UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex. rel.* CONSTANCE A. CONRAD,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 02-11738
HEALTHPOINT, LTD.,	)	
Defendant.	)	

COMPLAINT OF THE UNITED STATES

The United States brings this action against defendant Healthpoint, Ltd. ("Healthpoint"), to recover millions of dollars in payments by Medicaid and Medicare for an unapproved prescription drug product called Xenaderm. Xenaderm is a skin ointment primarily used to treat nursing home patients' bed sores (also known as "decubitus ulcers"). Defendant Healthpoint launched Xenaderm as a prescription drug in 2002, without any Food and Drug Administration ("FDA") approval. Xenaderm's principal active ingredient is trypsin, which, according to Xenaderm's label, is intended for the debridement of eschar and necrotic tissue, *i.e.*, for the removal of dead tissue around a wound.

Generally, Medicaid and Medicare pay for covered uses of drugs that have been approved by the FDA for safety and effectiveness, and, with certain conditions, older drugs that were on the market before the 1962 Amendments to the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.* Congress, however, has explicitly prohibited federal payment under these health care programs for prescription drugs determined by the FDA to be "less than effective" ("LTE"), as well as for products that are "identical, related or similar" ("IRS") to LTE products.

In 1970, the FDA announced its determination that trypsin was LTE as a debriding agent. As a result of this determination, which the FDA reiterated in 1976, Xenaderm, a product containing trypsin as a debriding agent and which came on the market much later, was ineligible for federal payments by Medicaid and Medicare.

Healthpoint nonetheless actively promoted Xenaderm as a prescription drug that, unlike non-prescription skin ointments, was "Medicaid reimbursed" and thus cost nursing homes nothing to administer on Medicaid patients. Even after Healthpoint received questions from state Medicaid Programs regarding Xenaderm's coverage status, Healthpoint failed to disclose that the FDA had determined trypsin to be LTE, thus rendering Xenaderm ineligible for reimbursement. From 2002 through 2006, Healthpoint knowingly caused Medicaid and Medicare to pay over $90 million in false prescription claims for unapproved and ineligible Xenaderm. The United States now files this action under the False Claims Act (the "FCA") and the common law to recover damages and civil penalties from Healthpoint for losses suffered by the Medicaid and Medicare programs.

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1345, and 1367(a), and under 31 U.S.C. § 3732.

2. The Court may exercise personal jurisdiction over Healthpoint under 31 U.S.C. § 3732(a), because Healthpoint transacts business in the District of Massachusetts.

3. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Healthpoint transacts business in the District of Massachusetts.

II. THE PARTIES

4. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which includes the Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"), and the FDA.

5. Relator Constance A. Conrad is a resident of the state of Pennsylvania. In 2002, Ms. Conrad filed an action alleging violations of the FCA on behalf of herself and the United States pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

6. Defendant Healthpoint, a subsidiary of DFB Pharmaceuticals, Inc., is a Texas corporation with its principal place of business in Fort Worth, Texas.

III. THE FALSE CLAIMS ACT

7. The False Claims Act provides, in pertinent part, that any person who:

> (a)(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;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . . or
>
> is liable to the United States Government 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 Government sustains because of the act of that person. . . .

31 U.S.C. § 3729.[1] For purposes of the False Claims Act,

> the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the

[1] The False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to this case by virtue of Section 4(f) of FERA, while Section 3279(a)(1) of the statute prior to FERA, and as amended in 1986, remains applicable here.

> information; or (3) acts in reckless disregard of the truth or falsity of the information,
>
> and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b) (1986).

8. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

IV. THE STATUTORY PROHIBTION ON PAYMENT FOR LTE DESI DRUGS

9. Congress first brought drug regulation under federal law in the 1906 Pure Food and Drug Act. *See* Pub. L. No. 59-384, 34 Stat. 768 (1906). Under the 1906 Act, there was no requirement that drugs be approved by the FDA. In 1938, Congress passed the FDCA, which required manufacturers to submit to the FDA a New Drug Application ("NDA") demonstrating safety in order to obtain approval to market a new drug. *See* Pub. L. No. 75-717, 52 Stat. 1040 (1938). In October 1962, Congress amended the FDCA to require manufacturers to demonstrate that a new drug not only was safe, but also effective for its intended uses, in order to obtain FDA approval to market a new drug. *See* 21 U.S.C. § 355(b)(1)(A).

10. Following passage of the 1962 Amendments to the FDCA, the FDA contracted with the National Academy of Sciences/National Research Council ("NAS/NRC") to evaluate the effectiveness of various classes of drug products that had been covered by an approval for safety before 1962. The NAS/NRC submitted findings to the FDA, which conducted its own evaluation and announced its findings in the Federal Register. This process was known as the Drug Efficacy Study Implementation ("DESI") Program.

11. If the DESI review concluded that a drug in a particular class was not effective for some or all of its labeled indications, the FDA published a Notice of Opportunity for a Hearing ("NOOH") in the Federal Register, proposing to withdraw approval for the drug and any IRS drugs. The NOOH gave any affected manufacturer the opportunity to challenge the ineffectiveness determination. If there was no challenge, approval of the drug products subject to the NOOH (including IRS drugs) was rescinded.

12. Drugs for which a NOOH has been issued are referred to as LTE DESI drugs. A drug product that is IRS to a LTE DESI drug is also considered to be an LTE DESI drug.

13. A combination drug product is a drug product that contains more than one drug or active ingredient. *See* C.F.R. § 310.6(b)(2). An LTE determination in a NOOH also applies to a combination product that contains an active ingredient determined to be LTE for the same indication for which it is included in the combination product. *See* 37 Fed. Reg. 23,185, 23,186 (Oct. 31, 1972).

14. In 1981, Congress prohibited federal payment under both Medicaid and Medicare for LTE DESI drugs. 42 U.S.C. § 1396b(i)(5) (Medicaid) and 42 U.S.C. § 1395y(c) (Medicare).

15. Under 42 U.S.C. § 1395y(c), Congress prohibited payment under Medicare for any expenses incurred for a drug product that 1) was approved by the FDA before October 10, 1962, 2) that may be furnished only upon a prescription, 3) that is the subject of a NOOH containing an LTE determination for all labeled indications, and 4) for which the Secretary has not determined there is a compelling justification for its medical need. The prohibition on payment also applies to drugs that are IRS to drugs meeting these conditions. 42 U.S.C. § 1395y(c)(2).

16. In 42 U.S.C. § 1396b(i)(5), Congress prohibited federal payment under Medicaid for drugs that are excluded from payment under 42 U.S.C. § 1395y(c).

17. Shortly after the enactment of 42 U.S.C. § 1395y(c) and §1396b(i)(5), the Secretary of HHS promulgated regulations, pursuant to notice and comment rulemaking, implementing the statutory prohibition on payment for LTE drugs under Medicare and Medicaid. *See* 42 C.F.R. § 441.25; 46 Fed. Reg. 48,550 (Oct. 1, 1981). Drug products that are IRS to a LTE DESI drug product also are ineligible to receive federal funding under Medicare and Medicaid. *See* 42 C.F.R. § 441.25(b).

V. THE MEDICAID AND MEDICARE PROGRAMS

A. The Medicaid Program

18. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

19. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

20. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

21. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C.

§§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

22. Generally, in order for a manufacturer's drugs to be covered under Medicaid, a manufacturer must enter into a standard Rebate Agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1).

23. The Rebate Agreement requires each participating manufacturer to provide CMS with a list of all of its "covered outpatient drugs." Rebate Agreement, II(a). (A copy of the Rebate Agreement between the Secretary and Healthpoint is attached hereto as Exhibit 1.)

24. The term "covered outpatient drug" is defined by the Medicaid Drug Rebate Statute and the Rebate Agreement. The statute specifically addresses the limited circumstances in which an unapproved drug on the market before 1962 falls within the statutory term "covered outpatient drug":

> (1) an unapproved pre-1962 drug that has "not been the subject of a final determination by the Secretary that it is a 'new drug;'" and
>
> (2) a pre-1962 drug reviewed under the DESI Program and which has not been the subject of a LTE determination by the FDA for some or all of its labeled indications in a NOOH.

See 42 U.S.C. § 1396r-8(k)(2); Rebate Agreement, I(g).

B. The Medicare Program

25. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. HHS administers the Medicare program through CMS.

26. Medicare Part D, a voluntary prescription drug benefit program for Medicare enrollees, became effective January 1, 2006.

27. Medicare Part D coverage is offered through private companies, known as Part D sponsors, that contract with CMS to administer prescription drug plans. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329. Throughout the payment year, each time a Medicare beneficiary gets a prescription filled under Part D, the sponsor notifies CMS of the event, including the cost it has incurred. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

28. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

29. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM") and receives reimbursement from the sponsor (or PBM) for the

portion of the drug cost not paid by the beneficiary. The Part D sponsor then notifies CMS of the drug dispensing event, including the amount it has paid to the pharmacy. CMS uses that information at the end of the payment year when it reconciles its advance payments to the sponsor with the costs that sponsor has incurred throughout the year.

30. In order for a drug to be reimbursable by a Part D sponsor, it must meet the definition of a "Part D drug." A Part D drug is generally defined to include a drug that may be dispensed only upon prescription, that meets the requirements of 42 U.S.C. § 1396r-8(k)(2)(A), and that is being used for a medically-accepted indication (as defined in 42 U.S.C. § 1396r-8(k)(6)). 42 U.S.C. § 1860D-2(e)(1); 42 C.F.R. § 423.100. Because the definition of a Part D drug incorporates the definition of "covered outpatient drug" in 42 U.S.C. § 1396r-8(k)(2)(A), it also includes not only drugs that have been approved by the FDA for safety and effectiveness, but also the two categories of drugs that were on the market before October 1962 (as described in 42 U.S.C. § 1396r-8(k)(2)(A)(ii) and 42 U.S.C. § 1396r-8(k)(2)(A)(iii)).

VI. MANUFACTURERS' OBLIGATION TO SUBMIT ACCURATE INFORMATION TO CMS

31. Under the Rebate Agreement, each manufacturer is required to update its list of covered outpatient drugs and to submit certain pricing and other information to CMS on a quarterly basis. Rebate Agreement, II(a).

32. Among the items of information a manufacturer must accurately supply in its quarterly submissions to CMS is a "DESI Code" for each of its drug products. The DESI Code reflects the regulatory status of the specific drug product and determines the drug product's eligibility for federal coverage and payment under Medicaid. *See* Medicaid Drug Rebate Program Release No. 4. (A copy of this release is attached hereto as Exhibit 2.)

33. The DESI Codes are as follows:

- DESI Code 2: Safe and Effective or non-DESI
- DESI Code 3: Under Review by the FDA
- DESI Code 4: Less Than Effective for Some Indications
- DESI Code 5: Less Than Effective for All Indications
- DESI Code 6: Withdrawn from the Market

See id.

34. Drug products that fall within DESI Codes 2-4 are eligible for Medicaid coverage and payment, whereas products that fall within DESI Codes 5-6 are ineligible for federal coverage and payment. *See id.*

35. In 1994, CMS advised drug manufacturers that they were "responsible for knowing the status of LTE/IRS drugs by reviewing DESI notices published in the Federal Register by the FDA." Medicaid Drug Rebate Program Release No. 12 at 2. (A copy of this release is attached hereto as Exhibit 3.) The following year, CMS further explained that "[m]anufacturers must identify in their list of covered outpatient drugs which they submit to HCFA those DESI/IRS drugs that they produce that are the subject of a NOOH." 60 Fed. Reg. 48,442, 48,457 (Sep. 19, 1995).

36. CMS maintains a master file of all "covered outpatient drugs" in its Medicaid Drug Rebate ("MDR") system. If a product does not qualify as a "covered outpatient drug," CMS removes the product from the MDR system and notifies state Medicaid Programs about the removal. Removal from the MDR system generally results in the automatic denial of payment of claims for the product by state Medicaid programs.

VII. TRYPSIN-CONTAINING PRODUCTS INTENDED FOR DEBRIDEMENT ARE LTE DESI DRUGS.

37. Parenzyme and Tryptar were two trypsin-containing prescription drug products on the market prior to 1962.

38. After the 1962 Amendments to the FDCA, Parenzyme and Tryptar were reviewed under the DESI Program for effectiveness.

39. On June 25, 1970, the FDA issued a notice in the Federal Register concluding that "[t]opical preparations containing trypsin, chymotrypsin, and aminacrine hydrochloride lack substantial evidence of effectiveness for labeled claims for anti-infective and debriding actions on sloughing and necrotic or infected tissue associated with wounds, burns, . . . and ulcers (decubitus, diabetic, or varicose)." 35 Fed. Reg. 10,396 (June 25, 1970). Based upon this determination, the FDA withdrew its approval of the NDA for Parenzyme. *See* 37 Fed. Reg. 3202, 3203 (Feb. 12, 1972).

40. On July 26, 1976, the FDA issued a notice in the Federal Register announcing its efficacy findings for Tryptar. While finding Tryptar effective for "liquefaction of viscid sputum," the FDA reiterated that Tryptar "lacks substantial evidence of effectiveness for all its other labeled indications," such as debriding. *See* 41 Fed. Reg. 27,772 (July 6, 1976).

41. As a result of the FDA's LTE determination, drug products, such as Xenaderm, containing trypsin intended as a debriding agent are ineligible to receive federal funding under Medicaid or Medicare. *See* 42 U.S.C. §§ 1396b(i)(5), 1395y(c); 42 C.F.R. § 441.25.

42. Xenaderm further is not eligible for payment under Medicaid or Medicare because it is not a covered outpatient drug or a Part D drug. 42 U.S.C. § 1396r-8(k)(2)(A); 42 U.S.C. § 1860D-2(e)(1).

VIII. HEALTHPOINT'S DISTRIBUTION OF UNAPPROVED XENADERM

A. Healthpoint's "DESI Driven Business Model" For Unapproved Drugs

43. Healthpoint is a privately held company founded in 1992. Although it claims to market "branded pharmaceuticals" for "tissue management, dermatology, and surgical

indications," Healthpoint's product line consists almost entirely of unapproved drug products – *i.e.*, drug products that have not been approved for both safety and effectiveness by the FDA.

44. Through at least 2006, Healthpoint employed a "DESI driven business model." (An excerpt from a Healthpoint document describing this strategy is attached hereto as Exhibit 4.) Healthpoint's DESI strategy involved developing and marketing new prescription drug products modeled after drug products that were on the market before October 1962, so that Healthpoint could avoid the time, effort, and expense of seeking and obtaining FDA approval for safety and efficacy.

B. Healthpoint Developed And Marketed Xenaderm Without FDA Approval.

45. Healthpoint first began marketing Xenaderm in April 2002.

46. According to its label, Xenaderm contains three active ingredients: castor oil, balsam of Peru, and trypsin.

47. Xenaderm's label states that it is used to "promote the healing and the treatment of decubitus ulcers, varicose ulcers, and dehiscent wounds." Xenaderm's label further states that "Trypsin is intended for the debridement of eschar and other necrotic tissue." Xenaderm's label lists no other indication for trypsin.

48. Healthpoint itself has questioned whether castor oil and balsam of Peru have any pharmacological activity in Xenaderm and has considered redesignating them as "inactive" ingredients.

49. As part of its "DESI driven business model," Healthpoint patterned Xenaderm after an unapproved pre-1962 product called Granulex. Xenaderm, however, differs materially from Granulex. The concentration of trypsin in Xenaderm is almost twice that of Granulex. (A copy of a Regulatory Position Paper prepared for Healthpoint noting this difference is attached hereto

as Exhibit 5.) Xenaderm also differs in dosage form from Granulex: Xenaderm is an ointment, whereas Granulex is a spray.

50. Healthpoint was aware of the difference in dosage form between Xenaderm and Granulex when it developed Xenaderm. During the development of Xenaderm, Healthpoint considered developing a spray dosage form but abandoned work on the spray dosage form because of poor solubility of trypsin in the formulation.

51. At no time prior to its introduction of Xenaderm into the market did Healthpoint complete any double-blind placebo-controlled clinical studies that established the safety and effectiveness of Xenaderm. A Healthpoint clinical researcher later conceded in an internal e-mail that Healthpoint's safety and efficacy data for Xenaderm was not just lacking, but "cruelly insufficient" under FDA standards. (A copy of this e-mail is attached hereto as Exhibit 6.) Healthpoint's General Manager also knew that the company did not have sufficient evidence to promote Xenaderm as a "safe and efficacious healing agent." (A copy of the e-mail containing this statement is attached hereto as Exhibit 7.)

52. At no time prior to the launch of Xenaderm did Healthpoint receive any approval from the FDA to market Xenaderm.

53. At no time prior to the launch of Xenaderm did Healthpoint submit Xenaderm's label to the FDA for review or approval.

IX. HEALTHPOINT'S KNOWLEDGE THAT MARKETING UNAPPROVED XENADERM WAS RISKY AND THAT XENADERM WAS INELIGIBLE FOR FEDERAL REIMBURSEMENT

A. Healthpoint Knew That Marketing Unapproved Xenaderm Was Risky.

54. Healthpoint knew that its "DESI driven business model" was inherently risky and that the unapproved drugs it sold could be subject to FDA regulatory action and removed from

the market at any time. (A copy of an e-mail from Healthpoint's Senior Director of Regulatory Affairs reflecting this knowledge is attached hereto as Exhibit 8.)

55. The FDA published and updated periodically a Compliance Policy Guide ("CPG") on Marketed Unapproved Drugs. The CPG specifically addressed all marketed unapproved prescription drugs, including DESI drugs and unapproved pre-1962 drugs that the FDA had not yet evaluated for safety or effectiveness. The FDA termed the latter category "Prescription Drug Wrap-Up" drugs.

56. In the CPG, the FDA set forth its enforcement priorities on various categories of unapproved drugs. The CPG identified the circumstances under which the FDA would exercise its enforcement discretion and refrain from taking enforcement action against these categories of unapproved drugs.

57. With respect to "Prescription Drug Wrap-Up" drugs, the FDA indicated that it would refrain from taking enforcement action against an unapproved drug first marked after November 1984, unless that drug product differed from an unapproved pre-1962 drug product in, among other things, formulation and dosage form.

58. Healthpoint officials were aware of the CPG and guidance documents issued by the FDA related to unapproved drugs. Healthpoint has represented to various state and federal government officials that Xenaderm was modeled after Granulex – an unapproved pre-1962 drug within the "Prescription Drug Wrap-Up" category. Healthpoint knew, however, that Granulex and Xenaderm contained different amounts of tryspin and came in different dosage forms.

59. Healthpoint further knew that, in 2003, the FDA issued Draft Guidance in which it declared that all drugs subject to the Prescription Drug Wrap-Up were marketed illegally unless the manufacturer could prove its drug was 1) grandfathered, or 2) not otherwise a "new drug."

The FDA also declared that it was highly unlikely that any currently marketed prescription drug was grandfathered or otherwise not a "new drug." (A copy of the FDA's 2003 Draft Guidance is attached hereto as Exhibit 9.) Healthpoint also knew that, in 2006, the FDA issued Final Guidance reiterating its view that all Prescription Drug Wrap-Up drugs were marketed illegally unless the manufacturer could prove its drug was 1) grandfathered, or 2) not otherwise a "new drug." (A copy of the FDA's 2006 Final Guidance is attached hereto as Exhibit 10.)

60. Healthpoint also received outside inquiries noting differences between Xenaderm and Granulex. (Copies of such inquiries are attached hereto as Exhibits 11-15.) In an internal e-mail discussing the inquiries, a Healthpoint official expressed concern that "[t]hese inquiries threaten to contact FDA stating that we cannot be complying with the rules covering DESI products." (A copy of this internal e-mail is attached hereto as Exhibit 16.)

B. Healthpoint Gamed The System To Ensure Reimbursement For Xenaderm.

61. Healthpoint understood that, under the Medicaid program, certain products could be reimbursed, while others could not, and that such reimbursement was "advantageous" to Healthpoint's business.

62. A significant number of patients in nursing homes are covered by the Medicaid program. For Medicaid patients, a nursing home generally has to pay for non-prescription products out of the per diem payment received for each beneficiary from Medicaid. By contrast, most prescription drug products dispensed to Medicaid patients in a nursing home are billed separately to Medicaid by the pharmacy that the nursing home uses to dispense its drugs.

63. From launch, Healthpoint marketed Xenaderm as "Medicaid Reimbursed." For example, in materials Healthpoint created to train its sales force, Healthpoint noted that any given nursing home spent an average of $850 per month on competing non-prescription products

and that "in most states this is a non-reimbursable expense and is absorbed/incurred by the facility (Medicaid, Title 19, Section 1927)." (A copy of these training materials is attached hereto as Exhibit 17.) By contrast, as Healthpoint advised in other sales training materials, Xenaderm was "Medicaid Reimbursed" and could be administered at "No cost to the facility or patient." (A copy of these training materials is attached hereto as Exhibit 18.) According to a Xenaderm sales training manual, the fact that Medicaid would foot the bill for Xenaderm was one of five "Major Features" of the product. (A copy of this training manual is attached hereto as Exhibit 19.)

64. In the period immediately after the launch of Xenaderm, Healthpoint referred to Xenaderm as a "DESI" drug.

65. In September 2002, however, Healthpoint's Director of Healthcare Systems distributed an Interoffice Memorandum instructing company employees not to "refer to Healthpoint's products including . . . Xenaderm simply as 'DESI' drugs when speaking to Medicaid personnel." The memorandum instructed employees to refer to Xenaderm as a "DESI 2" drug, or as a "Prescription product that is a 'covered drug' in most states." It explained that "using the appropriate terminology with Medicaid is crucial because reimbursement is dependent upon DESI classification." The memorandum stressed the importance of referring to Xenaderm as a "DESI 2" product because "DESI 2 drugs are typically called 'covered drugs' by Medicaid personnel and are usually reimbursed by Medicaid." (A copy of the Interoffice Memorandum containing these statements is attached hereto as Exhibit 20.)

66. At the same time, Healthpoint took no steps actually to confirm with CMS the appropriate DESI Code for Xenaderm – a drug that it knew was on the market without FDA approval and to which it had frequently referred as a DESI drug.

67. Healthpoint had reason to inquire into the appropriate DESI classification for Xenaderm because certain state Medicaid programs denied coverage for Xenaderm, while other state programs questioned Xenaderm's coverage as a DESI drug. In 2004, only 37 states provided Medicaid reimbursement for Xenaderm. Other states either did not approve Xenaderm for Medicaid reimbursement at all or imposed restrictions on reimbursement.

68. On June 22, 2004, after receiving an inquiry into the coverage status of Xenaderm by the State of New York's Medicaid Program, Healthpoint's Director of Government Affairs responded by e-mail that, "[s]ince Xenaderm is not considered a LTE DESI drug, it is eligible for Federal Funds Participation, and is considered a 'covered drug' under most State Medicaid programs." (A copy of this e-mail is attached hereto as Exhibit 21.) In fact, Healthpoint had never checked with CMS or FDA about whether Xenaderm was a "covered drug" or whether its active ingredient had been determined LTE. As a result, the Healthpoint Director of Government Affairs did not disclose to New York Medicaid that the FDA had found Xenaderm's active ingredient, trypsin, to be LTE for the only trypsin indication listed on the Xenaderm label.

69. From 2002 through December 2006, in quarterly submissions to CMS, Healthpoint falsely designated Xenaderm as having a DESI Code of "2." The false statements relating to Xenaderm were material to the claims for government reimbursement of Xenaderm. If Healthpoint had properly designated Xenaderm as having a DESI Code of "5" (the appropriate code since trypsin was LTE for the only indication for which it was listed on the Xenaderm label), the government would not have paid for the drug.

70. Healthpoint acted with reckless disregard of the truth or falsity of its statements because it either ignored, or never took steps to learn about, the FDA's determination that trypsin

was LTE as a debriding agent. Likewise, Healthpoint never sought guidance from CMS on the propriety of its repeated DESI Code "2" designations for Xenaderm.

71. As a result of the conduct set forth herein, from 2002 to December 2006, Healthpoint caused false prescription claims to be submitted to Medicaid and Medicare, and, from 2002 through 2006, Medicaid and Medicare paid almost $90 million for an unapproved drug that was ineligible for reimbursement.

COUNT I
(False Claims Act, 31 U.S.C. § 3729(a)(1) (1986))

72. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

73. From 2002 to 2006, Healthpoint submitted false quarterly statements to CMS regarding Xenaderm's eligibility for federal reimbursement. As a result of these submissions, Healthpoint knowingly caused the submission of false and ineligible prescription claims for Xenaderm to the Medicaid and Medicare programs in violation of 31 U.S.C. § 3729(a)(1).

74. By virtue of the false or fraudulent claims that Healthpoint caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT II
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009))

75. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

76. From 2002 to 2006, Healthpoint knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the government. Specifically, from 2002 to 2006, Healthpoint knowingly submitted false quarterly statements to CMS regarding Xenaderm's approval and eligibility for government

reimbursement. Healthpoint's false quarterly statements for Xenaderm caused the submission of false prescription claims for Xenaderm to be submitted to Medicaid and Medicare in violation of 31 U.S.C. § 3729(a)(1)(B).

77. By virtue of the false or fraudulent claims that Healthpoint knowingly caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT III
(Unjust Enrichment)

78. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

79. If Healthpoint had not falsely submitted that Xenaderm was eligible for federal reimbursement, the United States would not have paid for the drug. By retaining monies received from its sales of Xenaderm that were reimbursed by federal health care programs, Healthpoint retained money that was the property of Medicaid and Medicare and to which it was not entitled.

80. As a consequence of the acts set forth above, Healthpoint was unjustly enriched at the expense of the United States in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, plaintiff United States of America respectfully requests this Court to enter judgment for plaintiff and against defendant Healthpoint on each count of this Complaint, and to impose damages and penalties as follows:

Count I – an amount equal to three times the loss sustained by the Medicaid and Medicare programs, plus penalties of $11,000 for each false claim or statement;

Count II – an amount equal to three times the loss sustained by the Medicaid and

Medicare programs, plus penalties of $11,000 for each false claim or statement; and

Count III – an amount equivalent to the loss sustained by the Medicaid and Medicare programs, plus prejudgment interest.

Demand for Jury Trial

The United States demands a jury trial in this case.

Respectfully submitted,

TONY WEST
Assistant Attorney General

CARMEN A. ORTIZ
United States Attorney

Dated: March 31, 2011

/s/ Gregg Shapiro
GREGG SHAPIRO
JAMES J. FAUCI
Assistant United States Attorneys
United States Attorney's Office
John Joseph Moakley United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3366

JOYCE R. BRANDA
JAMIE YAVELBERG
SANJAY M. BHAMBHANI
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 305-0546

Certificate of Service

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on March 31, 2011.

/s/ Gregg Shapiro
Gregg Shapiro