on their own or through these journal clubs.

326. The better the find, the more likely that one or more Xolair sales managers or sales executives would either distribute the "home-made" off-label literature to other Xolair sales force members, or instruct them to access the study or article from an online library available to them.

K. SUMMARIES OF OFF-LABEL STUDIES

327. Defendants not only have distributed such off-label studies to their sales forces to be used in off-label marketing, they also frequently have provided sales managers and sales representatives with concise written summaries of the off-label studies which highlighted major off-label points and conclusions of the studies.

328. For example (and there were many), Defendants provided them a summary of Dr. Borish's study, "The Role of IgE in Asthma"; Dr. Peat *et al*'s study on "The Role of IgE in Asthma"; and others [attached hereto and incorporated herein by reference as **Exhibit "C"**].

329. The purpose of these summaries has been to make it easier for Xolair sales representatives to off-label market.

L. CONCEALMENT

330. Defendants have frequently instructed their Xolair sales forces to conceal the Xolair off-labeling marketing they were instructed to perform.

331. Specifically, Defendants frequently have reminded their sales forces to minimize a "paper trial" that would show the off-label marketing: by abstaining from direct references in e-mails; by showing off-label studies to HCPs and their staffs, but trying to limit leaving the studies with them; and by using code phrases or euphemisms like "pull through" and "best practices" to conceal the details of the off-label marketing push.

332. Defendants also have often instructed their sales forces to make off-label statements to HCPs, but not to put them in writing. Still other times, Defendants have instructed them to prompt the HCP to create a record, like an e-mail, that would create the appearance that the HCP actually had requested the off-label materials, so that when the Xolair sales representative or sales manager provided the off-label materials, it would look like Defendants were not initiating the actions.

333. As noted or suggested above, Defendants have made a library of off-label reprints available to their Xolair sales forces, from which they were expected to order reprints and physically distribute them, or orally communicate their core messages, to HCPs.

334. The off-label marketing was often approved by Defendants' inside lawyers, who actually developed and implemented strategies for attempting to conceal the off-label marketing.

335. For example, in 2006, Defendants planned and conducted a presentation, "approved by legal," for their Xolair sales forces, which was designated training session number 569 954 932 when it included 39 participants (including Kelly McQuaid, Alan Bennett, Amy Doehring, and Allison Kelly) during one of the many times it was conducted with Xolair sales force territories. A slide from the presentation slide [attached hereto and incorporated herein by reference as **Exhibit "D"**] stated as follows:

> **FDM – JRPT Approved for Promotional Use**
>
> **Description**
>
> • The IgE Educational Reprint Carrier is an unbranded piece that includes 2 reprints. This is a leave behind that should be reviewed in its entirety with Health Care Providers to gain a better understanding of the role of IgE in asthma. During your time reviewing this piece with Health Care Providers you [the sales representative or sales manager] are not to discuss or answer questions related to Xolair.
>
> • Once you have finished reviewing this piece you may use branded promotional resources to discuss Xolair; however, you should not refer back to the IgE Reprint Carrier.
>
> • You are not to imply that any of the patients described in these reprints are by definition appropriate for Xolair therapy.

336. The above-quoted slide shows the extent of Defendants' transparent attempts to hide their off-label marketing. Of course, the fact that the Xolair sales force was instructed to not discuss Xolair at the time that the off-label marketing piece was discussed with HCPs does not make it any less an act of off-label-marketing—especially when one considers that the Xolair

sales force hypes Xolair both before and after the off-label marketing piece was distributed and discussed.

337. In other words, that temporal gap is irrelevant. To think otherwise would be like ignoring the existence of a bribe where a business person presents a wad of cash to a politician in a position of influence, but does not discuss the importance of approval of his company's construction project until a day, a week, or a month later.

338. Moreover, the temporal gap was also often illusory in the first place, because Xolair sales representatives did, in fact, frequently discuss Xolair in the same conversations with HCPs about the off-label marketing pieces.

339. Indeed, the types of instructions that Defendants gave their Xolair sales forces—like those contained in the above-quoted slide—were, in any event, acts of "CYA" on Defendants' part. Defendants' sales managers, who were trained by superiors or who were trained by specialized trainers acting under superior's direction, frequently instructed Xolair sales representatives to aggressively engage in off-label discussions with HCPs about the benefits of Xolair.

340. Of course, it is also absurd to think that HCPs, after being briefed about an off-label study presented by a Xolair sales representative, would not follow up promptly with a question about how the study related to Xolair use, and that the Xolair sales representative would responded with, "Sorry, I can't answer that" or the substantial equivalent.

M. MONITORING OFF-LABEL USE

341. Defendants have monitored off-label use, and have targeted physicians for off-label use of Xolair, by utilizing written and oral feedback from sales representatives and sales managers, SMNs, PANs, Xolair Patient Progress Reports, Xolair Patient Injection Reports,

Xolair Patient Injection Records, Patient SMN Approval Tracking Forms, Appeal Letters to CMS and private payors, Xpansion enrollment cards (in which patients describe their Xolair use as "severe persistent," "moderate persistent" or "other," and send the cards to Genentech/Novartis), the Xpansion/Xolair "patient education and support" program, and other documents.

342. As part of the Xpansion program, Defendants have sent patients a "Daily Tracker" with an "Asthma Action Plan to help [patients] monitor and manage [their] allergic asthma"; an "Office Visit Planner to promote good communication with [the patient's] doctor or healthcare professional"; answers to frequently asked questions, and other information.

343. Defendants' off-label marketing not only has violated federal prohibitions against the practice, and the FCA in general, but also have violated Defendants' own standards.

344. For example, Novartis's own website (as of March 12, 2006), stated that Novartis' "**Use of Unapproved Promotional Materials ("Homemade bread")** is unlawful. To further quote the website: "Promotion includes any material provided to potential users or decision-makers regarding our products that makes a claim about a Novartis product. It also includes verbal statements made by representatives of our company. The use of any material or claims not approved by the Novartis Promotional Review Process in the promotion of our products is strictly prohibited."

N. DEFENDANTS RESPOND TO FDA WARNINGS ABOUT XOLAIR'S SAFETY WITH MORE OFF-LABEL MARKETING

345. As set forth above, on February 21, 2007, the FDA announced that it would require Genentech to strengthen the label warning for Xolair by requiring inclusion of a "black box" warning regarding Xolair's anaphylaxis risk, which was found to be double what it appeared to be when the drug was originally approved in 2003. A copy of this announcement

appears at www.fda.gov.bbs/topics/NEWS/2007/NEW01567.html [also attached hereto and incorporated herein by reference as **Exhibit "E"**]. The announcement also spelled out other serious potential side effects of the drug, and stated that the "FDA has asked Genentech to revise the Xolair label and provide a Medication Guide for patients to strengthen the existing warning for anaphylaxis."

346. Continuing to put concern with their profits above patient safety, Defendants responded defensively and deceptively, instructing their Xolair sales forces to emphasize a business-as-usual approach in dealing with concerned HCPs. The sales forces were instructed, orally and in writing, to downplay the risk of anaphylaxis—the exact opposite of the FDA's concern.

347. On February 21, 2007, Gus Lobos, LDP for Novartis' U.S. Xolair Brand team, sent an e-mail and attachment to Xolair sales managers and senior sales directors [attached hereto and incorporated herein by reference as **Exhibit "F"**], stating in part: "Team, Below please find the 2nd FDM approved by JPRT [Novartis' legal approval process] in response to this mornings FDA press release. This FDM should be utilized during the conference calls scheduled by the Xolair ASMs [areas sales managers] & BRMs [business regional managers] over the next few days…" A response was set forth for Defendants' reaction to media inquiries—one which emphasized that a warning for anaphylaxis had existed since the drug was initially approved by the FDA in 2003. The response stated that "[n]o fatal anaphylactic reactions have been reported to date," and regurgitated antiquated 2003 data that "[i]n clinical studies involving over 4,000 patients, the incidence of anaphylactic reactions was approximately 0.1% in patients receiving Xolair." In fact, studies now showed that the risk of an anaphylactic reaction was double (0.2%),

and that many serious adverse events, including deaths, had been reported by HCPs to the FDA—albeit perhaps without proof that Xolair had caused these adverse events.

348. On February 24, 2007, Charles Sabino, Novartis' Executive Director of the Xolair Franchise, sent an e-mail to the Novartis Xolair sales force called "Update on FDA Notification" [attached hereto and incorporated herein by reference as **Exhibit "G"**]. He stated in part that "[i]t is important that we all stay cool and confident as we navigate this situation. You have all built this brand to what it is today based on strong clinical selling and we need to continue to stay focused on clinical selling as we appropriately respond to customer inquiries." In short, Novartis' Xolair senior leadership instructed their Xolair sales force to continue to focus on making sales.

349. On February 26, 2007, Defendants issued a "Genentech and Novartis Statement Regarding Pending Xolair Label Update" [attached hereto and incorporated herein by reference as **Exhibit "H"**]. It emphasized: "The risk of anaphylaxis must be balanced against the benefits of Xolair" and stated that the companies were "confident in the demonstrated safety and efficacy profile of Xolair…for Subcutaneous Use to treat moderate-to-severe persistent allergic asthma." No mention was made of the years of Defendants' prior off-label marketing of Xolair for treatment of patients with mild asthma, despite the FDA's limited indication for Xolair. No warning was sounded for mild asthmatics taking Xolair. No warning was made that, contrary to the FDA's 2003 label restriction, Xolair had been distributed to many patients for use at home, with a vastly increased dangers if there were an anaphylactic reaction, because of the lack of a medical setting to monitor for the reaction. The February 2007 FDA Alert and the original, 2003 Xolair product insert, were included at the end of Defendants' written statement.

350. On February 26, 2007, Charles Sabino sent an e-mail to the Novartis Xolair sales force attaching "a new Field Direction Memo (FDM) with direction on communicating with [HCPs] about the recent FDA communications" [attached hereto and incorporated herein by reference as **Exhibit "I"**], attaching a PDF (also described as a "physician leave-behind") to be distributed to HCPs/customers called "FDA-Communication on Xolair Anaphylaxis," and stating to the Novartis Xolair sales force that "it is important that we continue to focus on clinical selling and closing for appropriate Xolair patients." The FDM repeated old data about the risk of an anaphylactic reaction, stated there had been no reports of death due to such a reaction, and encouraged closing Xolair sales.

351. On February 27, 2007, Gus Lobos distributed by e-mail to the Novartis Xolair sales force a "Xolair Anaphylaxis Objection Handler" (with both Novartis and Genentech's logos appearing on it) to be studied, and announced that training would be provided in the coming days. Even though Defendants knew that the Xolair PI would be changing very soon to further emphasize serious side effects, the Xolair sales force was told to use the 2003 PI. Even more surprising, especially for this situation, Defendants instructed the Novartis Xolair sales force to use off-label studies to meet HCP concerns: Busse *et al*, Soler *et al*, Holgate *et al*, DeMarco *et al*, Lanier *et al*, Stoloff *et al*, Bateman *et al*, Szefler *et al*, Dolan *et al*, etc., and the "[u]nbranded [off-label] IgE Educational Carrier (Peat/Borish)." The Xolair sales force was told, in dealing with HCP objections, to "[s]hift the focus from the 'problem' to the 'plan,'" make a variety of off-label sales pitches, distribute IgE test kits, and close sales. For HCPs expressing "concern[] about my patients on Xolair who self-inject at home," the Xolair sales force was told to acknowledge the issue (the HCP or patient concern), but was not told to instruct the HCP to administer Xolair only in hospitals, clinics, and medical offices.

352. Thus, Defendants knowingly withheld and concealed Xolair side-effect data from their Xolair sales forces and HCPs/customers and redoubled off-label marketing efforts, exactly while FDA scrutiny of Xolair was highlighting overwhelming clinical data that showed the severe side effects associated with Xolair, and exactly while the Xolair sales forces were hearing frequent concerns voiced by numerous HCPs about malignancy data and the risk of anaphylaxis. Defendants' Xolair sales forces also distributed collateral materials and sent out e-mails on how to address the significant rate of adverse events that continued to be reported from the field to Defendants' "Medical Hotline." These materials and e-mails downplayed, neutralized, and even refuted physician and/or patient concerns.

353. As set forth above, the FDA has twice—in 2009 and 2011—opined that Xolair is being prescribed for off-label uses (in 2009, as being used by patients with mild asthma, and in 2011, as being used by under-aged patients). In 2009, the FDA stated that the evidence of extensive off-label use is "troubling."

O. OFF-LABEL DOSAGES

354. Defendants not only have off-label marketed Xolair for proscribed disease states and levels, they have aggressively marketed use of Xolair at excess dosages, in order to realize greater profits from sales of the drug.

355. Xolair is to be administered subcutaneously every 4 weeks at 150 mg or 300 mg per dose, or every 2 weeks at 225 mg, 300 mg, or 375 mg per dose.

356. Specifically, per the FDA's 2003 limited approval of Xolair, administration of the drug is to be "150 to 375 mg by subcutaneous (SC) injection every 2 or 4 weeks. Determine doses (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). *See the dose determination charts below (Table 1 and Table 2)*

for appropriate dose assignment. Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control….Adjust does for significant changes in body weight." Xolair Product Insert, at 2-3 (emphasis in italics in original).

357. Table 1 concerns administration of Xolair every 4 weeks. Per Table 1, the following dosage administration is required:

Pre-treatment Serum IgE (IU/mL)	Body weight 30-60 kg	Body weight > 60-70 kg	Body weight > 70-90	Body weight > 90-150 kg
≥ 30-100	150 mg	150 mg	150 mg	300 mg
> 100-200	300 mg	300 mg	300 mg	see table 2
> 200-300	300 mg	see table 2	see table 2	see table 2
> 300-400	see table 2	see table 2	see table 2	see table 2
> 400-500	see table 2	see table 2	see table 2	see table 2
> 500-600	see table 2	see table 2	see table 2	see table 2

358. Table 2 concerns administration of Xolair every 2 weeks. Per Table 2, the following dosage administration is required:

Pre-treatment Serum IgE (IU/mL)	Body weight 30-60 kg	Body weight > 60-70 kg	Body weight > 70-90	Body weight > 90-150 kg
≥ 30-100	see table 1	see table 1	see table 1	see table 1
> 100-200	see table 1	see table 1	see table 1	225 mg
> 200-300	see table 1	225 mg	225 mg	300 mg
> 300-400	225 mg	225 mg	300 mg	DON'T DOSE
> 400-500	300 mg	300 mg	375 mg	DON'T DOSE
> 500-600	300 mg	375 mg	DON'T DOSE	DON'T DOSE
> 600-700	375 mg	DON'T DOSE	DON'T DOSE	DON'T DOSE

359. Hence, the FDA's 2003 restricted approval of Xolair made clear, by "DO NOT DOSE," that Xolair must not be administered to a patient whose pre-treatment serum IgE level and body weight are not within specific ranges.

360. However, Defendants' Xolair senior sales managers have frequently instructed

Xolair sales representatives to fill out SMNs for the maximum dosage, and to encourage HCPs to prescribe the maximum dosage, when the patient does not fall within these dosing guidelines for the administration of Xolair.

361. This most frequently has occurred when the patient had IgE levels over 700 IUs. Off-label dosages also have occurred when a patient was obese.

362. In other words, the algorithm used to determine Xolair dosing consists of the patient's pre-treatment IgE level and the patient's body weight. Once these markers are determined, the dosing schedule and the amount of Xolair to be given are set. However, Defendants' Xolair senior sales managers have led a directive that, if a patient falls outside of these guidelines, the Xolair sales representative is to instruct the physician that he/she give the maximum allowable dose outlined in the Xolair dosing chart. Defendants' sales managers coached Xolair sales representatives, when speaking to HCPs, to use a non-scientific argument that having these patients on Xolair is far better than not having them on Xolair.

363. Alternatively, Xolair sales representatives simply would alter a patient's IgE level or body weight on the SMN—just enough so that it would graduate a patient into the next dosing frame, creating either a higher frequency of dosing (every 2 weeks vs. once a month) or to give more Xolair to that patient; both can occur simultaneously.

364. Conversely, if the patient had too low an IgE level, sales representatives were instructed to state that the IgE level was at least 30—the minimum for administration of Xolair.

365. Further, many of Defendants' sales managers, including many of those listed immediately below, instructed their sales representatives, including Allison Kelly and Frank Garcia, to include in the falsified SMNs that the patient had tested positive for asthma or even that he or she had skin tests that showed perennial allergy.

366. Defendants' sales managers (including many of those listed immediately below) distributed to their Xolair sales forces a dosing guide chart—that Xolair sales representatives were instructed to use to influence HCPs on sales calls—that set forth dosages higher than those set forth in the FDA-approved charts for maximum dosages. Xolair sales representatives' effective utilization of this improper dosing guide chart also resulted in many Xolair sales representatives receiving higher bonuses.

367. All of these off-label dosage scenarios put the patient at significant, unnecessary medical risk, and resulted in the overbilling of government healthcare programs.

368. Collectively, such off-label dosages conservatively accounted for approximately 15% of all Xolair prescriptions/SMNs.

369. Among the numerous Xolair senior sales managers who gave these off-label dosage instructions were: Kelli Wilson (Genentech Regional Sales Manager) instructing co-Relator Mr. Fauci and his colleagues from 2003 to 2005, John Mastrianni (Genentech Division Manager) instructing Mr. Fauci and his colleagues from 2003 to 2004, and James Sullivan (Genentech Division Manager) instructing Mr. Fauci and his colleagues from 2004 to 2005; Jerry Kelly (Genentech District Sales Manager) instructing co-Relator Mr. Garcia and his colleagues in from 2003 to 2004; and Frank Garay, William Stewart, and Martin Clark instructing co-Relator Ms. Kelly and her colleagues from 2003 to 2007.

370. Other Xolair sales managers that have also given the Xolair off-label dosage directive include Jerry Kelly, William Stewart, Frank Garay, Martin Clark, and Daniel Giunta, who transmitted the instructions to the Relators and other Xolair sales representatives, including Curtis James, Lisa Wheeler, Patricia Pino, Kimberly Dickman, Alexis Pace, James Kostalidis, Frances Estramera Pascavage, Jessica Otinario, Katie Weafald Freeborn, Alla Spiegel, Joseph

Bonsignore, Jaye Bea Smalley, Bonnie Masnick, Pilar Carbone Celestin, Jerry Covell, Shamika St. John, Jonathan Kiesznoski, Nick Daschille, Maureen Freeder, Donna Bacilise, and Elise Keena.

371. At times, Defendants' sales managers even directly advised HCPs to prescribe excess dosages. For example, in 2003 or 2004, co-Relator Frank Garcia's manager, Jerry Kelly, encouraged Dr. Alan Pollowitz in New York, to prescribe the maximum dosage several times, including when a patient had IgE levels that exceeded 700 IUs, when some pediatric patients had IgE levels that exceeded 700 IUs, and when another patient was obese.

372. Increased sales of Xolair led to increased profits for Defendants and, under Defendants' compensation structures, led to increased commission payments for their sales representatives and sales managers.

XVIII. THE KICKBACKS SCHEME

373. Defendants have aggressively and illegally marketed Xolair by providing a very wide array of valuable kickbacks to HCPs (doctors, nurses, and doctors' additional staff), to induce them to overlook its troubling profile. These kickbacks—all of which were carried out nationally from 2003 forward (unless otherwise specifically indicated)—have targeted HCPs who have prescribed Xolair or were in a position to prescribe Xolair. Further, all of these types of kickbacks were frequently discussed by Defendants' sales managers and sales representatives, which confirms their existence beyond the specific ones (many of them) that Relators distributed. Also, these kickbacks normally had to be approved by management as sales and marketing expenses, which further shows managerial knowledge of them. Unless otherwise set forth herein, each component of the kickbacks scheme was a national program/campaign coordinated by Defendants and carried out by hundreds of sales representatives across the country.

374. The myriad kickbacks that are provided by Defendants to boost Xolair sales are clearly "over the top":

A. FREE CASH EQUIVALENTS AND EXPENSIVE GIFTS[15]

- ***American Express travelers checks (the equivalent of cash gifts)**

375. The American Express Travelers Cheque Program has been perhaps the single-most egregious kickback provided by Novartis. There is no conceivable legitimate purpose for distributing American Express traveler's checks to HCPs, their nurses, and other staff.

376. These travelers' checks are like cash, because they can be redeemed for cash or used to purchase items at virtually any retail store, restaurant, or other establishment that accepts them. They have been distributed in amounts typically ranging from $50.00 to $500.00. They have been used to ingratiate HCPs to the Xolair sales force and achieve access to doctors' offices.

377. For example, if a pulmonologist office employee exhibits some openness to the idea of reaching out to his/her pulmonologist employer about allowing the sales representative to have access to patient files to identify patient candidates for Xolair, the sales representative might give that pulmonologist office employee and/or pulmonologist an American Express travelers check as a "thank you." In short, they were used to "grease the wheels" and "open the door" to Xolair sales.

378. Because the travelers checks are like cash, as they are accepted by innumerable retailers across the country, they also have afforded Novartis sales managers and sales

[15] Novartis is one of approximately 12 pharmaceutical companies that have very recently begun reporting, at least to some extent, certain payments that it makes to physicians. Novartis reported that it made over $7.6 million in payments to physicians in the United States in the fourth quarter of 2010. Source: propublic.org. Of course, none of these payments were characterized as kickbacks to HCPs.

representatives the flexibility of being able to buy items for HCPs without creating the same "paper trail" involved when a purchase is made by a Novartis sales manager or sales representative, and a reimbursement request is sent to the Novartis sale and/or accounting departments, or when a Novartis sales manager or sales representative needs to request a regular Novartis bank check to pay for an item or to pay a HCP directly.

379. For example, a Novartis sales force member not only could simply hand an American Express travelers check to a HCP or HCP staff member, he or she could pay for an expensive dinner for a HCP's spouse with an American Express travelers check. In this way HCP family members could be "comp'd" for lavish meals without it being as obvious.

380. Among the many Novartis Xolair sales personnel who have distributed and/or used thousands of dollars of American Express traveler's checks, in the Northeast alone—as has been done throughout the United States, are:

- Co-Relator Allison Kelly, Novartis Xolair sale representative in Westchester, NY and environs, from 2003 through 2006—Ms. Kelly also used them as a Novartis Diovan and Lotrel sales representative from 2001 through 2003;

- Novartis Xolair District Sales Manager Frank Garay, utilizing them from 2001 through 2004;

- Grace Brown, Novartis Xolair sales representative in South Boston and counterpart to Genentech sales representative Patricia Pino;

- Kelly Edgos, a North Boston Xolair sales representative for Novartis and Genentech sales representative Stephen Fauci's counterpart in the New England sales district, distributed approximately $2,500 to $3,000 in American Express travelers' checks, in $300 to $500 increments, to Robert Schiffman, M.D. (Mount Auburn Hospital, Cambridge, MA), Najmuddin Patwa, M.D. (Stoneham, MA), Jeffrey Newton, M.D. (Andover, MA), and other HCPs;

- Todd Zaccera, Novartis Xolair sales representative in New Haven, Connecticut;

- Elizabeth Gugliotta, Novartis Xolair sales representative in Rhode Island and Genentech sales representative Curtis James' counterpart;

• Frances Estramera, Novartis Xolair sales representative in Queens, NY; and

• Kathryn Wefald, Novartis Xolair sales representative in New York City.

381. Many of the most successful Novartis Xolair sales representatives were the biggest utilizers of the American Express traveler's checks program.

382. On September 5, 2006, the Novartis Sales Communication department sent a memorandum to "All Sales Associates, Managers, and Regional Managers," as well as all "Sales Vice Presidents, Operations Directors," about "Travel & Expense – Amex Travelers Cheque Decommission" [attached hereto and incorporated herein by reference as **Exhibit "J"**]. This document, which was received by Allison Kelly in 2006, and shared by her with her former Genentech counterpart/co-Relator, Frank Garcia, and with former Genentech sales representative/Co-Relator Stephen Fauci, confirms the existence of the American Express Travelers Cheque Program and that it has been a company-wide "pattern or practice."

383. Most importantly, the fact that the memo was distributed company-wide, to all Novartis sales representatives, sales managers, regional sales managers, sales vice presidents, and operations directors—and not merely to all of Novartis' Xolair Novartis sales representatives, sales managers, regional sales managers, sales vice presidents, and operations directors—confirms that this program has been company-wide. That is, it has not been limited to Novartis' Xolair sales franchise. If the program had been limited to the Xolair franchise, this memo would not have been distributed to virtually every person in any sales position in Novartis, and it would state that it was applicable to Novartis' Xolair sales force.

384. Further, as set forth above, Ms. Kelly used the American Express Travelers Cheque Program not only as a Xolair sales representative from 2003 through 2006, but also as a

Novartis Diovan and Lotrel sales representative from 2001 through 2003. That of course also shows that the program extended far beyond Xolair, as the memo indicates.

385. Notably, the memo states that Novartis is "in the process of decommissioning the use of Travelers Cheques," that the "change" will occur, and that "replenishments of new cheques" generally would not be forthcoming. (emphasis in underlining added)

386. With too quick a reading of this memorandum, one might surmise that this illegal kickback was utilized by Novartis until it ended the program in September 2006.

387. However, as Ms. Kelly knows, and as the memo actually makes clear, the program did not end in 2006; it was just reduced. Sales managers and representatives continued to be allowed to use the travelers checks—to quote the memo—"when business requirements make it necessary." Novartis also continued to encourage sales associates, sales managers, and regional directors to use their American Express credit cards for business purposes, in lieu of the "cash only" method of the AmEx travelers checks.

388. Hence, this most egregious of kickbacks has been utilized by Novartis on a massive scale in all of their billions of dollars in annual drug sales. Although the program was scaled down in late 2006, it continued to be used, especially to influence the purchasing and prescribing of "critical accounts" and other high prescribers of all Novartis drugs.

389. Because the Novartis American Express Travelers Cheque program has been a company-wide practice, it has extended to Novartis' many blockbuster and near-blockbuster drugs, tainting those drugs' sales, including the following drugs with the following U.S. sales for these representative sales years:

Drug	**2003**	**2006**	**2007**	**2011**
Diovan/Co-Diovan (hypertension)	$1.107B	$1.858B	$5B	$5.665B

Gleevec/Glivec (chronic myeloid leukemia/gastro-intestinal stromal tumors)	$299M	$630M	$3.1B	$4.659B
Neoral/Sandimmune (transplantation)	$216M	$125M	$944M	$903M
Lamisil (fungal Infections)	$428M	$574M		
Zometa (cancer complications)	$574M	$696M	$1.3B	$1.487B
Lotrel (hypertension)	$777M	$1.35B	$748M	
Lescol (cholesterol reduction)	$309M	$256M	$665M	
Sandostatin (acromegaly)	$318M	$367M	$1B	$1.443B
Voltaren (pain/ Inflammation)	$8M	$8M	$747M	$794M
Cibacen/Lotensin/ Cibadrex (hypertension)	$306M			
Trileptal (epilepsy)	$305M	$549M	$692M	
Miacalcic (osteoporosis)	$239M	$199M		
Tegretol-incl. CR/XR (epilepsy)	$122M	$120M	$413M	
Exelon (Alzheimer's)	$181M	$187M	$632M	$1.067B

Visudyne (wet form of age-related macular degeneration)	$181M	$70M		
Leponex/Clozaril (schizophrenia)	$86M			
Foradil (asthma)	$9M	$14M		
Elidel (eczema)	$205M			
Famvir (viral infections)	$146M	$166M		
HRT Range (hormone replacement)	$125M			
Femara (breast cancer)		$338M	$937M	$911M
Zelnorm/Zlemac (irritable bowel syndrome)		$488M		
Comtan/Stalevo (Parkinson's disease)		$157M	$420M	$614M
Ritalin/Focalin (attention Deficit)		$264M	$375M	$550M
Exjade (iron chelator)			$357M	$850M
Lucentis (age-related macular degeneration)			$393M	$2.05B
Tobramycin (cystic fibrosis)			$273M	
Exforge				$1.2B

Tasigna	$716M
Xolair	$478M

$5.941B Total 2003	$8.418B Total 2006

390. Novartis sales personnel have distributed and/or used many thousands of dollars of American Express travelers checks in the Northeast alone to promote Novartis drugs, including Diovan, Elidel, Focalin, Foradil, Lamisil, Lescol, and the other drugs listed above. Novartis sales personnel in the Northeast who have promoted these other drugs through the distribution of American Express travelers checks, purchased by Novartis, have included the following:

• Martin Higgins was a Novartis cardiovascular sales representative in New York City and its environs in 1998 and/or 1999. During this time, Allison Kelly and Mr. Higgins were "counterparts," meaning sales representatives employed by Novartis assigned to the same territory. Mr. Higgins gave American Express travelers checks to HCPs and their staff in the Bronx, including internal medicine physicians and cardiologists, to promote sales of Diovan, Lotrel, and Lescol. These HCPs had a significant number of Medicaid and Medicare patients.

• In 1998 and/or 1999, Mr. Higgins gave American Express travelers checks to Robert Oropall, DPM to promote the sale of Lamisil, another Novartis drug. In those years, Dr. Oropall prescribed Lamisil to Medicare and Medicaid beneficiaries.

• In 1999 and 2000, Mr. Higgins gave American Express travelers checks to Carey S. Pollock, M.D. to promote the sale of Lotrel and Diovan. After receiving these traveler

checks, Dr. Pollock prescribed Lotrel and Diovan to his patients, including patients who were Medicare and/or Medicaid beneficiaries.

391. On September 10, 2001, Ms. Kelly attended a national plan of action ("POA") sales meeting at a hotel near the United Nations in New York City. At the time Ms. Kelly was employed as a sales representative in the Novartis sales group which was promoting Foradil and which had launched in May 2001, along with other drugs. Novartis had been running a sales contest tied to the promotion of Foradil which gave Novartis sales representatives the opportunity to win Rolex watches if they attained certain Foradil sales goals. At the September 10, 2001 POA, several Novartis sales representatives acknowledged that, between May and September 2001, they had given American Express travelers checks to HCPs and/or their staff:

• Deborah Weixler, a Novartis sales representative acknowledged that, between May and September 10, 2001, had given American Express travelers checks to Robert Mittman, M.D., as well as other HCPs and/or their staff in Queens to promote sales of Foradil and that Dr. Mittman and the other HCPs who had been given traveler checks had prescribed Foradil to Medicare and Medicaid beneficiaries;

• Steve Waterman, a Novartis sales representative acknowledged that he had given American Express travelers checks to Robert Mittman, M.D., as well as other HCPs and/or their staff in Queens to promote sales of Foradil and that Dr. Mittman and the other HCPs who had been given traveler checks had prescribed Foradil to Medicare and Medicaid beneficiaries;

• Jim Kostalidis, a Novartis sales representative acknowledged that he had given American Express travelers certificates to HCPs and/or their staff on Long Island, New

York to promote sales of Foradil and that the HCPs who had been given traveler checks had prescribed Foradil to Medicare and Medicaid beneficiaries; and

• Katie Freeborn Wefald, a Novartis Sales representative acknowledged that she had given American Express travelers certificates to HCPs and/or their staff in New York City to promote sales of Foradil and that the HCPs who had been given traveler checks had prescribed Foradil to Medicare and Medicaid beneficiaries.

• Ms. Wefald also delivered travelers checks to Marjorie Lee, M.D, a pulmonologist in Manhattan to promote sales of Lotrel and Diovan. The receipt of these traveler checks induced Dr. Lee to prescribe Lotrel and Diovan to patients who were Medicare and Medicaid beneficiaries.

392. Between 2002 and 2003, Ms. Kelly was employed as a sales representative by Novartis in the respiratory and skin disease group. During this time, Novartis respiratory and skin disease sales representatives gave American Express travelers checks to HCPs and/or their staff to promote sales of Focalin and Elidel. Frank Garay was a Novartis respiratory and skin disease sales manager. Mr. Garay gave American Express travelers checks to sales representatives that he managed for their distribution to HCPs and/or their staff in New York City and its environs. In addition, the following Novartis respiratory and skin disease sales representatives actually delivered American Express travelers checks to HCPs and/or their staff between 2002 and 2003:

• Ms. Kelly's Novartis counterpart, Rafael, delivered American Express travelers checks to HCPs, including pulmonologists and internal medicine physicians and their staff in the Bronx, to promote Foradil, and the HCPs who were given the traveler checks prescribed Foradil to Medicare and Medicaid beneficiaries;

• Douglas Nicol, another Novartis counterpart to Allison Kelly in New Jersey, delivered American Express travelers checks to cardiologists in New Jersey to promote sales of Diovan, Lotrel, Eldiel, and/or Lescol, and the HCPs who were given the travelers checks prescribed one or more of these drugs to Medicare and Medicaid beneficiaries.

393. Sales representatives delivered American Express travelers checks to HCPs and/or their staff in New York City, New Jersey, and Long Island to promote the sales of Elidel, and the HCPs who were given the traveler checks prescribed Elidel to Medicare and Medicaid beneficiaries.

394. All of these kickback-tainted prescriptions for Lamisil, Lotrel, Diovan, Foradil, Elidel, Lescol, and other Novartis drugs have resulted in the submission of false claims to government healthcare programs.

- **Expensive tickets to sports and entertainment events (e.g., tickets to New York Yankees and Boston Red Sox games)**

395. Defendants have routinely sought to boost, and have boosted, sales of Xolair by giving away expensive sports and entertainment tickets. These have included New York Yankees, Boston Red Sox, other baseball, basketball, football, and other sports and entertainment tickets that are highly coveted—especially because they have been high-quality seats often worth at least several hundreds of dollars apiece.

396. For example, Defendants' New England-area Xolair sales forces treated HCPs and family members to expensive Boston Red Sox, Boston Bruins, Boston Celtics, and New England Patriots games. The tickets were sourced and purchased by Genentech Regional Sales Manager Kelli Wilson and distributed throughout the region to encourage Xolair sales representatives to take their best and most productive HCP Xolair prescribers and try to team them up with less productive HCP Xolair prescribers.

397. At the direction of Xolair regional sales manager Kelli Wilson, co-Relator Stephen Fauci purchased approximately 40 expensive seats in the exclusive "800 Club" in Boston's Fenway Park for a baseball game between the Boston Red Sox and the Baltimore Orioles which occurred in early 2003. The event was attended by approximately 15 to 20 physicians, some family members of those doctors, and approximately 4 other Xolair sales representatives. Among those who attended were Russell Settitpane, M.D. (from Rhode Island), John Strongin, M.D. (from Burlington, MA), and Javed Sheikh M.D. (from Beth Israel Deaconess in Boston).

398. This was also done by other Boston-area Xolair sales representatives at other times, for similar and smaller groups of HCPs and their families. When the physician attendees were not local, Defendants would pay for them to stay at hotels. And they were never placed by Defendants in the "Red Roof Inn" or a "Super 8"; rather, top-tier hotels like the Copley, the Ritz-Carlton, and the Four Seasons were the norm.

399. As further examples, from 2003 through 2005, in greater New York, Defendants' Xolair sales forces treated HCPs and their families to New York Giants, New York Rangers, New York Mets, New York Yankees, and other sports events. Genentech sales representative Ken Clifford and District Manager John Mastrianni took HCPs to Yankees games—even paying for themselves and many HCPs to travel to the Yankees games in limousines. This has been a frequent practice, as Kelly Wilson told Stephen Fauci.

- **High–value celebrity and sports memorabilia (including celebrity autographs)**

400. These also have been worth at least hundreds of dollars per item. For example, and upon information and belief, football legend Joe Montana signed, or "electronically" signed, sports memorabilia that were distributed to some HCPs. Although Genentech announced in late

2006 that this type of gift would be restricted in the future, due to "compliance" concerns, Defendants frequently sent out memoranda indicating that their ethics and compliance departments cautioned against a sales practice, but the practices continued, with approval from upper management.

- **Underwriting HCPs' "open houses" (payments for parties when doctors have opened new offices and sought to advertise their growth)**

401. When a HCP opens a new office (e.g., a satellite office or a relocation), sales managers and sales representatives are encouraged to attempt to gain favor with that HCP—especially a HCP that is being targeted for increased Xolair sales—by offering to pay for, and actually paying for, a party to celebrate the opening of the new office. The tab for food, drinks and decorations normally is in the range of $1,000.00 to $3,000.00.

- **Payments for advertising (print advertisements and flyers) for HCPs who prescribe Xolair**

402. HCPs need to promote their practices, with all of the competition that exists in medicine in this country. To assist HCPs with this, Defendants frequently have offered to pay for print advertisements and flyers that stated the physician's name, his/her address and other contact information, and the fact that he or she treated asthma or allergy patients and prescribed Xolair.

403. Genentech has even paid for roadside billboards in Texas that announced that certain HCPs had opened new offices or had relocated offices, and that these doctors prescribed Xolair.

404. This free advertising has saved these HCPs hundreds or thousands of dollars, and has helped generate revenues for their practices. It also is a kickback that is well-designed to make HCPs feel obligated to prescribe Xolair: after all, the advertisements themselves mention

Xolair. This kickback saves HCPs hundreds or thousands of dollars that normally would be part of overhead for HCP advertising.

- **Opulent meals and expensive drinks for HCPs, nurses and other staff, with honoraria of $1,000.00 to $1,500.00 paid to speakers who frequently do not even speak about asthma, or make limited remarks**

405. As part of this national campaign, Defendants have instructed their Xolair sales forces to fully utilize their budgets to "wine and dine" HCPs who are good targets as Xolair prescribers.

406. For example, and there are so many, Genentech sales representative Curtis James coordinated a large number of very expensive dinners and lunches for HCPs in Rhode Island and its environs from 2003 to 2005. Many of these meals have included Genentech-paid (honoraria) Xolair speaker Russell Settitpane, M.D.

407. This is one of the most common kickbacks that was distributed by co-Relator Allison Kelly. She would ask a HCP to speak about Xolair to fellow doctors at a fancy restaurant. The speaker would receive a check in the amount of $1,000.00 to $1,500.00 for making a small sales pitch for Xolair, plus a fancy meal and drinks. The speaker and/or Xolair salesperson would invite other physicians to attend and partake in the lavish meal. Sometimes Xolair isnever even discussed by the speaker. Nonetheless, the speaker receives excellent compensation and a delightful meal, with other attendees also getting a fine dining experience. Defendants overwhelmingly have treated HCPs to meals and drinks at very fine, very expensive restaurants—to better ensure attendance, and the writing of Xolair prescriptions.

408. For example, Ms. Kelly, for Novartis, paid a $1,307.86 (plus tip) Pasta Pasta restaurant bill (Bronx, NY) on March 10, 2006 which included hundreds of dollars in alcoholic drinks, steaks, lobster tails, and other seafood. On March 7, 2006, only 3 days earlier, Ms. Kelly,

for Novartis, paid a $3,036.07 food and liquor bill (including tip) from Ruby Foo's Uptown restaurant in Manhattan. Similarly, Ms. Kelly, for Novartis, paid a $1,843.76 (including tip) Le Cirque restaurant bill (NYC) on March 1, 2007, which included hundreds of dollars in alcoholic drinks, king crab, other seafood, duck, and desserts [attached hereto and incorporated herein by reference as **Exhibit "K"**].

409. Similarly, Mr. Fauci took HCPs to the Capitol Grille in 2002. The dinner was an advance celebration of the FDA's anticipated approval of Xolair, upon Defendants' initial BLA. (A 4-level approval was anticipated: adult asthma, children's asthma, adult allergic rhinitis, and children's allergic rhinitis. However, the FDA rejected the NDA the next day (or very soon thereafter)). (In 2002, Defendants re-submitted a request for FDA approval, which was granted in part in June 2003—as described above.))

410. While Defendants' internal guidelines state that only modest accommodations, transportation, and meals should be provided to speakers, on top of their honoraria, Defendants have routinely ignored their own guidelines. Even charter planes and limousine services are often provided to the speakers—all to make them more enamored of the Xolair brand.

- **$500.00 to $1,000.00 payments to physicians for "preceptorships" (allowing sales representatives and/or managers to tag along for educational purposes, when asthma patients are purportedly being seen by the physicians)**

411. Co-Relator Allison Kelly believes that Novartis (but not Genentech) may have partially discontinued this kickback in 2006 or 2007.

412. Defendants would ask HCPs to provide "clinical" preceptorships to Defendants' sales representatives, in which a sales representative, in theory, would spend a day with the HCP as an "educational experience," to learn more about the HCP's practice and perhaps asthma and/or allergy treatment, by viewing the HCP's interactions with actual patients. The HCP

would receive an "honorarium" from one of the Defendants—normally $500.00 from Novartis and/or $1,000.00 from Genentech.

413. In actual practice, these preceptorships are frequently no more than payments for access to HCPs, because they are so frequently not carried out in the manner that Defendants have outlined them. Sales representative very rarely spend more than an hour or two with the HCP for that $500.00, and patients are rarely advised that the visitor is a pharmaceutical sales representative. Many of these preceptorships amount to payments to HCPs for a little bit of their time to socialize and/or hear the sales representative speak about Xolair. This is not a bad deal for HCPs: excellent compensation for letting a sales representative sit in your office or visit with you for half an hour to an hour.

414. Frequently, sales managers have accompanied sales representatives during preceptorships; with the substantial payments being made to HCPs, preceptorships are excellent opportunities for sales managers to meet the Xolair-prescribing (or potential Xolair-prescribing) HCPs.

415. For example, in Stephen Fauci's New England sales territory, Genentech's sales representatives have been expected to pay for at least 2 preceptorships per year, and almost every sales representative in his territory did so. At times, Genentech's regional Xolair sales manager, Kelli Wilson, accompanied sales representatives in her territory, including Curtis James, to preceptorships.

416. Attached hereto and incorporated herein by reference as **Exhibit "L"** is a form Novartis "Preceptorship Learning Acknowledgement," entered into with Joseph Brill, M.D. It makes no mention of the FDA indication for Xolair, and emphasizes understanding the "signs

and symptoms of allergic asthma" and the "role of IgE in allergic disease"–both areas which are at the heart of Defendants' off-label marketing of Xolair.

- **Other valuable items (if a HCP enjoyed a particular delicacy or hobby, sales representatives and/or managers could target that HCP with gifts of that delicacy or hobby (e.g., fine wines, cheeses, golf clothes or equipment))**

417. Defendants have encouraged their Xolair sales forces to "get on the good side" of HCPs to consummate Xolair sales. Sales representatives are routinely approved reimbursement for specific gifts to HCPs to accomplish this. Hence, "fine wines, cheeses, golf clothes or equipment" is hardly an exclusive list of the types of valuable items that are gifted to HCPs who could prescribe Xolair.

418. For example, John Mastrianni (co-Relator Fauci's DM) and Mr. Fauci took some physicians, including Najmuddin Patwa, M.D., to one or more cigar bars in Boston in 2004. In Genentech's "Patriot" (New England) sales district in that year alone, gift cards to health spas, Starbuck's coffee, Dunkin' Donuts, and a very wide variety of other retailers, were distributed to HCPs and their staffs, from receptionists in doctor's offices to leading hospital staff physicians.

- **Unrestricted grants to HCPs to allow HCPs to pay for a broad array of valuable items, including some of the above-described items**

419. Similar to the above, Defendants allow and give "unrestricted grants" to HCPs for a wide array of valuable items. The designation of the item as an "unrestricted grant" also serves to conceal the nature of the kickback. For example, approval of and/or accounting for the gift as an "unrestricted grant" can make the gift appear as a payment for asthma consulting services.

420. In 2003 or 2004, Genentech sales representative Patricia Pino advocated Dr. Amy Simon's receipt of an unrestricted grant of approximately $5,000.00, supposedly for continuing medical education ("CME") and/or other medical coursework. Co-Relator Stephen Fauci

objected to this grant request, but Genentech's regional Xolair sales manager, Kelli Wilson, approved it.

- **Patient Experience Program ("PEP") payments and co-payment waivers**

421. Under one part of Defendants' PEP, Defendants forgive the co-payments of patients who agree to speak favorably about asthma treatment by Xolair. This helps ensure that the patients continue with treatment by the HCP, because the expensive co-payments constitute a reason that the patient might discontinue taking Xolair.

422. Under another, related part of the PEP, patients are paid cash to speak favorably about Xolair. For example, many patients were flown to Arizona, with all expenses paid and payment of a stipend, for Defendants to train these patients to speak favorably about their Xolair experiences at future patient speaker events, and to study how to further maximize their experiences for marketing purposes. The patient speakers were also paid for their future speaking events, with travel, hotel, food, and other expenses paid by Defendants.

423. For co-pay assistance, it is frequently the sales representatives themselves who "call into" Defendants or go online to register the patients' "experience" with Defendants, in lieu of patients, creating false and unreliable data that is fed into the TENOR study—i.e., to "pad" the study.

424. Thus, one major purpose of the PEP has been to stock the TENOR Study—a Novartis-Genentech sponsored "scientific study" on the quality-of-life scores of patients taking Xolair—with patients taking Xolair who, it was already determined, would state that they had had a positive experience with the drug. This removes the random, scientific nature that is expected of such a study.

425. Xolair sales representatives receive compensation, directly (e.g., a bonus), or indirectly (e.g., by a commendation by e-mail, praise in an annual review, certificate of recognition, etc., all of which may affect salary), for succeeding at convincing physicians to persuade Xolair patients to participate.

426. The existence and purpose of the PEP is reflected in part by an e-mail dated October 6, 2006 from Peter Streit, Product Manager, Xolair Brand Team, to the Xolair Sales Team, about "Weekly Pep Report – October 5th." The e-mail set forth: "Attached is this week's PEP Report. **Remember the overall objective of the Patient Experience Program is: to change behavior of prescribers to allow a positive experience with Xolair!!!**" (emphases in original) The behavior would be changed in two ways: First, by compelling physicians to locate patients with a positive experience with Xolair, the physicians would be reminded of the drug's positive effects on patient quality of life, and make the physicians more likely to prescribe more Xolair. Second, the patients' positive experiences would be "fed into" the TENOR Study, which would artificially raise the study's results concerning the extent of patient satisfaction with Xolair. With publication of the TENOR Study's "results," the behavior of prescriber and non-prescribers would be influenced, because they would learn of positive patient experiences, as promoted by the "study." Mr. Streit continued by stating "**HCP with one or more patients enrolled:** The goal for each territory should be 100%. This would mean that every enrolled physician in a territory has at least 1 patient enrolled!!." In other words, the goal was, for each sales territory throughout the country, that each "enrolled physician," i.e., each Xolair-prescribing physician in each such territory that is participating in the program, should have at least one patient in the PEP. In this way, at least one patient for each enrolled physician was expected to "go to bat" for Xolair. Mr. Streit's e-mail went on to recognize the top 5 performing

territories in the last week (Omaha, Houston East, Austin, Las Vegas, and Denver South), to list "Key Metrics Achieved" (including a total of 806 patients enrolled nationwide in PEP), to note that "there were **10 additional physicians** who enrolled patients since last week, bringing the total to **383** physicians with **1 patient enrolled**," "**106** physicians with **2 patients enrolled (+7 since last week's report!)**," "**29 physicians** with **3 patients enrolled**"; and "**4** physicians with **5 patients enrolled** (this is a key metric to allow for physicians to experience a "Wow" patient)." (emphases in original)

427. Finally, in the e-mail, Mr. Streit congratulated the "North Stars/Minneapolis" territory "who led the Nation for the 2nd week in a row, and commended other sales territories for enrollments, including Chesapeake/Baltimore, Metropolis/New York, Little Rock, Lubbock, West Palm Beach, and San Antonio. A two-page attachment to the e-mail showed the "40+ Club" and the "Double Digit Club."

428. From approximately January 8 through 11, 2007, co-Relator Allison Kelly attended the Orlando Regional Xolair Meeting in Orlando, Florida. The PEPs were extensively discussed there by Defendants' Xolair sales managers. They described the PEPs as a "grass roots" effort to create a patient outreach program: encouraging patients to be "free" publicity for Xolair, to make Xolair a "fad" or a "trend." Xolair sales managers stated that $6.1 million had been budgeted by Defendants to advance the PEPs, and that 850 PEPs would take place, in which Xolair patients would be speakers.

429. An August 2006 memorandum from the "Xolair Marketing" department to "Hospital and Filed Sales/Clinical Specialists," which Ms. Kelly received, shows that patients and HCPs benefitted from a "$100 monthly co-payment benefit during their first 6 months of [Xolair] therapy ($600 maximum per patient enrolled)" and that Defendants intended the

program to improve Xolair quality-of-life studies [attached hereto and incorporated herein by reference as **Exhibit "M"**].

- **The President's Club**

430. Dr. Mridula Gupta Noori, one of the highest prescribers of Xolair in the country, was given the exorbitant kickback of being treated, "on behalf of" Defendants and the sales representative that targeted her, Frances Estramera Pascavage, to the "President's Club" in the Bahamas: a reward of an opulent, all-expense paid trip to a Bahamas resort, which was normally only provided to the most successful sales representatives, sales managers, and select company executives.

- **Gift certificates to opulent restaurants**

431. Gift certificates to opulent restaurants routinely have been distributed in amounts normally ranging from $100.00 to 1,000.00, to ingratiate Defendants to HCPs and their staffs.

432. For example, in 2003, in co-Relator Stephen Fauci's sales territory, his Novartis counterpart, Kelly Edgos, with the approval of manager Rob Rindini, provided gift certificates to Legal Seafoods, in the amount of $1,000 to $1,500, to numerous doctors in the greater Boston area (including Robert Schiffman, M.D. and Najmuddin Patwa, M.D.).

- **Expensive pens, often engraved with HCPs' names**

433. At several national conferences concerning asthma, allergies, and/or pulmonology, Defendants have provided expensive pens to HCPs. An engraver was present to inscribe the doctor's name. These have a value of approximately $200.00 to $400.00.

- **"Premium" gifts, including expensive medical books (e.g., sought-after anatomy books with color drawings)**

434. This is yet another type of gift that Defendants give to potential prescribers of Xolair. The anatomy books, for example, have a value of between $200.00 and $500.00.

- **Speaker training events in which Defendants paid for the HCPs' travel expenses, hotel, meals, and drinks**

435. This is distinct from other travel junkets provided by Defendants. While Defendants would frequently pay for speakers and attendees to attend and hear presentations about Xolair and asthma treatment, at some of America's premier resorts and hotels, this is payment for the speakers at those events to be trained at resorts and hotels in preparation for those events. These speaker training events often have a value of $1,500.00 to $4,000.00.

436. These are largely free 2-to-5-day vacations for the physicians who are targeted for speaker training, to become local, regional or national KOLs/"thought leaders" who would spread the word about Xolair in general and Xolair's off-label uses in particular. Often times the speakers are paid a stipend of $1,000, as well as all travel, hotel/resort, and food and drink expenses. The training rarely occurs in or near the trainee's home town, making the training event an expensive trip, with the speakers-in-training frequently sent to resort destinations.

437. For example, between 2003 and 2005, co-Relator Stephen Fauci organized three separate speaker training events for 3 different physician speaker trainees: Jeanne Gose, M.D. (Salem MA), Thomas Johnson, M.D. (Andover, MA), and Najmuddin Patwa, M.D. (Stoneham, MA). One of them was sent to San Francisco for the training.

- **Opulent "roundtable" meals and expensive alcoholic drinks**

438. These are more informal get-togethers for HCPs, without any planned program about asthma, Xolair or reimbursement optimization. In short, they are meals and drinks paid for by Defendants, normally with one or two sales representatives in attendance to pay the tab.

- **Speaker programs at resorts, country clubs and casinos, with lodging, meals and drinks paid for**

439. These events often have a value of $1,500.00 to $4,000.00. Although Defendants' compliance office announced in late 2006 that speaker programs at country clubs and casinos are disfavored, they continued after 2006 to take place at resorts and hotels with golf and tennis facilities that Defendants paid for.

- **Office parties for HCPs, their staffs, and guests (e.g., birthday parties, holiday parties, pizza parties)**

440. These events often have a value of $75.00 to $3,000.00, with the lower end being for pizza parties in HCPs' offices and the higher end being for lavish holiday parties in restaurants.

- **"Happy hours" at bars and restaurants for HCPs, their staffs, and guests**

441. These events often have a value of $100.00 to $1,000.00.

442. For example, happy hours have been frequently planned and executed by sales representatives Kim Dickman and Lisa Wheeler in Stamford, New Haven, and their environs.

- **Gourmet food and wine gift baskets**

443. These often have a value of $100.00 to $500.00, and like all the other kickbacks, are used to target Xolair prescribers and potential Xolair prescribers. Ms. Kelly distributed approximately 30 such gift baskets.

- **Expensive bottles of wine**

444. These often have a value of $100.00 to $1,000.00. Co-Relator Allison Kelly distributed approximately 10 expensive bottle of wine to HCPs on her target list.

- **Bogus/fake studies led by physician "thought leaders," with payments by Defendants to the thought leaders**

445. The TENOR study is Defendants' preeminent bogus study, on the quality of life of patients taking Xolair—with patients taking Xolair who, it was already determined, would

state that they had have a positive experience with the drug. This removes the random, scientific nature that is expected of such a study.

446. A purpose of one the PEPs was to stock the TENOR Study. (Only some of the TENOR data was from the PEP online and phone data collection; most TENOR patients were "collected" by Defendants' paying HCPs to enroll patients in the study, with the HCP's office filling out the principal paperwork and/or the patient's filling out a questionnaire).

- **Payments to "advisory ('ad') board" members**

447. Defendants routinely have made payments to "advisory ('ad') board" members — both physician ad boards and nurse ad boards—with the main purpose being payments to the physicians and nurses "serving on them," to ensure the prescribing of Xolair, as opposed to payments for advising Defendants about asthma and/or patients' experience with Xolair.

448. Physicians and nurses who are best situated to serve as "thought leaders" and high prescribers of Xolair are recruited to serve on these ad boards. Ad board members are paid high consulting fees, as well as hotel, food and travel expenses.

449. From 2003 forward, Defendants routinely provided grant funds and other resources to key teaching hospital administrators and national physician KOLS/"thought leaders" in order to gain access for Defendants off-label doctor promoters to make presentations pushing the off-label use of Xolair.

450. Smaller-scale grants were also provided to local physicians and organizations in each sales territory to create local KOLS/"thought leaders," to convert them into Xolair prescribers (or higher-level prescribers). For example, grants of $1,000.00 to $1,500.00 were made, in co-Relator Ms. Kelly's sales territory, to the Dominican Medical Society and the Bronx

Medical Society, as well as to individual doctors like Dr. James Pollowitz, who also was paid a wide array of kickbacks (honoraria, meals, etc.).

451. Local KOLS/"thought leaders" are very frequently paid a lot of money to purportedly promote scientific/medical ideas about off-label uses of Xolair, but so little actual work is done by so many local "thought leaders" that the payments are really nothing more than kickbacks—especially when the local "thought leader" is being paid $1,000.00 or $1,500.00 to chat about Xolair for a few minutes at a fancy dinner and very few or no doctor invitees/friends are able to show up—making it nothing more than a lucrative payment to dine with a few doctor friends, the sales representative, and/or the "thought leader's" spouse.

452. From 2003 forward, Defendants have conducted ad board meetings across the United States where doctors, paid by Defendants to speak on various off-label uses for Xolair at weekend "conferences" at high-end resorts to which other health care professionals, particularly potential prescribers of the drugs, were invited. At least hundreds of doctors have attended these nationwide.

453. Some of the speaker programs are advertised as being focused on Xolair's narrow indication. But the actual presentations are substantially off-label. Others are given titles that suggest the off-label focus of the presentations.

454. Xolair's top prescribers are often the most frequent speakers paid by Defendants to serve as KOLs. Their payments to these physicians are all very lucrative—far from minimal. Attendees are frequently also paid thousands of dollars for their attendance at the resorts where the presentations occur.

455. Xolair prescribers, and potential Xolair prescribers, routinely are provided all-expenses-paid, free trips to conferences at high-end hotels in which Defendants sponsor these

off-label speaking programs. These "programs" are really brief presentations, compared to the long days at the resorts. Large stipends are routinely doled out for attendees. This has been Defendants' pattern and practice, as with all kickbacks forming part of the kickbacks scheme.

456. The "crossing the line" into AKS territory here is clear: Defendants could promote the off-label uses of Xolair by simply mailing, e-mailing, or otherwise providing the information to doctors. Instead, Defendants open up their coffers to induce.

457. However, it has been the national KOLs/thoughtleaders/speakers at the programs who have been provided the most lucrative inducements in exchange for their off-label uses and promotions of Xolair. They are frequently paid at least tens of thousands of dollars per year, plus other covered expenses, in speaking/consulting fees. This, too, has been Defendants' pattern and practice.

- **Wastage Program**

458. On its surface, Defendants' Wastage Program has existed to ensure that HCPs would not be out of pocket for any vials of Xolair that are spilled, lost, or broken.

459. Even if that were this program's true and only purpose, the program is a prohibited kickback that is specifically designed to induce physicians to prescribe Xolair because, when a HCP normally spills, loses, or breaks a vial of medicine, he or she must bear the expense of the mishap. The Wastage Program removes that risk, as an inducement.

460. Of even greater concern, the program allows the HCP to be reimbursed when a patient is a "no-show" for his appointment for Xolair administration. That fact has been well known to many members of Defendants' Xolair sales forces—including Relators. Such a financial guarantee is clearly a prohibited inducement.

461. Specifically, Defendants' Xolair sales forces have been instructed to tell HCPs that, when patients do not show up for their Xolair treatment, that such an event triggers Defendants' Wastage Program, and that HCPs should fill out a "wastage" form, stating that the vials were spilled or broken or that the vials did not reconstitute properly (e.g., because of clumps), and to send the completed form to Defendants so that the HCPs would receive replacement vials at no additional charge.

462. This is a prohibited kickback because it is offered and provided as an inducement, to ensure that HCPs suffer no out-of-pocket loss for patient actions that otherwise normally would result in a loss to the HCP.

463. Under the Wastage Program, the HCP may seek reimbursement from Genentech. Genentech distributes to HCPs a form called a "Xolair Wastage Replacement Request Form" [attached hereto and incorporated herein by reference as **Exhibit "N"**].

464. To submit the request, the HCP or sales representative faxes the form to Genentech Customer Service at 650-225-8517. In the form, the HCP or sale representative is asked to fill out fields that include: (1) the sales representative's name; (2) phone number; (3) e-mail address; (4) fax number; (5) customer (HCP) name; (6) sales territory number; (7) customer (HCP) address; (8) customer (HCP) city and state; (9) customer (HCP) zip code; and (10) the reason for the wastage replacement request, including the quantity of Xolair that was wasted and whether the reason was that the Xolair was destroyed (dropped), that the Xolair was reconstituted but that the patient missed the appointment; that blood had been pulled pack into the syringe; that that the Xolair could not be administered to the patient due to exacerbation; or that an admixture error had occurred which made the solution unsuitable for use.

465. The form also has a line for someone to sign and date, indicating that the product being replaced has not been billed to a patient or a private or Government payer.

466. This program constitutes an illegal kickback because it is an inducement for HCPs to buy Xolair, in violation of the AKS. Again, in the normal course of these types of errors occurring, it is the HCP's financial loss, because Medicare, Medicaid, or private insurance would never reimburse the HCP under these circumstances. Here, however, Genentech has put itself in the place of government healthcare programs to ensure no out-of-pocket loss for the purchase price of the drug, which is a prohibited kickback.

467. One of the main purposes of this program is to allow HCPs to receive free Xolair, to increase their profits. HCPs are encouraged to report that patients have not shown up for appointments or that a vial has broken, which triggers a free replacement vial. Although this comes out of sales representatives' commissions, because it is characterized, for sales and accounting purposes, as one less vial sold, it leads to higher sales overall by sales representatives because the program guarantees that HCPs will not be out of pocket, and sales are stimulated by the free "replacement" items.

B. FREE MEDICAL AND OFFICE EQUIPMENT

468. Defendants have provided a variety of expensive equipment to HCPs to induce them to administer Xolair because storing and mixing/reconstituting Xolair, testing for asthma, and tracking asthma patients are all expensive, time-consuming propositions for the many HCPs, who, in contrast, do not incur these major expenses in prescribing FDA-approved competitor drugs like Advair and Singulair.

- **Swirlers/spinners (for mixing Xolair)**

469. It is time-consuming for HCPs to mix Xolair before administering the drug. To save them time, Defendants have provided them with free swirlers/spinners. Coupons for them are given to the HCPs, who can then go online, enter the promotional code, and other information, and the free swirler/spinner arrives within days—paid for by Defendants. These are also useful to HCPs in general—beyond their utility in assessing asthma and/or prescribing Xolair.

470. These have a market value of approximately $460.00 in recent years. The specific type of swirler that HCPs can and do get, courtesy of Defendants, is the IKA (manufacturer's name) MS 450 Swirler. The coupons that are distributed to HCPs contain both Genentech and Novartis' name on them [attached hereto and incorporated herein by reference as **Exhibit "O"**]. They are redeemable at www.IKAusa.com.

471. This is one of the most prevalent types of kickbacks provided by Defendants—an extremely widespread national directive by Defendants.

472. At times, the Xolair sales representatives themselves order the swirlers for the HCPs and/or deliver them to the HCPs' offices, so that the sales representative would be more directly recognized by the HCP as having provided a gift.

473. For example, co-Relator Stephen Fauci distributed the swirler coupon to every HCP he called on, distributing approximately 30 coupons during his employment by Genentech. Some HCPs ask for the free swirlers, because of the demand on office staff time in mixing the drug. When Defendants noted that some HCPs were interested in receiving swirlers, they instituted this ongoing national program.

- **Pulmonary function machines (to test for asthma)**

474. These have been provided, free of charge, to HCPs, to save them money and

make it easier for them to test pulmonary function values in deciding whether or not to prescribe Xolair. These machines are also useful to HCPs in general—beyond their utility in assessing asthma and/or prescribing Xolair.

475. For example, Xolair sales representatives Curtis James, Kim Dickman, Lisa Wheeler, and Patricia Pino distributed them—each on average distributing one such machine to one HCP. They are very expensive machines, costing between approximately $1,500 and $3,000.

- **Refrigerators (to store Xolair)**

476. Xolair has to be stored in a refrigerator in order to be kept cool. Competitors' asthma drugs do not require such expense/storage. So Defendants provide free mini-refrigerators to many HCPs to induce them to administer Xolair. These refrigerators are also useful to HCPs in general—beyond their utility in storing Xolair. This is yet another a national program, as confirmed by Stephen Fauci when he served on the 2004 National Sales Representative Panel.

477. In 2006 or 2007, Genentech's Xolair's Director of Sales, Leslie Flynn, sent a "CYA" e-mail and/or memorandum in which she stated that sales representatives should cease distributing refrigerators, but the national campaign continued, with her and Defendants' knowledge. The e-mail and/or memorandum was created to create an appearance of belated compliance, if anyone ever questioned the practice later. The e-mail and/or memorandum stated that Genentech's accounting department had discovered that sales representatives were buying the refrigerators.

478. Defendants widely distributed the free refrigerators to HCPs across the country. For example, in Stephen Fauci's New England territory (the "Patriot division"), Curtis James, Kim Dickman, Lisa Wheeler, Patricia Pino, and James Sullivan (when he was a sales

representative) distributed them to HCPs in 2004. One or two of these sales representatives, either Curtis James or Lisa Wheeler, joked, "Can we get a discount from Home Depot if we buy the refrigerators in bulk?"

- **IgE test kits (to test for asthma)**

479. These have been routinely provided to HCPs, free of charge, to save them money and make it easier for them to test for asthma. These had a market value of approximately $140.00. These may also be useful to some HCPs in general—beyond their utility in assessing asthma and/or prescribing Xolair.

480. A July 21, 2006 e-mail and attachment from Novartis Xolair District Sales Manager Martin Clark to various Novartis Xolair sales representatives asked them for feedback on how to better "'ramp up' faster on these 2 key resources (PEP kits and IgE kits)…to get better pullthru on these resources (getting to lead to more Xolair vials for you & your partner)" [attached hereto and incorporated herein by reference as **Exhibit "P"**].

481. From April 2006 through December 2006 alone, Defendants distributed 7,297 IgE test kits nationwide.

482. On February 21, 2007, the LDP (senior manager, above DM) of the Novartis U.S. Xolair Brand Team, Gus Lobos, sent an e-mail to Novartis Xolair sales representatives instructing them to "please focus on distributing the IgE kits to our PUD's [pulmonologists]," and attached the February 18, 2007 IgE test specimen report.

483. In 2006, Ms. Kelly was a Senior Xolair Specialist, in the Respiratory/ Dermatology Therapeutic Franchise of Novartis' Pharmaceuticals Division. Martin ("Marty") R. Clark was her manager; he was the Senior New York Area Sales Manager that oversaw her sales territory. Elizabeth Johnson, the Xolair East Regional Director, was Ms. Kelly's "next level"

manager. In late 2006 or early 2007, Ms. Kelly underwent a performance evaluation. As part of that evaluation, she was required to appraise herself, and Mr. Clark appraised her. Regarding Novartis' explicitly stated objectives that she and other sales representatives achieve "[f]lawless [e]xecution of Xolair [k]ey [p]rograms" and "[u]tilization of [p]romotional funds," Novartis used as specific "performance standards" whether the sales representative achieved "Patient Experience Program (100% kit distribution and continued pull-through effort on every call)," "[p]ull through IgE [t]est [k]its to increase patient starts," "[a]ppropriate use of CRM funds," and "maximiz[ation] of REF funds."

484. In self-evaluation, Ms. Kelly noted that she had successfully placed all PEP kits and IgE test kits within the targeted medical offices in her territory, had placed third in the nation in the PEP Blitz ranking and 1st within the Northeast region with 7 new patients; and had appropriately used her CRM and REF budget. Mr. Clark's evaluation of those matters, in contrast, included that "…Allison consistently ranked last or near last on PEP kit pullthrough reports in 2006 prior to the initiation of the Fall 2006 PEP kit contest," and that she had "finished 5/8 in the NY Area for IgE kits used with 35 in total. She improved her ranking on this metric as she was ranked at or near the bottom of the NY Area for numerous progress reports for much of 2006." Despite the differences in their assessments on this particular matter, it remains clear that Novartis used the IgE test kits, PEP kits, and use of fund distribution to HCPs as key metrics for expected sales performance. Mr. Clark also lauded her for much of her performance, including doing "a solid job of identifying and cultivating new, emerging KOLs like Anne Maitland [M.D.], and Kishore Ahuja [M.D.] as examples," and observed that she had "partnered well with her BRM, Jerry Covell, on some key managed Medicaid plans like Affinity for example."

485. Defendants have evaluated other members of their Xolair sales forces in a substantially similar way: by measuring their performance not only by their sales, but also by their effectiveness at utilizing these and other kickback tools at their disposal, which they were fully expected to use to boost sales.

486. In the fall of 2006, Defendants disseminated a newsletter, called "National Product Team News," to Novartis and Genentech sales representatives that not only demonstrates the extent that Novartis and Genentech have utilized kickbacks in the form of free IgE test kits to HCPs in order to increase Xolair sales, but also shows that Defendants have offered tips to their Xolair sales forces—described as "best practices"—for follow-up visits to HCPs to encourage their use of the kits, and recommended another "best practice" of engaging HCPs in off-label discussions by disseminating off-label studies. The "National Product Team News" publication, Volume 10, Fall 2006 [attached hereto and incorporated herein by reference as **Exhibit "Q"**], stated in relevant part:

> **In this issue:**
>
> *** * ***
>
> IgE Test Kit Best Practices
>
> **National Specialty Focus Pilot**
>
> *** * ***
>
> **TARGET AUDIENCE:**
>
> Nationally, there have been 8 territories identified to have a single specialty focus on either Allergists or Pulmonologists with the allergy team also crossing calls over on some shared pulmonary practices.
>
> * * *
>
> [Question posed to Novartis Xolair Sales Specialist Zackary Harron:] What tools are you using to move the Pulmonologists forward? "I let my Pulmonologists know they could enroll in CAP and contact the BRM as

appropriate. I also am giving the IgE [test] kits to my Pulmonary offices to help simplify and shorten the IgE testing process.["]

* * *

IgE Test Kit Best Practices

So you have placed [IgE test] kits in all your offices, reviewed the contents with the HCP and even gained commitment from the physician that they will use the kits. Two weeks later you return with additional kits only to find that the original ones have not been moved from the spot that you left them. What should you do? Here are some suggestions:

- Schedule a lunch to review the contents of the kit and the 11 step process for blood collection.
- Dedicate time during ACE speaker programs to discuss proper procedures for testing as well as review patient types.
- Follow up with the offices and ask questions and address any of the HCP's question or concerns.
- Discuss with the physician the importance of IgE and RAST testing for all appropriate patients.

* * *

- Review the Demarco and Burrows reprints to encourage the physician to test appropriate patients.
- Inform the physician that the RAST is limited to six allergens and that if the results are negative and the IgE level is > 30 they should consider expanding the panel.
- Kits should not be stored in vehicles as they are sensitive to temperature extremes of 0-38C (32-100F).

* * *

Shared Best Demonstrated Practices

How many of you have walked into an Allergy or Pulmonary office with the frustrated thought in your head "what new information am I going to share to day with Dr. Smith?" Time to time we have all struggled through that scenario in our sales careers, but that will soon change! Beginning with this edition of NPT News, we will share best demonstrated practices

> from our Xolair sales associates across the country in order to make each Xolair sales call new, fresh, clear, and creative!
>
> We start our search for best demonstrated practices with our Novartis friend from Texas Brit Shoptaw:
>
> **Question**: What is the most useful Marketing Piece for you in your sales and Why?
> **Answer**: By far the Xolair Sales Aid! I especially like to turn to the four case study profiles! The patient cases are real world which helps to paint the Xolair picture to my customers. The Low-IgE, the Frequent Exacerbator, and the Nighttime Sufferer are patient types my Physicians relate to.
> **Question**: What Specialty are you using that Marketing Piece with the most?
> **Answer**: I use them more with my Pulmonologist's because they tell me all their patients are controlled. So, by discussing the different case studies in the Xolair Sales Aid, the Physicians tend to visualize and discuss their patients that fit those profiles.
>
> National Product Team News," Vol. 10, Fall 2006 (emphases in underlining added; emphases in boldface in original).

487. Although patients with controlled asthma are not properly prescribed Xolair because those patients are not suffering from moderate to severe persistent asthma, Defendants are clearly telling their Xolair sales forces, above, to off-label market to HCPs for Xolair use by such off-label patients.

> **Computers (allegedly to register and track asthma patients)**

488. In the Midwest, including Chicago, and in some other sales territories, including Florida, sales managers have approved sales representatives' provision of free computers to HCPs, to register and track asthma patients. These have a market value of approximately $500.00 to $1,300.00. This has not been a national campaign, but has occurred in several regional sales territories. At least 50 free computers have been distributed by Genentech sales representatives; the actual number given to HCPs may greatly exceed 50. These computers are also useful to HCPs in general—beyond their utility in purportedly tracking asthma patients.

- **10cc diluent (preservative-free sterile water for injection), 3cc syringes, 18-gauge large-bore needles for reconstitution, 25-gauge needle for administration, alcohol swabs, and a Sharps container.**

Each HCP is provided these free items when Xolair vials are shipped.

C. FREE SERVICES

489. Defendants have provided a variety of free services to HCPs, which are normally overhead/expenses to be borne by the HCP, because of Defendants' deep concern that prospective prescribers of Xolair would not prescribe the drug because of the administrative hassles and expenses of doing so.

- **Sales representatives and managers singled out asthma patients by sorting through HCPs' patient charts and HCP computer records.**

490. It has been a virtually routine practice across the country for sales representatives to infiltrate specific HCPS' offices and go through patient charts. Defendants even developed and distributed sticky tabs to be given to HCPs' "nurses" to flag potential Xolair patients, but this was done on a "wink wink" basis, as Defendants, through sales managers, instructed Xolair sales representatives to engage in this practice themselves—not HCPs' independent nurses, who could not be trusted to follow through in a way that maximized tabbing and Xolair sales.

491. During the 2004 National Sales Representative Panel Meeting that Stephen Fauci participated in, Defendants' sales managers and sales representatives discussed this as a nationwide practice. The concern of some sales representatives, that doing this constituted HIPAA violations, was raised. Specifically, Frank Johannes, Ken Clifford, and many others discussed this. In the New England sales district, at least 75% of Xolair sales representatives engaged in this practice during Mr. Fauci's employment—virtually every sales representative except Mr. Fauci, Ken Clifford, and Megan Antonelli. District managers Diaz, Sullivan, and Mastrianni heavily encouraged it.

- **Statements of Medical Necessity ("SMNs")**

492. As also discussed above, numerous sales representatives and managers have filled out Statements of Medical Necessity ("SMNs") for HCPs and their staffs, have obtained physicians' signatures, and have sent them off to specialty pharmacies, health insurers, managed care organizations ("MCOs"), and/or government healthcare programs, to ensure that HCPs actually followed through and prescribed Xolair.

493. SMNs are, effectively, prescriptions.

494. Defendants' access of this private patient health information, and the manipulation of these documents, has been done to ensure that non-qualified patients receive Xolair, as described above. Fraudulent SMNs, as a whole (in which the Xolair sales representative have filled out part or all of the SMN for the HCP), conservatively account for approximately 15% of all SMNs.

- **Appeal Letters**

495. Sales representatives and managers have frequently filled out appeals letters for HCPs when health insurers, MCOs, and/or government healthcare programs denied approval for administration of Xolair.

496. Defendants have provided for delivery of Xolair to patients in their homes, to reduce the costs to HCPs of administering Xolair, despite the fact that the FDA-approved indication for Xolair requires administration of the drug in a medical office setting, hospital, or clinic, because of the serious risk of anaphylaxis and other serious side effects.

497. Although most home deliveries were shipped, some Xolair sales representatives actually hand-delivered the vials to patients.

498. For example, in the New England District, sales representative Donna Bender "brown bagged" (hand-delivered) Xolair to patients' homes.

- **Coding and reimbursement assistance to HCPs**

499. Defendants routinely have provided coding and reimbursement assistance to HCPs—including the hiring of the LASH Group to provide such assistance (e.g., to advise HCPs to bill for patient levels 4-5 when patient levels 1-2 were proper, and to advise HCPs on CPT codes and ICD-9s to use, to ensure coverage and maximization of reimbursement). This included the LASH Group's hosting dinners to teach HCPs how to bill for maximum reimbursement from Medicare and Medicaid.

500. This directive to HCPs is described below under its own subject heading.

501. Defendants themselves also frequently have hosted fancy dinners to instruct HCPs on how to maximize opportunities to profit from government healthcare programs.

502. For example, on July 1, 2006 the Competitive Acquisition Program ("CAP") for Medicare part B drugs and biologics commenced, some three years after it was established by the 2003 Medicare Modernization Act ("MMA"). To encourage physicians to participate, CMS identified a list of approximately 180 drugs that are available to participating physicians.

503. Physicians were given two opportunities to enroll, May 8-June 2, 2006 and June 3-30, 2006. Under the CAP, participating doctors would no longer purchase particular Medicare Part B drugs under the "buy and bill" process. Rather, they would order the drugs for their patients from BioScrip, the only CAP vendor until 2008. Physicians' offices would bill CMS for the administration of the drug. Thereafter, BioScrip, as the CAP vendor, would be responsible for shipping CAP drugs, billing CMS for the drug, and collecting the patients' drug co-payment after administration.

504. Beginning in late 2005 or early 2006, Novartis and Genentech created and carried out their own campaign for the promotion of CAP, to boost sales of Xolair. Defendants have targeted pulmonologists, allergists, internists, and general practitioners who were high prescribers of Xolair, or potentially high prescribers of Xolair.

505. Defendants did not wait for HCPs to inquire about the CAP. Defendants initiated the dialogue, to promote sales of Xolair. Promotional efforts have included company-sponsored dinners across the country, and other marketing outreaches.

506. For example, on October 24, 2006, beginning at 7:30 p.m., Novartis treated HCPs to a fancy meal and drinks at Bambara restaurant at 202 South Main Street, in Salt Lake City, Utah 84101. The invitation, which was printed by Novartis, stated: "Please join your fellow colleagues at CHEST for dinner. Nick Opalich, Managing Partner, Strategica Health Partners, LLC on behalf of Bioscrip will be presenting on: **CAP-Competitive Acquisition Program for Medicare**." Prospective attendees were asked to RSVP to Jerry Covell with Novartis. The purpose of this meal was to ingratiate HCPs while educating them on how to maximize billing Medicare.

507. Similarly, on November 14, 2006, beginning at 7:30 p.m., Novartis treated physicians to a fancy meal and drinks at Brasserie Perrier at 1619 Walnut Street, Philadelphia, PA. The invitation, which was printed by Novartis, stated that "BIOSCRIP (CAP vendor, VP of Operations, Russ Corvese will be presenting on: **CAP-Competitive Acquisition Program for Medicare**," and specified that the restaurant was a "First rate American Brasserie—modern French cuisine with Italian and Asian influence." Prospective attendees were asked to RSVP to Lynn Tommelleo or Jerry Covell with Novartis. Again, the purpose of this meal was to ingratiate HCPs while educating them on how to maximize billing Medicare.

508. Besides the nationwide dinner presentations, Defendants' sales push for Xolair under its own CAP campaign is illustrated by the October 2, 2006 e-mail from Peter Streit, Xolair Brand Team Product Manager, to the Xolair sales force about "SPOC and Medicare CAP." It states: "Xolair Sales Team, Please see attached JPRT- approved PDF regarding Medicare CAP and SPOC. Contact your BRM or Area Sales Manager if you have questions." The attached memorandum dated August 2006 and attached "FAQs and Key Messages on CAP" (messages for the sales force to publicize to HCPS), stated, in part, that "[t]his information is for your background use only and should not be proactively discussed with customers. If asked an unsolicited question concerning CAP, you may inform the customer of the general status of the program and refer them to BioScrip or CMS resources."

509. However, Defendants' dinner invitations and other acts of outreach to HCPs about CAP show that Defendants were actually soliciting HCPs' participation in CAP to boost Xolair sales. Defendants created venues for presentations about CAP and invited physicians to attend, but feigned a lack of solicitation, in writing, by coyly stating in memoranda that sales representatives may merely respond to independent inquiries by HCPs. The memoranda and FAQs instructed the Xolair sales force to promote the fact that: "The CAP primarily affects physicians. CAP physicians no longer obtain CAP drugs via the buy-and-bill process; instead they will order these drugs through the CAP vendor. As such, CAP physicians will not be liable for any un-reimbursed drug costs or uncollected coinsurance." "FAQs and Key Messages on CAP," at 2.

510. This message was created to assist the Xolair sales force in overcoming a frequent obstacle to Xolair sales: that physicians were wary of off-label prescribing Xolair because of low profit margins, un-reimbursable drug costs, and uncollectable coinsurance. The "FAQs and

Key Messages on CAP" also stated that "[b]ased upon the strict conflict of interest provisions, SPOC will not offer services to the CAP vendor but in some instances SPOC may offer assistance to the CAP participating physician and/or their patients." *Id.* at 3.

511. In September 2006, Gerald Covell, a Novartis Business Accounts Manager, authored an e-mail and New York City Update slide presentation which, in part, reflects the objectives of the program. It shows that, in that sales territory, three specific doctors were targeted in 2006 for CAP, and four doctors in 2007. It stated that re-enrollment of current enrolled practices was also an objective.

512. Further, the slide presentation also reflects Defendants' efforts to maximize billing of Medicaid patients. It states that, in New York, it is a "situation" that "[p]hysicians are required to buy and bill for Fee for Service Medicaid," "HOPDs only get reimbursed" the low amount of "$67.50," and "[m]anaged Medicaid Plans (most) follow Fee for Service Medicaid and require physicians to buy and bill." *Id.* at 6. Mr. Covell emphasized the "New York Medicaid Opportunity" for sales by stating that "73% of NY Medicaid are enrolled in a Managed Medicaid plan." *Id.* at 7. The slide presentation also listed sixteen (16) "Major Managed/Medicare/ Medicaid Care Payors," which shows many of the largest purchasers of Xolair, i.e., that were reimbursed by Medicare and/or Medicaid, including Medicare and/or Medicaid themselves, many managed care organizations ("MCOs"), other private health insurers, and some supplemental health insurers. *Id.* at 8. New York Medicaid purchasers were highlighted on page 9.

513. The slide presentation also reflects Defendants' marketing push to "Get Managed Medicaid Plans to allow a SP [specialty pharmacy] to supply Xolair and bill instead of the physicians having to buy and bill," to achieve "Pull Through," and to target 340B hospitals. *See*

id. at 10. Finally, this slide presentation also reflects the fact that physician roundtables were a focal point for boosting sales, and that there were to be "Office Managers Night Out (Best Practice Discussions)." *See id.* at 13. This slide presentation exemplifies Defendants' use of the terms "pull through" and "best practices," which were "code," or euphemisms, for implementation of many of the aggressive, illegal activities highlighted by this lawsuit. In the context of this slide presentation, for example, the "pull through" refers to the implementation by the Xolair sales force of aggressive practices to maximize the actualization of Xolair purchases by nudging HCPs to utilize specialty pharmacies. The "best practice" of "Office Managers Night Out" refers to the fact that Defendants paid for HCPs' office manager dinners and happy hours to attempt to nudge them to prescribe Xolair off label and in general, maximize reimbursement from Medicare and Medicaid, etc. At such events, there was often little talk of business. Later, however, after treating office managers to such events, medical offices would be more open to Defendants' Xolair sales push. A second attached slide presentation, dated October 19, 2006, addressed maximization of billing the new Medicare Part D Program which started on January 1, 2006. The above and foregoing details about the targeting of Medicaid and Medicare business (enrolless and beneficiaries) is incorporated by reference into the below subsections entitled "The Medicaid Push" and "The Medicare Push," in the Claims Submission Section of this Complaint.

HIPAA

514. Many of Defendants' free services to HCPs have involved violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, insofar as the HCPs' patients did not give informed consent to allow Defendants to access their private health records for Defendants' purposes.

_. STATEMENTS OF MEDICAL NECESSITY ("SMNs")

515. Defendants also have engaged in a national campaign of encouraging, aiding, abetting, and causing HCPs and others to falsely represent facts on SMNs for Xolair.

516. Genentech and Novartis created a document entitled "Statement of Medical Necessity for Xolair (Omalizumab) For Subcutaneous Use" ("SMN") to satisfy the requirement that a physician-administered drug must be reasonable and "medically necessary" for the treatment of an indicated condition in order to qualify for reimbursement under government healthcare programs. This SMN included specially demarcated boxes in which to insert the pretreatment IgE level of the patient, concomitant therapies, the patient's weight and the physician's clinical impressions, among other information, thus creating documentation that the patient met the criteria for administration of Xolair. The completed SMN, signed by the prescribing physician, constituted the formal prescription for Xolair.

517. Xolair gets approved by the patient's health insurance when the treating physician sends 2 forms to the chosen specialty pharmacy: the SMN and the PAN. The SMN is the Xolair prescription that the physician fills out. The PAN, which is signed by the patient, authorizes the physician and the specialty pharmacy to exchange information about the patient's case. The specialty pharmacy ("SP") then determines whether the patient's health plan covers Xolair, and the patient's co-payment/out-of-pocket costs.

518. Defendants have further instructed their sales representatives, when necessary to achieve "pull through" (consummation of the sale or prescription), to fill out the SMNs for physicians and, when so doing, to place false information therein, such as increased body weight to increase the dosage, and thereby increase the sales, of Xolair, and/or to exaggerate the clinical impressions of a patient's asthmatic symptoms in order to make his asthma appear moderate to

severe so that the administration of Xolair would qualify as "medically necessary" and thus reimbursable under government healthcare programs.

_. "FILL THE FUNNEL"

519. From 2003 forward, Defendants have had a national program/campaign, frequently called "Fill the Funnel," to encourage sales representatives to send in as many SMNs as possible to Defendants' 5 contracted specialty pharmacies, whether or not a patient is qualified. Defendants' sales representatives received commissions under this program according to the number of submissions.

520. These sales practices and, in particular, the "active asthma" promotion, have triggered a huge increase in the number of SMNs and have greatly increased sales of Xolair.

521. Many details regarding this scheme are also set forth in sections above.

522. In order to receive reimbursement from government healthcare programs for a prescription of Xolair, a physician must complete a SMN, indicating, *inter alia*, the patient's condition, that the condition falls within the approved use of the drug, the dosage prescribed, etc., and submit a claim form such as a CMS Form 1450 or 1500 in which the doctor, *inter alia*, certifies that the treatment is medically indicated and covered.

523. Many Novartis and Genentech sales representatives throughout the country have filled out the SMNs themselves, using patient information obtained improperly, including from patient medical records (in violation of HIPAA), in order to facilitate the transaction for the physicians and increase sales.

524. In the process, information is often manipulated on the SMN forms. For example, many representatives check off maximum dosing to ensure more vials are used to establish greater sales, many check off that the patient has a perennial allergy when he or she

does not, and many state that the patient has had one of the requisite tests (e.g., rast or skin) and qualify, when they have and do not.

525. The majority of patients taking Xolair do not in fact fall within the 30-700 IgE level (as required by the approved label); however, this critical fact is routinely omitted or misrepresented on the SMN forms filled out by the Xolair sales representatives. Having the sales representatives fill out the SMN forms, often with inaccurate and misleading information, substantially distorts the reimbursement process–by making it appear that the prescription falls within the boundaries of the approved and covered/eligible use, when it does not.

526. In addition, Xolair sales representatives have often encouraged physicians that, if the patient falls off or outside the dosing chart because they are above the 700 IgE level, the doctor should just prescribe the maximum dosage. This has the effect of boosting sales, but also compromises patient safety. Relators estimate that 25%-30% of all patients on Xolair in fact fall outside the approved IgE range: with IgE levels below 30 or above 700. Relators also have specific knowledge of improper targeting of pediatric clinics to promote use of Xolair by pediatric allergists. (Pediatric use—i.e., under 12 years of age—of Xolair is unapproved.) Sales representatives would then inaccurately fill out the SMN form to disguise the fact that the patient is under the age of 12. Sales representatives also have routinely discussed billing and coding and have disseminate information on the same, per managers' instructions—all in an effort to ensure that the prescription will be reimbursed regardless of whether the patient is eligible or the drug is covered for that patient.

527. Xolair sales representatives' highly intimate involvement in patient health records and troubleshooting of HCPs' Medicare, Medicaid, and other insurers' payment/reimbursement issues is reflected not only by SMNs, but also by a form that Defendants, as a matter of routine

policy and procedure, distributes to the Xolair sales force for their use. This form is called the "Xolair Issues Resolution Form."

528. The "Xolair Issues Resolution Form" has fields that Xolair sales personnel and others completed, identifying the applicable Xolair sales representative, sales manager, physician, physician contact information, the applicable specialty pharmacy ("SP"), the payer (e.g., Medicare, Medicaid, MCO, etc.) and its contact information, patient initials and patient's employer, details concerning the SMN, a brief description of the issue, and a brief description of the steps needed to resolve the issue. It is important to recognize that the issue is normally a Xolair payment or reimbursement issue.

529. The completed forms are to be e-mailed to Defendants' local account managers who are "point people" with the SPs. A box in the form is to be checked to answer, "Is this a national issue that should immediately be communicated to the Hot Spots Team?" That helps Defendants track barriers to their off-label sales objectives and kickbacks scheme.

_. UPCODING FOR ADMINISTRATION OF XOLAIR

530. Defendants have engaged in a national campaign to illegally and misleadingly instructing HCPs to upcode for the administration of Xolair.

531. Defendants have instructed and nudged them, through incorrect and misleading information—provided by Defendants themselves and through independent contractor the LASH Group—to submit claims for reimbursement for the administration of Xolair at improper rates: by advising HCPs to bill for patient levels 4-5 when patient levels 1-2 were proper, and by advising HCPs to use improper Current Procedural Terminology ("CPT") and Diagnosis Codes ("ICD-9s"), to ensure coverage, and reimbursement at higher rates.

532. For example, the 2005 Medicare reimbursement codes and rates for Evaluation and Management ("E & M"/office visits) were:

Level 1 (99211) $21.60

Level 2 (99212) $38.66

Level 3 (99213) $52.68

Level 4 (99214) $82.62

Level 5 (99215) $120.14

533. On December 6, 2004, Jonathan Williams, the LASH Group's Senior Manager for Reimbursement Consulting, sent an e-mail to Genentech Xolair sales managers, advising them the 2005 Medicare payment allowables for E & M/office visit codes. Defendants used these rates, and other rates from 2003 forward, to educate HCPs on the profit potential from prescribing Xolair, in conjunction with the "marketing the spread" information they were provided.

534. Hence, the overbilling that Defendants have promoted and caused, is very significant.

535. Defendants also have utilized the LASH Group to promote this overbilling.

536. Since Xolair was launched in 2003, until at least July 10, 2006, Defendants assiduously and specifically instructed HCPs throughout the country, orally and in writing, to use improper CPT codes, especially CPT code 96401, to seek government healthcare program reimbursement for the administration of Xolair. On April 17, 2006, Novartis' Senior Xolair Area Sales Manager, Mid-Atlantic region, Daniel Giunta, forwarded an e-mail to Xolair sales representatives [attached hereto and incorporated herein by reference as **Exhibit "R"**] which stated in part: "Don't ignore chemo codes just because your physician doesn't see cancer

patients…You won't get paid for Xolair and intravenous immunoglobulin (IVIG) services unless you have a handle on drug-therapy coding. Follow these expert tips…" Then it set forth the alleged propriety of using CPT code 96401, and other improper CPT codes that would allow HCPs to maximize billing by "the spread."

537. CPT code 96401 is for infusion therapy, and is used by oncologists to bill for the administration of cancer drugs. It is not to be used for reimbursement of administration of a subcutaneous injection of an asthma medication.

538. CPT code 96401 is to be used for "chemotherapy administration; subcutaneous or intramuscular nonhormonal antineoplastic [formerly code G-0355]."

539. Even after the American Medical Association and JCAHO specifically stated that CPT code 96401 was improper, Defendants continued to market to Xolair purchasers and prospective purchasers, to use CPT code 96401 (which triggered reimbursement for between $40.00 and $60.00) instead of CPT code 90772, which was proper and allowed for much lower reimbursement (only about $12.00). In September 2006, Jerry Covell gave a PowerPoint presentation called "New York City Update" to New York City-area Xolair sales representatives, including Ms. Kelly, in which he: addressed problems with the 96401 CPT code (stating that some customers are now utilizing 90772), shared reimbursement and coding strategies, discussed HCPs to be targeted, encouraged optimizing Xolair sales to New York Medicaid patients (stating that 50% of many HCPs' patients are Medicaid eligible and that "73% of NY Medicaid are enrolled in a Managed Medicaid plan," encouraged "pull through" to "[g]et Managed Medicaid Plans to allow a SP [specialty pharmacy] to supply Xolair and bill instead of the physician having to buy and bill."

540. Defendants also improperly have instructed HCPs to use other CPT codes for Xolair administration, including 95115, 95117, and 95199, which are for inapplicable, non-FDA-approved allergen immunotherapy.

541. As noted above, in September 2006, Gerald Covell, a Novartis Business Accounts Manager, authored an e-mail and New York City Update slide presentation. These items also reflect Defendants' marketing to physicians of use of specific CPT codes for administration of Xolair. It states: "96401 UPDATE Followed up with targeted accounts to address concerns regarding the 96401 change. Many practices are now utilizing 90772. Others will utilize 96401 until CPT 2007 is published." *Id.* at 5 (emphasis in underlining in original). This e-mail appears to reflect a change in course by Defendants, away from telling HCPs to use CPT code 96401.

542. Defendants, independently and through the LASH Group, also specifically have instructed and nudged HCPs to bill for patient billing levels 4-5 when patient levels 1-2 were proper for the administration of Xolair.

543. Level 4 or 5 is used for a "complex" administration of a drug or other medical service. It may be appropriate when an asthma patient is first seen by a physician, evaluated for asthma, and administered Xolair, when all criteria are met. However, in subsequent office visits for Xolair administration, frequently overseen by a nurse, without evaluation of asthma history and other factors, levels 4 and 5 are not proper. But recognizing the challenge that Defendants faced in selling Xolair, Defendants have engaged in a direct campaign to advise and convince HCPs that it was okay to bill for such a high-level visit, at a higher reimbursement rate.

BEST PRICE FRAUD

544. The Medicare Rebate Program is designed to ensure that the reimbursement rate that Medicare and Medicaid pay for prescription drugs is not higher than the prices that

pharmaceutical companies offer to all other persons and entities. In effect, the objective is to give Medicare and Medicaid (and thus the taxpayer) the lowest available price on prescription drugs under the Medicare and Medicaid programs. *See* 42 U.S.C. §1396r-8, including §1396r-8(a)(1).

545. Also sometimes called the federal "Best Price" program, the Medicare Rebate Program is a cost-savings law that was passed in 1990 in response to increasing Medicaid expenditures for prescription drugs. If drug makers choose to participate in the program, they must provide the Government with the "Best Price."

546. Under the Medicare Rebate Program, pharmaceutical companies are required to provide rebates to the U.S.A. and the States to compensate for any drugs purchased above the manufacturer's "Best Price." Pharmaceutical companies do so by entering into Rebate Agreements with the HHS Secretary. *See* 42 U.S.C. §1396r-8(a)(1).

547. Like almost all pharmaceutical companies, Defendants chose to participate in the Medicare Rebate Program and, from 2003 forward, entered into Rebate Agreements concerning Xolair with the HHS Secretary.

548. The Rebate Agreements are standardized, executed forms that are provided to the Secretary of HHS, promising the "Best Price" to CMS [form/example attached hereto and incorporated herein by reference as **Exhibit "S"**]. *See* 42 U.S.C. §1396r-8(a)(1).

549. The Rebate Agreements require drug manufacturers to submit standardized Quarterly Reports to the Secretary of HHS (CMS-367s) [form/example attached hereto and incorporated herein by reference as **Exhibit "T"**].

550. These standardized Quarterly Reports (CMS-367s) must be signed by the CEO, CFO, or a person with directly delegated authority from one of them, 42 C.F.R. 447.510(e)—i.e., it is not seen by virtually any employee.

551. The Quarterly Reports ("CMS-367s") include information concerning each of the manufacturer's "covered" drugs, including such information as its "Average Manufacturer Price" ("AMP"), "Baseline AMP," and "Best Price."

552. From 2003 forward, Defendants regularly provided Quarterly Reports (CMS-367s) concerning Xolair to the HHS Secretary.

553. After receiving these Quarterly Reports, and based upon the information contained in them, CMS then informs the States how much rebate the States are entitled to collect with respect to each drug.

554. For "single source drugs" and "innovator multiple source drugs," manufacturers are required to rebate 15.1%, or the difference between AMP and "Best Price" at which the manufacturer sells the product to a non-public health service or Veterans Administration customer, whichever is greater.

555. As noted above, the pharmaceutical company is required to report its "Best Price" for each prescription drug to the Center for Medicare and Medicaid Services ("CMS"), which calculates the unit rebate amount and reports that amount to the State Medicare/Medicaid agency, which then calculates the total rebate.

556. A pharmaceutical company may have an enormous financial incentive to falsify its "Best Price" reporting in order to decrease the overall rebate liability. Failure to accurately report the "Best Price," which is required to include any and all rebates, discounts, grants,

coupons, and other incentives offered to purchasers, constitutes pharmaceutical fraud under the FCA.

557. Under 43 C.F.R. 447.502, participating drug manufacturers like Defendants, must separate out all rebates, including bundles, and quantify them, to ensure that the "Best Price" is given.

558. "Best price" information is shrouded in secrecy because of a legalized ban on price disclosures by pharmaceutical manufacturers. The Supreme Court recently acknowledged that secrecy: "To gain payment under Medicaid for covered drugs, a [pharmaceutical] manufacturer must enter a standardized agreement with HHS; in the agreement, the manufacturer undertakes to provide rebates to States on their Medicaid drug purchases….Calculation of a manufacturer's 'average' and 'best' prices, undertaken by the pharmaceutical company, is a complex enterprise requiring recourse to detailed information about the company's sales and pricing. § 1396r-8(k); 42 C.F.R. 447.500-520 (2010). To enable HHS to calculate the rebate for each drug, manufacturers submit the relevant data to HHSA on a quarterly basis. § 1396r-8(b)(3). With exceptions set out in the legislation, HHS is prohibited from disclosing the submitted [pricing] information 'in a form which discloses the identity of a specific [drug] manufacturer…[or] prices charged for drugs by such manufacturer. § 1396r-8(b)(3)(D)." *Astra USA, Inc. v. Santa Clara Cty.*, 131 S.Ct. 1342, 1346 (2011) (emphasis in original). Thus, details are not readily available to almost anyone other than the drug manufacturer's CEO, CFO, or a person with directly delegated authority from one of them.

559. Further, only persons in the highest echelon of Defendants' companies could know their catalog prices for Xolair: Even the Secretary of HHS cannot audit a drug company for confidential catalog prices; it can only conduct an informal "survey." 42 U.S.C. § 1396r-

8(b)(3)(B). "As a practical matter, the confidentiality of the pricing information and the lack of audit powers inhibit the ability of the State to monitor drug fraud…" *In re Pharm. Indus. Avg. Wholesale Price Litig. ("AWP Litig.")*, 321 F. Supp.2d 187, 199 (D. Mass. 2004).

560. From 2003 forward, Defendants routinely have failed to accurately report the "Best Price" for Xolair—and the related AMP and Baseline AMP (and/or ASP)— to CMS.

561. Defendants, in their Quarterly Reports (CMS-367s) to CMS concerning Xolair, purposely have failed to factor in rebates, discounts, and incentives on Xolair that were inherent in all of the kickbacks provided to HCPs (all of the kickbacks detailed in this Complaint which inherently constituted rebates for Xolair's price), and particularly failed to report that free Xolair was provided to numerous HCPs through Defendants' Wastage Program, a national program. Had Defendants done otherwise, they would have been alerting and admitting to CMS the vast kickbacks scheme detailed herein. There is no public record of Defendants having self-reported the kickbacks. Hence, it defies logic that Defendants has reported the information to CMS, for best price or other purposes.

562. As set forth herein, Defendants' Wastage Program not only has resulted in numerous HCPs receiving Xolair at $0.00 when vials broke or were spilled, but also has resulted in numerous HCPs receiving Xolair at $0.00 when a patient is a "no-show" for an appointment, the HCP loses the ability to bill the patient for drug administration and/or related medical services, and the HCP fills out a Wastage Program form to get a refund or replacement vial(s) from Defendants.

563. Relators, and nearly every sales representative in Defendants' Xolair sales forces, assisted HCPs with this process that resulted in countless HCPs receiving Xolair at a price of zero.

564. If Defendants had accurately reported the "Best Price" for Xolair by factoring in the $0.00 price per vial given to HCPs through the Wastage Program, as well as all the other kickback-related rebates, discounts, and incentives detailed above, then Defendants would have been obligated to provide a much lower price for Xolair to all Medicare and Medicaid beneficiaries.

565. Relators know that Defendants, from 2003 forward, did not provide CMS with rebates and discounts based on the kickbacks scheme set forth in this Complaint. Indeed, to the contrary, Defendants have engaged in a pattern or practice of concealing the kickbacks provided. For example, Defendants concealed from HCPs Defendants' backing and financing of SPOC and LASH services, as detailed above.

_. STAUTORY SCHEMES, PROVIDER AGREEMENTS, AND HOSPITAL COST REPORTS

566. Defendants' off-label marketing practices, kickbacks, and other wrongful conduct knowingly caused doctors, hospitals, and pharmacies to file false reimbursement requests and cost reports with government healthcare programs, in violation of statutory schemes, provider agreements, and hospital cost reports.

567. CMS issues standardized, form provider agreements and hospital cost reports that HCPs are required to utilize. All of the HCPs that Defendants have marketed to, and have provided kickbacks to, utilize these standardized, form provider agreements and hospital cost reports. All of the providers specifically named in this Complaint and attached exhibits have utilized them.

568. In order to be eligible for **Medicare** reimbursement, both hospitals and doctors are required to sign a Provider Agreement which states: "I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]….I understand that payment of a claim

by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the AKS and Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare."

569. Hospitals, but not physicians, are also required to submit a Hospital Cost Report with their submissions of requests for claims reimbursement. It states: "Misrepresentations or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report [were] provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result."

570. The person signing the Hospital Cost Report must certify: "To the best of my knowledge and belief, [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations."

571. These statutory schemes, provider agreements, and hospital cost reports make clear that AKS compliance, and compliance with other federal health care laws, are a precondition of Medicare and Medicaid payment. They make no exceptions for violations caused by third parties like Defendants.

572. Further, it is established law that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and such

liability is not conditioned on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct. *See, e.g., U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45, 63 S.Ct. 379, 87 L.Ed. 443 (1943); *U.S. v. Bornstein*, 423 U.S. 303, 309-13, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976).

573. Defendants' kickbacks, misbranding, and off-label marketing also have caused HCPs' non-compliance with applicable State health care statutes.

574. For example, claims for Medicaid payment in **Illinois** "may be withheld…upon receipt by the Department [of Healthcare and Family Services] of evidence" of "fraud or willful misrepresentation under the Illinois Medical Assistance Program." Ill. Admin. Code tit. 89, § 140.44(a). Under Ill. Admin. Code tit. 89, § 140.35, titled "False Reporting and Other Fraudulent Activities," medical providers are subject to the requirements of both the federal AKS, which "prohibits kickbacks, false reporting and other fraudulent activities," *id.*, § 140.35(b), and the Illinois AKS, "pertaining to penalties for vendor fraud and kickbacks," *id.*, § 140.35(a). The Illinois AKS also extends liability to any entity that "willfully, by means of a false statement or representation, or by concealment of any material fact or by other fraudulent scheme or device...obtains or attempts to obtain benefits or payments under this Code to which [it] is not entitled, or in a greater amount than that to which [it] is entitled." 305 Ill. Comp. Stat. 5/8A-3(a).

575. Similarly, under a portion of the **Indiana** Medicaid statute, Indiana Code §§ 12-15-1 to 12-15-44, if the state's Medicaid office "determines that a provider has violated a Medicaid statute or rule adopted under a Medicaid statute, the office may" deny "payment to the provider for Medicaid services provided during a specified time," *id.* § 12-15-24-1. Another portion of the statute provides that a person who "furnishes items or services to an individual for

which payment is or may be made under this chapter and who solicits, offers, or receives a kickback in connection with the furnishing of the items or services or the making or receipt of the payment" commits a misdemeanor. *Id.*, § 12-15-22-2. The State's regulations also make clear that the state's Medicaid office "may deny payment" of claims "arising out of...acts or practices" including (1) "Engaging in a course or conduct or performing an act deemed by the office to be improper or abusive of the Medicaid program," 405 Ind. Admin. Code § 1-1-4(a)(6)(E), and (2) "Violating any provisions of state or federal Medicaid law or any rule or regulation promulgated pursuant thereto," *id.*, § 1-1-4(a)(6)(H).

576. Similarly, the **Massachusetts** Medicaid program "may withhold payments to a provider...if [it] believes that the provider has received any overpayments or committed any violations." 130 Mass. Code Regs. 450.249(B). Massachusetts law governing "Medical Assistance" provides:

> Whoever solicits or receives any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this chapter, or whoever offers or pays any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this chapter shall be punished....
>
> Mass. Gen. Laws, ch. 118E, § 41.

577. Violations are punishable by "a fine of not more than ten thousand dollars," and/or "imprisonment in the state prison for not more than five years or in a jail or house of correction for not more than two and one-half years."

578. Similarly, the **New York** Medicaid program provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether

paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. tit. 18, § 518.1(c). The regime defines "unacceptable practice," to include "[b]ribes and kickbacks," *id.*, § 515.2(b)(5), and lists within this category both "soliciting or receiving," id., § 515.2(b)(5)(ii), and "offering or paying," id., § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," *id.*, §§ 515.2(b)(5)(ii), (iv). New York's anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366-d, -f.

579. Similarly, the **California** Medicaid program may withhold payment when it receives evidence "of fraud or willful misrepresentation by a provider as defined in Section 14043.1." Cal. Welf. & Inst. Code § 14107(a)(2). Section 14043.1 defines "fraud" as "intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to herself or herself or some other person. It includes any act that constitutes fraud under applicable federal or state law." *Id.*, § 14043.1(I). California also has a regulation that lists fraud as grounds for suspension from California's Medicaid program. *See id.*, § 14123. Under California's provider agreement, which providers must sign to participate in the state's Medicaid program, the first page requires that providers agree "to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code." Chapter 7 of the code includes California's AKS, which applies to:

> Any person who solicits or receives any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind . . . in return for the purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any goods, facility, service or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8.

Cal. Welf. & Inst. Code § 14,107.2(a).

580. Similarly, under **New Mexico**'s provider agreement, which providers must sign in order to participate in that state's Medicaid program, Article VIII, entitled "Imposition of Sanctions for Fraud or Misconduct," states:

> If the provider obtains an excess payment or benefit willfully, by means of false statement, representation, concealment of any material fact, or other fraudulent scheme or devise with intent to defraud, criminal sentences and fines and/or civil monetary penalties shall be imposed pursuant to, but not limited to, the Medicaid Fraud Act, NMSA 1978, §§ 30-44-1 *et seq.*, 42 U.S.C. § 1320a- 7b, and 42 C.F.R. § 455.23.

581. The misrepresentations in the provider agreements and hospital cost reports, and the noncompliance with federal and state health care laws, are material because they have had a natural tendency to influence, or have been capable of influencing, the decisions of the decisionmaking bodies to which they have been addressed (CMS). Indeed, the express contractual language is dispositive of materiality.

_. ADDITIONAL DETAILS ABOUT XOLAIR FALSE CLAIMS

582. At all relevant times herein, reimbursement specialists employed by Defendants, the Lash Group, a consulting group hired by Defendants, have coached and provided comprehensive instructions to HCPs, at Defendants' direction, on how to maximize reimbursement from Medicare and Medicaid for administration of Xolair.

583. Defendants' reimbursement specialists, and those employed by LASH group, have provided telephone support to Defendants' Xolair buyers to facilitate the presentment of false claims to Medicare and Medicaid by Defendants' customers/accounts.

584. Defendants intended that, as a direct result of the instruction and support on off-label billing provided by their reimbursement specialists to Accounts, that these Accounts would make false or fraudulent claims to Medicare and Medicaid for off-label use of Xolair.

585. As a direct result of the work by Defendants' and Lash Group's reimbursement specialists, HCPs have presented false or fraudulent claims for government healthcare program reimbursement of claims for Xolair.

586. At all relevant times herein, from 2003 forward, there have been open discussions at meetings of sales representatives and management about the fact that the vast majority of patients on Xolair do not, in fact, meet the approved indications and eligibility criteria.

587. Novartis and Genentech have hired and paid a large sales force to drive sales of Xolair. On August 25, 2006, Mr. Clark sent an e-mail to the Xolair sales force which forwarded a roster of a total of approximately 140 Xolair sales personnel from both companies [attached hereto and incorporated herein by reference as **Exhibit "U"**].

588. However, the total sales force has been larger than that. Another sales force roster shows almost 200 sales managers and representatives companies [attached hereto and incorporated herein by reference as **Exhibit "V"**].

589. However, when one also considers Defendants' Xolair marketing teams, Defendants have had more than 300 employees, at any given time, advancing the illegal activities set forth herein.

590. Relators possesses a list of HCPs that received Xolair for the week ending July 7, 2006. It also shows year-to-date and rolling 12-month totals [attached hereto and incorporated

herein by reference as **Exhibit "W"**]. This reflects a fraction of the total number of Xolair buyers and purchasers from 2003 to the present.

591. Defendants have distributed to their Xolair sales forces, who in turn distributed them to and showed them to HCPs, diagrams which emphasized the off-label messages. For example, in one slide/diagram approved by Defendants' upper management for distribution, which was widely used, the fact that alternative therapies, like ICSs, should be used prior to Xolair was omitted and instead, Defendants explained and illustrated that "Xolair inhibits the IgE- mediated asthma inflammatory cascade before it starts" [attached hereto and incorporated herein by reference as **Exhibit "X"**].

_. CO-RELATOR FAUCI'S EXTENSIVE, CORROBORATIVE KNOWLEDGE

592. Because Mr. Fauci objected repeatedly to Defendants' sales practices and largely resisted and/or refused to engage in them, there are fewer examples of his personally engaging in the off-label marketing and kickbacks that are described herein. However, he obtained extensive first-hand knowledge of these illegal practices on the part of Defendants' sales forces because he served on the 2004 National Xolair Sales Representative Panel, with approximately 8 other Xolair sales representatives from Genentech. (Genentech holds 2 such panels per year.) In preparation for that panel meeting, Mr. Fauci held two or three conference calls with the vast majority of Genentech sales representatives (at that time) about what sales efforts were enjoying success. Xolair sales managers Diaz, Mastrianni, and Jason Reich also participated in some of these calls. Mr. Fauci then passed on the collected information to Leslie Flynn. Some of that information is reflected in Mr. Flynn's National Sales Representative Panel Meeting (San Francisco) Minutes dated November 5, 2004. Stephen Fauci attended, and participated in the lead-up to, that event, as summarized herein. Many Genentech sales representatives specified, in

response to him, that the off-label and kickback-type marketing efforts were succeeding with HCPs—and specified many of the barriers to Xolair sales that they were encountering. Mr. Fauci also attended national, regional, and local sales meetings in which he learned of off-label and kickback-related marketing efforts, and successes, by listening to presentations led by Xolair sales managers and select Xolair sales representatives, and by conversing with them between presentations and during dinners and other Genentech- and Novartis-sponsored events (like happy hours). (Co-Relators Kelly and Garcia also attended national, regional, and local sales meetings.)

593. Thus, while all members of Defendants' Xolair sales forces (including those listed in **Exhibit "B"**), by definition, engaged in off-label marketing and distribution of kickbacks on Defendants' behalf, because doing so essentially was a job requirement, as a part of Defendants' normal marketing policies and procedures, Mr. Fauci was in the unique position of having extensively corroborated the practices, on a nationwide basis—as compared to most Novartis or Genentech sales representative who did not serve on this or similar panels.

594. Through these collective channels, Mr. Fauci specifically corroborated off-label marketing and/or kickback distribution by the following people in Defendants' sales forces (Again, this is not to imply that only those listed below engaged in off-label marketing or kickbacks; Defendants' repeated directives made clear that this was a from-the-top-down directive that all members of the Xolair sales forces were expected to do so—although the word "kickbacks" was very rarely used):

Genentech's Xolair sales force

Director's Office

• Xolair Director Sales Leslie Flynn—extensively directed Genentech and Novartis' sales forces to engage in off-label marketing and kickback-related activities; the four Genentech district managers ("DMs") reported to Kelli Wilson, who reported to Leslie Flynn.

• Genentech FDSO Bill Huff—sent e-mails instructing the Xolair sales force not to enter into Pro Rep (a Microsoft Windows-based notes/reporting and productivity-measurement system that Defendants utilized) any comments about off-label discussions with HCPs.

• District Manager ("DM") John Mastrianni—formerly a sales representative for other Genentech drugs (TPA and TNK), Mr. Mastrianni then became a DM for those drug, and subsequently became a DM for the Xolair franchise in the New England sales district.

• DM James Sullivan—previously a Genentech sales representative with a base city of Portland, Maine, Mr. Sullivan took over Mr. Mastrianni's DM job in 2004 and spoke frequently about off-label marketing to boost Xolair sales, including at division meetings in Boston in 2004 and in addressing Genentech's Xolair Northeast division at a hotel near LaGuardia airport in New York in 2004.

• Sales representative Patricia Pino (base city Boston South)—following Defendants' directives, she was a very persistent off-label marketer, and one who shared her strategies with Mr. Fauci; gave honoraria of unrestricted educational grant to Amy Simon, M.D. of Tuft University Medical Center, which was approved by sales manager Kelly Wilson, over Mr. Fauci's objection; the grant was for continuing medical education ("CME") and medical books for Amy Simon, M.D.

• Sales representative Stephen Fauci (base city Boston North)—Before the 2003 Xolair launch, in 2001, Mr. Fauci treated physicians, including immunologist, to expensive meals at the Capitol Grille; the doctors were on the staffs of Massachusetts General Hospital, Newton-

Wellesley Hospital, Mount Auburn Hospital (Cambridge), Brigham & Women's Hospital in Boston, and the Leahy Clinic (Burlington, Mass.); also engaged in some other activities described elsewhere in this Complaint.

• Sales representative Curtis James (base city Providence, RI)—aggressively off-label marketed, filled out SMNs for HCPs, provided free swirlers to HCPs; took HCPs to very expensive dinners; gave free Red Sox triple-A league tickets to Anthony Ricci, M.D.

• Sales representative Lisa Wheeler (base city Hartford, CT)—frequently disseminated and spoke about off-label papers with HCPs; filled out SMNs for HCPs; treated HCPs to lavish dinners.

• Sales representative Kimberly Dickman (base city New Haven, CT)—among the sales representatives, spearheaded the effort to market the spread by creating a spreadsheet template, which was subsequently endorsed by Defendants' upper Xolair sales management for use nationally, after Mr. Mastrianni, Ryan Diaz, and Kelly Wilson approved and boosted it; to be used on a Palm Pilot and/or other hand-held devices, the spreadsheet template was shown to HCPs to illustrate the administrative costs, acquisition costs of Xolair and the profit that could be realized by HCPs because of the spread/differential.

• Sales representative Kenneth Clifford (base city Albany, NY)—either stated to and/or was observed by Mr. Fauci (as used in this list of certain members of the Xolair sales force, "observed by" may indicate the person's use of an e-mail or other written or oral communication), and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Jerry Kelly—made clear that it was mandatory that sales representatives in his territory fully utilize their budgets to woo HCPS with expensive dinners, fully use off-label

studies, fill out SMNs for HCPs, write appeal letters, and fight appeals with Medicare/Medicaid—even by urging the sales representatives pretend that they were nurses from the health care facilities to further this objective.

• Sales representative Joe Bonsignore (base city Poughkeepsie, NY)—developed an unapproved slide deck to market to nurses the use of Xolair on mild asthmatics; Mr. Garcia and Ms. Kelly sat through a presentation by Mr. Bonsignore in which he used this slide deck, which listed and summarized off-label studies; Mr. Fauci did not attend that presentation but saw the slide deck.

• Sales representative Frank Garcia (base city White Plains, NY)—engaged in off-label marketing and distribution of kickbacks to HCPs, as discussed elsewhere in this Complaint.

• Sales representative Shameeka St. John (base city Brooklyn, NY)—engaged in extensive off-label marketing and pretended to be a nurse for appeals.

• Sales representative Nicholas Dacchille (base city Queens, NY)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Elisa Keena (base city Hempstead)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Dahna Bender (base city Bayshore)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Jason Reich—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

However, upon information and belief, Mr. Reich also objected to many of Defendants' illegal practices.

• Sales representative David Caruso (base city Hackensack, NJ)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative David Sokolowski (base city Morristown, NJ)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Judith Newman (base city New Brunswick)—a nurse who gave Xolair shots to patients and, during a break-out session called "Best Practices" that she led during a sales meeting in the LaGuardia Airport Hilton in New York, provided a memorandum (which showed the Genentech logo) to other sales representatives, that explained how to give Xolair shots; Director Xolair Sales Leslie Flynn was there; the subject and contents of Ms. Newman's break-out session was approved by management in advance of the sales meeting.

• Sales representative Kevin Clarke (base city Toms River)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Dwayne Blackwell (base city Philadelphia North)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Charisse Sanzo (base city Philadelphia Central)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative DM Ryan Diaz—was very heavily involved in off-label marketing and directing Xolair sales representatives to provide kickbacks, including free swirlers and refrigerators; during a break-out session during a regional POA sales meeting in either Fort Lauderdale or Dallas in 2004, he used flip charts that instructed sales representatives on how to use off-label materials.

• Sales representative Samantha Hidlebird (base city Philadelphia South/Wilmington, DE)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Frank Johannes (base city Allentown, PA)—was on the 2004 National Sales Representative Panel with Mr. Fauci, whom he advised about the success of Dr. Casale's paper and other off-label studies in promoting Xolair sales.

• Sales representative David Jacobs (base city Harrisburg, PA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Stacey Lazzaro (base city Baltimore East)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Bob McConnell—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Rosanna Love—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Russell Gerald—in a session in Fort Lauderdale, FL in 2004, he spoke to DM Mastrianni, DM Rob Rindini, DM Kelli Wilson, and Mr. Fauci and others about the success his entire Florida team was having with off-label marketing Xolair.

• Sales representative Gwen Carter (base city Miami, FL)— either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Kevin Quinn (base city Fort Myers, FL)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Chris Chang—told Mr. Fauci at a national meeting in February 2003 in Las Vegas that his team was enjoying success with off-label marketing.

• Sales representative Tim Hassett (base city Syracuse, NY)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Michele Romesberg (base city Pittsburgh South)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative David Zito (base city Cleveland, OH)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Lisa Packo (base city Cleveland, OH)--either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative David Lewandowski (base city St. Paul)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Donna Bordwell (base city Quad Cities)--either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Senior District Manager ("SDM") Jennifer LaBerge—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative David Marcou (base city Phoenix North)—used to send out e-mails about off-label papers he was using; told Mr. Fauci he was doing everything possible, including expensive dinners and kickbacks, to get Xolair prescriptions written.

• Sales representative Larry Aldy (base city Las Vegas)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Mark Neumann (base city Fresno, CA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Jerry Anderson (base city Santa Barbara, CA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Ron Sparacino (base city Orange Cty., CA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Stacey Stames (base city San Jose', CA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Brad Kennedy (base city Flint, MI)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Jim Rediehs (base city Chicago South)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Chuck Sherline (base city Chicago North)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Carter Finnell—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• DM Connie Fairbanks—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

Novartis' Xolair sales force

Director's Office

• Vice President Eddie Williams—spoke at the POA national sales meetings in Fort Lauderdale and Dallas in 2004, about the importance of off-label marketing to boost Xolair sales. (The Xolair franchise's POAs are national meetings that are attended by sales managers and sales representatives from both Genentech and Novartis; further, Defendants' marketing teams also attended them—not just their sales forces.)

• East Director Norbert Stone—spoke at many regional sales meetings, including a sales meeting at a hotel near LaGuardia Airport in New York, about the importance of off-label marketing to boost Xolair sales, and utilized flip charts to illustrate Defendants' strategies and points.

East Region

• Area Sales Manager ("ASM") Robert Rindini—spoke at numerous POA meetings, including two in Fort Lauderdale and one in Texas, about marketing the spread, off-label marketing, expensive dinners, and other kickbacks, as keys to high Xolair sales.

• Sales representative Susan Severin (base city Portland, Maine)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Grace Brown (base city Boston South, MA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Todd Quinn (base city Worcester, MA)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Elizabeth Gugliotta (base city Providence, RI)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Joe White (base city Hartford, CT)--either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Joan McGrath (base city Albany, NY)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Area sales manager ("ASM") Frank Garay—made clear that he expected Novartis' Xolair sales force to use every resource and tool that Defendants had made available to them, including off-label marketing and inducements, to boost Xolair sales.

• Sales representative Pilar Carbone (base city Brooklyn, NY)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Frances Estremera (base city Queens, NY)—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• Sales representative Alexis Pace (base city Hempstead, NY)--either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

• ASM Daniel Giunta—either stated to and/or was observed by, Mr. Fauci, and/or acknowledged in some way, engaging in off-label marketing or kickback-related activities.

_. DEFENDANTS' WRITTEN TRAINING MANUALS

595. Defendants' written training manuals—which they called "modules" and distributed to their Xolair sales forces and required them to study and use—foreshadow and reflect a great deal of the fraud that would transpire from 2003 forward.

596. In April 2003, Defendants provided four training booklets, called "Learning Modules," to their Xolair sales forces. At this point of first distribution of the Learning Modules to the Xolair sales force, Xolair had not even been FDA approved. Also surprising, Defendants are beginning the launch of Xolair prior to acceptance of the drug by any payors yet. These facts reflect how aggressively Defendants planned to market Xolair, to achieve a large share of the lucrative asthma and allergy drug market. Defendants called these written training booklets, collectively, "the Xolair Learning System." Defendants also provided their sales forces with accompanying CD-ROMs, called "Take a CDRom Breather," to supplement this form of training. Most or all Xolair sales managers and sales representatives were told to undergo this study program at home. Ms. Kelly, Mr. Fauci and Mr. Garcia mostly utilized these study materials in April, May, and/or June 2003, prior to the Xolair launch and FDA approval in June 2003. They then referred to "the Xolair Learning System" at various times after the drug was FDA approved and the drug was launched.

597. The cover memo accompanying the first 4 modules, dated April 18, 2003, was from Craig Haines, a leader in Defendants' Xolair Product Training department, and Lane Wilson, Defendants' Xolair Product Manager. The memo contained both Genentech and Novartis' logos.

598. At least two additional modules were distributed by Defendants soon thereafter.

599. As the introduction to Module 1 states, Module 1 focused on the anatomy and physiology of the upper and lower respiratory airways. Module 2 focused on immunology, "which you will need to know to understand the allergic asthma state, as well as the mechanism of action of Xolair." Module 3 focused on allergic asthma disease state—the second part of which focused on "the clinical presentation, diagnosis, and guidelines for treatment." Module 4 focused on "the asthma marketplace." Module 5 focused on "Xolair product knowledge." Module 6 provided the Xolair sales force with "an opportunity to synthesize all of the knowledge you've gained in the first 5 modules into a comprehensive, integrated Xolair selling strategy."

600. Parts of these "Learning Modules" reveal some of Defendants' earliest intentions to off-label market Xolair. However, it has been in Defendants' unwritten training of the Xolair sales force—i.e., in national, regional and local meetings, and in less formal communications between sales managers and sales representatives—that Defendants more directly and openly have trained their sales forces to engage in off-label marketing and providing kickbacks on behalf of Defendants. Indeed, Defendants have discouraged their employees from being so blunt as to use words like "kickbacks," "off-label marketing," and similar statements, in written form—which leaves a paper trail.

601. For example, what would become part of the off-label message about Xolair's effectiveness in combatting "allergic asthma" was introduced to the Xolair sales force in Module 1, concerning the anatomy and physiology of the respiratory tract. Defendants stated therein:

The Allergic-Asthma Connection

> Increasingly, researchers are beginning to look at diseases, like allergic rhinitis (upper airways), sinusitis (upper airways), and asthma (lower airways) as different clinical manifestations of a single disease process. Although the exact relationship between the upper and lower airways is not clear, data from many different areas support the hypothesis of a single, unified airway or "one airway, one disease."

> The important point to keep in mind is that scientists increasingly recognize that many of the same pathologic processes that occur in a lower airway disease, like asthma, may also be occurring in an upper airway disease, like allergic rhinitis. The implication is that if similar disease processes are at work at different points in the respiratory tract, a medication that is effective in one airway may also be effective in treating another airway.
>
> Currently, [FDA] approval for Xolair is only being sought for the treatment of moderate-to-severe allergic asthma. However, considering the "one airway, one disease" hypothesis and preliminary data from randomized, controlled clinical trials[,] Novartis Pharmaceuticals and Genentech may pursue additional indications in IgE mediated diseases. Certainly, our focus for the remaining modules of the Xolair Learning System will be allergic asthma, a lower airway disease, but keep the one airway, one disease concept in mind as we discuss the immunology and pathophysiology of allergic disease in Modules 2 and 3.

602. The above-quoted excerpt from Defendants' Module 1 expressly cited, by footnote, multiple off-label studies in support of the "one airway, one disease concept," specifically Busse W., Epidemiology of rhinitis and asthma, *Eur Respir Rev.* 1997, 284-295; De Benedictis FM, del Guidice MM, Serverini S, *et al*, Rhinitis, sinusitis, and asthma: one linked airway disease, *Pediatric Respiratory Reviews* 2001, 2:358-364; The International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee, Worldwide variation on prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and atopic eczema: ISAAC, *Lancet* 1998, 351:1225-1332; Settitpane RJ, Hagy GW, Settitpane GA, Long-term risk factors for developing asthma and allergic rhinitis: a 23-year follow-up study of college students, *Allergy Proc.* 1994, 15:21-25; Grossman J, One airway, one disease, *Chest* 1997, 111:115-165; and Lundblad L, Allergic rhinitis and allergic asthma: a uniform airway disease, Allergy 2002, 57(11): 969-971.

603. Even if "allergic asthma" is a bona fide scientific classification for a type of asthma, what is significant is that Defendants capitalized on the term "allergic asthma" as part of their off-label marketing campaign to HCPs, to try to get HCPs to prescribe Xolair for the

unapproved use of treating allergies. Defendants instructed the Xolair sales force to utilize the "one airway, one disease concept" to promote the drug to HCPs, and thereby capture a lucrative portion of the market for treating allergies, like SAR. Even before obtaining FDA approval for the limited indication of moderate to severe, persistent asthma, Defendants were carefully plotting the off-label marketing campaign.

604. Defendants' off-label marketing of Xolair for allergic rhinitis is reflected by a summary sheet/handout entitled "Pollinating Seasons" that was written by Genentech Xolair sales representative Judith Newman, from the Philadelphia area [attached hereto and incorporated herein by reference as **Exhibit "X"**]. With the consent of Defendants' sales managers, she distributed this handout to numerous other members of Defendants' Xolair sales forces during a break-out session at a regional Xolair sales meeting near LaGuardia Airport in New York in 2004. Kelli Wilson ran the sales meeting, and Leslie Flynn attended the breakout session. In the handout, and during the break-out session, Ms. Newman discussed the allergy season, SAR, off-label marketing, and particularly selling to allergists the idea of prescribing Xolair for use with immunotherapy and/or rush immunotherapy.

605. In Module 4, entitled "The Asthma Marketplace: Competitors and Patient Perspectives," Defendants also elaborated on "allergic asthma," describing it as the "most common form of asthma occurring as a result of exposure to an allergen." This module is also notable for acknowledging that mild asthma cases constitute the majority of asthma cases; expounding on the claimed side effects (e.g., osteoporosis, tongue lesions) of ICSs, which are usually prescribed for patients with persistent asthma; stating that ICSs are "[n]ot effective for immediate relief of exacerbations; slow onset of action"; and expounding on the side effects and other advantages of other asthma treatment modalities besides Xolair.

606. In Module 4, Defendants also informed their sales forces that, of the 8.5 million adults who suffer from asthma, more than 5 million have "allergic asthma" and 81.5% of those 5 million may be eligible for Xolair treatment; that "[t]reatment of asthma is big business"; that "[i]n 2002, approximately $4.2 billion was spent on prescription drugs to treat asthma, including both quick-relief and long-term-control medications," that "[t]he market is currently dominated by combination therapy (Advair)"; that "[c]urrently, five competing companies [GlaxoSmithKline, Merck, AstraZeneca, Aventis, and Schering] dominate the asthma market…Their products will not only compete with Xolair in the treatment of allergic asthma, but will be used in combination." Defendants also stated that "[m]ost healthcare providers view Advair as having a significant contribution to compliance. In a market study recently conducted by Novartis and Genentech, Advair was perceived as a potent and first-line, gold standard, mainstay of [asthma] therapy. This will be difficult competition for Xolair." Nonetheless, Defendants stated: "While there are a number of currently available asthma drugs that help to quickly improve asthma symptoms in the short-term and reduce asthma exacerbations over the long term, there clearly is an unmet need. With this introduction, Xolair will help fill this need." Thus, the stage was set for the Xolair sales force to understand that they needed to change the mindsets of HCPs who "perceived" that Advair and other established treatments modalities were not, in fact, adequate.

607. Again, Defendants claimed that 8.5 million adults suffer from asthma, with 5 million having allergic asthma, and that of those patients, 81.5% "may be eligible for treatment with Xolair." However, according to Defendants' own statistic, only approximately 32% of asthmatics fall into the moderate to severe persistent asthma category, so only 32% of the 5 million allergic asthmatics meet the Xolair indication. The training materials also make clear

that Defendants contemplated supporting a redefinition of asthma severity, abandoning the traditional 4-level category of severity from mild intermittent to severe persistent, in favor of a categorization that defines asthma severity based upon degree of control. These early training materials reference "the need for new approaches to the treatment of asthma," and focus on the premise that "asthma patients are currently sub-optimally controlled [on their current medications], with 83% of parents of adult asthmatic children and 75% of adult patient...[making] unscheduled visits to healthcare providers…." As Xolair's early studies showed that Xolair decreases exacerbations in patients taking ICSs, Xolair's key selling point is "control of symptoms."

608. However, Module 4 is perhaps most notable for setting forth the place for Xolair in the immunotherapy treatment. Defendants sought to bridge the gap between asthma treatment and allergy treatment by stating that "this treatment, also known as allergy shots, is used to treat asthma through immunosuppressive techniques involving suspected antigens. It can help to reduce the effect of chronic stimulation on hyperresponsive airways, thereby desensitizing patients to trigger allergens and preventing asthma attacks. In the treatment of asthma, immunotherapy is used adjunctively in the few patients who fail to respond to conventional asthma treatment and appropriate environmental control efforts." It was also stated that "[i]mmunotherapy...can be effective for [asthma] patients when there is clear evidence of a relationship between exposure to an allergen and asthma symptoms….In addition to avoiding common asthma triggers, treating any underlying conditions contributing to asthma can also help patients minimize asthma symptoms and exacerbations….These include[] rhinitis/sinusitis…." To be accurate, immunotherapy is overwhelmingly used to treat allergies—not asthma—and Xolair was never FDA approved for treating allergies.

609. In Module 5, Defendants explained that the Xolair sales force could expect a lot of resistance from HCPs, especially pulmonologists, to the sales pitch of prescribing Xolair as part of immunotherapy. Without even pointing out that Xolair was not even poised to be approved by the FDA for treatment of allergies, Defendants explained that the National Heart, Lung, and Blood Institute was very skeptical of the efficacy of immunotherapy in treating allergic asthma:

> The NHLBI Guidelines have given immunotherapy only a limited endorsement [for allergic asthma treatment], suggesting that it may be considered for those asthma patients who fail to respond to conventional asthma therapy and appropriate environmental control measures. In other words, immunotherapy might be used for patients who have failed to respond to medications, who require multiple medications to maintain control of their asthma symptoms, or who do not take their medication. Other cases where immunotherapy may be warranted include those patients for which clear evidence of a relationship between symptoms and exposure to an unavoidable allergen to which the patient is sensitive is present. Also, immunotherapy candidates should experience symptoms during the major part of a year, not just seasonally.
>
> According to the NHLBI Guidelines, many of the controlled trials used to establish the efficacy of immunotherapy in asthma use only a single allergen, such as ragweed or grass pollen, rather than the multiple-allergen combinations that are routinely administered in clinical practice. Although the NHLBI has been critical of immunotherapy in that regard, many allergists vigorously disagree with this assessment. *The Annals of Allergy, Asthma, and Immunology* contain numerous articles citing the success of immunotherapy in controlling asthma as well as other allergy-based diseases.
>
> Learning Module 5, at 4-61 to 4-62 (2003).

610. Defendants' sales forces have used many of these articles from *The Annals of Allergy, Asthma, and Immunology* to off-label promote Xolair for use in immunotherapy treatment, to nip the "allergic cascade" in the bud and thereby prevent asthma attacks.

611. In Module 5, Defendants also state:

> This controversy is strongly evident in clinical practice. In recently conducted market research studies conducted by Novartis and Genentech, allergists characterized immunotherapy as worthwhile, but pulmonologists felt that it was inconvenient and disappointing. Allergists felt that immunotherapy was a helpful adjunct, while

> pulmonologists found it overrated, difficult to administer, time consuming, and capable of only limited application….
>
> …[I]t is important to note here that pulmonologists are not accustomed to using injectables, like immunotherapy, and in the future, Xolair. Allergists, on the other hand, are very accustomed to using immunotherapy and injectables in general. In fact, a significant portion of the income of allergists is derived from immunotherapy.
>
> Learning Module 5, at 4-62 (2003).

612. Knowing that allergists were a "softer" target, Defendants later told their Xolair sales forces to focus heavily on marketing Xolair to allergists—and that this could open up a huge market.

613. In Module 5, Defendants further state:

> Because the primary customers for Xolair will be allergists and pulmonologists, as sales representatives, you will need to be aware of the controversial nature of immunotherapy as an asthma treatment. Note again that Xolair *is not immunotherapy* and does not depend on the identification of specific allergens in order to prevent allergic reactions. In immunotherapy, a patient's known allergens must be identified and then injected, leading to possible adverse effects. With Xolair, the anit-IgE mechanism prevents reactions to any and all potential allergens irrespective of the allergen specificity.
>
> Learning Module 5, at 4-63 (2003) (emphasis in italics in original).

614. In Module 5, Defendants also state that "[i]mmunotherapy is always given in an allergist's office because severe bronchoconstriction and, rarely, anaphylaxis, can occur. Patients must wait approximately 20-30 minutes following their allergy shot to ensure that no reaction develops…" Notably, Defendants acknowledged immunotherapy's risk of anaphylaxis, but still engaged in the practice of providing Xolair directly to asthma patients for home administration, despite Xolair's own risk of anaphylaxis. Moreover, the Product Insert ("PI") for Xolair that the FDA soon approved in June 2003 explicitly stated: "IMPORTANT: XOLAIR SHOULD ALWAYS BE INJECTED IN YOUR DOCTOR'S OFFICE."

615. In Module 5, entitled "Xolair Product Knowledge," Defendants educate their sales forces about the drug, in anticipation of Xolair's approval by the FDA. "Allergic asthma" was described as "the most common form of asthma occurring as a result of exposure to an allergen." The alleged limitations of competing asthma drugs Advair and Singular, was described. Singulair was described as "an oral allergy medicine...approved by the FDA in 1998. It works to reduce symptoms of allergic asthma by blocking leukotrines." Defendants state that "[i]n 2000, the FDA approved Advair, the first and only inhaled combination medication approved to treat both underlying components of the disease: inflammation and bronchoconstriction. Advair contains inhaled corticosteroid (fluticasone propionate) to reduce inflammation and an inhaled long-acting bronchodilator (salmeterol) to help prevent bronchoconstriction." However, Defendants state that "[d]espite these advances, asthma remains a prevalent disease, necessitating the development of medications for better long-term disease management. Improved understanding of the pathophysiology and advancements in asthma therapy have paved the way for a new asthma treatment….Genentech and Novartis Pharmaceuticals Corporation propose that Xolair be classified as a **long-term control medication**." (emphasis in boldface original) Defendants defined "long-term control medications" as "drugs that are taken daily on a long-term basis to achieve and maintain control of persistent asthma. Includes inhaled corticosteroids and long-term bronchodilators…plus others."

616. Defendants state in Module 5 that "Xolair addresses the common origin of allergic disorder by preventing symptom development, rather than treating symptoms or inflammation alone," that "Xolair blocks IgE, which prevents mast cell degranulation and the release of inflammatory mediators, thereby interrupting the allergic cascade," that "Xolair reduces asthma exacerbations and improves asthma control," "Xolair allows steroid dose-

reduction while maintaining asthma control," "Xolair improves asthma symptoms and respiratory function," and "Xolair improves asthma-related quality of life."

617. In Module 5, Defendants also emphasize the potential side-effects of Advair and Singulair. Among other things, Defendants state: "Specifically, significant side effects have been associated with long-term corticosteroid use in some patients. It has been shown that growth rates in children are highly variable, and that poorly controlled asthma may delay growth…Most studies show no effect with low-to-moderate doses of inhaled corticosteroids, and higher doses of inhaled corticosteroids have fewer risks than oral corticosteroids. Nevertheless, patients and physicians remain concerned about the possible side effect of inhaled corticosteroids on growth rates and other adverse events including **hypothalamus axis (HPA)** suppression, bone reabsorption, which could lead to osteoporosis, and cataracts." (emphasis in boldface in original)

618. Defendants also orally reminded their sales forces to tell HCPs of the side effects of these competing drugs, including stunted growth in children.

619. In summarizing the nature of asthma therapies, like Advair and Singulair, that predated the advent of Xolair, Defendants state in Module 5 that there are three "issues with current asthma therapy: inadequate relief[,] significant side effects and safety concerns[,] and adherence problems."

620. Module 5 also contains a point that many in the Xolair sales force have been advised to state to promote use of the drug at home, to downplay the risks of doing so: "Xolair is an injectable designed to be administered subcutaneously, or under the skin. Subcutaneous injections allow a drug to be injected into an area where there are fewer nerve endings allowing for a less painful injection."

621. Module 5 also contains points that led Defendants to the idea of kickbacks that could remove anticipated barriers to selling Xolair, especially as compared to competing asthma drugs like Advair and Singulair—namely the free refrigerator, free mixers, and wastage program: "Notice that Xolair must be stored in refrigerated conditions. This requirement for cold storage has implications for suppliers and prescribers. Also note that reconstituted Xolair can be stored for up to 4 hours at room temperature or up to 8 hours in the refrigerator. This has important implications because it means that Xolair, with its somewhat lengthy preparation process, can be reconstituted in advance, prior to a patient's arrival. While this may be more convenient for both patients and physicians, it may also lead to wastage if patients miss their appointments." This foreshadows Defendants' program of reimbursing HCPs for the purchase price of Xolair when patients did not meet their appointments.

622. Defendants' Module 6 is entitled "Xolair Reimbursement and Distribution; Process and Services." In Module 6, Defendants state, or strongly imply (as the case may be), that certain free services and products are to be provided to HCPs to grease the way for Xolair sales. It is stated that the 5 specialty pharmacies retained by Defendants, a Third Party Vendor, and Defendants themselves, directly through their own internal Single Point of Contact ("SPOC") Program, exist to induce HCPs to prescribe Xolair—lest they be overwhelmed with the administrative and financial hassles associated with obtaining approval for the drug, and administering the drug. Although Defendants mask their support services as programs to enhance compliance with the healthcare laws, the opposite is true: they are thinly veiled kickbacks, in violation of the AKS.

623. In Module 6, Defendants state or strongly imply that Xolair sales representatives are to do everything possible to assist these illegal programs. Defendants explicitly instruct their

Xolair sales forces to conceal from HCPs the fact that SPOC is backed and financed by Defendants—to hide that link to the kickback: "Note that in communications with your customers [HCPs], you should use the term 'Third-Party Vendor' and omit the reference to SPOC." SPOC was mostly administered by Genentech out of its San Francisco offices, and interfaced heavily with Defendants' sales forces in obtaining SMNs.

624. Whether Defendants' sales forces were assisting HCPs with SMNs and appeal letters, Defendants' SPOC Program were assisting HCPs with them, or Defendants provided such assistance through the 5 specialty pharmacies that received compensation for their work, the provision of these support services—in any and all such manners—are kickbacks.

625. Defendants' Xolair sales forces were in regular contact with the 5 specialty pharmacies to jointly focus on obtaining Medicare, Medicaid, and other payors' approvals for reimbursement for Xolair prescriptions.

626. Defendants have focused their resources heavily on obtaining Government Healthcare Programs' approval of Xolair prescriptions because, as Defendants' sales managers sometimes stated, those programs—in contrast to MCOs (e.g., HMOs and PPOs)—would not scrutinize the cost of Xolair, the diagnosis, and the propriety of treatment with Xolair, as closely or as frequently as MCOs. Indeed, two of Relator's own Xolair sales managers, Frank Garay and Martin Clark, instructed her to be careful not to waste much time with "stingy" MCOs that were less likely to approve Xolair.

627. From late 2003 or early 2004 forward, Defendants' sales managers, across the country—including Jerry Kelly, Frank Garay, and John Mastrianni, James Sullivan, Kelli Wilson—instructed Xolair sales representatives, during sales meetings and ride-alongs, to seek

access to HCP's medical charts on patients, flag potential Xolair patients, fill out SMNs, and write appeals letters.

628. From late 2003 or early 2004 forward, Defendants' sales managers, across the country—including John Mastrianni, James Sullivan, Kelli Wilson, Jerry Kelly, and Frank Garay—instructed Xolair sales representatives, during sales meetings and ride-alongs, to advise HCPs that patients could receive Xolair shipments at their homes, to emphasize to HCPs that this would same the HCPs time and money—even though the FDA's approval did not allow for at-home administration of Xolair. Because of its viscous nature, it is difficult for a patient to self-administer the drug, or for an untrained other person to administer it. Plus, the risk of anaphylactic reactions placed this marketing and conduct outside of the parameters of the FDA's approval of the drug.

629. In Module 6, Defendants acknowledge the requirement that Xolair be administered in physicians' offices, while simultaneously showing their intention to send Xolair directly to patients' homes, for their administration outside of physicians' and nurses' vigilant eyes to protect them from the potentially lethal side effect of anaphylaxis. In many instances, Defendants had Xolair shipped to patients' homes to alleviate HCPs' financial burdens in administration of the drug, to ensure that prescriptions would be written by HCPs that were concerned with the effects on their overhead and lack of personnel.

630. Further, in Module 6 Defendants describe their Access To Care ("ATC") Program. Although described as a program to benefit completely uninsured patients who have been prescribed Xolair for an approved indication, many such patients were actually prescribed Xolair for off-label uses. Further, Defendants misused the ATC Program by extending it to under-insured patients—not merely uninsured patients.

631. In addition, in Module 6 Defendants describe free items provided to HCPs, which were used by Defendants to induce HCPs to prescribe Xolair:

- 10cc diluent (preservative-free sterile water for injection),
- 3cc syringes,
- 18-gauge large-bore needles for reconstitution,
- 25-gauge needle for administration,
- alcohol swabs, and a
- Sharps container (as needed)

632. As set forth above, these items were actually the "tip of the iceberg" as to what free items Defendants actually provided to HCPs to induce them to prescribe Xolair.

633. In Module 6, "you" refers to the Xolair sales representative and, to a lesser extent, the Xolair sales manager. As noted above, Xolair sales managers went through sales training that included (but was more extensive than) the same sales training that the Xolair sales representatives underwent.

634. Notably, many of the statements quoted immediately below, including many of those stating "What does this mean for you?," are veiled references to the fact that Defendants, orally and in writing, instructed and expected their Xolair sales forces to do everything possible to provide hands-on support to HCPs to provide the product- and service-related kickbacks described below, and the other kickbacks not specifically referenced by the training modules. In short, Defendants expected them to surmount the expected obstacles to maximized Xolair sales—for example, to sell Xolair even though 75% of patients will be enrolled with MCOs and MCOs have not even approved Xolair; it is not on their formularies yet—let alone national guidelines for the treatment of asthma, like those of the NHLBI, which focus largely on the

treatment of asthma with FDA-approved, effective inhaled corticosteroids. For example, there are veiled references to the fact that Defendants expected Xolair sales representatives to be active participants in filling out SMNs for HCPs, seeking Medicare, Medicaid and private pa reimbursement, and assisting with appeals letters—all of which should have been done, if at all, independently by HCPs and their staffs. This is underscored by Defendants' statements, quoted below, that: "[o]f course, you play a major part in these processes, one that continues well beyond convincing customers of the clinical features and benefits of the product"; that, during sales-representative-led inservices in HCPs' offices, "[d]iscuss your ongoing involvement and commitment to providing support throughout the process"; and that "a small practice with one office manager may appreciate your help in getting that initial paperwork over to the Preferred Specialty Pharmacy." These statements are "code" for what Defendants intended, and sales managers instructed, sales representatives to do: to assist HCPs through the entire process—including delivery of the drug to HCPs' offices and even patients' homes, relieving HCPs from reimbursement troubleshooting, assisting HCPs with ICD-9 and CPT coding, assisting HCPs with reconstituting the drug and injections, and filling out SMNs and appeals letters. Defendants frequently referred to such deal-closing work as "pull through."

635. Module 6 also notably includes statements by Defendants, quoted below, that their Xolair sales forces, while conducting "inservices" with HCPs, should expect physicians to ask, "What restrictions and prior authorization requirements can we expect?," and that a suggested answer from the sales representative is: "We expect that about 90% of payers will require prior authorization for Xolair. We also anticipate that over 80% of payers will restrict its use in some way, ie, according to diagnosis, specialist prescriber, maximal dosage, or administration in the physicians' office only." Among other things, this statement shows

Defendants' knowledge that payers—Medicare, Medicaid, MCOs, etc.—would actually question the appropriateness of Xolair for certain diagnoses—which would never be a concern unless off-label prescribing for non-approved diagnoses, improperly high dosages, and prohibited off-label, at-home administration of Xolair, were anticipated.

636. Defendants begin Module 6 by stating that Defendants' support services would be paramount because Xolair would be an expensive drug and would require a lot of paper work for HCPs:

> **Introduction**
>
> Because Xolair belongs to a novel therapeutic class and because it is subject to the premium pricing associated with biologic agents, extensive support services that ensure its smooth and simple distribution and reimbursement will enhance the success of the product with your customers [HCPs].
>
> For example, we anticipate that six months after launch, 75% of **payers** will cover Xolair. The vast majority will require **prior authorization**. Prior authorization requires interaction with payers that may trigger objections from physicians who already feel deluged by paperwork from managed care organizations (MCOs). Furthermore, a patient treated with an injectable agent often requires ancillary supplies, training, and ongoing support to ensure compliance. Once again, physicians may object to further demands on their time—particularly when that time is not reimbursed by a payer.
> We are committed to eliminating these objections. That's why we have put in a special pharmacy network to assist with reimbursement purposes for Xolair to ensure that the things are as simple as possible for your customers and their patients.
> These processes ensure that every Xolair prescription flows through carefully controlled channels designed to provide consistent and comprehensive services. As you [the sales representative or sales manager] will see, these channels offer multiple benefits to your customers, including:
>
> - rapid reimbursement with minimal hassles
> - convenient nursing support and ancillary supplies at no extra cost to the patient
> - enhanced patient compliance and persistence programs
> - valuable patient education materials

This program examines these services and processes and what you [the sales representative or sales manager][16] can do to make sure your customers are able to move through them seamlessly.

Module 6 (emphasis added as underlining; emphasis in original as boldface and italics).

637. Defendants elaborate in Module 6:

Overview

In order to make access to Xolair as smooth as possible for both physicians and patients, each Xolair prescription will be directed through one of two channels:

- Primary Distribution Network, make up of five preferred specialty pharmacies,
- Secondary Distribution Network

As you can see in Figure 1-1, we expect that at least 75% of Xolair patients will use the Primary Distribution Network. The remaining patients, primarily those outside of conventional managed care organizations (MCOs), will receive Xolair through the Secondary Distribution Network.
This program will focus on the Primary Distribution Network, since it is how most of your customers will receive Xolair.

* * *

Who's Who in the Xolair Primary Distribution Network?

Distribution and reimbursement of Xolair along this pathway involves four key "players":

- Preferred Specialty Pharmacies (PSPs)
- Single Point of Contact (SPOC) program
- SPOC's Third-Party Vendor (TPV)
- Access to Care (ATC) Foundation

[16] As used throughout this Complaint, "the Xolair sales representative and sale manager" usually means "the Xolair sales representative and, less frequently but to no small extent, the Xolair sales manager," because the vast majority of oral and written Xolair sales and marketing communications between Defendants and HCPs was conducted through Xolair sales representatives. However, at times Xolair sales representatives were accompanied by Xolair sales managers on sales calls to HCPs, at other times Xolair sales managers conducted their own sales calls on HCPs, and very frequently Xolair sales managers went through sales training that included (but was more extensive than) the same sales training that the Xolair sales representatives underwent.

* * *

The Preferred Specialty Pharmacies

The Preferred Specialty Pharmacies are five of the country's leading pharmacy distributors. As we mentioned, they will provide distribution and reimbursement support for about 75% of patients who receive a Xolair prescription. Table 1-1 (on pages 2-10) gives you a closer look at each of these Preferred Specialty Pharmacies. As a group, they have been:

- selected by Genentech and Novartis after a long and rigorous review process
- proven to have the experience, internal capacities, and overall quality control processes to provide complete and consistent support to your physicians and patients
- contracted by Genentech and Novartis to provide specific support services according to a well-defined and timely schedule

* * *

As you will see in the pages that follow, the Preferred Specialty Pharmacies do much more than ship out a vial of Xolair. In fact, *that* may be the easiest part of their job. Their overall mission is *to reduce any burden on your physicians and their office staff by providing a full range of support services.* That translates into the following overall responsibilities:

- serving as the patient's primary contact in securing reimbursement from a payer
- supporting the patient once distribution has been authorized
- ensuring that the product and all of its **ancillary supplies** are delivered on schedule
- providing patient case management

* * *

What does this mean for you [the sales representative or sales manager]?

The network of Preferred Specialty Pharmacies is one of the greatest conveniences for patients and physicians associated with prescribing Xolair. When you introduce the concept to your customers, take some time to highlight the benefits they'll receive by working with any one of the five Preferred Specialty Pharmacies. These benefits include:

- An experienced service to tackle reimbursement directly with the payer, with minimal hassles for the physician, the office staff, and the patient
- A convenient source for nursing services and ancillary supplies, at no extra cost to the patient
- A comprehensive source of valuable patient education materials
- A means of enhancing patient compliance and persistence

Obviously, then, it is to the physician's great advantage to use a Preferred Specialty Pharmacy. Here are two scenarios in which the services established for Xolair may not apply:

- The patient's payer will only reimburse products delivered by a specific distributor who happens to be outside the Primary Distribution Network.
- Physicians who want to buy and dispense Xolair to their patients directly can do so through any of the five Preferred Specialty Pharmacies. However, they will have to negotiate all terms and conditions directly with the pharmacy.

While we anticipate that these situations will occur infrequently, we will be providing more information on what they mean to you in future training venues.

The Single Point of Contact (SPOC) Program

Supported financially by Genentech and Novartis is an *internal* Genentech resource dedicated to facilitating distribution and reimbursement services. SPOC maintains a relationship with the Preferred Specialty Pharmacies and also oversees the activities of the Third-Party Vendor, which will be described in more detail in the next section.

* * *

SPOC's Third-Party Vendor

SPOC has contracted with a Third-Party Vendor to handle certain distribution responsibilities that will not be handled by the Preferred Specialty Pharmacies. Highly experienced in customer service and complex reimbursement issues, SPOC's Third-Party Vendor will:

- manage patients after they have been denied a **first-level appeal** for reimbursement by their health insurance companies (you will learn more about how this works in Chapter 2)
- manage patients who, for reasons that will be explored in Chapter 2, cannot be serviced by the Preferred Specialty Pharmacies
- manage "overflow" patients in the event that the five Preferred Specialty Pharmacies experience an extremely high volume of Xolair prescriptions
- provide support services on an "as needed" basis to patients who must access Xolair through the Secondary Distribution Network

Keep in mind that SPOC's Third-Party Vendor is not a distributor of pharmacy products. Once reimbursement authorization is obtained for a given patient, SPOC's Third-Party Vendor will contact the Preferred Specialty Pharmacy that initially managed the patient for actual distribution of the product. (If the patient is receiving Xolair through the Secondary Distribution Network, SPOC's Third-Party Vendor will turn over product distribution to the payer-required pharmacy.)

* * *

The Access to Care Foundation

An *internal* Genentech resource for all other Genentech products, both Genentech and Novartis support the Access to Care (ATC) Foundation for Xolair patients. The ATC focuses on one specific patient population: *the completely uninsured patient who has received a Xolair prescription for an approved indication.* Using strict guidelines to ensure that patients meet financial, regulatory, and other criteria, the ATC will evaluate these patients and help qualified individuals explore other coverage options or obtain a defined supply of free drugs. Other coverage options include:

- Medicare
- Medicaid and other state assistance programs
- Health insurance programs available during an employer's open enrollment period
- Health insurance available under **COBRA (Consolidated Omnibus Budget Reconciliation Act)**

Patients who are simply **underinsured** (that is, those who have health insurance but whose plan does not include pharmacy benefits, does not cover injectable products, provides a low maximum benefit, or otherwise does not adequately cover Xolair) are not eligible for review by the ATC Foundation.

What does this mean for you?

If the physician knows that a particular patient is uninsured, make sure the physician's office still faxes the proper forms to a Preferred Specialty Pharmacy, which in turn will channel the patient to the ATC if appropriate. When a patient is referred to the ATC, it will fax notification of that referral to the physician. You are welcome to contact ATC directly to follow up on a physician inquiry about a patient referred to ATC.

The Extended Role of SPOC

As you learned earlier, SPOC will oversee the five Preferred Specialty Pharmacies and the Third-Party Vendor to ensure that they all meet their commitments to your customers efficiently and effectively. It is also important to know that SPOC's role in Xolair distribution and reimbursement extends beyond these two critical functions. Table 1-2 outlines many of the specific responsibilities of SPOC with regard to each of the major Xolair constituents.

What does this mean for you?

One of the primary roles you will be asked to play in this process is that of communicator. As you can see, this is a relatively involved process with lots of players and contact points. The chart below (Table 1-2) depicts when and when not to call one of

these players. This will help you better manage your own process of communication with these services and your customers. Note that in communications with your customers, you should use the term "Third-Party Vendor" and omit the reference to SPOC.

* * *

THE BOTTOM LINE

- About 75% of all Xolair patients will receive distribution of the product and reimbursement support through the Primary Distribution Network.
- About 25% of patients, eg, those insured by Federal or state programs, those treated at staff model HMOs, or those contracting with mail-order pharmacies, will receive Xolair through the Secondary Distribution Network.
- The Preferred Specialty Pharmacies are five experienced distributors who are under contract with Xolair SPOC to provide comprehensive distribution and reimbursement support to Xolair customers and their patients.
- SPOC is an internal Genentech resource, supported financially by Novartis and Genentech and dedicated to facilitating the distribution and reimbursement process. SPOC will supervise and monitor the Preferred Specialty Pharmacies and the Third-Party Vendor.
- SPOC's Third-Party Vendor provides reimbursement support to patients who, for various reasons, cannot be serviced by the Preferred Specialty Pharmacies.
- The Access to Care (ATC) Foundation is an internal Genentech resource that helps qualified uninsured patients explore other reimbursement options and provides free drugs as appropriate.

* * *

Steps in the Xolair Distribution and Reimbursement Process

Step 1: The Physician Prescribes Xolair
Step 2: The Physician Selects One Preferred Specialty Pharmacy From the List of Five Distributors and Faxes it the Necessary Paperwork

- The *Statement of Medical Necessity*, which the physician completes. It provides payers with details about the patient's medical condition as well as prescribing information for Xolair. Some payers allow it to replace an actual prescription, while others require that the physician also write a separate prescription. See Appendix A for a copy of this form.

- The *Patient Authorization Form*, which gives Genentech and Novartis permission to review the patient's medical information form and forward it to providers or

payers in order to perform reimbursement services when necessary. This permission is required by a Federal Statute known as the **Health Insurance Portability and Accountability Act**, or **HIPAA.** See Appendix B for a copy of this form.

DID YOU KNOW?

Payers may also require additional paperwork from the physician's office. For example:

- Health and physical
- IgE test results
- Chart notes from a given office visit
- Payer's own prior authorization request form
- Hospital information

What does this mean for you?

- Prior to launch, make sure that you have given each of your target physicians the list of the five Specialty Pharmacies, which also contains the telephone and fax numbers of each organization.
- Make sure your customers have an ample supply of the *Statement of Medical Necessity* and the *Patient Authorization Form* after launch.
- Advise physicians that if they are considering Xolair for a specific patient, they should obtain the patient's signature on the *Patient Authorization Form* during the office visit. That's because any delays in faxing a signed form to the Specialty Pharmacy (such as the time it takes to get the patient back into the office to sign the form) will delay the entire distribution and reimbursement process. Remember, if the patient has not completed and signed the authorization form, you are not permitted to discuss the case with the physician nor can the patient be referred to the ATC or TPV.

* * *

DID YOU KNOW?

We expect by the end of 2003, about 75% of MCOs will cover the cost of Xolair. The majority will restrict its use in some way. Here are some of the restrictions you may run into:

- Prior authorization is mandatory
- The prescriber must be a specialist
- Treatment must be administered at the doctor's office
- Treatment must not exceed specific doses

* * *

- If the second-level appeal is denied, there is really no further recourse with the payer. We anticipate that some MCOs will ultimately refuse to cover Xolair in some way.

* * *

Table 2-1: Comprehensive Support Services Provided by Each Preferred Specialty Pharmacy

Service	Description
Ship the Xolair Patient Support Kit	The Xolair Patient Support Kit is designed to provide new patients with important educational information on Xolair.
Ship Ancillary Supplies	• Shipped to the patient's home or the physician's office • 10cc diluent (preservative-free sterile water for injection) • 3cc syringes • 18-gauge large-bore needles for reconstitution • 25-gauge needle for administration • Alcohol swabs • Sharps container (as needed)
Provide in-home training injection training if appropriate	The physician determines whether the patient requires injection training and whether that training will be provided by the physician's staff. The Preferred Specialty Pharmacy will provide and pay for the cost of one session of in-home training if requested by the physician.

* * *

THE BOTTOM LINE

* * *

- A patient with no health insurance is triaged[17] to the Access to Care Foundation.

Overview

[17] Defendants define "triage" to mean the "process used to determine where a particular patient best fits in the overall Xolair distribution and reimbursement process."

The five Preferred Specialty Pharmacies are committed to rapid fulfillment of each Xolair prescription. In fact, their compensation depends on their success in moving through the distribution and reimbursement process according to specified timetables.

* * *

What does this mean for you?

Remember, none of the processes you have learned about begin until the Preferred Specialty Pharmacy receives the completed State of Medical Necessity and a signed Patient Authorization Form. Suggest to your customers that even if they have not yet firmly decided to prescribe Xolair for a particular patient, they can expedite reimbursement and delivery by having the patient sign the *Patient Authorization Form* before leaving the office. This will avoid the extra time and inconvenience of requiring the patient to come back to the office just to sign a form.

* * *

Overview

As you know by now, the distribution and reimbursement processes for Xolair have been developed to be a successful *and* simple for every customer. Of course, you play a major part in these processes, one that continues well beyond convincing customers of the clinical features and benefits of the product. Your role is twofold:

- Educate your customers when you introduce Xolair
- Support your customers when they prescribe Xolair

* * *

Figure 4-1: ***The Xolair Sales Representative's Primary Roles***

Obviously, you'll need to be completely familiar with the Xolair distribution and reimbursement processes before you call on any potential customers. In fact, it is so important that you master the various programs, pathways, and paperwork discussed previously that we have repeated the flowchart form (in Fig. 4-2) on the following page. Make sure you know it inside and out!

* * *

Educating Your Customers

One of the most critical steps in introducing Xolair to your customers [HCPs] will be to reassure them that they will not be overwhelmed by excessive telephone calls or massive amounts of paperwork.

In order to do that, you can educate them about the distribution and reimbursement services that are already in place to support their staff and their patients. Two effective tactics for doing this are to:

- Conduct inservice training programs in the physician's office
- Anticipate challenges and prepare effective responses

* * *

Inservice Training Programs

Hosting small and informal sessions in the physician's office well in advance of any Xolair prescribing gives you an ideal opportunity to:

- Clearly explain the distribution and reimbursement processes for Xolair
- Illustrate the robust support services provided by the Preferred Specialty Pharmacies, Genentech and Novartis
- Describe the ongoing communication between these services and the physician's office
- Discuss your ongoing involvement and commitment to providing support throughout the process

What does this mean for you?

You will receive a Practice Management tool kit to help you plan and execute inservice training programs with your customers. Using this resource and others that will be available to you, make sure that any inservice training programs you conduct cover the points listed in Table 4-1. Preparing for and practicing the delivery of an inservice training program are ways you can make sure this important step will provide the value your customer is expecting from you.

Anticipate and Respond to Customer Challenges

Anticipating and responding to customer challenges will be critical to your ongoing support of your Xolair customers. Keep in mind that it will take some time before we know more about specific challenges—and effective solutions—that you will face. SPOC and sales management will be in constant communication to ensure that you get the most up-to-date information about evolving distribution and reimbursement issues as quickly as possible.

Table 4.1. Points to Cover in a Xolair Inservice Training Program

Possible MD Questions	**Answers**
Reimbursement	
How do we initiate the reimbursement process?	By selecting one of the five Preferred Specialty Pharmacies to represent the patient and faxing

	the appropriate forms to that Specialty Pharmacy
What forms are necessary?	• The Statement of Medical Necessity • The Patient Authorization Form
How will the physician know what is happening with a specific patient?	As soon as the Preferred Specialty Pharmacy receives your completed paperwork, you will receive a fax notifying you that the patient's case file has been opened. If the patient is triaged to any other program, you will receive a notification by fax.
How long does reimbursement take?	Depending on the patient, the payer, and the plan, an initial reimbursement decision without appeal should be reached in 2 to 30 days.
What restrictions and prior authorization requirements can we expect?	We expect that about 90% of payers will require prior authorization for Xolair. We also anticipate that over 80% of payers will restrict its use in some way, ie, according to diagnosis, specialist prescriber, maximal dosage, or administration in the physician's office only.
How do we handle unusual situations?	The Genentech or Novartis representative will be happy to work with you to resolve any unusual situations.
Who do we call for help?	You can contact the Preferred Specialty Pharmacy. Of course, I am also happy to help you get access to any information you need.

Table 4.1. Points to Cover in a Xolair Inservice Training Program (continued)

Possible MD Questions	**Answers**
Distribution	
Where is the product shipped?	Depending on your preference and any payer requirements, Xolair can be shipped to the healthcare provider or directly to the patient's home.
What ancillary supplies will the patient receive?	The patient will receive diluent, syringes, needles for reconstitution and administration, alcoholic swabs, and a Sharps container.

* * *

Patient education	
What materials does the patient receive?	Every patient will receive a Xolair Patient

	Support Kit.
Should I determine it's appropriate, who provides injection training?	Patients who require injection training can receive it at the physician's office or in one session at home, from a LVN or RN; the training provided at no extra cost to the patient by the Preferred Specialty Pharmacy.

* * *

Supporting Your Customers

Once a physician prescribes Xolair, you will be providing ongoing support to the physician, the office staff, and, where appropriate, the patient. Your goals are to ensure that:

- Your customers and their staff do not feel overwhelmed
- No Xolair prescription "slips through the cracks" anywhere along the distribution and reimbursement pathways
- You appear supportive but never intrusive

Keep in mind that because there are so many different types of practices, patients, and payers, there is no single right way to provide support. For example:

- A large practice may feel very comfortable in maintaining its own dialogue with the Preferred Specialty Pharmacy, while a small practice with one office manager may appreciate your help in getting that initial paperwork over to the Preferred Specialty Pharmacy.
- One payer may have already established specific guidelines for Xolair reimbursement, while another payer may require additional documentation as it defines restrictions for the first time. In the latter case, the physician's office may welcome your help in obtaining these documents or moving them through the correct pathway, provided a Patient Authorization Form (PAF) was completed by the patient.

You'll need to determine in each individual circumstance how to best get the job done.

What does this mean for you?

There will be many reports available to help you achieve your goal of customer support. For example, you will be able to review the following analyses:

- **Weekly Launch Tracker**, which provides a geographic look at key metrics, such as the number of *Statements of Medical Necessity (SMNs)* submitted, the number

of patients currently on Xolair, the status of reimbursement requests (approved, pending, denied), a the number of prescriptions

- **Weekly Trend by Physician**, which looks at these same metrics by physician
- **"Rapid Action,"** which pinpoints new referrals, new approvals and new shipments of Xolair by physician
- **Monthly Managed Care Trend Report**, which provides plan influence by physician and by managed care plan

THE BOTTOM LINE

- You will need to educate your customers about the Xolair distribution and reimbursement process and provide ongoing support after the prescription is written.
- When you first introduce Xolair, host inservice training programs that explain the distribution and reimbursement process and demonstrate the comprehensive support services available to physicians, their staff, and their patients.
- Familiarize yourself with challenges that you may expect from your customers and develop an effective response to each.
- There is no single right way to provide support for Xolair customers. You will need to choose from an array of activities that work for the particular customers, patient, and payer. It is a dynamic process with different scenarios.

Module 6 (emphasis added as underlining; emphasis in original as boldface and italics).

638. As set forth above, Module 6 makes clear that Defendants' contracted 5 Preferred Specialty Pharmacies would, at no cost to patients, provide nurses who would travel to patients' homes or to HCPs' offices, to train the patients on how to self-inject Xolair.

639. Each Xolair SMN that physicians were required to sign stated, at the bottom of the page: "I certify that the rationale for Xolair therapy for Allergic Asthma is necessary for this patient, and I will be supervising the patient's treatment accordingly." However, when patients self-administered Xolair at home, they were not under physicians' supervision—they were not even in a medical setting.

640. In the Learning Module entitled "Introduction to Managed Care and Distribution," Defendants state that "[**i]t is important to remember that you cannot discuss**

reimbursement or coding in an effort to gain better reimbursement advantage from payers"; yet state that their sales representatives are to proactively assist HCPs with obtaining Xolair reimbursement (despite other admissions by Defendants that this practice is illegal); explain to Xolair sales representatives that they face a major obstacle to sales because national medical guidelines and MCOs regard the alternative of inhaled corticosteroids ("ICSs") as the "cornerstone" of asthma therapy; acknowledge that MCOs, Medicare, and Medicaid usually covers injectable drugs when they are administered in the physician's office or hospital (i.e., not in patients' homes); explain that MCOs and pharmacy benefit managers ("PBMs") may regard Xolair to be prohibitively expensive for some patients; explain that it can be "crucial" to Xolair sales to "recruit[] the physician as an advocate or 'product champion'"; acknowledge that "Medicare covers drugs that are…as a part of the physician's professional services in the office or hospital"; state that the CPT code for a subcutaneous injection is 90782; and state that "it is fraudulent to use a more complex [CPT or E/M] code than appropriate."

641. To be more specific, Defendants state in part in this Learning Module:

PROGRAM OVERVIEW

The Xolair™ marketing team has identified a number of strategies that will help ensure rapid adoption of Xolair. Because of the complex nature of today's prescription drug reimbursement environment, these strategies go well beyond the promotion of Xolair clinical features and benefits to healthcare professionals.

Several of these strategies address managed care and how it influences reimbursement coverage, distribution, and physician practices. Many of these issues are unique to Xolair, and they create an added sales challenge to every Xolair call. (Of course, with every added sales challenge comes a new selling opportunity, which is really what this training program is all about!)

These strategic issues require comprehensive training for the sales organization so that each individual Xolair Sales Representative can:

- Apply managed care and distribution concepts and terms appropriately in discussions with customers

- Effectively explain the distribution and reimbursement services supporting Xolair
- Provide answers and follow-up questions to customers regarding Xolair; distribution and reimbursement questions
- Connect customers with appropriate Xolair support resources

The *Introduction to Managed Care and Distribution Program* and its companion program, *Xolair Distribution and Reimbursement Processes and Services*, are designed to provide you with basic guidelines on how to support Xolair sales by effectively addressing Xolair reimbursement and distribution issues with physicians and the office staff.

Introduction

* * *

About 80% of patients likely to benefit from Xolair will be enrolled in private health plans. Most Americans who have private health care benefits are enrolled in some form of managed care plan. Some Xolair patients will be Medicaid beneficiaries. More than half of Medicaid beneficiaries nationwide are enrolled in a managed care plan. The bottom line is that managed care, in some form or other, will have a great influence on how Xolair is covered and reimbursed. To understand how managed care will influence Xolair, let's begin by looking at the key players in the managed care arena.

* * *

How to Use This Program

* * *

- **"What Does This Mean For You?"** summaries, which highlight any implications the chapter material will have for your day-to-day responsibilities.

* * *

Chapter 1: Payers, Plans, Patients and Providers

* * *

Government. The number of people who receive medical insurance through the US government's two entitlement programs—Medicare and Medicaid—is enormous. More than 75 million Americans currently receive healthcare benefits through these two programs (roughly half that number in each program.) A federal agency, the Centers for Medicare and Medicaid Services (CMS, formerly the Healthcare Financing Administration, or HCFA), finances and operates the Medicare and Medicaid programs.

* * *

Even if a drug is expensive, physicians are much more likely to prescribe it if they know in advance that the drug will be paid for, or if they know that reimbursement support is available. This is why it will be important to familiarize the physicians you call on with the Xolair distribution and reimbursement support services. Reimbursement support services are designed to have teams that assist physicians in securing prior authorization and appealing denied claims. Also, be sure to educate your customers on the Xolair patient support programs described in the *Xolair Distribution and Reimbursement Processes and Services Program.*

* * *

Managed care and asthma patients

As you've learned, most patients who are candidates for treatment with Xolair will be enrolled in some form of managed care plan. Now we'll focus on understanding both the opportunities and the obstacles that managed care may present for the asthma patient.

* * *

Disease Management and Treatment Guidelines

MCOs have responded to asthma's high treatment costs by implementing disease management and treatment guidelines. Asthma **disease state management (DSM)** focuses on changing and monitoring both *patient* behavior—educating patients on how to do their part in preventing asthma exacerbations—and *physician* behavior—getting physicians to comply with tested treatment guidelines to ensure optimal asthma treatment and care. MCOs understand that a well-designed asthma DSM program holds the promise of improving patient care while reducing costs.

* * *

Many MCOs, for example, support physician-focused management with use of inhaled corticosteroids as the cornerstone of therapy. This approach is advocated in the National Asthma Education and Prevention Program (NAEPP) guidelines and the National Heart, Lung, and Blood Institute (NHLBI, a division of NIH, the National Institutes of Health) guidelines. NAEPP expert panels have developed guidelines for the diagnosis and management of asthma. Other organizations, such as the World Health Organization (WHO), have developed practice parameters for the diagnosis and treatment of asthma, including the:

- Joint Task Force on Practice Parameters of the American Academy of Allergy, Asthma and Immunology
- American College of Allergy, Asthma and Immunology (ACAAI)
- Joint Council of Allergy, Asthma and Immunology

These guidelines all recognize that asthma should be a controllable disease in the majority of patients—which is one of the reasons MCOs are keen to have participating

physicians follow the guidelines. Asthma guidelines are intended to help clinicians bring a patient's asthma under control and are constantly being reviewed and revised.

What does this mean for you?

Currently, Xolair therapy is not a part of the treatment guidelines referred to above. However, Genentech and Novartis are hard at work building an evidence-based case for updating the guidelines to include Xolair treatment. As a Xolair Sales Representative, it's important to know that a key component of DSM for asthma is monitored filling of prescriptions for asthma drugs.

* * *

Asthma Specialists and Primary Care Physicians (PCPs)

Despite the success of treatment guidelines and the willingness of MCOs to improve the quality of care for asthma sufferers, tensions remain. The wants and needs of patients and providers are often in conflict with the willingness of payers to pay. One of the key reasons for conflict is the debate regarding whether patients with moderate-to-severe asthma need to be treated by asthma specialists. According to the American College of Allergy, Asthma and Immunology (ACAAI), outpatient chronic care for asthma is provided primarily by general practice physicians (65%), allergy and immunology specialists (26%) and pulmonary medical specialists (5%). While "expert care" (ie, allergy and pulmonology specialists) is focused on patients with more severe asthma, medical care for moderate and severe asthma is often provided by primary care or general practice physicians.

* * *

The Role of Nurses

Nurses may play a key role in MCO disease management programs. For example, it is common for nurses to act as **case managers** for patients who are participating in asthma DSM programs. Nurse case managers may work with moderate or high-risk patients to ascertain their symptoms, medications, days missed from work or school, and so forth.

* * *

Profiling Your Customers

Importance of profiling. Your best strategy for meeting the needs of managed care physicians is to be prepared for every Xolair sales call by developing and maintaining accurate customer profiles. Each physician profile should include:

- MCO affiliations
- principal physician reimbursement method and financial incentives (ie, capitated [PMPM], discounted fee for service)

- practice's "payer mix" (eg, private payer MCOs, Medicare, Medicaid)
- formulary policies and your product's formulary position
- MCO contract terms for Xolair
- relevant clinical practice guidelines

* * *

In one way or another, virtually all MCOs provide benefits that cover an enrolled member's prescription drug expenses. **Coverage** is the process by which pharmaceuticals are determined to be eligible for payment. Terms of drug coverage are outlined in insurance contracts and usually include medications that are:

- FDA-approved
- deemed not experimental or investigational
- for the treatment of illness or injury
- medically necessary
- appropriate to the patient or treatment setting

* * *

The medical vs. pharmacy benefit

First, it's important to understand that MCOs and Medicare and Medicaid generally offer two types of benefits—major medical and pharmacy—which are also referred to as the "medical benefit" and the "pharmacy benefit." Each benefit has certain criteria that determine whether a pharmaceutical product is eligible for payment and which benefit should be used. When Xolair is covered, one of these two benefits will apply. The explanation that follows will help you understand under what circumstances each of these benefits could apply.

The Medical Benefit

The medical benefit:

- covers all approved medical expenses
- usually covers injectable drugs when they are administered in the physician's office or hospital (a possible exception is when the drug is patient-ordered and delivered to the physician's office for administration)
- sometimes includes a maximum limit that the MCO will pay (ie, X dollars per year or during the patient's lifetime)
- requires no co-pay for injectable drugs (co-pay may apply for office visit when physician administers the drug)

* * *

The Pharmacy Benefit

The pharmacy benefit:

- covers prescription drugs up to a predetermined annual or lifetime maximum
- requires that patients submit a prescription for the prescribed product to a retail or mail order pharmacy and pay their copayment or coinsurance when the product is dispensed
- provides coverage when an injectable is self-administered or when the drug is patient-ordered and delivered to the physician's office for administration

* * *

What does this mean for you?

Historically, these two benefits (medical and pharmacy) offered coverage for pharmaceuticals with little overlap. But lately the use of one benefit versus the other in covering a specific pharmaceutical, especially certain injectables, has become less clearly defined. At this time, it is anticipated that Xolair will be covered by the medical benefit. But it is also true that sometime in the future and in certain situations, Xolair will be covered by the pharmacy benefit. As a Xolair Sales Representative, you will need to be aware of which benefit plan is involved so you better understand the issues involved in obtaining authorization.

* * *

What does this mean for you [the Xolair sales representative or sales manager]?

Educating the physician about the clinical advantages of Xolair and recruiting the physician as an advocate or "product champion" can be a useful strategy. This can be crucial because a physician's recommendation is usually the most influential factor when deciding on a specific drug from a particular therapeutic class (eg, all drugs available for the treatment of asthma). Physicians should also be reminded that Xolair is unique among asthma treatments in its specific mechanism of action. This makes Xolair a "first-in-its-class" drug.

* * *

Chapter 3: Injectable Drug Coverage

* * *

Pharmacy and Therapeutics (P&T) Committee

As you've learned, coverage is the process by which pharmaceuticals are determined to be eligible for payment. Coverage decisions are generally made by the health plan's **Pharmacy and Therapeutics (P&T) Committee** and **TEC Assessment.**

P&T Committee responsibilities

The P&T Committee develops, maintains, communicates, and updates a health plan's (or PBM's) **formulary** (described below). Committee responsibilities typically include:

- evaluation and selection of pharmaceutical products for formulary inclusion or exclusion based on clinical and economic data
- communication of information about drug products and their utilization to physicians, pharmacists, and nurses within the organization
- monitoring of quality issues such as appropriate drug use (this process includes drug utilization review [DUR] and drug use evaluation [DUE] programs)
- monitoring of adverse drug reactions
- development and monitoring of protocols for the use of formulary and non-formulary products
- development of generic and therapeutic substitution policies in compliance with state laws
- communication of Committee decisions to healthcare professionals contracted by the plan

* * *

Managed Care Formularies

MCOs and PBMs usually use a formulary to manage utilization and cost control. The formulary is a list of drugs that contracting physicians may prescribe. Formularies often include guidelines for prescribing, protocols for dispensing the product, and drug utilization recommendations.

* * *

What does this mean for you?

Under a tiered arrangement, drugs like Xolair (which will probably be Tier 3 or higher) may be prohibitively expensive for some patients. While some MCOs have maximum out-of-pocket limits to protect patients, others have spending caps in place, which limit how much the MCO will pay towards a patients' prescription drug needs in a given year or during their lifetime.

* * *

Prior authorization

When a drug is not on the formulary, it will not be reimbursed without prior authorization. At many MCOs, medications requiring **prior authorization** (**PA**) before

the drug is reimbursed include newly introduced medications and biologics. Prior authorization is essentially a formulary compliance tool, designed to verify the medical necessity of the prescribed agent and to ensure that it is being prescribed according to established health plan protocols, such as clinical practice guidelines.

* * *

In granting prior authorization, the patient's physician needs to make a case for medical necessity. Health plan protocols vary, but in the case of most newly introduced drugs, the physician will be required to submit a letter of medical necessity to the MCO or PBM. (You will learn about *Statement of Medical Necessity* in the next program.) The physician's justification for the use of the product is generally reviewed by a clinical practitioner (a nurse or pharmacist) and then approved or denied based on preset criteria established by the MCO or PBM.

* * *

What does this mean for you?

As you will see later in *Xolair Distribution and Reimbursement Processes and Services,* the PA process for Xolair will be initiated by one of the Preferred Specialist Pharmacy organizations that we have contracted with to support Xolair once the physician writes the prescription. Then Genentech and Novartis will have the procedures in place to support the office's request for Xolair.

* * *

Medicare Coverage of Injectables

Coverage of physician-administered drugs

Medicare covers drugs that are administered "incident to" a physician's service, meaning that the drug is administered as a part of the physician's professional services in the office or hospital. There must be a compelling overall medical reason that the drug requires physician administration for it to be eligible for Medicare coverage. Medicare looks at how a product is administered overall, not on an individual basis, and is unlikely to cover a generally self-administered product solely because it is administered in the office.

Did You Know?

The Medicare program provides limited benefits for outpatient prescription drugs. Medicare covers drugs that are furnished "incident to" a physician's services provided that the drugs are "not usually" self-administered by patients. The Benefits Improvement and Protection Act (BIPA) of 2000 relaxed the language in this provision from "which cannot be self-administered" to those which are "not usually self administered."

What does this mean for you?

Because Xolair is a subcutaneous injection, Medicare will most likely not reimburse for it. While it is important to know this, you must also remember that the vast majority of patients that will benefit from Xolair are not Medicare eligible.

* * *

THE BOTTOM LINE

- Medicare covers physician-administered drugs but does not cover self-injectable medications, nor does it cover routine retail prescriptions.

Medicaid Coverage of Injectables

MCOs know that asthma is a controllable disease and that proper patient education can significantly reduce unnecessary physician office visits. Therefore, MCOs serving Medicaid populations have made asthma care a top priority. Ninety percent of Medicaid managed care plans provide an asthma disease management program in their benefits, according to a survey conducted by the **American Association of Health Plans (AAHP)** during 2001. The AAHP is the main trade association for managed care organizations. Medicaid MCOs have invested significant time and money to educate patients, improve their home environments, decrease exposure and eliminate allergens.

Medicaid MCOs have also worked extensively with physicians to promote ongoing monitoring and effective treatment of asthma patients. For example, Anthem Blue Cross Blue Shield of Connecticut discovered an increase in asthma-related emergency room visits and inpatient hospitalizations during the winter of 1999. In response, they implemented a disease management program focused on the subset of asthma patients most at risk for hospitalization. In a one-year period, total inpatient days for Medicaid beneficiaries participating in the program decreased by 80%.

Medicaid and Xolair

Each state government designs, administers, and runs its own program, and each state determines individually if it will cover new products. Federal Medicaid does not allow formularies. Instead, it has a preferred drug list (PDL). Xolair is first-in-class and will not be approved without prior authorization.

* * *

Chapter 4: Injectable Drug Coding and Reimbursement

* * *

This chapter takes a look at some of the important details that accompany health plan's drug benefit design by addressing:

- **Coding—**the alphanumeric and numeric systems that payers require for the identification of healthcare services and products, including pharmaceuticals, on insurance claim forms.
- **Payment—**the systems payers use to ensure that pharmacy facilities receive accurate and appropriate payment.

What does this mean for you?

It is important to remember that you cannot discuss reimbursement or coding in an effort to gain better reimbursement advantage from payers.

* * *

Coding Systems Relevant to Injectable Drugs

The following coding systems are used to bill for injectable drugs, like Xolair, and the services related to the patient's disease:

- Current Procedural Terminology (CPT) Codes
- Healthcare Current Procedural Coding System (HCPCS) Codes
- International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes
- National Drug Codes (NDCs)

We discuss each of these coding systems below.

CPT Codes. The American Medical Association (AMA) develops and maintains CPT codes. CPT codes are five-digit codes with descriptive terms for reporting services performed by healthcare providers. The primary purpose of COPT codes is for physicians to bill for their professional services for procedures performed, regardless of the care setting.

HCPCS Codes. HCPCS (pronounced *Hic-picks*) codes generally are used to bill for drugs and supplies. HCPCS codes are alphanumeric, with a single letter followed by four digits. HCPCS codes representing injectable drugs begin with the letter "J."
HCPCS codes for new products are assigned once a year (deadline for coding application is April 1 with new codes becoming effective the following January 1). With very few exceptions, new therapies do not have unique HCPCS codes at launch. It often takes a year or longer for manufacturers to obtain a unique HCPCS code for new drugs. This is due, in large part, to the requirement that a new product be on the market for at least six months before a HCPCS application can be made.

* * *

ICD-9-CM Codes. ICD-9-CM diagnosis codes are used to document patient diagnoses in all care settings. ICD-9-CM diagnosis codes are required for virtually all physician and hospital claims, to communicate the condition of the patient and to justify the medical necessity for the reimbursement of medical and surgical procedures. ICD-9-CM diagnosis codes are organized by disease type and include three to five digits. The first three digits specify a disease and are followed by a decimal point. The next two digits provide additional detail about the patient's specific condition.

* * *

Table 4-1: Reimbursement Coding in the Physician's Office

Service or Product Billed	**Coding System**	**Actual Code**	**Code Title or Description**
Physician procedures	CPT	90782	Therapeutic, prophylactic or diagnostic injection (specify material injected), subcutaneous or intramuscular
Drugs and supplies	HCPCS	J3490	Unlisted drug (administered other than by oral method; required only when the physician bills for the drug, purchases the drug, or is required to the prior authorization)
Patient Diagnosis	ICD-9-CM	493.0	Asthma

* * *

Payment in the Physician's Office

In most plans that do not capitate their physicians, payers use a fee schedule in which each CPT code corresponds to a predetermined payment amount that the payer will reimburse the physician. When a patient receives an injection or infusion at the physician's office, the physician can bill for the drug *and* for the service during which the drug is administered. The CPT code for a subcutaneous injection is 90782, *therapeutic, prophylactic, or diagnostic injection (specify material injected), subcutaneous or intramuscular*. Physicians can bill for an office visit in accordance with evaluation and management (E/M) guidelines (See **Did You Know?** box) but may not bill if the reason for the office visit is solely to administer the injection. Most payers will not pay an additional amount for an injection if the physician bills for an office visit on the same day.

Did You Know?

Evaluation and management codes

CPT codes used to describe general office visits for new or existing patients are known as **evaluation and management (E/M) codes.** The level of E/M code billed depends on the complexity of the visit and the resources used. Different payers have different guidelines for what each level comprises, and it is fraudulent to use a more complex code than appropriate. The decision of when to bill an E/M code, and at what level, is made at the provider's discretion.

* * *

THE BOTTOM LINE

- The ultimate decision for coding on the claim submitted for payment is left to the physician, who must code in accordance with the definitions in the CPT manual. Typically, a physician will make a notation on the patient chart as to the services provided to a patient during the appointment, and the billing or coding department will then submit the claim form with the appropriate code to the payer.
- A claim may be denied, and in some situations, the physician may be held accountable for fraud if claims fail to include the appropriate codes or to observe correct coding practices.

* * *

What does this mean for you?

In interactions with Xolair customers, you will need to demonstrate that you are familiar with the specific codes with the administration of Xolair. Here are the key points to remember:

If physicians *purchase* Xolair and administer the product in the office, they will need to use the following codes:

- CPT codes to bill for the injection procedure or other service provided
- HCPCS "J" code to bill for the drug
- ICD-9-CM diagnosis codes to identify the patient's condition

If the drug is supplied and billed for through one of the Xolair Preferred Specialty Pharmacies or the patient brings the product into the office for administration and physicians are *not* purchasing the drug, they will need to use the following codes:

- CPT codes to bill for the injection procedure or other service provided

- ICD-9-CM diagnosis codes to identify the patient's condition

In this case, they do not need to bill for the product using a J code; however, the payer may require that the product administered be identified on the claim to justify the billing of the injection CPT code.

If a pharmacy is billing for Xolair, it will use the product's NDC code on an electronic claim. Remember, if you were selling a traditional oral medication (eg, antibiotic) coverage, coding, and payment issues would be so routine that the Xolair Sales Representative might not ever become involved with them. However, with an injectable procedure like Xolair, these issues can become complex. Policies and procedures are likely to be unique with each plan that operates in your territory. Regardless of Xolair's clinical advantages, which are significant, it often will be necessary for you to be knowledgeable about Xolair coverage, coding and payment issues that are relevant to the customer's practice in order to ensure widespread acceptance of the product at launch.

* * *

Did You Know?

Xolair and Distribution

- As you will learn in the next program, Xolair will be distributed through a preferred specialty pharmacy network that Genentech/Novartis has selected specifically to support this important new product.
- This network features companies that are among the leaders in the specialty drug pharmacies industry. As you will see, these specialty pharmacies offer a variety of patient and provider support services that will prove very important in supporting promotional efforts for Xolair. As part of this network, Genentech and Novartis selected five well-qualified specialty pharmacies who operate across the country. It will be essential for you to become familiar with each specialty pharmacy's sales representative in your area, as well as their reimbursement team, who will be involved in managing patient case reimbursement submissions in their home and/or regional offices.

* * *

Summary

Managed care will have a great influence on the reimbursement of Xolair. This program should have helped you to understand how coverage issues and controls may influence how Xolair is reimbursed. In the next program, you will earn about the specific processes and extensive support services provided by Genentech and Novartis to ensure Xolair's successful distribution and reimbursement.

* * *

Appendix A: Medicare and Medicaid Coverage

*** * ***

Medicare and APCs (for hospital *outpatient* services)

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Because Medicare does not cover self-administered drugs, it is not likely to cover Xolair in the hospital outpatient setting.

Learning Module, "Introduction to Managed Care and Distribution" (emphases added as underlining; other emphases in original).

_. DEFENDANTS HAVE CAUSED THE MASS SUBMISSION OF FALSE CLAIMS AND THE CREATION OF FALSE RECORDS.

642. Defendants have embarked upon this course of unlawful conduct knowing it would lead directly to the submission of myriad false claims for Xolair, and related physician services, to government healthcare programs, when by law these claims are not reimbursable and would not have been legally reimbursed by such programs had the truth about Defendants' illegal marketing practices been known.

643. Hence, the participation of doctors, hospitals, pharmacies, and pharmacists in the submission of the false claims was not only foreseeable; it was an intended consequence of Defendants' schemes.

644. When pharmaceutical companies misbrand drugs, encourage off-label uses for their drugs, and provide kickbacks for purchasing their drugs, the number of prescriptions rises, thereby causing government healthcare programs to pay out more for prescriptions that are not eligible for payment. Defendants have intended for their off-labeling marketing scheme, kickbacks scheme, and other schemes, to improperly increase the submissions of Xolair

prescriptions, and submission of claims for reimbursement for admisntering Xolair, including those reimbursed by the government healthcare programs.

A. SPECIALTY PHARMACIES

645. Defendants have sold Xolair in two ways: via "buy and bill" and without "buy and bill."

646. Under the "buy and bill" method, the HCP purchases the drug from a specialty pharmacy ("SP"), and submits the claim for reimbursement of the drug to private health insurance and/or a government healthcare program (e.g., Medicare or Medicaid). Under this method, the HCP is normally a physician—most commonly, an allergist/immunologist, pulmonologist, or internist (internal medicine). He or she also submits a claim for reimbursement of professional services—for administration of the drug and possibly other related services—to private health insurance and/or government healthcare programs.

647. A SP is a supplier of specialty drugs. Xolair is a specialty drug. As Genentech's own website currently explains, at www.genentech-access.com, a "specialty pharmacy sends Xolair (omalizumab) for subcutaneous use to your doctor's office. All Xolair is supplied through a specialty pharmacy. You can't have your prescription filled at your local drugstore."

648. When a physician chooses not to "buy and bill" for Xolair, a SP buys the drug. In or about 2003, Defendants contracted with five (5) SPs for the specific purpose of processing claims for Xolair, buying Xolair, and submitting claims to government healthcare programs: namely Priority Healthcare Corporation, Option Care, Inc., Nova Factor, Inc., CuraScript Pharmacy, Inc., and Caremark Rx, Inc.

649. In all non-"buy and bill" scenarios, Defendants have caused these 5 specialty pharmacies, through the above-detailed actions, to submit—at the very least—tens of millions of

dollars of false claims for reimbursement to the Medicare and Medicaid Programs from June 2003 forward.

650. At some point in the last six (6) years, Defendants began using a sixth SP for Xolair.

651. These 6 specialty pharmacies have the following principal addresses, etc.:

• **Priority Healthcare Corporation**, 250 Technology Park, Lake Mary, Florida 32746; tel. 866-757-3929; fax 866: 269-3113, www.priorityheathcare.com.

• **Option Care, Inc.**, 485 East Half Day Road, Suite 300, Buffalo Grove, Illinois 60089; tel. 888-282-5166, fax: 888-570-4700, www.optioncare.com; in July 2007, Walgreen Company acquired Option Care, and the website has since changed to WalgreensHealth.com. Genentech's own website, genentech–access.com, lists the following, updated information for "Option Care":

• **Walgreens Specialty Pharmacy**

1143 Highlands Drive

Ann Arbor, MI 48108-2237

Physician and patient inquiries: (888) 347-3416

Physican fax line for direct referrals: (877) 231-8302

Website: www.walgreenshealth.com

• **Nova Factor, Inc.**: In existence since 1990, Nova Factor, Inc. was acquired by Accredo Health, Inc. in 1997, which is a wholly owned subsidiary of Medco Health Solutions; Nova Factor/Accredo Health Group, Inc. is located at 1640 Century Center Parkway, Memphis, Tennessee 38134; tel. 866-839-2162, fax 866-531-1025; www.accredohealth.net/nova. Genentech's own website, genentech–access.com, lists the following, updated but substantially similar information for "Nova Factor":

Accredo Nova Factor, Inc.

1640 Century Center Parkway

Memphis, TN 38134

Phone: (866) 839-2162

Fax: (866) 531-1025

Hours: 7:30 a.m.-7:00 p.m. CT, Monday through Friday

Website: www.novafactor.com

• **CuraScript Pharmacy, Inc.**, 6272 Lee Vista Blvd., Orlando, Florida 32822; tel. 888-281-5464, fax 888-773-7386, www.curascript.com. Genentech's own website, genentech–access.com, lists the following, updated but substantially similar information for CuraScript:

CuraScript SD

6272 Lee Vista Blvd.

Orlando, FL 32822

Phone: 888-281-5464

Fax: 888-773-7386

Hours: 8:00 a.m.-9:00 p.m. ET, Monday through Friday, 9:00 a.m.-1:00 p.m. ET, Saturday

Website: www.curascript.com.

• **Caremark Rx, Inc.** (now "CVS Caremark"), Woonsocket, Rhode Island, tel. 800-237-2767, fax 800-323-2445, www.caremark.com. Genentech's own website, genentech–access.com, lists the following, updated but similar information for Caremark:

CVS Caremark Specialty Pharmacy Services

2211 Sanders Road

Northbrook, IL 60062

Phone: (800) 237-2767

Fax: (800) 323-2445

Hours: 6:30 a.m.-8:00 p.m. CT, Monday through Friday

Website: www.caremark.com

652. Because of multiple mergers and acquisitions that these SPs have undergone since 2003, Genentech's website currently lists "the Xolair Specialty Pharmacy Network" as "being made up of these 4 primary suppliers": Accredo Nova Factor, Inc.; CVS Caremark Specialty Pharmacy Services, CuraScript SD, and Walgreens Specialty Pharmacy. *See* www.genentech-access.com.

653. Even when a physician does not choose to "buy and bill" for Xolair, and it is the SP—not the physician or his/her group—that is buying the Xolair, it is still the physician who is prescribing the drug, under the influence of the off-label marketing scheme, kickback schemes, and other schemes set forth herein.

654. When a physician buys and bills, or does not buy and bill, he or she still normally submits a claim for reimbursement of professional services, for administration of the drug and possibly other related services, to private health insurance and/or government healthcare programs.

655. Through their numerous Xolair sales managers listed above, Defendants advised the Relators that approximately one-third of all Xolair sales was through the "buy and bill" process, and that "approximately two-thirds," "between half and two-thirds," and/or "almost two-thirds" of all Xolair sales, was not through the "buy and bill" process, i.e., involved the purchase of the drug by these SPs.

656. However, initially, from 2003 through 2005, much more than two-thirds of Xolair sales involved purchases by these SPs.

657. That is because when Xolair was launched in 2003, Defendants did not simultaneously "launch" and achieve astonishing results with the "buy and bill" program, which did not go into effect until early 2004, and even then did not achieve a lot of momentum. In short, the "buy and bill" push did not begin until early 2004 and was slow to gain momentum because of numerous HCPs' hesitation to purchase an inventory of an expensive biologic like Xolair and handle more administrative work via the claims submission process—especially considering that the profit margin on the spread between the HCPs price for the Xolair and sales price to the patient was not very significant.

658. Thus, in 2003, nearly 100% of Xolair purchases were by the 5 SPs—not by doctors. By the end of 2004, no more than 15% of Xolair prescribers were "buying and billing," and more than 85% of Xolair purchases were by the 5 SPs. By the end of 2005, no more than 25% of Xolair prescribers were "buying and billing," and more than 75% of Xolair purchases were by the 5 SPs. By the end of 2006, no more than 30% of Xolair prescribers were "buying and billing," and more than 70% of Xolair purchases were by the SPs.

659. In short, from 2003 forward, and through the present, these SPs have been the predominant purchasers of Xolair, that submitted claims for reimbursement to government healthcare programs, including Medicare and Medicaid.

660. These figures, particularly the figures of "approximately two-thirds ," "between half and two-third," and/or "almost two-thirds," are supported by a recent Xolair Drug Use Review by the FDA, which observed that "[s]ales data for year 2010 indicated that approximately 62% of Xolair was sold to mail-order/specialty pharmacy settings...." Dept. of

Health & Human Services, Public Health Service, FDA, Center for Drug Evaluation & Research, Office of Surveillance & Epidemiology, Drug Use Review (concerning Xolair), Dec. 5, 2011, at 4.

661. In other words, 62% is, in fact, "between half and two-thirds" and "almost two-thirds"; the FDA's recent Xolair Drug Use Review corroborates Relator's knowledge and observations, as Xolair sales representatives, that these SPs have carried out this major role. As noted above, Genentechs' website also corroborates their knowledge.

B. MEDICARE AND MEDICAID BILLING

662. Relators' Xolair sales managers also advised them that about 8% of all Xolair sales are billed to the Medicaid Program, and that about 4% of all Xolair sales are billed to Medicare Program.

663. This fact is corroborated by Defendants' 2003 Xolair Learning Module entitled "Introduction to Managed Care and Distribution." That Learning Module states in relevant part: "Private payers will constitute the majority of the Xolair payer mix. In the government arena, Medicaid will be the key driver. However, it will only represent approximately 8% of total [Xolair] revenue." *Id.* at 1-10. Further, a pie chart in this Learning Module, entitled "Figure 1-1: Likely payer mix for Xolair," illustrated that 84% would constitute private pay, 8% would be reimbursed by Medicaid, 4% would be reimbursed by Medicare, and 4% would constitute uninsured/self pay. *Id.* at 11.

664. Although Medicare and Medicaid has only covered a total of approximately 12% of Xolair sales, Xolair sales have been so large that Medicare and Medicaid's coverage are also very large.

665. Defendants' statements to Relator, and the estimates provided in the Learning Module, are also borne out by data comparing Xolair reimbursement by the States through the Medicaid Program payments (i.e., "drug utilization data") with Defendants' total Xolair sales in the United States.

666. From the launch of Xolair in 2003 through 2011, Xolair sales in the United States totaled $4.2 billion. Sources: gene.com (Genentech's website), Roche and Genentech's annual reports from 2004 through 2012, Novartis 6-Ks filed with the SEC from 2004 through 2012, Bloomberg.com, pdl.com, and drugs.com. (These sales are broken down as follows, by year: $25.1M in 2003, $187.6M in 2004, $320.6M in 2005, $425M in 2006, $472M in 2007, $517M in 2008, $571M in 2009, $985M in 2010, and $705M in 2011.)

667. According to publicly available data from CMS, from 2003 through 2011, the States paid $292,308,360.03 in Medicaid reimbursements for Xolair. Source: www.cms.gov/MedicaidDrugRebateProgram/SDUD/list.asp.

668. $292,308,360.03 is almost exactly 7% of $4.2 billion (6.96% of $4.2 billion).

669. Hence, Defendants' representations that Medicaid covers, or would cover, approximately 8% of all Xolair sales is relatively accurate. The data shows that Medicaid covers approximately 7% of all Xolair sales, and the data from CMS excludes information on Medicaid coverage for Xolair from one state: Arizona. Hence, the figure is even closer to 8%.

670. As the Medicare Program covers approximately half as much in Xolair reimbursements as the Medicaid Program, and the Medicaid Program has provided reimbursement for Xolair of approximately $300 million ($292,308,360.03) from 2003 through 2011, the Medicare Program has provided reimbursement for Xolair of approximately $150 million (half of $292,308,360.03) from 2003 through 2011. Thus, collectively, the Medicaid and

Medicare Programs have provided reimbursement for Xolair of approximately $450 million from 2003 through 2011.

671. Defendants have caused the specialty pharmacies named above to submit false claims to the Medicare and Medicaid Programs. As set forth above, 62% of all Xolair sales were to specialty pharmacies. Hence, the specialty pharmacies submitted claims of approximately $181,231,183 of Xolair (62% of $292,308,360.03) to Medicaid from 2003 through 2011. As 38% of purchases were by physicians, physicians submitted Medicaid claims totaling approximately $111,077,176 from 2003 through 2011.

672. The vast majority of these claims submissions by physicians were by the physicians who are listed in the Rapid Action Report (Detail) ending July 7, 2006—which tracked all Xolair purchases by physicians. That report contains the names of over 5,000 physicians that Defendants have targeted as Xolair prescribers.

673. Relators allege that Defendants have caused over 1,000 physicians to submit false claims to the Medicare and/or Medicaid Programs. (Not every doctor named in the Rapid Action Report actually purchased Xolair, and most of those who prescribed Xolair, obtained the drug from one of the 5 SPs.)

674. Because Medicare claims submissions were approximately half that of Medicaid claims submissions (by Defendants' own acknowledgment), the 5 SPs submitted claims of approximately $90,615,591 of Xolair (.5 x 62% of $292,308,360.03) to Medicare from 2003 through 2011. As approximately half of the 38% of purchases were by physicians, physicians submitted Medicare claims totaling approximately $55,538,588 from 2003 through 2011. Again, the vast majority of these claims submissions by physicians were by the physicians who are

listed in the Rapid Action Report (Detail) ending July 7, 2006—which tracked all Xolair purchases.

675. The vast majority of the physicians who are listed in the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006, were enrolled in the Medicare and/or Medicaid Programs. The vast majority of these physicians actually prescribed Xolair, as is evident from examining the document. Indeed, the report lists, among other things, the total equivalent number of vials shipped to the physician from January 1, 2006 through July 7, 2006, as well as the total equivalent number of vials shipped to the physician in the rolling 12-month period from early July 2005 through July 7, 2006.

C. "THE MEDICAID PUSH"

676. From 2003 forward, Defendants have aggressively targeted physicians with large volumes of patients enrolled in the Medicaid Program by both tracking which physicians are enrolled in Medicaid and by targeting doctors who service patients in lower-income neighborhoods—like Queens and the Bronx in New York, in or near Relators Kelly and Garcia's sales territories.

677. During national, regional, and local sales meetings, in e-mails and in person (orally), Defendants' Xolair sales managers (including those of Relators listed repeatedly above), have frequently told Xolair representatives to target African-Americans and Hispanics in inner-cities (and the doctors treating them), who are not only frequently on Medicaid, but who also constitute a likely pool of asthma patients because of widespread research that shows the prevalence of asthma in lower-income, inner-city neighborhoods that are relatively highly populated with African-Americans and Hispanics.

678. Xolair sales managers have stated at times that Medicaid is a "soft target" for Xolair sales for these reasons, and because prior authorizations are not required for many Xolair prescriptions because there are few or no formulary restrictions with Medicaid. Further, Defendants analyzed sophisticated data that they purchased from a company called IMS, which provides detailed information about doctors' prescribing habits, in furtherance of this "Medicaid push." IMS provides information and technology for healthcare companies, including numerous pharmaceutical and biotechnology companies. Its global headquarters is at IMS Health, 11 Waterview Blvd., Parsippany, New Jersey 07054.

679. To this end, Defendants have distributed literature to their Xolair sales forces about the impact of asthma on inner-city communities. For example, on December 6, 2006, Marty Clark, Novartis' Xolair New York Area Sales Manager, distributed to Xolair sales representatives in his district, and to others, a "good article on asthma", which he had received from Jonathan Kiesznoski with Novartis the day before. The article was entitled "Anti-asthma drug being tested for effectiveness in inner-city kids." The article commenced by stating that "[a]cademic medical centers in a dozen cities nationwide are launching a major study to determine whether Volair [sic] (omalizumab) can reduce the severity of allergic reactions and asthma attacks in inner-city children."

680. Defendants not only have told Xolair sales representatives to engage in a Medicaid push to capture Medicaid patients at 340b/indigent hospitals and clinics, Defendants created specific plans, communicated them to their Xolair sales forces, and told them to carry it out to earn more sales bonuses.

681. Defendants, through senior and mid-level sales managers (including Dan Giunta, Genentech mid-Atlantic senior Area Sales Manager, Steve David with Novartis, and Greg

Hurdle with Novartis), told Defendants' Xolair sales representatives to target hospitals and clinics in inner-city or poor neighborhoods. In particular, Mr. Hurdle distributed to Xolair sales managers and representatives, nationwide, lists of such hospitals and clinics to target. Top management with Defendants—including Belinda Mikel, Director of Managed Markets and Business Relations, and Charles Sabino, Novartis' Xolair Director of Sales—were copied on these e-mails and attachments.

682. Following such instructions, Genentech DM Jerry Kelly, who supervised co-Relator Garcia, planned a teleconference on February 25, 2004 for the Xolair sales representatives that he supervised, regarding "an opportunity that we have in the Division for business…This could be the start we have been looking for in '04." The call was to concern Disproprtionate Share Hospitals ("DSHs") (*See below* legal explaination of DSHs.).

683. But it was changed from a conference call with the Novartis and Genentech New York Area sales forces,[18] to a full-blown major meeting at the Marriott Marquis in Times Square, New York City, on March 2, 2004 from 2 to 5 p.m. At this meeting, which focused heavily on a Medicaid push for 340b/DSH Xolair prescriptions, Mr. Kelly instructed Xolair sales representatives, including Relator Frank Garcia, to incorporate visits to DSH clinics into his regular sales calls cycles. (Mr. Kelly also began prioritizing them for ride-alongs with Mr. Garcia.) Managers and regional managers from both Novartis and Genentech, including Jerry Kelly, Bill Stewart, and a Novartis regional manager, attended the meeting.

[18] The New York Area Xolair sales force consisted of Jerry Kelly, Nicholas Dacchille, Alla Spiegel, JayBea Smalley, Elisa Keena, Dahna Bender, Frank Garcia, and Joseph Bonsignore from Genentech; and Alexis Pace, Jim Kostailidis, Bonnie Masnick, Allison Kelly, Jessica Otiniano, Bill Stewart, Kathryn Wefald, Pilar Carbone, and Frances Estremera from Novartis.

684. Sales representatives were told that this type of marketing was illegal and not to discuss the meeting with others, which concerned Relators Garcia and Kelly, as well as Nick Dacchille, Joe Bonsignore, Elissa Keena, Dahna Bender, and Alla Spiegel.

685. Defendants' Medicaid push and related focus on 340b hospitals and clinics is reflected in many e-mails from Defendants' upper and mid-level echelons, including a March 17, 2006 e-mail from Maryanne Maliwat about "340B Pricing," in which she noted that DSHs "serve large numbers of indigent populations" and that "[t]he ability to purchase supplies an drugs at a lower cost allows them to continue providing care to these [indigent] populations."

686. In September 2006, Gerald Covell gave a "New York City Update" to the Novartis Xolair sales force [most of which is attached hereto and incorporated herein by reference as **Exhibit "Y"**] that is largely a reflection of the nationwide Medicaid push. During that presentation, Mr. Covell, in part, instructed the sales representatives on how to nudge "Medicaid doctors" at 340B hospitals to prescribe more Xolair. He had previously distributed to the sales representatives a list of New York-area 340B hospitals and clinics to target for Medicaid business [attached hereto and incorporated herein by reference as **Exhibit "Z"**]. One slide in the "New York City Update" slide presentation stated as follows:

NEW YORK MEDICAID TACTICS

•Get Managed Medicaid Plans to allow a SP [specialty pharmacy] to supply Xolair and bill instead of the physicians having to buy and bill.

•Work with FMC to open discussions with Health Plans around this Best Practice.

•Pull Through

•CarePlus

•MetroPlus (MCO for HHC) (Dr. Saperstein, Med Director and Dr. Rogers HHC Asthma Task Force)

•Article 28 Clinics (Dr. Beth Corn)

•340 B Hospitals (sent out list)

•Monthly Conference Calls

•Neighborhood Asthma Initiative (Roger Hayes)

Gerald Covell, "New York City Update" (Sept. 2006) at 10 (emphasis in boldface and underlining in original).

687. Mr. Covell, orally and in his accompanying slide presentation, emphasized that selling Xolair to Medicaid patients was a great opportunity. On page 7 of the slide presentation, he explained the "New York Medicaid Opportunity" by stating that Medicaid MCOs comprise a large share of the market, that "[m]any physicians have hire [sic] then [sic] 50% of their patients in NY Medicaid", and that "73% of NY Medicaid are enrolled in a Managed Medicaid plan." *Id.* at 7. The fact that many New York doctors had over half of their patients enrolled in Medicaid, and that asthma was a largely inner-city disease, were themes that Defendants repeated over and over in their exhortations to their Xolair sales forces to boost Xolair sales by seizing "low-hanging Medicaid fruit."

688. Pages 8 and 9 of Mr. Covell's presentation also identified major Medicaid payors, and identified six (6) major health plans and/or HCPs in New York that were buying and billing Xolair and, by definition, submitting Xolair reimbursement claims to Medicaid through their affiliated doctors and/or on-site pharmacies: Hudson Valley Health Plan, Montefiore/HIP/Oxford CMO, CenterCare, Fidelis, Affinity, and the New York Presbyterian Health Plan.

689. All of the above reflects an effort to directly reach out to Medicaid doctors, beneficiaries, and the hospitals and clinics where they were most likely to be found. Mr. Covell's slide presentation also addressed targeting Medicare-enrolled patients. *See, e.g., id.* at 16, 19.

690. As suggested above, Defendants' "Medicaid Push" also entailed targeting Managed Medicaid Plans. Mr. Covell's 2006 "New York City Update" also reflects that targeting. One slide therefrom read:

> **MANAGED CARE EDUCATION ON XOLAIR**
>
> **Tactics**
>
> **•Working with FMC to identify areas for educational opportunities with in the Health Plans (managed Medicaid). GHI requested in-service on Xolair.**
>
> **•Working with the Case Manager Society of America NYC, NJ and PA chapters to sponsor a CCM accredited program on Asthma.**

Id. at 11 (emphasis in boldface and underlining original).

691. Defendants' focus on Medicaid beneficiaries has often been couched in terms of focusing on State programs, hospitals, and clinics, and/or describing indigent communities as "special populations." For example, one slide from Mr. Covell's 2006 presentation stated:

> **Special Populations**
>
> □ State Pharmacy Assistance Program participants
>
> □ People in long-term care facilities

Id. at 17 (emphasis in boldface and underlining original).

692. A related slide in Mr. Covell's presentation explained that patients in long-term

care facilities were a good target because "[t]hose with Medicare and full Medicaid coverage have no premiums, deductibles, or copayments"—all making them more willing to agree to take Xolair. *Id.* at 19 (emphasis in boldface and underlining original).

693. Part of Defendants' "Medicaid push" also entailed a campaign to overcome obstacles from Medicaid MCOs. As an illustration, Gerald Covell sent an e-mail on July 24, 2006 to Marty Clark, Xolair New York Area Sales Manager, which Mr. Clark then forwarded to Novartis' Xolair sales force in that territory. The e-mail was about overcoming obstacles from MCOs—including Medicaid MCOs—to getting patients on Xolair. Mr. Covell gave as an example of such an obstacle that MCO Metro Plus requires "buy and bill" for its Medicaid population.

694. Another component of the "Medicaid push" was the coaching of Xolair sales representatives on detailing Medicaid-billing HCPs on how to avoid rejections on Medicaid claims submissions for HCPs that engaged in "buy and bill" of Xolair. For example, as early as November 20, 2003, Carolyn Johnston, a coding specialist with Genentech, sent an e-mail to Genentech's Xolair sales force about codes to be avoided to increase the odds of Medicaid (or Medicare approval).

695. Defendants also considered Medicaid patients "low-hanging fruit" because Medicaid reimbursement does not face one of the major hurdles facing drug coverage for Medicare Part A and B patients: "MediGap," i.e., Medicare Part A and Part B patients without secondary insurance.

696. Under Medicaid, the patient genrally has no deductible or co-payment for the price of Xolair—only very little or no co-payment for the patient's visit to the doctor's office for adminsitration of the drug. In contrast, the patient has to pay for 100% of the price of Xolair if

uninsured, 20% of the price if covered by Medicare, and had a hefty co-payment obligation under private health insurance. This contrast/profile is another reason that Medicaid patients were considered "low-hanging fruit" by Defendants.

697. Indeed, Defendants even went so far as to market publicly that they offered generous financial assistance programs for a wide swath of people to help ensure that Medicaid patients did not "slip between the cracks." In particular, at all relevant times herein Genentech has had a "patient assistance program" ("PAP") called the Access to Care Foundation ("ATC"). Under the ATC, the design was not—as Genentech's website makes it appear—to provide free Xolair for asthma patients who come from families with under $100,000 in income. If that were the case, Genentech would be giving away Xolair to the vast majority of non-Medicaid and non-privately insured eligible Xolair users who still had considerable financial means.

698. Rather, the ATC has been used as a marketing device so that asthma patients and asthma-treating physicians might inquire about Xolair when they might not otherwise, due to logical assumptions that private insurance or government programs would not pick up the tab. The patient could then be targeted as a patient, prescribed Xolair, given it for free until Medicare or especially Medicaid eligibility later kicked in, and then the patient would not "slip between the cracks." (Also, Defendants used the program to fund the Medicare co-payments of patients—to ensure that patients were not lost when Medicare would fund 80% of the cost of the drug._

699. Section 602 of the Veterans' Health Care Act of 1992, 42 U.S.C., § 340B(a)(4) ("§ 340B") requires drug manufacturers to provide outpatient drugs to covered entities, including Disproportionate Share Hospitals ("DSHs"), at a reduced price.

700. Congress enacted Section 340B Program in 1992. The program requires participating pharmaceutical manufacturers to enter into a pharmaceutical pricing agreement ("PPA") with the Secretary of HHS.

701. The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified Government-supported facilities, known as "covered entities," that serve America's most vulnerable patient populations. Congress intended for covered entities to use the benefit of the discount to reach more eligible patients and provide more comprehensive services. House Report No. 102-384, Pt. II, at 12, 102nd Cong. 2d Sess.

702. Eligible "covered entity" hospitals include DSHs, children's hospitals exempt from the Medicare prospective payment system, cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals ("CAHs").

703. Such hospitals, including DSHs, must be not-for-profit, and either be owned or under contract with State or local governments. With the exception of CAHs, they must also serve a disproportionate share of low-income patients by meeting payer-mix criteria related to the Medicare DSH Program.

704. The 340B Program exists so that covered entities may stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The cost reductions afforded through the program allow hospitals to maintain broader operations, including the provision of necessary, non-pharmacy services for patients. For example, a covered entity may use 340B savings to offset low reimbursement for general, non-pharmacy care; and 340B savings allow covered entities to cover Medicare and Medicaid reimbursement shortfalls for inpatient services.

705. Defendants' Xolair sales representatives have been directed by Defendants' management to target DSHs because Medicaid patients/beneficiaries, and Medicaid-enrolled doctors, abound there; and to "market the spread" between standard pricing and the discounts that they are permitted to offer to DSH hospitals pursuant to § 340B.

706. In February 2004, Defendants encouraged their sales representatives in the New York area, including co-Relators Kelly and Garcia, to target doctors at 340B clinics and DSH and VA hospitals and encourage them to utilize Medicaid funding for Xolair. The co-Relators attended meetings, and were privy to other discussions, where managers instructed and encouraged this targeting, while at the same time stating that the practice was "illegal." This business strategy was subsequently expanded by Defendants nationally, to include other regions of the country.

D. "THE MEDICARE PUSH"

707. Beginning in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income Medicare individuals receiving the greatest subsidies. (Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.)

708. For this reason, in 2005, even before Part D took effect, Defendants began a "Medicare push" to boost Xolair prescriptions by Medicare-enrolled doctors treating asthma and allergy patients.

709. In short, Medicare Part D was targeted as a potential boon for Xolair sales.

710. Further, from 2006 forward, Defendants reinforced the "Medicare push" by targeting the Medicare Part D coverage gap, informally known as the Medicare "donut hole." The "donut hole" is the difference between the initial coverage limit and the catastrophic

coverage threshold, as described in the Medicare Part D Program. After a Medicare beneficiary surpasses the prescription drug coverage limit, the Medicare beneficiary is financially responsible for the entire cost of prescription drugs until the expenses reaches the catastrophic coverage threshold. Thus, the "donut hole" is created.

711. Although Defendants initially considered the Medicare market for Xolair to be half of the payer mix as compared to Medicaid (8% Medicaid, and 4% Medicare, according to one of Defendants' 2003 Xolair training "learning modules"), Defendants quickly recognized that Medicare was a growing source of revenue–particularly because of the new Medicare Part D Drug Program, by which more Medicare patients than ever would be eligible for Medicare reimbursement for Xolair, and despite Defendants' continued emphasis that asthma is disproportionately an inner-city disease affecting many low-income families that are on Medicaid and treated by Medicaid-enrolled doctors).

712. To this end, in 2005, Defendants began requiring Xolair sales representatives to distribute to existing and potential Xolair prescribers, but intended for their Xolair patients, a written piece entitled "**Open enrollment for Medicare Part D prescription drug coverage begins November 15, 2006, and ends December 31, 2006**." (emphasis in boldface in original) The piece encouraged patients taking Novartis drugs—like Xolair—to call the "Novartis Medicare Rx Assistance Line 1-888-827-2783." [11/13/06 disclosures]

713. As part of this "Medicare push," as suggested above, Defendants even engaged in a marketing campaign to help ensure that its Medicare Part D revenues would not suffer because of the Medicare Part D "donut hole"—an area in which Part D generally does not provide prescription drug coverage for Medicare Part D beneficiaries.

714. On October 6, 2006, Novartis, through Jacqueline Esposito, distributed to "All [Sales] Field Forces" a memorandum about the "Donut Hole Flashcard." This memorandum and the flashcard—attached hereto and incorporated herein by reference as **Exhibits "AA" and "BB",** respectively—emphasized and explained, in part, that 85% of all Medicare Part D beneficiaries (over 19 million people in America) would not be adversely affected by the Donut Hole throughout 2006.

715. Yet another piece distributed to the Xolair sales representatives near this same time exhorted them to "remind physicians that they should not fundamentally change their prescription-writing habits due to the donut hole considerations" and that "[p]hysicians and patients should keep the clinical benefits of the product in mind."

E. SPECIFIC DOCTORS IN (OR VERY NEAR) RELATORS' SALES DISTRICTS

716. Through communications with the HCPs they interfaced with to sell Xolair, as well as their staffs, through information provided by Defendants about the HCPs' payer mixes (private pay v. Medicare v. Medicaid, etc.), and through information provided by other Xolair sales representatives, the Relators became knowledgeable about the existence and level of Medicaid and Medicare billing carried out by HCPs in their sales territories and neighboring sales territories.

717. Because Defendants targeted physicians with a lot of patients from "inner city" and/or minority neighborhoods, whose patients were very frequently covered by the Medicaid Program, a large number of Medicaid-enrolled physicians who purchased Xolair were submitting claims to Medicaid, or prescribing Xolair to Medicaid beneficiaries, which caused SPs to submit claims to Medicaid.

718. During the course of Relators' employments, Relators at times received e-mails, attachments, and/or other documents from one or more Defendants which underscore the focus on marketing and selling Xolair to Medicaid-enrolled physicians and/or physicians likely to be treating or actually treating patients from "inner city" and/or minority neighborhoods.

719. Through this acquired knowledge, Relators allege that the HCPs listed below, among others across the country, either prescribed Xolair and submitted claims for reimbursement for Xolair to government healthcare programs (including Medicare and/or Medicaid) after buying the drug, or did not buy Xolair but prescribed the drug and submitted the prescription or SMN to one of Defendants' 5 designated specialty pharmacies, which purchased the drug and submitted the claims for reimbursement for Xolair to government healthcare programs (including Medicare and/or Medicaid).

720. Relators do not, of course, allege that the Xolair prescriptions set forth in the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], reflect the total universe of Xolair Medicare and Medicaid claims submissions from 2003 forward, as this Rapid Action Report only covers a 12-month period from mid-2004 through mid-2006. Nor do Relators intend to state or imply that any particular physician prescribed only the amounts of Xolair described in the report, which only reflects a one-year period.

721. Kishore Ahuja, M.D.**,** internal medicine and allergist/immunologist, Medicare and Medicaid Enrollee, Xolair speaker, 3071 Perry Avenue, Bronx, NY 10467, and 1031 McBride Avenue, Suite D208, Woodland Park, NJ 07424, has prescribed Xolair for Medicare and Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the

5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 261 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

722. Alan Kaufman, M.D.**,** allergist/immunologist, Medicare enrollee, Xolair speaker, 3626 East Tremont Avenue, Bronx, NY 10465, and 559 Gramatan Avenue, Mount Vernon, NY 10465, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 418 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

723. Golda Hudes, M.D., allergist/immunologist, Medicare and Medicare enrollee, 1515 Blondell Avenue, Suite 220, Bronx, NY 10461, has prescribed Xolair for Medicare and Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 437 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

724. Ralph Binder, internal medicine, pulmonologist, and critical care, Medicare enrollee, 329 White Plains Road, Eastchester, NY 10709, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 375 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

725. Anil Gupta, M.D.**,** allergist/immunologist and pediatrician, Medicare and Medicaid enrollee, 1807 Randall Avenue, Bronx, NY 10473, and 1624 Crosby Avenue, Bronx, NY 10461, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], at least 70 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

726. David Rosenstreich, M.D.**,** allergist/immunologist, Medicare and Medicaid enrollee, Xolair speaker, 1515 Blondell Avenue, Suite 220, Bronx, NY 10461, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for

reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 88 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

727. Ira Finegold, M.D., allergist/immunologist, Medicare and Medicaid enrollee, Xolair speaker, 121 East 60th Street, Suite 4C, New York, NY 10022, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 81 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

728. Guido Volcovuci, M.D., internal medicine and pulmonologist, Medicare and Medicaid enrollee, 4915 Broadway, Apt. 1-A, New York, NY 10034, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 147 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

729. Joan G. Lehach, M.D.**,** allergist/immunologist, Medicare and Medicaid enrollee,

Xolair speaker, 1488 Metropolitan Avenue, New York, NY 10462, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 42 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

730. Larry Bernstein, M.D., allergist/immunologist, Medicare and Medicaid Enrollee 110-55 72nd Road, Suite L1, Forest Hills, NY 11375, and 1180 Morris Park Avenue, Bronx, NY, 10461, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 118 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

731. David B. Rosenzweig, allergist/immunologist, Medicare and Medicaid enrollee, 3555 Bainbridge Avenue, Suite 1D, Bronx, NY 10467, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week

ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 272 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

732. Saagar B. Karlekar, M.D.**,** pediatrician, formerly with an office at 711 Nereid Avenue, Bronx, NY 10466, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 56 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

733. Larry Schulman, M.D., pulmonologist/internal medicine, Medicare enrollee, 161 Fort Washington Avenue, New York (Washington Heights), NY 10032, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 44 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

734. Carlton McGregor, M.D., pulmonologist and internal medicine, Medicare and Medicaid enrollee, 161 Fort Washington Avenue, New York (Washington Heights), NY 10032,

has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 44 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

735. David Posner, M.D., pulmonologist, Medicare enrollee, 178 East 85th Street, New York, NY 10028-2119, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 184 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

736. Edwin Neil Schachter, M.D., critical care, internal medicine, and pulmonologist, Medicare and Medicaid enrollee, Faculty Practice (Pulmonary Assoc.), 5 East 98th Street, New York, NY 10029, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 99 vials is the total equivalent number of

vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

737. Stephen David Siegel, M.D., cardiologist and internal medicine, Medicare enrollee, 245 East 35th Street, New York, NY 10006, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 446 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

738. Charles Shapiro, M.D., allergist/immunologist, Medicare and Medicaid enrollee, 1967 Turnbull Avenue, Bronx, NY 10473, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 544 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

739. Stanley Bart Cohen, M.D., pediatrician, Medicare and Medicaid enrollee, 95 Pitman Street, Providence, RI 02906, 128 Post Avenue, Suite K, New York, NY 10034, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair

prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 78 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

740. Beth E. Corn, M.D., allergist/immunologist, Medicaid enrollee, Xolair speaker, 5 East 98th Street, New York, NY 10029, has prescribed Xolair for Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 372 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

741. Louis R. Depalo, M.D., critical care, internal medicine, and pulmonologist, Medicare and Medicaid enrollee, 1130 Park Avenue, Suite 3, New York, NY 10128, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 120 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

742. Thomas K. C. King, M.D., internal medicine and pulmonologist, Medicare and Medicaid enrollee, Weil Cornell Pulmonary Associates, 1305 York Avenue, New York, NY 10028, and 520 East 70th Street, New York, NY 10021, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 85 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

743. Kenneth Michael Prager, M.D., internal medicine and pulmonologist, Medicare enrollee, 161 Fort Washington Avenue, New York (Washington Heights), NY 10032, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 116 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

744. Gwen S. Skloot, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Pulmonary Associates, 5 East 95th Street, 10th Floor, New York, NY 10029, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has

written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 69 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

745. Ina Itzkovtiz, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, 215 West 125th Street, 2nd Floor, New York, NY 10027, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 62 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

746. Susan B. Levit, M.D., internal medicine, Medicare and Medicaid enrollee, 1220 Avenue P, Brooklyn, NY 11229, 1902 86th Street Brooklyn, NY 11214, and 9708 Seaview Avenue, Brooklyn, NY 11236, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 20 vials is the total equivalent

number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

747. Arthur Deluca, M.D., pediatrician and pulmonologist, Medicaid enrollee, 30-14 37th Street, Astoria (Queens), NY 11103, has prescribed Xolair for Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 26 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

748. Philip Marcus, M.D., pulmonologist and critical care, formerly a Medicare and Medicaid enrollee, deceased as of April 2012, formerly with a business address of 100 Veterans Boulevard, Massapequa, NY 11758, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 407 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

749. Jason B. Karp, M.D., internal medicine, pulmonologist, and critical care, Medicare enrollee, Northshore Pulmonary Associates, P.C., 6 Ohio Drive, Lake Success, NY 11042, has prescribed Xolair for Medicare patients and either has bought the Xolair and

submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 272 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

750. Steven G. Orshan, M.D., internal medicine, pulmonologist, and critical care, Medicare enrollee, 3003 New Hyde Park Road, New York, NY 11042, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 77 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

751. Seymour I. Huberfeld, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, 3003 New Hyde Park Road, New York, NY 11042, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein

by reference as **Exhibit "W"**], 61 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

752. Arthur Trust, M.D., internal medicine, pulmonologist, and critical care, Medicare enrollee, 3003 New Hyde Park Road, New York, NY 11042, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 30 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

753. Paul Bruce Lang, M.D., allergist/immunologist, Medicare enrollee, North Shore Allergy & Asthma Institute, 1 Hollow Lane, Suite 110, New Hyde Park, NY 11042, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 585 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

754. Robert Mittman, M.D., allergist/immunologist, Medicare enrollee, 2900 Hempstead Turnpike, Suite 206, Levittown (Queens), NY 11576, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused

1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 220 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

755. Debra Lebo, M.D., allergist/immunologist, Medicare and Medicaid enrollee, ENT Associates of New York, 74-11 37th Avenue, Jackson Heights, NY 11372, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 76 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

756. Craig Thurm, M.D., internal medicine and pulmonologist, Medicare and Medicaid enrollee, 134-20 Jamaica Avenue, Jamaica, NY 11418, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 93 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

757. Jill P. Karpel, M.D., internal medicine and pulmonologist, Medicare and Medicaid enrollee, Xolair speaker, North Shore University Hospital, 410 Lakeville Road, Suite 107, New Hyde Park, NY 11040, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 366 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

758. Michael Landor, M.D., internal medicine, Medicare and Medicaid enrollee, New York Immunology, 69-20 Main Street, Flushing, NY 11367, and 86-16 Jamaica Avenue, Woodhaven, NY 11421, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 100 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

759. Alan Jeffrey Schechter, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Xolair speaker, Nassau Chest Physicians, P.C., 233 East Shore Road, Great Neck, NY 11023, and 643 Broadway, Massapequa, NY 11758, has prescribed

Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 274 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

760. Sabina Grochowski, M.D., internal medicine, Medicare enrollee, 850 7th Avenue, Suite 500, New York, NY 10019, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 210 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

761. Ana Jaramillo, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Western Queens Health Associates, 82-01 37th Avenue, Jackson Heights, NY 11372, Broadway Cardiopulmonary, P.C., 31-41 45th Street, Long Island City, NY 11103, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and

incorporated herein by reference as **Exhibit "W"**], 24 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

762. Khaleeq Arshed, M.D., internal medicine and pulmonologist, Medicare enrollee, 37-56 75th Street, Jackson Heights (Queens), NY 11372, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 165 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

763. David L. Menchell, M.D., allergist/immunologist, Medicare and Medicaid enrollee, 73-03 198th Street, Fresh Meadows (Queens), NY 11366, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 226 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

764. Mitchell B. Boxer, M.D., allergist/immunologist, Medicare enrollee, 560 Northern Boulevard, Great Neck, NY 11021, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written

Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 198 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

765. Gary W. Freeberg, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Nassau Chest Physicians, P.C., 233 East Shore Road, Great Neck, NY 11023, and 643 Broadway, Massapequa, NY 11758, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 63 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

766. Mridula Gupta Noori, internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, 6860 Austin Street, Suite 303, Forest Hills, NY 11375, and 5 Station Square, Forest Hills, NY 11375, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 1,542 vials is the total equivalent

number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

767. Mohammad Jawaid, M.D., internal medicine, Medicare and Medicaid enrollee, Western Queens Health Associates, 82-01 37th Avenue, Jackson Heights, NY 11372, 31-41 45th Street, Long Island City, NY 11103, 21-82 Steinway Street, Astoria (Queens), NY 11105, and 150 East 77th Street, New York, NY 10075, and 110 East 59th Street, Suite 10B, New York, NY 10022, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 48 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

768. Ruy C. Tio, M.D., allergist/immunologist, Medicare enrollee, All Island Allergy, L.L.C., 1715 East 17th Street, Brooklyn, NY 11229, 27-47 Crescent Street, Astoria (Queens), NY 11102, and 230 Hilton Avenue, Suite 115, Garden City, NY 11550, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 46 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

769. Sotirios Kassapidis, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, 157-14 20th Road, Whitestone, NY 11357, and 22-31 33rd Street, Astoria (Queens), NY 11105, and 2510 30th Avenue, Long Island City, NY 11102, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 1,489 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

770. Christos Iakovou, M.D., internal medicine, pulmonologist, and critical care, Medicare enrollee, 58-20 Frances Lewis Boulevard, Bayside (Queens), NY 11036, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 102 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

771. Richard W. Desmond, M.D., internal medicine and pulmonologist, Medicare enrollee, 23-22 30th Avenue, Suite 2, Astoria (Queens), NY 11102, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty

pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 82 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

772. Jeffrey M. Wolf, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Nassau Chest Physicians, P.C., 233 East Shore Road, Great Neck, NY 11023, and 643 Broadway, Massapequa, NY 11758, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 35 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

773. Anat B. Warren, M.D., allergist/immunologist, Medicare enrollee, 2035 Lakeville Road, New Hyde Park, NY 11040, and 180-05 Hillside Avenue, Jamaica, NY 11432, and 31-75 23rd Street, Astoria (Queens), NY 11106, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference

as **Exhibit "W"**], 68 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

774. Jonathan M. Waxner, M.D., internal medicine, pulmonologist, and critical care, Medicare and Medicaid enrollee, Nassau Chest Physicians, P.C., 233 East Shore Road, Great Neck, NY 11023, and 643 Broadway, Massapequa, NY 11758, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 102 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

775. Kamal Tadros, M.D., internal medicine, Medicare and Medicaid enrollee, Rosedale Medical, 235-20 147th Avenue, Suite 1, Rosedale, NY 11422, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 377 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

776. Lawrence Chiaramonte, M.D., allergist/immunologist, Medicare and Medicaid enrollee, Urban Health Plans, 1065 Southern Boulevard, Bronx, NY 10459, and MediAlliance,

625 West Fordham Boulevard, Bronx, NY 10458, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 54 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

777. John A. Saryan, M.D., has been an allergist/immunologist, Medicare enrollee, with the Lahey Clinic Medical Center, 41 Burlington Mall Road, Burlington, Massachusetts 01805. Dr. Saryan also has seen patients at this additional Lahey Clinic location: North Shore, One Essex Center Drive, Peabody, Massachusetts 01960. The Lahey Clinic participates in and accepts Medicare and Medicaid. Dr. Saryan has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 95 vials of Xolair were shipped to Dr. Saryan from January 1, 2005 through March 11, 2005, and 498 vials of Xolair were shipped to Dr. Saryan from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 348 vials is the total equivalent

number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

778. John F. Beamis, Jr., M.D., has been a pulmonologist and practiced internal medicine at the Lahey Clinic Medical Center, 41 Burlington Mall Road, Burlington, Massachusetts 01805. The Lahey Clinic participates in and accepts Medicare and Medicaid. Dr. Beamis (Jr.) has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 0 vials of Xolair were shipped to Dr. Beamis from January 1, 2005 through March 11, 2005, and 96 vials of Xolair were shipped to Dr. Beamis from the launch of Xolair in 2003 through March 11, 2005.

779. Mohammed Ghiath Reda, M.D., pulmonologist, critical care, and internal medicine, Medicare and Medicaid enrollee, Waltham Medical Group, 6 Lexington Street, Suite 2, Waltham, Massachusetts 02452, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 22 vials of Xolair were shipped to Dr. Reda from January 1, 2005 through March 11, 2005, and 201 vials of Xolair were shipped to Dr. Reda from the launch of Xolair in 2003 through March 11, 2005. According to the

Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 135 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

780. Amy Simon, M.D., pulmonologist and internal medicine, Medicare and Medicaid enrollee, Pulmonary Clinical Critical Care, 800 Washington Street, Suite 269, Boston, Massachusetts 02111, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 14 vials of Xolair were shipped to Dr. Simon from January 1, 2005 through March 11, 2005, and 152 vials of Xolair were shipped to Dr. Simon from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 152 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

781. Thomas F. Johnson, M.D., allergist/immunologist and internal medicine, Medicare enrollee, New England Allergy and Immunology, 555 Turnpike Street, Suite 31, North Andover, Massachusetts 01845, has prescribed Xolair for Medicare patients and either has bought the Xolair and submitted claims for reimbursement to Medicare, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare. According to the Xolair Rapid Action Report

(Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 57 vials of Xolair were shipped to Dr. Johnson from January 1, 2005 through March 11, 2005, and 501 vials of Xolair were shipped to Dr. Johnson from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 454 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

782. Bimal P. Jain, M.D., pulmonologist and internal medicine, Medicare and Medicaid enrollee, Pulmonary Physicians, 500 Lynnfield Street, Lynn, Massachusetts 01904, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 0 vials of Xolair were shipped to Dr. Jain from January 1, 2005 through March 11, 2005, and 64 vials of Xolair were shipped to Dr. Jain from the launch of Xolair in 2003 through March 11, 2005.

783. Javed Sheikh, M.D., pediatrician and allergist/immunologist, Medicare and Medicaid enrollee, Beth Israel Deaconess Medical AIM, 1 Brookline Place, Brookline, Massachusetts 02445, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the

Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 62 vials of Xolair were shipped to Dr. Sheikh from January 1, 2005 through March 11, 2005, and 351 vials of Xolair were shipped to Dr. Sheikh from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 316 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

784. Thomas Raphael Martin, M.D., pediatrician and pediatric pulmonologist, Medicaid enrollee, Children's Hospital Boston, 300 Longwood Avenue, Boston, Massachusetts 02115, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 12 vials of Xolair were shipped to Dr. Martin from January 1, 2005 through March 11, 2005, and 70 vials of Xolair were shipped to Dr. Martin from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 106 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

785. Jeanne E. Gose, M.D., Ph.D., allergist/immunologist and pediatrician, Medicare and Medicaid enrollee, Asthma and Allergy Affiliates, Inc., 865 Turnpike Street, North Andover, Massachusetts 01845, has prescribed Xolair for Medicare and/or Medicaid patients and either

has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 29 vials of Xolair were shipped to Dr. Gose from January 1, 2005 through March 11, 2005, and 93 vials of Xolair were shipped to Dr. Gose from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 99 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

786. Ralph J. Cahaly, M.D., pediatrician and allergist/immunologist, Medicare and Medicaid enrollee, Asthma and Allergy Physicians, 115 Water Street, Milford, Massachusetts 01757, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 26 vials of Xolair were shipped to Dr. Cahaly from January 1, 2005 through March 11, 2005, and 104 vials of Xolair were shipped to Dr. Cahaly from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 44 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

787. Kenneth R. Dovidio, P.A., physician assistant in general medicine, 555 Turnpike Drive, Suite 31, North Andover, Massachusetts 01845, has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending March 11, 2005 [attached hereto and incorporated herein by reference as **Exhibit "CC"**], 10 vials of Xolair were shipped to Dr. Dovidio from January 1, 2005 through March 11, 2005, and 25 vials of Xolair were shipped to Dr. Dovidio from the launch of Xolair in 2003 through March 11, 2005. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 112 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

788. Outside of Mr. Fauci's sales territory, Robert J. Settipane, M.D., pediatrician and allergist/immunologist, Medicare and Medicaid enrollee, Allergy and Asthma Center of Providence, 95 Pitman Street, Providence, RI 02906, has been one of the highest prescribers of Xolair in New England. He has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 188 vials is the total equivalent

number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

789. Outside of Mr. Fauci's sales territory, Russell Settipane, M.D., internal medicine and allergist/immunologist, Medicare and Medicaid enrollee, with the Allergy and Asthma Center of Providence, 95 Pitman Street, Providence, RI 02906, has been one of the highest prescribers of Xolair in New England. He has prescribed Xolair for Medicare and/or Medicaid patients and either has bought the Xolair and submitted claims for reimbursement to Medicare and/or Medicaid, or has written Xolair prescriptions that have caused 1 or more of the 5 specialty pharmacies to buy the Xolair and submit claims for reimbursement to Medicare and/or Medicaid. According to the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], 248 vials is the total equivalent number of vials shipped to this physician in the rolling 12-month period from early July 2005 through July 7, 2006.

790. As noted above, from 2003 forward, Xolair sales managers told Relators—in training sessions, meetings, conferences, and one-on-one discussion with sales managers—to focus on Medicaid-enrolled doctors and Medicaid patients, that allergens that caused allergic asthma was far more common in these communities, and similar messages.

F. THE MEDICAID PUSH AND XOLAIR'S HIGHEST PRESCRIBERS

791. Many of Defendants' Xolair sales managers instructed their Xolair sales representatives that, due to the high cost of Xolair and the prevalence of asthma in lower-income communities, that the Xolair sales representatives could boost sales by focusing sales and marketing efforts on Medicaid-enrolled physicians. They also advised Xolair sales

representatives that Medicaid patients/beneficiaries were the most likely group to be approved for Xolair and maintained on a lengthy course of therapy. Xolair sales managers essentially advised their Xolair sales forces that Medicaid-enrolled doctors and Medicaid beneficiaries were "low-hanging fruit" because of the above factors, and because Medicaid engaged in much less scrutiny of SMNs, and because with Medicaid there was no need to check or ensure that the patient could afford Xolair—in stark contrast to the patient's hefty co-pay obligation with private insurance or the patient's need to pay in full for the drug if he or she was not covered by Medicare, Medicaid, or private insurance.

792. Defendants also frequently told their Xolair sales forces, including Allison Kelly and Frank Garcia, to heavily focus Xolair sales efforts on targeting physicians who are on staff with, or otherwise associated with, 340b/disproportionate share hospitals (DSHs) and clinics, because Medicaid-enrolled physicians, patients, and money abounded there.

793. For example, Frank Garcia's sales manager, Jerry Kelly, as well as Jerry Kelly's supervisor, Kelli Wilson, instructed Mr. Garcia and other Xolair sales representatives to focus heavily on Medicaid doctors, with indigent or inner-city patients, because Medicaid-enrolled physicians and the Medicaid Program in general were "soft targets" as compared to privately insured patients, because private health insurers would be more skeptical of, and scrutinize, prescriptions for Xolair, as compared to Medicaid MCOs and Medicaid in general. Jerry Kelly and Kelli Wilson told Mr. Garcia and other Xolair sales representatives that such a focus would lead to fewer rejections and appeals. Jerry Kelly specifically told Mr. Garcia and Allison Kelly to focus on Montefiore Hospital in the Bronx, for example, because of the large concentration of Medicaid doctors and Medicaid patients there.

794. The "Medicaid push" was a recurring message even before the launch of Xolair in the summer of 2003. The following are some examples of places and situations in which Xolair sales managers instructed Xolair sales representatives, or worked with them, to push for Xolair sales that would be covered by Medicaid: (1) at the Novartis-only Xolair pre-launch national sales meeting in San Diego, California in early 2003; (2) at the Novartis and Genentech joint launch/national sales meeting in Orlando, Florida in June or July 2003; and (3) in very numerous meetings and e-mails about boosting Xolair sales to 340b-DSH hospitals serving lower-income communities—a push for such Medicaid-340b-DSH hospital Xolair sales that began in 2003 and continued through at least 2007. Allison Kelly attended all of these meeting and saw a large number of e-mails regarding (3). Regarding the specific Medicaid-340b-DSH hospital Xolair sales, Allison Kelly attended a meeting at the Marriott Laguardia, near Laguardia Airport in New York, in which DM Bill Stewart spoke heavily about this push and explained the strategy. Further, from 2005 to 2007, Allison Kelly attended meetings at the Montefiore Medical Center (the academic medical center and university hospital for the Albert Einstein College of Medicine), in the Bronx, New York, which were variously attended by Xolair sales managers Jerry Covell, Bill Stewart, sales representative Pilar Carbone, and the head of Montefiore's pharmacy, that focused on treating Montefiore's Medicaid patients with Xolair, increasing Xolair prescription writing by Montefiore's Medicaid-enrolled doctors, and the potential financial benefits to Montefiore and the doctors themselves.

795. In a meeting held at the Marriott Marquis Hotel in Times Square, New York, on March 2, 2004, from approximately 2 to 5pm, which was attended by several of Defendants' district sales managers and regional sales managers and multiple sales representatives (including Jerry Kelly, Pilar Carbone, Nick Dachailles, Donna Bender, Alla Spiegel, Frank Garcia, and

Allison Kelly), sales representatives, including Mr. Garcia and Ms. Kelly, were instructed by superiors to focus more attention on selling Xolair to doctors with 340b/DSHs and to incorporate more of such clinics and hospitals into their sales calls. Mr. Garcia's DM, Jerry Kelly, subsequently made visits to 340b/DSHs in future ride-alongs with Mr. Garcia.

796. Similarly, in the Xolair sales franchise, Genentech DMs Mastrianni and Sullivan instructed Genentech sales representatives Patricia ("Pat") Pino (Boston sales district), Curtis James (Rhode Island sales district), and Kim Dickman (Connecticut sales district), that they should target Medicaid doctors and Medicaid patients/beneficiaries in low-income areas within their sales districts.

797. From their work with Defendants, Relators have observed that there is a very strong correlation between the highest prescribers of Xolair and physician enrollment in the Medicaid program. It is no coincidence that one of the very highest prescribers of Xolair (and the single highest prescribers of Xolair in the U.S. during one or more years), was Dr. Mridula Gupta Noori, who submitted a high volume of reimbursement claims to Medicaid, or caused 1 or more of the 5 specialty pharmacies to submit claims for reimbursement to Medicaid.

798. Indeed, within Defendants' Xolair sales forces, it was widely known, just as it was for Ms. Kelly, Mr. Garcia, and Mr. Fauci, that Defendants' Medicaid focus, i.e., the "soft target" of selling to Medicaid-enrolled physicians, was succeeding in boosting Xolair sales.

799. Defendants' "Medicaid push" for Xolair, and the fact that asthma is a disproportionately inner-city disease, together equated in a sales strategy that yielded strong results for the vast majority of Xolair sales representatives that followed the Medicaid push, and resulted in Medicaid claims submissions by the overwhelming majority of highest-volume, Medicaid-enrolled Xolair prescribers.

800. By mid-2005, some two years after the launch of Xolair, the Xolair sales forces had been well apprised by sales managers, and hence were well aware themselves, that most of the top Xolair prescribers were Medicaid-enrolled physicians, especially in the cities, as a result of the "Medicaid push."

801. Hence, virtually all of the highest prescribers of Xolair that are listed in the Xolair Rapid Action Report (Detail) for the week ending July 7, 2006 [attached hereto and incorporated herein by reference as **Exhibit "W"**], which reflects Xolair sales over the previous 12 months, have frequently submitted reimbursement claims to Medicaid, or have caused 1 or more of the 5 specialty pharmacies to submit claims for reimbursement to Medicaid.

802. Defendants shipped 300 or more equivalent vials of Xolair to the following Medicaid-enrolled Xolair prescribers during the rolling 12-month period from early July 2005 through July 7, 2006. All of these HCPs were in the top 1% of Xolair prescribers listed in the Rapid Action Report (Detail) Ending July 7, 2006. As that listed consisted of approximately 5,000 HCPs,[19] these HCPs were in the top 1% of Xolair prescribers during that time period. Only Medicaid-enrolled HCPs have been listed below, to best ensure that this list captures the names of HCPs who were targeted by Defendants as "Medicaid doctors." These facts and circumstances, other facts described in this Complaint, and other facts known to the Relators, show that these HCPs submitted claims for Xolair to Medicaid, or signed off on SMNs that led to the SPs identified herein to submit claims for reimbursement to Medicaid:

[19] The Rapid Action Report consists of 81 pages listing 65 HCPs per page. 81 x 65 =5,265. Plus, 4 additional HCPs were listed on page 82. That totals 5,264. Removing duplicate HCP names and HCPs who did not prescribe any Xolair during the relevant time period, the number equals very close to 5,000. Far fewer than 500 HCPs of the 5,000 HCPs prescribed 300 or more vials during the relevant time period, and only 184 of them are listed below as confirmed Medicaid enrollees. Hence, there can be no doubt that these Medicaid-enrolled HCPs were in the top 1% of Xolair prescribers from early July 2005 through early July 2006.

• Alan R. Varraux, M.D., 60 West Columbia Street, Suite F, Orlando, FL 32806, Medicaid enrollee: 1,165 vials;

• Thomas O'Neill, M.D., 159 Executive Drive, Suite F, Danville, VA 24541, Medicaid enrollee: 609 vials;

• Mazhar E. El-Amir, M.D., 192 Harrison Avenue, Jersey City, NJ 07304, Medicaid enrollee: 846 vials;

• Robert B. Miller, M.D., 96 Jonathan Lucas Street, Suite 812, Charleston, SC 29425, Medicaid enrollee: 673 vials;

• Winston Evans, M.D., 7800 Southwest 87th Avenue, Suite 340, Miami, FL 33173, Medicaid enrollee: 628 vials;

• Richard L. Siegel, M.D., 3450 East Fletcher Avenue, Suite 210, Tampa, FL 33173, Medicaid enrollee: 1,707 vials;

• Gabriel E. Gonzalez, M.D., 12959 Palm West Drive, Suite 230, Loxahatchee, FL 33470, Medicaid enrollee: 607 vials;

• Joseph T. Inglefield III, M.D., 220 18th Street, Circle SE, Hickory, NC 28602, Medicaid enrollee: 565 vials;

• Alan Alvarado, M.D., 3440 North Valdosta Road, Valdosta, GA 31602, Medicaid enrollee: 526 vials;

• Steven Rosenberg, M.D., 1890 State Road 436, Suite 215, Winter Park, FL 32792, Medicaid enrollee: 507 vials;

• Eric J. Kozlow, M.D., 120 Davis Street, Asheboro, NC 27203, 104 West Northwood Street, Greensboro, NC 27401, Medicaid enrollee: 1,209 vials;

• Kent J. Nastasi, M.D., 1372 Westgate Center Drive, Winston-Salem, NC 27103, Medicaid enrollee: 645 vials;

• Ligaya V. Centeno, M.D., 1740 Oak Tree Road, Edison, NJ 08820, 3 Hospital Plaza, Suite 405, Oldbridge, NJ 08857, Medicaid enrollee: 522 vials;

• Mario Magcalas, M.D., 10794 Pines Boulevard, Suite 205, Pembroke Pines, FL 33026, Medicaid enrollee: 602 vials;

• Luis A. Matos, M.D., 1505 Franklin Road S.W., Roanoke, VA 24016, 1715 Thompson Drive, Lynchburg, VA 24501, Medicaid enrollee: 540 vials;

• Charles Shapiro, M.D., 202-28 45th Avenue, Bayside, NY 11361, 1967 Turnbull Avenue, Suite 2, Bronx, NY 10473, Medicaid enrollee: 544 vials;

• Quan C. Nguyen, M.D., 1200 Peoples Plaza, Newark, DE, 19702, Medicaid enrollee: 741 vials;

• John Simelaro, D.O., 4190 City Avenue, Suite 330, Philadelphia, PA 19131, Medicaid enrollee: 2,782 vials;

• Randy Stoloff, M.D., 6980 Dallas Highway, Villa Rica, GA 30108, Medicaid enrollee: 539 vials;

• Jaime Kratz, M.D., 8202 Washington Street, Port Richey, FL 34668, Medicaid enrollee: 555 vials;

• Mridula G. Noori, M.D., 68-60 Austin Street, Suite 303, Forest Hills, NY 11375, Medicaid enrollee: 1,479 vials;

• Steven E. Harris, M.D., 3820 Medical Park Drive, Austell, GA 30106, 400 Tower Road NE, Marietta, GA 30060, Medicaid enrollee: 1,659 vials;

• Gurmit Gill, M.D., 975 Franklin Avenue, Second Floor, Garden City, NY 11530, Medicaid enrollee: 907 vials;

• Sotirios Kassapidis, M.D., 157-14 20th Road, Whitestone, NY 11357, 22-31 33rd Street, Astoria, NY 11105, 2510 30th Avenue, Long Island City, NY 11102, Medicaid enrollee: 1,310 vials;

• John Belany, D.O., 611 Eastland Avenue SE, Warren, OH 44484, Medicaid enrollee: 852 vials;

• Richard Y. Feibelman, M.D., pulmonologist, 515 West State Road 434, Suite 201, Longwood, Florida 32750, Medicaid enrollee: 344 vials;

• Michael S. Sherman, M.D., allergist/immunologist, 1 Bethany Road, Building 1, Suite 11, Hazlet, New Jersey 07730, and 22 North Main Street, Marlboro, New Jersey 07746, Medicaid enrollee: 352 vials;

• Roger A. Friedman, M.D., allergist/immunologist, 5877 Cleveland Avenue, Columbus, Ohio 43231, Medicaid enrollee: 353 vials;

• Roy M. Levinson, M.D., pulmonologist, 218-c Sunset Road, Willingsboro, New Jersey 08046, Medicaid enrollee: 330 vials;

• Mark T. Pollock, M.D., pulmonologist, 2665 North Decatur Road, Suite 230, Decatur, Georgia 30033, Medicaid enrollee: 354 vials;

• Clifford G. Risk, M.D., pulmonologist, 320 Bolton Street, Marlborough, Massachusetts 01752, Medicaid enrollee: 322 vials;

• Thomas S. Bumbalo III, M.D., pulmonologist, 1202 Medical Center Drive, Wilmington, North Carolina 28401, Medicaid enrollee: 354 vials;

• Jacob Dale Schrum, M.D., allergist/immunologist, 807 Children's Way, Jacksonville, Florida 32207, Medicaid enrollee: 364 vials;

• Edward Fein, M.D., pulmonologist, 333 Forsgate Drive, Suite 201, Jamesburg, New Jersey 08831, Medicaid enrollee: 310 vials;

• David Ellis Geller, M.D., pediatric pulmonologist, 496 South Delany Avenue, Suite 406A, Orlando, Florida 32801, Medicaid enrollee: 442 vials;

• Philip Marcus, M.D., pulmonologist, 233 East Shore Road, Great Neck, New York 11023, and 643 Broadway, Massapequa, New York 11758, Medicaid enrollee: 407 vials;

• Robert Demarco, M.D., pulmonologist, 925 Trailwood Drive, Youngstown, Ohio 44512, Medicaid enrollee: 416 vials;

• John Patrick Overholt, M.D., allergist/immunologist, 400 Sugartree Lane, Suite 100, Franklin, Tennessee 37064, Medicaid enrollee: 402 vials;

• Paul S. Salva, M.D., pediatric pulmonologist, 780 Chestnut Street, Suite 11, Springfield, Massachusetts 01107, Medicaid enrollee: 454 vials;

• Robert E. Younger III, M.D., allergist/immunologist, 1720 Gunbarrel Road, Suite 400, Chattanooga, Tennessee 37421, Medicaid enrollee: 433 vials;

• Johnson Wong, M.D., allergist/immunologist, 8 Hawthorne Place, Suite 104, Boston, Massachusetts 02114, Medicaid enrollee: 450 vials;

• David B. Rosenzweig, M.D., allergist/immunologist, 355 Bainbridge Avenue, Suite 1D, Bronx, New York 10467 and 30 East 40th Street, New York, New York 10016, Medicaid enrollee: 779 vials;

• Eric J. Kozlow, M.D., allergist/immunologist, 120 Davis Street, Asheboro, North Carolina 27203, and 104 West Northwood Street, Greensboro, North Carolina 27401, Medicaid enrollee: 423 vials;

• John Saryan, M.D., allergist/immunologist, 41 Mall Road, Burlington, Massachusetts 01805, Medicaid enrollee: 348 vials;

• Muhammad Shaukat, M.D., pulmonologist, 1115 North Central Avenue, Kissimmee, Florida, 34741, Medicaid enrollee: 394 vials;

• Robert McGovern, M.D., allergist/immunologist, 125 Liberty Street, Suite 307, Springfield, Massachusetts 01103, Medicaid enrollee: 303 vials;

• Jeffrey Marvin Rosch, M.D., pediatric allergist/immunologist, 501 Howard Avenue, Suite A202, Altoona, Pennsylvania 16601, Medicaid enrollee: 331 vials;

• Alan Halsey, M.D., allergist/immunologist, 3658 Lithia Pinecrest Road, Valrico, Florida 33596, Medicaid enrollee: 398 vials;

• Jill P. Karpel, M.D., pulmonologist, 295 Community Drive, Great Neck, New York 11021, Medicaid enrollee: 366 vials;

• Jose R. Alvarez, M.D., pulmonologist, 201 Northwest 82nd Avenue, Suite 105, Plantation, Florida 33324, Medicaid enrollee: 327 vials;

• Michael Peter Miller, M.D., allergist/immunologist, 100 Covey Drive, Suite 210, Franklin, Tennessee 37067, Medicaid enrollee: 401 vials;

• Mitchell Rothstein, M.D., pulmonologist, 425 North Lee Street, Suite 202, Jacksonville, Florida 32204, Medicaid enrollee: 440 vials;

• Kent Knauer, M.D., allergist/immunologist, 3909 Orange Place, Suite 2300, Orange Village, Ohio 44122, Medicaid enrollee: 419 vials;

• Eugene Gatti, M.D., allergist/immunologist 54 East Main Street, Marlton, New Jersey 08053, Medicaid enrollee: 413 vials;

• Albert P. Hirdt, D.O., allergist/immunologist, 4 Victory Court, Newburgh, New York 12550, Medicaid enrollee: 492 vials;

• Nancy Isobel Linneman, M.D., pulmonologist, 95 Crystal Run Road, Middletown, New York 10941, Medicaid enrollee: 436 vials;

• Maria C. Castells, M.D., allergist/immunologist, 1 Jimmy Fund Way, Smith Building Room 626D, Boston, Massachusetts 02115, Medicaid enrollee: 437 vials;

• Gregory Toci, D.O., pediatric allergist/immunologist, 239 Hurfville Crosskeys Road, Suite 2, Sewell, New Jersey 08080, Medicaid enrollee: 499 vials;

• Mahesh Bajaj, M.D., allergist/immunologist, 125 Liberty Street, Suite 307, Springfield, Massachusetts 01103, Medicaid enrollee: 316 vials;

• Walter Donat, M.D., pulmonologist, 593 Eddy Street, Providence, Rhode Island 02903, Medicaid enrollee: 348 vials;

• Anthony J. Ricketti, M.D., pulmonologist, 1542 Kuser Road, Suite B7, Trenton, New Jersey 08619, Medicaid enrollee: 317 vials;

• Saju Sebastian Eapen, M.D., allergist/immunologist, 1505 Franklin Road Southwest, Roanoke, Virginia 24016, Medicaid enrollee: 328 vials;

• Gary Agia, D.O., pulmonologist, 17 West Red Bank Avenue, Suite 206, Woodbury, New Jersey 08096 and 438 Ganttown Road, Suite A-7, Sewell, New Jersey 08080, Medicaid enrollee: 330 vials;

• Marc W. Cromie, M.D., allergist/immunologist, 6624 Lee Highway, Chattanooga, Tennessee 37421, Medicaid enrollee: 307 vials;

• Bruce Decotiis, M.D., allergist/immunologist, 1673 Route 88, Brick, New Jersey 08724, Medicaid enrollee: 314 vials;

• Louis Dubois, M.D., pulmonologist, 130 Center Way, Corning, New York 14830, Medicaid enrollee: 364 vials;

• Faisal Fakih, M.D., pulmonologist, 1788 West Fairbanks Avenue, Suites A and B, Winter Park, Florida 32789, Medicaid enrollee: 304 vials;

• Carlos Obregon, D.O., pulmonologist, 100A Kings Way, Sewell, New Jersey 08080, Medicaid enrollee: 300 vials;

• Timothy J. Sullivan III, M.D., allergist/immunologist, 5555 Peachtree Dunwoody Road, Suite 235, Atlanta, Georgia 30342, Medicaid enrollee: 345 vials;

• Bjorn Thorarinsson, M.D., pulmonologist, 613 23rd Street, Plaza B, Ashland, Kentucky 41101, Medicaid enrollee: 345 vials.

• Howard Israel, M.D., allergist/immunologist, 1605 North Cedar Crest Boulevard, Suite 605, Allentown, Pennsylvania 18104, Medicaid enrollee: 400 vials;

• Helen A. Aguila, M.D., pediatric pulmonologist, 90 Bergen Street, Suite 5100, Newark, New Jersey 07103, Medicaid enrollee: 304 vials;

• Susan Denise Borchers, M.D., pulmonologist, 7630 Rivers Edge Drive, Columbus, Ohio 43235, Medicaid enrollee: 390 vials;

• Curt M. Watkins, M.D., allergist/immunologist, 201 Pine Bluff Road, Suite 28, Salisbury, Maryland 21801, Medicaid enrollee: 370 vials;

• Michael Lawrence, M.D., allergist/immunologist, 35 Pearl Street, Suite 300, Brockton, Massachusetts 02301, Medicaid enrollee: 442 vials;

• Eduardo E. Arreaza, M.D., allergist/immunologist, 220 Alexander Street, Suite 402, Rochester New York 14607 and 10 Hagen Drive, Rochester, New York 14625, Medicaid enrollee: 324 vials;

• Javed Sheikh, M.D., allergist/immunologist, One Brookline Avenue, Suite 623, Brookline, Massachusetts 02445, Medicaid enrollee: 316 vials;

• Stephen J. Klemawesch, M.D., allergist/immunologist, 6294 1st Avenue North, Saint Petersburg, Florida, 33710, Medicaid enrollee: 370 vials;

• Ralph Cahaly, M.D., allergist/immunologist, 115 Water Street, Milford, Massachusetts 01757, Medicaid enrollee: 329 vials;

• Joseph Vincent Follett, M.D., allergist/immunologist, 2125 Valleygate Drive, Suite 201, Fayetteville, North Carolina 28304, Medicaid enrollee: 459 vials;

• Jose Antonio Bardelas, M.D., allergist/immunologist, 100 Westwood Avenue, High Point, North Carolina 27262, Medicaid enrollee: 367 vials;

• Rajesh Patel, M.D., allergist/immunologist, 1301 South International Parkway, Suite 1011, Lake Mary, Florida 32746, Medicaid enrollee: 319 vials;

• Anthony R. Rooklin, M.D., pediatric allergist/immunologist, 1 President Avenue, Morton, Pennsylvania 19070, Medicaid enrollee: 487 vials;

• Beth E. Corn, M.D., allergist/immunologist, 5 East 98th Street, New York, New York 10029, Medicaid enrollee: 372 vials;

• Neil Howard Gershman, M.D., allergist/immunologist, 7800 Southwest 87th Avenue, Suite C-340, Miami, Florida 33173, Medicaid enrollee: 345 vials;

• Jeffery B. Miller, D.O., pulmonologist, 2600 West Tuscarawas Street, Suite 100, Canton, Ohio 44708, Medicaid enrollee: 342 vials;

• Raquelle Alexander, M.D., allergist/immunologist, 601 7th Street South, Saint Petersburg, Florida 33701, Medicaid enrollee: 308 vials;

• Larry Smith, M.D., allergist/immunologist, 2601 Parkwood Drive, Suite B, Brunswick, Georgia 31520, Medicaid enrollee: 367 vials;

• Jonathan Waxner, M.D, pulmonologist, 233 East Shore Road, Great Neck, New York 11023, and 643 Broadway, Massapequa, New York 11758, Medicaid enrollee: 375 vials;

• Andrew Kirschner, D.O., family practitioner, 2 Bala Plaza, Bala Cynwyd, Pennsylvania 19004, Medicaid enrollee: 368 vials;

• Craig Kalik, M.D., allergist/immunologist, 3658 Lithia Pinecrest Road, Valrico, Florida 33596, Medicaid enrollee: 422 vials;

• Francis Lee, M.D., pulmonologist, 400 Matthew Street, Suite 305, Marietta, Ohio 45750, Medicaid enrollee: 485 vials;

• Howard Boltansky, M.D., allergist/immunologist, 3301 New Mexico Avenue Northwest, Suite 223, Washington, DC 20016, Medicaid enrollee: 427 vials;

• Anthony R. Ricci, D.O., allergist/immunologist, 63 Cedar Avenue, Suite 7, East Greenwich, Rhode Island 02818, Medicaid enrollee: 307 vials;

• Jose Birriel, M.D., pediatrician, 351 Northwest Le Jeune Road, Suite 406, Miami, Florida 33126, Medicaid enrollee: 314 vials;

• Salvatore Devincenzo, M.D., pulmonologist, 70 Hatfield Lane, Suite 101, Goshen, New York 10924, Medicaid enrollee: 404 vials;

• Theodore Harvey Sher, M.D., 1611 South Green Road, Suite 231, South Euclid, Ohio 44121, Medicaid enrollee: 383 vials;

• Harold Moessner, M.D., allergist/immunologist, 1909 Mallory Lane, Suite 308, Franklin, Tennessee 37067, Medicaid enrollee: 314 vials;

• Joseph N. Grizzanti, D.O., pulmonologist, 44 Godwin Avenue, Suite 201, Midland Park, New Jersey 07432, Medicaid enrollee: 400 vials;

• David Ettensohn, M.D., critical care physician, 73 Beechwood Avenue, Pawtucket, Rhode Island 02860, Medicaid enrollee: 311 vials;

• Cynthia Kelly, M.D., allergist/immunologist, 601 Children's Lane, Norfolk, Virginia 23507, Medicaid enrollee: 354 vials;

• Hitesh Makkar, M.D., pulmonologist, 95 Arch Street, Suite 210, Akron, Ohio 44304, Medicaid enrollee: 332 vials;

• Charles Fayton, M.D., pediatrician, 6477 College Park Square, Suite 118, Virginia Beach, Virginia and 930 Majestic Avenue, Suite 110, Norfolk, Virginia 23504, Medicaid enrollee: 364 vials;

• Charles Fuenning, M.D., pulmonologist, 95 Arch Street, Suite 210, Akron, Ohio 44304, Medicaid enrollee: 354 vials;

• Fred Fuad Mudawwar, M.D., allergist/immunologist, 300 Stafford Street, Suite 262, Springfield, Massachusetts 01104, Medicaid enrollee: 313 vials;

• Golda Hudes, M.D., allergist/immunologist, 1515 Blondell Avenue, Suite 220, Bronx, New York 10461, Medicaid enrollee: 437 vials;

• William A. Nish, M.D., allergist/immunologist, 2510 Limestone Parkway, Gainesville, Georgia 30501, Medicaid enrollee: 387 vials;

• Mohan Durve, M.D., allergist/immunologist, 6681 Ridge Road, Suite 305, Parma, Ohio 44129, Medicaid enrollee: 420 vials;

• Daniel Hamilos, M.D., allergist/immunologist, 55 Fruit Street, Boston, Massachusetts 02114, Medicaid enrollee: 327 vials;

• Gregory V. Marcotte, M.D., allergist/immunologist, 1700 Shallcross Avenue, Suite 1, Wilmington, Delaware, 19806, Medicaid enrollee: 346 vials;

• Eric Scott Heffelfinger, D.O., pulmonologist, 196 West Sproul Road, Suite 210, Springfield, Pennsylvania 19064, Medicaid enrollee: 471 vials;

• Kamal Tadros, M.D., internist, 235-20 147th Avenue, Suite 1, Rosedale, New York, 11422, Medicaid enrollee: 377 vials;

• Ileana M. Rodicio, M.D., allergist/immunologist, 9000 Southwest 137th Avenue, Miami, Florida 33186, Medicaid enrollee: 362 vials; and

• Joseph T. Inglefield, III, M.D., allergist/immunologist, 220 18th Street Circle Southeast, Hickory, North Carolina 28602, Medicaid enrollee: 446 vials.

803. Many low-income patients are "dual eligible"—those who qualify for both Medicare and Medicaid. In the case of dual eligibles, Medicare is the primary source of drug coverage.

COUNTS

***For all Counts appearing below, "Defendants" means *all* Defendants.**

*** For all Counts appearing below, "Defendants conspired" means that Genentech and Novartis—i.e., *all* Defendants—conspired with each other to accomplish all of the illegal acts set forth in this Complaint.**

COUNT ONE:

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(a)(1) and (2)

804. Relator Kelly and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

745. This is a *qui tam* action brought by Kelly and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

746. The Federal False Claims Act, 31 U.S.C. §3729(a)(1) and (2) provide:

Liability for certain acts. Any person who--

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid

Id.

747. Xolair prescriptions for off-label purposes and for ineligible patients would not have been presented but for the unlawful promotional activities made by Defendants, the improper manipulation of SMNs, and the kickback activity. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)-(2).

748. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. §3729(a)(1).

749. For example, those false claims include claims for reimbursement for off-label/non-medically accepted prescriptions of Xolair which would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this complaint.

750. By virtue of the above-described acts, among others, Defendants knowingly made used or caused to be made or used false records or statements to get false claims paid by the United States, and possibly continues to do so, in violation of 27 U.S.C. §3729(a)(2).

751. For example, claims for reimbursement for off-label prescriptions of Xolair would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Complaint including their false records and statements.

752.

753. In addition, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under the Medicaid, Medicare and other federally-funded health programs. In other words, claims arising from an unlawful exchange violative of the Anti-Kickback Statute are, as a matter of law, ineligible for reimbursement and upon submission are false claims subject to the provisions of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

750. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute, and in turn caused false claims to be submitted in violation of the Federal False Claims Act, §3729(a)(1). Specifically, Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Xolair to the United States. Those claims were false, as they were ineligible for reimbursement, and therefore by submitting or causing these false claims to be submitted, Defendants further violated 31 U.S.C. §3729(a)(1) from at least 2003 to the present.

751. By engaging in the fraudulent and illegal practices described herein, Defendants violated the Anti-Kickback Statute. Defendants' material violations of the Anti-Kickback Statute lead to the submission of claims for Xolair to the United States. Those claims were false, as they were ineligible for reimbursement, and by making or causing to be made false records or statements to get those false claims paid, Defendants further violated 31 U.S.C. §3729(a)(2) from at least 2003 to the present.

752. Plaintiff United States, unaware of the falsity of the claims that the Defendants caused doctors, pharmacies hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims -- prescription drug reimbursement claims for Xolair -- were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

753. For those claims that Defendants submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint Defendants acted with the requisite scienter.

754. By reason of Defendants' unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Defendants' drug and these practices thus provided substantial profits to Defendants.

755. By reason of these unlawful practices by Defendants, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Xolair rather than recommending less expensive procedures or treatment options for their patients.

755. The amounts of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be made by Defendants, and in reliance on the accuracy thereof paid and continues to pay for Defendants' unlawfully induced Xolair prescriptions.

756. It is believed that as a result of Defendants' violations of 27 U.S.C. § 3729(a)(1), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

757. It is illegal to pass the costs of unlawful promotional activities back to any Federal Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating 31 U.S.C. § 3729(a)(1)-(2), Defendants' conduct violated 31 U.S.C. § 3729(a)(7) as alleged below.

758. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendants made or caused doctors, pharmacies hospitals and other health care providers to make to get false claims paid, and in reliance on the accuracy

thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendants' drugs – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

759. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims for Defendants' drugs. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

760. By reason of Defendants' unlawful practices, as aforesaid, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to prescribe and purchase substantial quantities of Defendants' drugs and thus provided substantial profits to Defendants. Moreover these purchases of Defendants drugs occurred rather than purchases of less expensive procedures or treatment options for patients.

761. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants' false records and statements made or used or caused to be made or used to the United States were material. Plaintiff United States, being unaware of the falsity of the record and/or statements made or caused to be made by Defendants, and in reliance on the accuracy thereof, paid claims that Defendants knew to be false, as they intended.

762.

763. Kelly is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT TWO:

CONSPIRACY TO DEFRAUD: FEDERAL FCA, 31 U.S.C. § 3729(a)(3)

769. Relator Kelly and the United States reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein.

770. This is a *qui tam* action brought by Kelly and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

771. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(C)

provides: Liability for certain acts. Any person who—

> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, … *Id.*

774. In violation of 31 U.S.C. §3729(a)(3), by the foregoing acts and omissions, Defendant Defendants conspired with physicians, paid consultants and others including but not limited to those physicians identified in this complaint to defraud the United States by getting false and fraudulent claims for Xolair paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

331. Defendants knowingly conspired to defraud the United States causing increased sales of Xolair through unlawful promotion and other unlawful activities in violation of law. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

332. Defendants knowingly conspired to violate the FCA by causing false or

fraudulent claims to be presented and to make or use false records or statements to get such claims reimbursed, all of which damaged the Federal Health Care Programs. Said claims were improper and would not have been made but for the unlawful promotional activities, which caused the prescriptions of Xolair to be made. Said claims were also monetarily excessive in cost due to the unlawful promotional activities of the Defendants. Said actions constitute violations of 31 U.S.C. § 3729(a)(3).

333. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotion of Xolair. It is illegal to pass the costs incurred in unlawful promotional activities back to any Federal Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 31 U.S.C. § 3729(a)(3). Federal Health Care Programs have been damaged and suffered losses because of the illegal actions by Defendants.

774. By the foregoing acts and omissions, Defendants took actions in furtherance of their conspiracies, including but not limited to the payment of substantial sums of monies and/or illegal kickbacks to its co-conspirators as well as entering into unlawful contracts. Indeed, Defendants conspired to violate the AKS by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions of Xolair, including for off-label uses. Said actions constitute violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(3). Defendants committed other overt acts set forth above in furtherance of that conspiracy, all in violation of the laws of and causing damage to the United States.

775. As a consequence of Defendants' violations of 27 U.S.C. §3729 (a)(3), the United States has suffered substantial losses in an amount that exceeds the tens of millions of dollars,

and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendants conspired to get paid or allowed.

776. Kelly is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of herself and the United States.

COUNT THREE:

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. § 3729(a)(7)

334. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

335. The Federal FCA, 31 U.S.C. § 3729(a)(7), makes it illegal for any person to "knowingly" make, use or cause to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law. Claims to Government Health Care Programs as described above were false or fraudulent and the statements and records were false because they were monetarily excessive.

336. Defendants' conduct violated 31 U.S.C. § 3729(a)(7), and caused harm and damage to Government Health Care Programs.

COUNT FOUR:

VIOLATIONS OF THE CALIFORNIA FCA

Cal. Gov't Code § 12651(a)(1)

337. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

338. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

339. Defendants knowingly presented or caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov't Code § 12651(a)(1).

340. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIVE:

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(2)

341. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by

reference.

342. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state… for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

343. Defendants knowingly made, used and/or caused to be made or used false records and statements to get false and fraudulent claims paid and approved by the California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(2).

344. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIX:

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(3)

345. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

346. The California False Claims Act, Cal. Gov't Code § 12651(a)(3), specifically provides:

"Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:

…Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . . ."

347. Defendants conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

348. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVEN:

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(7)

349. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

350. The California False Claims Act, Cal. Gov't Code § 12651(a)(7), specifically provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and

may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state . . . .

351. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Cal. Gov't Code § 12651(a)(7).

352. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHT:

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT C.R.S. §25.5-4-305(1)(a)

353. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

354. The Colorado Medicaid False Claims Act, C.R.S. §25.5-4-303.5 *et seq.* specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

"Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval ."

355. Defendants knowingly presented or caused to be presented to the Colorado Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of C.R.S. §25.5-4-305(1)(a).

356. The State of Colorado paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINE:

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT C.R.S. §25.5-4-305(1)(b)

357. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

358. The Colorado Medicaid False Claims Act, C.R.S. §25.5-4-303.5 *et seq.* specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

> "Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim."

359. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Colorado, in violation of C.R.S. §25.5-4-305(1)(b).

360. The State of Colorado paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TEN:

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT C.R.S. §25.5-4-305(1)(g)

361. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

362. The Colorado Medicaid False Claims Act, C.R.S. §25.5-4-303.5 *et seq.* specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

"Conspires to commit a violation of [the Colorado Medicaid False Claims Act]."

363. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of C.R.S. §25.5-4-305(1)(g).

364. The State of Colorado paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ELEVEN:

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT C.R.S. §25.5-4-305(1)(f)

365. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

366. The Colorado Medicaid False Claims Act, C.R.S. §25.5-4-303.5 *et seq.* specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

"Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act.'"

367. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of C.R.S. §25.5-4-305(1)(f).

368. The State of Colorado paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWELVE:

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT
Conn. Sec. 17b-301b(a)(1)

369. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

370. The Connecticut False Claims Act, Conn. Sec. 17b-301a *et seq.*, specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

"Knowingly present[s], or cause[s] to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services."

371. Defendants knowingly presented or caused to be presented to the Connecticut Medicaid program false claims for payment and approval, claims which failed to disclose the

material violations of the AKA and other laws, in violation of Conn. Sec. 17b-301b(a)(1).

372. The State of Connecticut paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTEEN:

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT
Conn. Sec. 17b-301b(a)(2)

373. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

374. The Connecticut False Claims Act, Conn. Sec. 17b-301a *et seq*., specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

> "Knowingly make[s], use[s] or cause[s] to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services."

375. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Connecticut, in violation of Conn. Sec. 17b-301b(a)(2).

376. The State of Connecticut paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FOURTEEN:

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT
Conn. Sec. 17b-301b(a)(3)

377. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

378. The Connecticut False Claims Act, Conn. Sec. 17b-301a *et seq.*, specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

> "Conspire[s] to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services."

379. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Conn. Sec. 17b-301b(a)(3).

380. The State of Connecticut paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTEEN:

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT
Conn. Sec. 17b-301b(a)(7)

381. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

382. The Connecticut False Claims Act, Conn. Sec. 17b-301a *et seq.*, specifically provides, in part, that any person is liable to the state for a civil penalty of not less than five

thousand dollars and not more than ten thousand dollars, plus three times the amount of damages that the state sustains because of the act of that person if the person:

> "Knowingly make[s], use or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services."

383. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Conn. Sec. 17b-301b(a)(7).

384. The State of Connecticut paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTEEN:

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(1)

385. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

386. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

> (a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

387. Defendants knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

388. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTEEN:

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(2)

389. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

390. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

> (a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

391. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

392. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTEEN:

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(3)

393. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

394. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(3), specifically provides, in part, that any person who:

> (a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

395. Defendants conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

396. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETEEN:

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(7)

397. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

398. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §

1201(a)(7), specifically provides, in part, that any person who:

> (a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

399. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

400. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY:

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(1)

401. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

402. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for

the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

403. Defendants knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308.14(a)(1).

404. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-ONE:

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(2)

405. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

406. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to

the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

407. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

408. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-TWO:

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(3)

409. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

410. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(3), specifically provides:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

411. Defendants conspired to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

412. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-THREE:

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(7)

413. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

414. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(7), specifically provides, in part:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government;

415. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of D.C. Code § 2-308.14(a)(7).

416. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FOUR:

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(a)

417. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

418. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), specifically provides, in part, that any person who:

> (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval; …is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

419. Defendants knowingly presented or caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Fla. Stat. § 68.082(2)(a).

420. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FIVE:

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(b)

421. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

422. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), specifically provides, in part, that any person who:

> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; …
>
> is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

423. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Florida, in violation of Fla. Stat. § 68.082(2)(b).

424. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SIX:

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(c)

425. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

426. The Florida False Claims Act, Fla. Stat. § 68.082(2)(c), specifically provides, in part, that any person who:

> (c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose

of getting a false or fraudulent claim allowed or paid;. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

427. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

428. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SEVEN:

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(g)

429. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

430. The Florida False Claims Act, Fla. Stat. § 68.082(2)(g), specifically provides, in part, that any person who:

(g) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

431. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Fla. Stat. § 680.82(2)(g).

432. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-EIGHT:

VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT O.C.G.A. § 49-1-168.1(a)(1)

433. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

434. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-1-168 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval."

435. Defendants knowingly presented or caused to be presented to the Georgia Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of O.C.G.A. § 49-1-168.1(a)(1).

436. The State of Georgia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-NINE:

VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT O.C.G.A. § 49-1-168.1(a)(2)

437. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

438. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-1-168 *et seq.*, specifically provides, in part, that any person who:

"Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program."

439. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Georgia, in violation of O.C.G.A. § 49-1-168.1(a)(2).

440. The State of Georgia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY:

VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT O.C.G.A. § 49-1-168.1(a)(3)

441. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

442. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-1-168 *et seq.*, specifically provides, in part, that any person who:

"Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid."

443. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of O.C.G.A. § 49-1-168.1(a)(3).

444. The State of Georgia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-ONE:

VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT

O.C.G.A. § 49-1-168.1(a)(7)

445. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

446. The Georgia False Medicaid Claims Act, O.C.G.A. § 49-1-168 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia."

447. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of O.C.G.A. § 49-1-168.1(a)(7).

448. The State of Georgia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-TWO:

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(1)

449. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

450. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

451. Defendants knowingly presented or caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Haw. Rev. Stat. § 661-21(a)(1).

452. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-THREE:

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(2)

453. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

454. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(2), specifically provides, in part, that any person who:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

455. Defendants knowingly made, used and caused to be made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

456. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FOUR:

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(3)

457. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

458. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

459. Defendants conspired to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

460. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FIVE:

VIOLATIONS OF THE HAWAII FCA

Haw. Rev. Stat. § 661-21(a)(7)

461. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

462. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(7), specifically provides, in part, that any person who:

> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

463. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Haw. Rev. Stat. § 661-21(a)(7).

464. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SIX:

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3 (a)(1)

465. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by

reference.

466. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

467. Defendants knowingly caused to be presented to the Illinois Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

468. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SEVEN:

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(2)

469. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

470. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses or causes to be made or used, a false record or statement to

get a false or fraudulent claim paid or approved by the State;

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

471. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

472. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-EIGHT;

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(3)

473. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

474. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(3), specifically provides, in part, that any person who:

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

475. Defendants conspired to defraud the State of Illinois by getting false and fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

476. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-NINE:

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(7)

477. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

478. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(7), specifically provides, in part, that any person who:

> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

479. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

480. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY:

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5(1)

481. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

482. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b)(1) (2005) specifically provides, in part, that any person who:

> presents a false claim to the state for payment or approval . . . shall be liable to the state for civil penalties [of at least $5,000 per occurrence] and three times the amount of damages that the state sustains because of the act of that person.

483. Defendants knowingly presented or caused to be presented to the Indiana Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of IC 5-11-5.5-2(b)(1).

484. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-ONE:

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5(2)

485. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

486. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b)(2) (2005) specifically provides, in part, that any person who:

> makes or uses a false record or statement to obtain payment or approval of a false claim from the state . . . shall be liable to the state for civil penalties [of at least $5,000 per occurrence] and three times the amount of damages that the state sustains because of the act of that person.

487. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Indiana, in violation of IC 5-11-5.5-2(b)(2).

488. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-TWO:

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5(7)

489. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

490. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b)(7) (2005) specifically provides, in part, that any person who:

> conspires with another person to perform an act [prohibited by the Act]. . . shall be liable to the state for civil penalties [of at least $5,000 per occurrence] and three times the amount of damages that the state sustains because of the act of that person.

491. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of IC 5-11-5.5-2(b)(7).

492. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-THREE:

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5(6)

493. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

494. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b)(6) (2005), specifically provides, in part, that any person who:

> makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state. . . shall be liable to the state for civil penalties [of at least $5,000 per occurrence] and three times the amount of damages that the state sustains because of the act of that person.

495. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of IC 5-11-5.5-2(b)(6).

496. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FOUR:

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT IOWA CODE §685.2(1)(a)

497. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

498. The Iowa False Claims Act, §685.1 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

"Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

499. Defendants knowingly presented or caused to be presented to the Iowa Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Ia. Code. § 685.2(1)(a).

500. The State of Iowa paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FIVE:

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT
IOWA CODE §685.2(1)(b)

501. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

502. The Iowa False Claims Act, §685.1 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

"Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

503. Defendants knowingly made, used and caused to be made and used, false records

and statements to get false and fraudulent claims paid and approved by an agency of the State of Iowa, in violation of Ia. Code. § 685.2(1)(b).

504. The State of Iowa paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-SIX:

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT
IOWA CODE §685.2(1)(c)

505. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

506. The Iowa False Claims Act, §685.1 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

"Conspires to commit a violation of [the Iowa False Claims Act.]"

507. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Ia. Code. § 685.2(1)(c).

508. The State of Iowa paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-SEVEN:

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT
IOWA CODE §685.2(1)(g)

509. Relator restates and realleges the allegations contained in Paragraphs 1-324 above

as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

510. The Iowa False Claims Act, §685.1 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not less than five thousand dollars and not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state."

511. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Ia. Code. § 685.2(1)(g).

512. The State of Iowa paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-EIGHT:

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3A

513. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

514. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, specifically provides, in part, that: "No

person shall knowingly present or cause to be presented a false or fraudulent claim."

515. Defendants knowingly presented or caused to be presented to the Louisiana Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 46 La. Rev. Stat. c. 3 § 438.3A.

516. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-NINE:

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3B

517. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

518. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, specifically provides, in part, that:

> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

519. Defendants knowingly engaged in misrepresentation and made, used and caused to be made and used, false records and statements to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Illinois, in violation of 46 La. Rev. Stat. c. 3 § 438.3B.

520. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY:

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3C

521. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

522. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3C, specifically provides, in part, that:

> No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

523. Defendants conspired to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid, in violation of 46 La. Rev. Stat. c. 3 § 438.3C.

524. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-ONE:

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.2A(1)

525. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

526. Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.2A(1), specifically provides that:

> "No person shall solicit, receive, offer or pay any remuneration, including but not limited

to kickbacks, bribes, rebates, or … payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following . ..

(1) In return for referring an individual to a health care provider, …for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs."

527. In addition, the Louisiana FCA, supra, section 438.3 provides that:

"No person shall knowingly present of cause to be presented a false or fraudulent claim…shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds…shall conspire to defraud, or attempt to defraud, the medical assistance programs… ."

528. Furthermore, the Louisiana FCA, supra, section 438.4 provides that:

"No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility … to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive."

529. Defendants solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat. c. 3 § 438.2A(1).

530. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-TWO:

VIOLATIONS OF THE MARYLAND FALSE CLAIMS ACT OF 2010
Md. Health-General Code Ann. §2-602(a)(1)

531. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

532. The Maryland False Claims Act of 2010, Md. Health-General Code Ann. § 2-601 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

> "Knowingly present[s] or cause[s] to be presented a false or fraudulent claim for approval."

533. Defendants knowingly presented or caused to be presented to the Maryland Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Md. Health-General Code Ann. § 2-602(a)(1).

534. The State of Maryland paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-THREE:

VIOLATIONS OF THE MARYLAND FALSE CLAIMS ACT OF 2010
Md. Health-General Code Ann. §2-602(a)(2)

535. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

536. The Maryland False Claims Act of 2010, Md. Health-General Code Ann. § 2-601 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not

more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

"Knowingly make[s], use[s] or cause[s] to be made or used a false record or statement material to a false or fraudulent claim."

537. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Maryland, in violation of Md. Health-General Code Ann. § 2-602(a)(2).

538. The State of Maryland paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FOUR:

VIOLATIONS OF THE MARYLAND FALSE CLAIMS ACT OF 2010
Md. Health-General Code Ann. §2-602(a)(3)

539. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

540. The Maryland False Claims Act of 2010, Md. Health-General Code Ann. § 2-601 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

"Conspires to commit a violation under [the Maryland False Claims Act of 2010.]"

541. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting

false and fraudulent claims allowed and paid, in violation of Md. Health-General Code Ann. § 2-602(a)(3).

542. The State of Maryland paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FIVE:

VIOLATIONS OF THE MARYLAND FALSE CLAIMS ACT OF 2010
Md. Health-General Code Ann. §2-602(a)(7)

543. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

544. The Maryland False Claims Act of 2010, Md. Health-General Code Ann. § 2-601 *et seq.* specifically provides, in part, that a person is liable to the state for a civil penalty of not more than ten thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person if that person:

> "Knowingly make[s], use[s], or cause[s] to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the state."

545. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Md. Health-General Code Ann. § 2-602(a)(7).

546. The State of Maryland paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-SIX:

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(1)

547. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

548. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

549. Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

550. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-SEVEN:

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(2)

551. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

552. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

553. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of claim by the Commonwealth of Massachusetts, in violation of Mass. Gen. Laws Ch. 12, § 5B(2).

554. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-EIGHT:

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(3)

555. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

556. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(3), specifically provides, in part, that any person who:

> "(3) conspires to defraud the commonwealth or any political subdivision thereof through

the allowance or payment of a fraudulent claim;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person."

557. Defendants conspired to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

558. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-NINE:

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(8)

559. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

560. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(8), specifically provides, in part, that any person who:

"(8) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person."

561. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Mass. Gen. Laws Ch. 12, § 5B(8).

562. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY:

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MI ST Ch. 400.607(2)

563. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

564. The Michigan Medicaid False Claims Act, MI ST Ch. 400.607(2) and MI ST Ch. 400.612 specifically provides, in part, that any person:

"shall not make or present or cause to be made or presented a claim . . . that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards

. . . [and that such person]

who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages in any conduct prohibited by this statute, shall forfeit and pay to the state the full amount received, and for each claim a civil penalty of not less than $5,000.00 or more than

$10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person."

565. Defendants knowingly presented or caused to be presented to the Mich. Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of MI ST Ch. 400.607(2).

566. The State of Michigan paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-ONE:

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MI ST Ch. 400.603

567. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

568. The Michigan Medicaid False Claims Act, MI ST Ch. 400.603 and MI ST Ch. 400.612 specifically provides, in part, that any person:

"shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits… [or] for use in determining rights to a Medicaid benefit [and such person] having knowledge of the occurrence of an event affecting …[the] initial or continued right of any other person on whose behalf he has applied…shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled

. . . [and that such person]

who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages in any conduct prohibited by this statute, shall forfeit and pay to the state the full amount received, and for each claim a civil penalty of not less than $5,000.00 or more than $10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person."

569. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Michigan, in violation of MI ST Ch. 400.603.

570. The State of Michigan paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-TWO:

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MI ST Ch. 400.606

571. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

572. The Michigan Medicaid False Claims Act, MI ST Ch. 400.606 and MI ST Ch. 400.612 specifically provides, in part, that any person who:

"shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim . . . [and that such person]

who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages

in any conduct prohibited by this statute, shall forfeit and pay to the state the full amount received, and for each claim a civil penalty of not less than $5,000.00 or more than $10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person."

573. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of MI ST Ch. 400.606.

574. The State of Michigan paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-THREE:

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MI ST Ch. 400.607(3)

575. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

576. The Michigan Medicaid False Claims Act, MI ST Ch. 400.607(3) and MI ST Ch. 400.612 specifically provides, in part, that any person:

"shall not knowingly make, use, or cause to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act

. . . [and that such person]

who receives a benefit that the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact, or who engages in any conduct prohibited by this statute, shall forfeit and pay to the state the full amount

received, and for each claim a civil penalty of not less than $5,000.00 or more than $10,000.00 plus triple the amount of damages suffered by the state as a result of the conduct by the person."

577. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of MI ST Ch. 400.607(3).

578. The State of Michigan paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-FOUR:

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT
Minn. Stat. §15C.02(a)(1)

579. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

580. The Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*. specifically provides, in part, that a person is liable to the state or the political subdivision for a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim, plus three times the amount of damages that the state or the political subdivision sustains because of the act of that person, if the person:

"Knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval."

581. Defendants knowingly presented or caused to be presented to the Minnesota Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Minn. Stat. § 15C.02(a)(1).

582. The State of Minnesota paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-FIVE:

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT
Minn. Stat. §15C.02(a)(2)

583. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

584. The Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*. specifically provides, in part, that a person is liable to the state or the political subdivision for a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim, plus three times the amount of damages that the state or the political subdivision sustains because of the act of that person, if the person:

> "Knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision."

585. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Minnesota, in violation of Minn. Stat. § 15C.02(a)(2).

586. The State of Minnesota paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-SIX:

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT
Minn. Stat. §15C.02(a)(3)

587. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

588. The Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*. specifically provides, in part, that a person is liable to the state or the political subdivision for a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim, plus three times the amount of damages that the state or the political subdivision sustains because of the act of that person, if the person:

> "Knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim."

589. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Minn. Stat. § 15C.02(a)(3).

590. The State of Minnesota paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-SEVEN:

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT
Minn. Stat. §15C.02(a)(7)

591. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

592. The Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*., specifically provides, in part, that a person is liable to the state or the political subdivision for a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim, plus three times the amount of damages that the state or the political subdivision sustains because of the act of that person, if the person:

> "Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or a political subdivision."

593. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Minn. Stat. § 15C.02(a)(7).

594. The State of Minnesota paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-EIGHT:

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Montana Code § 17-8-403(a)

595. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

596. The Montana False Claims Act, Montana Code § 17-8-401 *et seq.* specifically provides, in part, that any person may be liable to a governmental entity for a civil penalty of not less than $5,000 and not more than $10,000 plus three times the amount of damages that a governmental entity sustains because of the person's act, along with expenses, costs, and attorney fees, if the person:

"Knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval."

597. Defendants knowingly presented or caused to be presented to the Montana Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Montana Code § 17-8-403(a).

598. The State of Montana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTY-NINE:

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Montana Code § 17-8-403(b)

599. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

600. The Montana False Claims Act, Montana Code § 17-8-401 *et seq.*, specifically provides, in part, that any person may be liable to a governmental entity for a civil penalty of not less than $5,000 and not more than $10,000 plus three times the amount of damages that a governmental entity sustains because of the person's act, along with expenses, costs, and attorney fees, if the person:

"Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity."

601. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Montana, in violation of Montana Code § 17-8-403(b).

602. The State of Montana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY:

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Montana Code § 17-8-403(c)

603. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

604. The Montana False Claims Act, Montana Code § 17-8-401 *et seq.* specifically provides, in part, that any person may be liable to a governmental entity for a civil penalty of not less than $5,000 and not more than $10,000 plus three times the amount of damages that a governmental entity sustains because of the person's act, along with expenses, costs, and attorney fees, if the person:

> "Conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity."

605. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Montana Code § 17-8-403(c).

606. The State of Montana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-ONE:

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Montana Code § 17-8-403(g)

607. Relator restates and realleges the allegations contained in Paragraphs 1-324 above

as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

608. The Montana False Claims Act, Montana Code § 17-8-401 *et seq.*, specifically provides, in part, that any person may be liable to a governmental entity for a civil penalty of not less than $5,000 and not more than $10,000 plus three times the amount of damages that a governmental entity sustains because of the person's act, along with expenses, costs, and attorney fees, if the person:

> "Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors."

609. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Montana Code § 17-8-403(g).

610. The State of Montana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-TWO:

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(a)

611. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

612. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable

to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

(a) Knowingly presents or causes to be presented a false claim for payment or approval.

613. Defendants knowingly presented or caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Nev. Rev. Stat. § 357.040(1)(a).

614. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-THREE:

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(b)

615. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

616. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), specifically provides, in part, that a person who:

"With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

. . .

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim."

617. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

618. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-FOUR:

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(c)

619. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

620. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(c), specifically provides, in part, that a person who:

"With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

. . .

(c) Conspires to defraud by obtaining allowance or payment of a false claim."

621. Defendants conspired to defraud the State of Nevada by obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

622. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-FIVE:

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(g)

623. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

624. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(g), specifically provides, in part, that a person who:

> "With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (g) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state…."

625. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Nev. Rev. Stat. 357.040(1)(g).

626. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-SIX:

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b I. (a)

627. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

628. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.*, specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty (of not less than $5,000 and not more than $10,000) and three times the amount of damages that the state sustains because of the act if that person:

> "presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim."

629. Defendants knowingly presented or caused to be presented to the New Hampshire Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of N.H. RSA § 167:61-b I. (a).

630. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-SEVEN:

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b I.(b)

631. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

632. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.*,

specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty (of not less than $5,000 and not more than $10,000) and three times the amount of damages that the state sustains because of the act if that person:

> "makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false"

633. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of New Hampshire, in violation of N.H. RSA § 167:61-b I.(b).

634. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-EIGHT:

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b (I)(c)

635. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

636. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.*, specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty (of not less than $5,000 and not more than $10,000) and three times the amount of damages that the state sustains because of the act if that person:

> "conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent."

637. Defendants conspired to submit a false claim to Government Health Care

Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of N.H. RSA § 167:61-b I.(c).

638. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTY-NINE:

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b I (e)

639. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

640. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.*, specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty (of not less than $5,000 and not more than $10,000) and three times the amount of damages that the state sustains because of the act if that person:

> "makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…"

641. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of N.H. RSA § 167:61-b I.(e).

642. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY:

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT
New Jersey Stat. § 2A:32C-3(a)

643. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

644. The New Jersey False Claims Act, New Jersey Stat. § 2A:32C-1 *et seq.* specifically provides, in part, that a person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person:

> "Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval."

645. Defendants knowingly presented or caused to be presented to the New Jersey Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of N.J. Stat. § 2A:32C-3(a).

646. The State of New Jersey paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-ONE:

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT
New Jersey Stat. § 2A:32C-3(b)

647. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

648. The New Jersey False Claims Act, New Jersey Stat. § 2A:32C-1 *et seq.* specifically provides, in part, that a person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person:

> "Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State."

649. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of New Jersey, in violation of N.J. Stat. § 2A:32C-3(b).

650. The State of New Jersey paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-TWO:

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT
New Jersey Stat. § 2A:32C-3(c)

651. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

652. The New Jersey False Claims Act, New Jersey Stat. § 2A:32C-1 *et seq.* specifically provides, in part, that a person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person:

"Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State."

653. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of N.J. Stat. § 2A:32C-3(c).

654. The State of New Jersey paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-THREE:

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT
New Jersey Stat. § 2A:32C-3(g)

655. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

656. The New Jersey False Claims Act, New Jersey Stat. § 2A:32C-1 *et seq.* specifically provides, in part, that a person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person:

"Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State."

657. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of N.J. Stat. § 2A:32C-3(g).

658. The State of New Jersey paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-FOUR:

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. Stat. §§ 27-14-4A and N.M. Stat. §§ 27-14-4B

659. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

660. The New Mexico Medicaid False Claims Act, §§ 27-14-1 *et seq.*, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person":

> "4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;
>
> 4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program"

661. Defendants knowingly presented or caused to be presented to the New Mexico Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of N.M. § 27-14-4A and N.M. § 27-14-4B.

662. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-FIVE:

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. Stat. §§ 27-14-4C

663. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

664. The New Mexico Medicaid False Claims Act, §§ 27-14-1 *et seq.*, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if the person":

> "4C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false."

665. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of New Mexico, in violation of N.M. § 27-14-4C.

666. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-SIX:

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT
N.M. Stat. §§ 27-14-4D

667. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

668. The New Mexico Medicaid False Claims Act, §§ 27-14-1 *et seq.*, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if the person."

669. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of N.M. § 27-14-4D.

670. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-SEVEN:

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. Stat. §§ 27-14-4E

671. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

672. The New Mexico Medicaid False Claims Act, §§ 27-14-1 *et seq.*, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if the person":

> "4E. makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…"

673. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit

money to the state, in violation of N.M. § 27-14-4E.

674. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-EIGHT:

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT
N.Y. C.L.S. St. Fin. § 189(1)(a)

675. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

676. The New York False Claims Act, N.Y. C.L.S. St. Fin. § 187 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval . . . shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person."

677. Defendants knowingly presented or caused to be presented to the New York Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of N.Y. C.L.S. St. Fin. § 189(1)(a).

678. The State of New York paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTY-NINE:

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT
N.Y. C.L.S. St. Fin. § 189(1)(b)

679. Relator restates and realleges the allegations contained in Paragraphs 1-324 above

as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

680. The New York False Claims Act, N.Y. C.L.S. St. Fin. § 187 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person."

681. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of New York, in violation of N.Y. C.L.S. St. Fin. § 189(1)(b).

682. The State of New York paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY:

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT
N.Y. C.L.S. St. Fin. § 189(1)(c)

683. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

684. The New York False Claims Act, N.Y. C.L.S. St. Fin. § 187 *et seq.*, specifically provides, in part, that any person who:

"Conspires to commit a violation of [the New York False Claims Act] . . . shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person."

685. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of N.Y. C.L.S. St. Fin. § 189(1)(c).

686. The State of New York paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-ONE:

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT
N.Y. C.L.S. St. Fin. § 189(1)(g)

687. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

688. The New York False Claims Act, N.Y. C.L.S. St. Fin. § 187 *et seq.*, specifically provides, in part, that any person who:

"Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person."

689. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of N.Y. C.L.S. St. Fin. § 189(1)(g).

690. The State of New York paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-TWO:

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT
N.C. Art. 52 §1-607(a)(1)

691. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

692. The North Carolina False Claims Act, N.C. Art. 52, § 1-605 *et seq.*, specifically provides, in part, that a person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation if the person:

> "Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval."

693. Defendants knowingly presented or caused to be presented to the North Carolina Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of N.C. Art. 52, § 1-607(a)(1).

694. The State of North Carolina paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-THREE:

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. Art. 52 §1-607(a)(2)

695. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

696. The North Carolina False Claims Act, N.C. Art. 52, § 1-605 *et seq.*, specifically provides, in part, that a person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation if the person:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

697. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of North Carolina, in violation of N.C. Art. 52, § 1-607(a)(2).

698. The State of North Carolina paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-FOUR:

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT
N.C. Art. 52 §1-607(a)(3)

699. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

700. The North Carolina False Claims Act, N.C. Art. 52, § 1-605 *et seq.*, specifically provides, in part, that a person who commits any of the following acts also shall be liable to the

State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation if the person:

"Conspires to commit a violation of [the North Carolina False Claims Act.]"

701. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of N.C. Art. 52, § 1-607(a)(3).

702. The State of North Carolina paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-FIVE:

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT
N.C. Art. 52 §1-607(a)(7)

703. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

704. The North Carolina False Claims Act, N.C. Art. 52, § 1-605 *et seq.*, specifically provides, in part, that a person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation if the person:

"Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State."

705. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of N.C. Art. 52, § 1-607(a)(7).

706. The State of North Carolina paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-SIX:

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. Title 63, § 5053.1 (B)(1)

707. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

708. The Oklahoma Medicaid False Claims Act, Okla. Stat. Title 63, § 5053.1 *et seq*., specifically provides, in part, that any person who:

> "Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval. . . is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars ($5,000.00) and not more than Ten Thousand Dollars ($10,000.00) . . . plus three times the amount of damages which the state sustains because of the act of that person."

709. Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Okla. Stat. Title 63, § 5053.1(B)(1).

710. The State of Oklahoma paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-SEVEN:

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. Title 63, § 5053 (B)(2)

711. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

712. The Oklahoma Medicaid False Claims Act, Okla. Stat. Title 63, § 5053.1 *et seq*., specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state. . . is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars ($5,000.00) and not more than Ten Thousand Dollars ($10,000.00) . . . plus three times the amount of damages which the state sustains because of the act of that person."

713. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Oklahoma, in violation of Okla. Stat. Title 63, § 5053.1(B)(2).

714. The State of Oklahoma paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-EIGHT:

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. Title 63, § 5053 (B)(3)

715. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

716. The Oklahoma Medicaid False Claims Act, Okla. Stat. Title 63, § 5053 *et seq*., specifically provides, in part, that any person who:

> "Conspires to defraud the state by getting a false or fraudulent claim allowed or paid. . . is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars ($5,000.00) and not more than Ten Thousand Dollars ($10,000.00) . . . plus three times the amount of damages which the state sustains because of the act of that person."

717. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Okla. Stat. Title 63, § 5053.1(B)(3).

718. The State of Oklahoma paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETY-NINE:

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT
Okla. Stat. Title 63, § 5053 (B)(7)

719. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

720. The Oklahoma Medicaid False Claims Act, Okla. Stat. Title 63, § 5053 *et seq*., specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state. . . is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars ($5,000.00) and not more than Ten Thousand Dollars ($10,000.00) . . .

plus three times the amount of damages which the state sustains because of the act of that person."

721. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Okla. Stat. Title 63, § 5053.1(B)(7).

722. The State of Oklahoma paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED:

VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT
R.I. Gen. Laws. § 9-1.1-3(a)(1)

723. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

724. The Rhode Island State False Claims Act, R.I. Gen. Laws. § 9-1.1-1 *et seq.*, specifically provides, in part, that any person who:

"Knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval . . . is liable to the state for a civil penalty of not less than five thousand dollars ($ 5,000) and not more than ten thousand dollars ($ 10,000). . . . plus three (3) times the amount of damages which the state sustains because of the act of that person . . ."

725. Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of R.I. Gen. Laws. § 9-1.1-3(a)(1).

726. The State of Rhode Island paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED ONE:

VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT
R.I. Gen. Laws. § 9-1.1-3(a)(2)

727. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

728. The Rhode Island State False Claims Act, R.I. Gen. Laws. § 9-1.1-1 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state . . . is liable to the state for a civil penalty of not less than five thousand dollars ($ 5,000) and not more than ten thousand dollars ($ 10,000). . . . plus three (3) times the amount of damages which the state sustains because of the act of that person . . ."

729. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Rhode Island, in violation of R.I. Gen. Laws. § 9-1.1-3(a)(2).

730. The State of Rhode Island paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TWO:

VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT
R.I. Gen. Laws. § 9-1.1-3(a)(3)

731. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

732. The s Rhode Island State False Claims Act, R.I. Gen. Laws. § 9-1.1-1 *et seq.*, specifically provides, in part, that any person who:

> "Conspires to defraud the state by getting a false or fraudulent claim allowed or paid . . . is liable to the state for a civil penalty of not less than five thousand dollars ($ 5,000) and not more than ten thousand dollars ($ 10,000). . . . plus three (3) times the amount of damages which the state sustains because of the act of that person . . ."

733. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of R.I. Gen. Laws. § 9-1.1-3(a)(3).

734. The State of Rhode Island paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED THREE:

VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT
R.I. Gen. Laws. § 9-1.1-3(a)(7)

735. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

736. The Rhode Island State False Claims Act, R.I. Gen. Laws. § 9-1.1-1 *et seq.*, specifically provides, in part, that any person who:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, is liable to the state for a civil penalty of not less than five thousand dollars ($ 5,000) and not more than ten thousand dollars ($ 10,000). . . . plus three (3) times the amount of damages which the state sustains because of the act of that person . . . "

737. Defendants knowingly made, used or caused to be made or used a false record or

statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of R.I. Gen. Laws. § 9-1.1-3(a)(7).

738. The State of Rhode Island paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED FOUR:

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(A)

739. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

740. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically provides, in part, that any person who:

> (A) Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

741. Defendants knowingly presented or caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

742. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED FIVE:

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(B)

743. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

744. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), specifically provides, in part, that any person who:

> "Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person."

745. Defendants made, used and caused to be made and used, records and statements to get false and fraudulent claims under the Medicaid program paid and approved by the State of Tennessee knowing such records and statements were false, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

746. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED SIX:

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(C)

747. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

748. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C), specifically provides, in part, that any person who:

> "Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person."

749. Defendants conspired to defraud the State of Tennessee by getting claims allowed and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(C).

750. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED SEVEN:

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(D)

751. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

752. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(D), specifically provides, in part, that any person who:

"Makes, uses, or causes to be made or sued, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program knowing such record or statement is false;

. . .

is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person."

753. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

754. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED EIGHT:

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(1)-(2)

755. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

756. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), specifically provides, in part, that a person commits an unlawful act if the person:

"knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

(A) on an application for a contract, benefit, or payment under the Medicaid program; or

(B) that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program."

757. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(2)(B), specifically provides, in part, that a person commits an unlawful act if the person:

"knowingly or intentionally conceals or fails to disclose an event: (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized… ."

758. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

759. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT ONE HUNDRED NINE:

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(4)(B)

760. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

761. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

"knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

. . .

(B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program"

762. Defendants by knowingly and intentionally causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and provider agreements pertaining to the Medicaid program, are in violation of Tex. Hum. Res. Code § 36.002(4)(B).

763. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TEN:

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(5)

764. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

765. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

"except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program . . . ."

766. Defendants knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §36.002(5).

767. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED ELEVEN:

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(9)

768. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

769. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

> "knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . ."

770. Defendants knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §36.002(9).

771. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT ONE HUNDRED TWELVE:

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

Va. Code Ann. § 8.01-216.3(A)(1)

772. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

773. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), specifically provides, in part, that any person who:

> "Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth."

774. Defendants knowingly presented or caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

775. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED THIRTEEN:

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(2)

776. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

777. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), specifically provides, in part, that any person who:

"Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth."

778. Defendants knowingly made, used and caused to made and used, false records and statements to get false and fraudulent claims paid and approved by the Commonwealth of Virginia, in violation of Va. Code Ann. §8.01-216.3(A)(2).

779. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED FOURTEEN:

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(3)

780. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

781. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(3), specifically provides, in part, that any person who:

"Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth."

782. Defendants conspired to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann. § 8.01-216.3(A)(3).

783. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED FIFTEEN:

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(7)

784. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

785. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7), specifically provides, in part, that any person who:

"knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth."

786. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit

money to the state, in violation of Va. Code Ann.§ 8.01-216.3(A)(7).

787. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED SIXTEEN:

VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT R.C.W. § 74.09.202(1)(a)

788. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

789. The Washington Medicaid Fraud False Claims Act, R.C.W. § 74.09.201 *et seq.*, specifically provides in part, that a person is liable to the government entity for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars, plus three times the amount of damages which the government entity sustains because of the act of that person, if the person:

> "Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

790. Defendants knowingly presented or caused to be presented to the Washington Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of R.C.W. § 74.09.202(1)(a).

791. The State of Washington paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED SEVENTEEN:

VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT R.C.W. § 74.09.202(1)(b)

792. Relator restates and realleges the allegations contained in Paragraphs 1-324 above

as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

793. The Washington Medicaid Fraud False Claims Act, R.C.W. § 74.09.201 *et seq.*, specifically provides in part, that a person is liable to the government entity for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars, plus three times the amount of damages which the government entity sustains because of the act of that person, if the person:

> "Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."

794. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Washington, in violation of R.C.W. § 74.09.202(1)(b).

795. The State of Washington paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED EIGHTEEN:

VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT R.C.W. § 74.09.202(1)(c)

796. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

797. The Washington Medicaid Fraud False Claims Act, R.C.W. § 74.09.201 *et seq.*, specifically provides in part, that a person is liable to the government entity for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars, plus

three times the amount of damages which the government entity sustains because of the act of that person, if the person:

"Conspires to commit one or more of the violations [of the Washington Medicaid Fraud False Claims Act.]"

798. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of R.C.W. § 74.09.202(1)(c).

799. The State of Washington paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED NINETEEN:

VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT R.C.W. § 74.09.202(1)(g)

800. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

801. The Washington Medicaid Fraud False Claims Act, R.C.W. § 74.09.201 *et seq.,* specifically provides in part, that a person is liable to the government entity for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars, plus three times the amount of damages which the government entity sustains because of the act of that person, if the person:

"Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government entity, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government entity."

802. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of R.C.W. § 74.09.202(1)(g).

803. The State of Washington paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TWENTY:

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS ACT
Wisc. Stat. § 20.931(2)(a)

804. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated by reference.

805. The Wisconsin False Claims Act, Wisc. Stat. § 20.931, specifically provides in part that any person is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation if said person:

> "Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance."

806. Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Wisc. Stat. § 20.931(2)(a).

807. The State of Wisconsin paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TWENTY-ONE:

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS ACT
Wisc. Stat. § 20.931(2)(b)

808. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

809. The Wisconsin False Claims Act, Wisc. Stat. § 20.931, specifically provides in part that any person is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation if said person:

"Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance."

810. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Wisconsin, in violation of Wisc. Stat. § 20.931(2)(b).

811. The State of Wisconsin paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TWENTY-TWO:

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS ACT
Wisc. Stat. § 20.931(2)(c)

812. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

813. The Wisconsin False Claims Act, Wisc. Stat. § 20.931, specifically provides in part that any person is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation if said person:

"Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program."

814. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Wisc. Stat. § 20.931(2)(c).

815. The State of Wisconsin paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ONE HUNDRED TWENTY THREE:

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS ACT
Wisc. Stat. § 20.931(2)(g)

816. Relator restates and realleges the allegations contained in Paragraphs 1-324 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

817. The Wisconsin False Claims Act, Wisc. Stat. § 20.931, specifically provides in part that any person is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation if said person:

"Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance program."

818. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit

money to the state, in violation of Wisc. Stat. § 20.931(2)(g).

819. The State of Wisconsin paid said claims and has sustained damages because of these acts by the Defendants.

* * *

820. Under all Counts set forth above, Relator and all Plaintiffs both seek all damages available at law and in the premises, including, but not limited to, treble damages, civil penalties of $5,500.00 to $11,000.00 per false claim, any greater amounts allowed by statute, as well as attorneys' fees, costs, expenses, and interest.

821. Under all Counts set forth above, Relator seeks the maximum available relator's share of each Government's recovery.

822. WHEREFORE, the U.S.A., California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin pray that judgment be entered in their favor, and against Defendants Novartis, AG; Novartis Corporation; Novartis Pharmaceuticals Corporation; Genentech, Inc.; the Roche Group; and Roche Holdings, Inc., jointly and severally.

PRAYER FOR RELIEF

_. WHEREFORE, Plaintiffs pray for judgment:

• that Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the equivalent provisions of the State statutes set forth above;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the United States has sustained because of

Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of the Connecticut False Claims Act, Chapter 319v, Sec. 17b-301 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount

equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14- 1 *et seq.*, and N.M. Stat. Ann. §44-9-1 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5- 182(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus civil penalties for each violation of I.C. §5-11-5.5 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount

equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I) *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of the Wisc. Stat. §20.931 *et seq.*;

• that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605

et seq.;

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Montana has sustained because of the Defendants' actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*;

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Colorado has sustained because of the Defendants' actions, plus a civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat., § 25.5-1-104 *et seq.*;

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Washington has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each violation of the R.C.W. § 74.09.201 *et seq.*;

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Minnesota has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each violation of the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*;

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages Maryland has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each violation of the Maryland False Health Claims Act of 2010 (Subtitle 6, False Claims Against State Health Plans and State Health Programs, § 2-601 *et seq.*);

• that this court enter judgment in Plaintiffs' favor and against Defendants in an amount

equal to three times the amount of damages Iowa has sustained because of the Defendants' actions, plus a civil penalty of $10,000 for each violation of the Iowa Medicaid False Claims Act;

• that this Court enter judgment in Plaintiffs' favor and against Defendants to the fullest extent possible under all False Claims Acts asserted herein—including by awarding damages and civil penalties in a higher amount to the extent that any such statute, presently or in the future, authorizes a higher amount than set forth herein;

• that Plaintiffs be awarded the maximum amount allowed pursuant to §3730(d) of the federal False Claims Act, and the equivalent provisions of the State statutes set forth above;

• that Plaintiffs and Relators be awarded all costs of this action, including attorneys' fees and expenses; and

• that Plaintiffs recover such other relief as the Court deems just and proper, or that is necessary to make Plaintiffs whole.

JURY DEMAND

Plaintiffs/Relators, for themselves, the U.S.A., and the States, hereby demands a jury trial on all Counts.

Respectfully submitted:

s/ Steven F. Grover

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CERTIFICATE OF SERVICE

*I hereby certify that a copy of the foregoing was served on the U.S.A., all States named herein, and the District of Columbia, by U.S. Mail, properly addressed and first-class postage prepaid, on this 9**th day of Oct., 2012.***

s/ Steven F. Grover

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Steven F. Grover