

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,) Criminal Number _____
)
)
v.) **VIOLATIONS:**
)
SERONO LABORATORIES, INC.,) 18 U.S.C. § 371 - Conspiracy to
) introduce into interstate commerce,
Defendant.) with intent to defraud and mislead,
) adulterated medical devices
) 18 U.S.C. § 371 - Conspiracy to offer
) and pay illegal remuneration
)
)

INFORMATION

The United States Attorney charges that:

COUNT ONE

(CONSPIRACY TO INTRODUCE INTO INTERSTATE COMMERCE, WITH INTENT TO
DEFRAUD AND MISLEAD, ADULTERATED MEDICAL DEVICES)

PRELIMINARY ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

SERONO LABORATORIES and Serostim

1. The Defendant, **SERONO LABORATORIES, INC.** (hereinafter referred to as "**SERONO LABS**") was incorporated in Massachusetts and maintained its corporate headquarters in Massachusetts. **SERONO LABS** was a subsidiary of Serono, S.A., formerly known as Ares Serono, S.A., an international pharmaceutical and biotechnology company with corporate headquarters in Geneva, Switzerland.
2. Defendant **SERONO LABS** marketed and sold the drug Serostim, which is the proprietary name or trademark of the generic drug, "somatropin." Somatropin is recombinant human growth hormone, consisting generally of growth hormone taken

from a mammalian cell line and modified, using recombinant DNA technology, by adding the human growth hormone gene. Defendant **SERONO LABS** received accelerated approval from the U.S. Food and Drug Administration (“FDA”) in August of 1996 for Serostim to treat AIDS wasting, also known as cachexia, a condition involving profound involuntary weight loss in AIDS patients, with a preferential loss of lean body mass over fat mass. At the time the FDA approved Serostim, AIDS wasting was an AIDS defining condition that constituted the leading cause of death among AIDS patients.

3. Serostim came on the market concurrently with the advent of protease inhibitor drugs. These drugs, often referred to as Highly Active Anti-Retroviral Therapy, or HAART, dramatically curtailed, in the United States, the proliferation of the AIDS virus itself, particularly when used in combination with one another (commonly referred to as “AIDS cocktails”). Given the decreased viral loads in HIV-positive patients taking these drugs, the incidence and prevalence of the AIDS wasting syndrome began to markedly decline among AIDS patients. Consequently, the demand for Serostim began to drop significantly immediately following launch of the drug in the Fall of 1996.
4. Serostim was an injectable drug that was prescribed per milligram (“mg.”) and was dispensed in vials. The dosing range for Serostim was from 4 to 6 mg. per patient per day based upon the patient's weight. The dose most commonly administered was 6 mg. per day. In August of 1996, the FDA approved Serostim based upon a 12-week course of treatment, although many patients received Serostim for more than 12 weeks.
5. Serostim was a very expensive drug. The average wholesale price (“AWP”) was \$42 per mg. At 6 mg. per day, a prescription for Serostim was 168 mg. per 28-day cycle,

and the cost per 28-day cycle was approximately \$7056. A twelve-week course of therapy cost approximately \$21,168. Due to its cost, among other factors, many physicians treating AIDS patients did not use Serostim as a "first line" or primary choice of therapy.

6. Commencing in 1997, and continuing thereafter, Defendant **SERONO LABS** launched a campaign to "redefine AIDS wasting" in order to create a market for Serostim by expanding the disease state for which Serostim could be prescribed as a treatment. Defendant **SERONO LABS'** sales force made sales presentations and disseminated literature stating wasting was being "masked" by weight gain in the post-HAART era and that patients were still experiencing AIDS wasting following the advent of HAART, despite an absence of weight loss. Defendant **SERONO LABS** trained its sales and marketing employees to represent to physicians, patients, and others that "body cell mass," or "BCM," was the most metabolically active component of the body and that patients who had lost BCM were wasting, even if they had lost no weight or had actually gained weight. Estimates of body cell mass in humans could be made by using bioelectrical impedance analysis, or "BIA," medical devices, only in conjunction with certain software devices that purported to compute estimates of body cell mass. To "unmask" AIDS wasting, Defendant **SERONO LABS**, as alleged in Count One of this Information, promoted the use of the BIA and accompanying computer software devices to measure body cell mass.
7. During the clinical trials performed to obtain FDA approval for Serostim, the safety and efficacy of Serostim were evaluated in test subjects who had AIDS wasting based upon changes in the amount of weight and lean body mass the subjects experienced. Changes

in body cell mass were not evaluated in the clinical trials and did not form the basis for FDA approval of Serostim.

The BIA and Software Devices

8. Defendant **SERONO LABS** purchased, and caused the purchase by others of, the BIA and software devices **SERONO LABS** used to promote sales of Serostim from RJI Systems, Inc., later known as RJI Sciences, Inc. (hereinafter referred to as "RJI"), a corporation located in Clinton Township, Michigan. Rudolph J. Liedtke (hereinafter referred to as "Liedtke") was the President and principal owner of RJI. RJI and Liedtke developed, manufactured and sold BIA and computer software devices, including various software packages known as Fluid and Nutrition Analysis (or "FNA"), SomaScan, and Cyprus 1.2 Condensed, in conjunction with, and pursuant to agreements with, Defendant **SERONO LABS** and others known and unknown to the United States Attorney.
9. The BIA device manufactured and sold by RJI and Liedtke consisted of a portable device with two protruding electrodes to be attached to the hand and foot of human test subjects. The BIA measured the rate at which low levels of electrical current pass through the body. A microchip embedded within the BIA device measured the degree to which the electrical current encountered "impedance" while passing through the body and calculated "resistance" and "reactance" measurements. The resistance and reactance measurements obtained by performing a BIA test on a human subject reflected the degree to which the subject's body resisted the flow of the current and the extent to which the current was stored in the body.

10. The resistance and reactance measurements generated by the BIA device were used to estimate the body composition of individual humans. Estimates of body composition were computed by applying the resistance and reactance measurements generated by the BIA device to predictive equations. Such predictive equations were developed by mathematically calculating the statistical relationship between the resistance and reactance measurements obtained by performing BIA tests on a sample population of human subjects and actual measurements of body composition for that population. Predictive equations used to estimate body composition of humans varied depending on the characteristics and size of the sample population used to develop the equation and on the methodology used to measure the body composition within that population.
11. The BIA device was a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(h), in that the BIA device was an impedance plethysmograph used to estimate human body composition by estimating "peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs." 21 C.F.R. § 870.2770.
12. Each package of computer software used to convert the resistance and reactance measurements generated by the BIA device into estimates of body composition was a medical device within the meaning of the FDCA in that it was a "component, part, or accessory" to BIA devices pursuant to 21 U.S.C. § 321(h).

FDA Regulation of BIA and Software Devices

13. The Center for Devices and Radiological Health ("CDRH") was the office within the FDA responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe

and effective for their intended uses and are labeled accurately and in compliance with the law.

14. The BIA and computer software devices could not be sold without first obtaining premarket clearance and/or premarket approval from the FDA, depending on the intended use of the devices. FDA could grant what was called a 510(k) premarket clearance if it determined, following review of the data submitted in support of the applicant's premarket notification, that a device was substantially equivalent to a device (known as a "predicate device") that was marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments to the FDCA. A device could only be found substantially equivalent to a predicate device if, among other things, the intended use of the current device was the same as the intended use of a predicate device. If the intended use of the device was different from the intended use of a predicate device, substantial equivalence could not be found. Under such circumstances, the manufacturer could not legally market the device in interstate commerce unless the FDA had first reviewed and approved a premarket application to market the device.
15. FDA categorized devices into three classes -- Class I, Class II, and Class III -- depending on the degree of regulation necessary to ensure the safety and effectiveness of the devices for their intended uses. Devices that were first introduced into commercial distribution after May 28, 1976, were presumed to be Class III devices by operation of law. 21 U.S.C. § 360c(f)(1). A Class III device, unless the subject of a 510(k) premarket clearance, required premarket approval before it could be legally marketed in interstate commerce. 21 U.S.C. § 360e. Premarket approval review by the

FDA generally entailed, among other things, a review of clinical trials and scientific data offered to confirm the safety and efficacy of the device as well as a review of the device's labeling, which must include adequate directions for use.

16. On or about June 24, 1986, RJL and Liedtke submitted a 510(k) premarket notification to FDA's CDRH relating to a BIA device identified therein as "Body Comp Analyzer" and a computer software device accompanying the BIA device. In that 510(k) submission and in ensuing correspondence with CDRH, RJL and Liedtke stated that the Body Comp Analyzer and accompanying computer software had the same intended uses as those identified in a 510(k) premarket notification that RJL had filed with CDRH in 1983 - specifically, estimating total body water, lean body mass, and fat - and that the computer software only performed calculations that previously would have been done by hand to estimate body composition. RJL and Liedtke further represented that the predictive equations in the computer software were based on a population consisting of 278 healthy and obese college students whose body composition was measured through hydrostatic weighing. RJL and Liedtke also stated that total body water measurements of the college students were determined using deuterium oxide dilution. RJL and Liedtke represented to CDRH that the intended uses of the BIA device and accompanying computer software did not include measuring body cell mass or diagnosing any disease state.
17. Based on the representations made by RJL and Liedtke in their 510(k) submission and related communications, CDRH concluded that the modified Body Comp Analyzer and accompanying computer software were substantially equivalent to a device marketed prior to the medical device amendments of 1976. On February 3, 1987, CDRH granted

premarket clearance to RJL to distribute the Body Comp Analyzer and the accompanying computer software devices, referred to by CDRH as the “Modified Model BIA-103 Body Comp Analyzer,” for the intended uses of estimating total body water, lean body mass, and fat in healthy humans.

**Development of New BIA Software Packages for Measuring Body Cell Mass
(A Use that Was Never Approved by the FDA)**

18. Thereafter, Defendant **SERONO LABS**, RJL, Liedtke, and others known and unknown to the United States Attorney developed various versions of software for the BIA device that were designed to calculate, among other things, body cell mass, total body water, fat free mass, and intracellular and extracellular water. The various software packages were named “Fluid and Nutrition Analysis” or “FNA,” “Cyprus,” “SomaScan,” and “Cyprus 1.2 Condensed.” Each of these software packages, pursuant to 21 U.S.C. § 351(f)(1)(B)(i), required FDA approval before they could be legally marketed for use in measuring body cell mass and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements as these were new intended uses. At no time, did any individual or entity submit an application for premarket approval to the FDA with respect to any of these software packages, nor has FDA ever approved an application for premarket approval for any of the software packages under 21 U.S.C. § 360e.

A. The FNA Software

19. Commencing in at least 1994, RJL and Liedtke assisted others known and unknown to the United States Attorney in developing a predictive equation that would purportedly calculate estimates of body cell mass using the BIA resistance and reactance readings. This predictive equation (herein the “Z equation”) purported to estimate body cell mass based upon measurements of total body potassium in a population referred to herein as

the "ABC database" that consisted of approximately 332 humans, including individuals who were healthy and others who had been tested as HIV-positive.

20. Commencing sometime during 1994, RJL, Liedtke, and others known and unknown to the United States Attorney developed new computer software for use in interpreting BIA test results that incorporated the Z equation and marketed the software under the name "Fluid and Nutrition Analysis," or "FNA." The FNA software purported to calculate the individual test subject's estimated body cell mass, total body water, intracellular and extracellular water, fat free mass, extracellular tissue, and fat. The FNA software also computed purported "normal" ranges for the individual test subject's total body water and intracellular and extracellular water by comparing the individual's BIA test results to a select portion of the population included in the ABC database. The inclusion of the Z equation and the ABC database in the FNA software, and the use of the computer software to purportedly measure body cell mass and as a tool for diagnosing AIDS wasting, as alleged herein, were new intended uses that required premarket approval from FDA before their introduction or delivery for introduction into interstate commerce
21. In or about January, 1995, RJL and Liedtke met with representatives of Defendant **SERONO LABS** and with others known and unknown to the United States Attorney regarding possible uses of BIA technology by Defendant **SERONO LABS**. Thereafter, on or about February 27, 1995, representatives of RJL forwarded to Defendant **SERONO LABS'** Director of Regulatory Affairs a copy of the letter dated February 3, 1987, from CDRH to Liedtke stating that CDRH had granted RJL Section 510(k) clearance to market the Modified Model BIA-103 Body Composition Analyzer.

22. Between September, 1995, and June, 1996, RJI shipped approximately 25 BIA devices together with FNA Version 3.1 software packages to Defendant **SERONO LABS** for use in evaluating body composition in AIDS patients.

B. The Cyprus Software

23. The “Cyprus” software, developed for the BIA device commencing in or about 1998, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus software further computed purported normal ranges for each of these measurements for individual test subjects by comparing the individual’s test results to a select portion of a database of humans derived from the National Health and Nutrition Examination Survey (NHANES).

C. The SomaScan Software

24. The “SomaScan” software, developed for the BIA device commencing in or about August, 1999, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The SomaScan software further computed purported precise “ideal” amounts for each of these measurements for individual test subjects by comparing the individual’s test results to a select portion of the NHANES database and eliminating any standard deviation from the calculations. The SomaScan software was not submitted to FDA for premarket approval and was not approved by FDA for shipment in interstate commerce for the intended uses of measuring body cell mass or diagnosing AIDS wasting. The inclusion of the Z equation, employing the NHANES database as the population base for computing

"ideal" body composition values in the SomaScan software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, as alleged herein, were new intended uses, and required premarket approval from FDA before introduction or delivery for introduction into interstate commerce.

D. The Cyprus 1.2 Condensed Software

25. The "Cyprus 1.2 Condensed" software, developed for the BIA device in or about February, 2000, incorporated the Z equation for estimating body cell mass and calculated purported measurements of body cell mass, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus 1.2 Condensed software also computed purported "normal" amounts and "normal" ranges for these values for each individual by comparing the individual test subject's results to a select portion of the NHANES database and including a standard deviation for these calculations. The inclusion of the Z equation, employing the NHANES database as the population base for computing "normal" body composition values in the software, and the use of the computer software to measure body cell mass and as a tool for diagnosing AIDS wasting, as alleged herein, were new intended uses, and required premarket approval from FDA before introduction or delivery for introduction into interstate commerce.

Serostim and the Medicaid Program

26. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources were insufficient to meet the costs of necessary medical services.

Commonly called Medicaid, the program was administered by the states, but was funded jointly by the federal and state governments.

27. To participate in the Medicaid program, a state was required to develop a plan that was approved by the Secretary of Health and Human Services as meeting federal requirements. The state paid qualified providers for furnishing necessary services covered by the state plan to individuals who were eligible for medical assistance. The federal government contributed a portion of the costs that each participating state incurred in purchasing items and services from qualified providers on behalf of eligible persons. The state bore the remainder of the costs.
28. State Medicaid programs were “federal health care programs” within the meaning of 18 U.S.C. § 24, in that they were public plans affecting commerce under which medical benefits, items and services were provided to individuals under the plans.
29. The federal government contributed to the costs of prescriptions for persons who were Medicaid beneficiaries, including but not limited to persons disabled due to HIV infection and AIDS under the state Medicaid programs.
30. Medicaid paid for approximately 80% of all Serostim prescriptions nationwide. The total claims paid by Medicaid nationwide from 1997 through 2004 exceeded \$600 million.

The Conspiracy

31. Commencing as early as September, 1996, and continuing thereafter until at least January, 2002, the exact dates being unknown to the United States Attorney, within the State and District of Massachusetts and elsewhere, the Defendant

SERONO LABS

and others known and unknown to the United States Attorney, including RJL and Liedtke, knowingly and willfully combined, conspired, and agreed, to commit an offense against the United States, to wit, 21 U.S.C. §§ 331(a), 333(a)(2), by introducing and delivering for introduction into interstate commerce, and causing to be introduced and delivered for introduction into interstate commerce, with intent to defraud and mislead, adulterated medical devices consisting of BIA computer software known as FNA, Cyprus, SomaScan, and Cyprus 1.2 Condensed for use in calculating body cell mass and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements, which devices were adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B)(i), in that neither Defendant **SERONO LABS**, nor others known and unknown to the United States Attorney, including RJL and Liedtke, had obtained premarket approval from the FDA to introduce such medical devices into interstate commerce for this purpose.

Purpose of the Conspiracy

32. It was the purpose of this conspiracy that Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including RJL and Liedtke, introduced and delivered for introduction, into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, with intent to defraud and mislead, adulterated medical devices to increase the market for Serostim and to increase the market for BIA devices and computer software. To that end, Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including RJL and Liedtke, participated in the development and dissemination of BIA computer software that purported to measure body cell mass for use in diagnosing AIDS wasting based

upon a test subject's purported loss of body cell mass. The disease state of AIDS wasting, for which the drug was tested and approved by FDA, consisted of profound involuntary weight loss and loss of lean body mass in AIDS patients, and did not include loss of body cell mass. Use of BIA computer software that purported to measure loss of body cell mass enabled Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including RJI and Liedtke, to expand the market for Serostim beyond the disease state for which the drug was tested and approved and to expand the market for the BIA devices and computer software devices.

Manner and Means by which the Conspiracy Operated

33. It was part of the conspiracy to disseminate BIA devices and “FNA” software in interstate commerce to sales representatives of Defendant **SERONO LABS** and to others known and unknown to the United States Attorney in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass, without first obtaining FDA approval for this use of the device with the FNA software, so as to increase the prescribing and sale of Serostim.
34. It was part of the conspiracy to develop and disseminate the “SomaScan” software in interstate commerce to sales representatives of Defendant **SERONO LABS** and to others known and unknown to the United States Attorney in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "ideal" levels of body cell mass and other body composition parameters for individual BIA test subjects, all without first obtaining FDA approval for these uses of the device with the SomaScan software, so as to increase the prescribing and sale of Serostim.

35. It was part of the conspiracy to develop and disseminate the “Cyprus 1.2 Condensed” software in interstate commerce to sales representatives of Defendant **SERONO LABS** and to others known and unknown to the United States Attorney in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of body cell mass and to compute purported "normal" levels of body cell mass and other body composition parameters, all without first obtaining FDA approval for these uses of the device with the Cyprus 1.2 Condensed software, so as to increase the market potential for Serostim.
36. It was further part of the conspiracy that Defendant **SERONO LABS** and others known and unknown to the United States Attorney induced physicians to prescribe, and third-party payors to pay for, Serostim based upon misrepresentations and omissions of material facts. Defendant **SERONO LABS** misled physicians and third-party payors regarding the validity of BIA testing in diagnosing AIDS wasting and did not disclose that the BIA software devices had not been approved by FDA or scientifically validated for the purposes of determining whether patients were experiencing purported changes in body cell mass and/or suffering from AIDS wasting. As a consequence of these material misrepresentations and omissions, Defendant **SERONO LABS** caused third-party payors, including Medicaid, to reimburse for Serostim prescriptions that would not have been written and/or for which the third-party payors would have declined to pay.

Overt Acts

In furtherance of this conspiracy, the Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including RJL and Liedtke, engaged in the following overt acts:

37. In or about September, 1996, a representative of Defendant **SERONO LABS** traveled to Clinton Township, Michigan, and met with others known and unknown to the United States Attorney, including RJL and Liedtke, regarding possible uses of the BIA and FNA software devices by Defendant **SERONO LABS** in marketing Serostim.
38. In or about October, 1996, representatives of Defendant **SERONO LABS** met with others known and unknown to the United States Attorney, including Liedtke and employees of RJL, in Massachusetts regarding the sale and delivery of BIA and FNA software devices by RJL to Defendant **SERONO LABS** and others known and unknown to the United States Attorney.
39. In or about December, 1996, Defendant **SERONO LABS** received in Massachusetts approximately 50 BIA devices, accompanied by approximately 50 FNA software devices that included the Z equation, manufactured by RJL and Liedtke and shipped from Michigan. Pursuant to directions and specifications from Defendant **SERONO LABS**, RJL and Liedtke affixed plates to the outside of these BIA devices bearing name "Serono."
40. Commencing in or about February, 1997, and continuing thereafter, Defendant **SERONO LABS** provided the BIA devices and FNA software received from RJL and Liedtke to **SERONO LABS'** sales representatives and to others known and unknown to the United States Attorney for use in measuring body cell mass, diagnosing AIDS wasting in humans who were potential candidates for receiving the drug, and promoting sales of Serostim.
41. Commencing in or about March, 1997, and continuing thereafter, employees of RJL traveled from Michigan to Massachusetts and elsewhere, at Defendant **SERONO**

- LABS'** request, and provided training to **SERONO LABS'** sales representatives in performing BIA tests on humans.
42. Commencing in 1997, and continuing thereafter, Defendant **SERONO LABS'** representatives performed, free of charge, BIA tests directly on AIDS patients in physician and medical clinic offices and at events sponsored by service organizations offering assistance to AIDS patients. Defendant **SERONO LABS'** sales representatives provided the BIA test results to doctors and patients and, in many instances, purported to interpret the test results for the purpose of diagnosing whether the patients were wasting and determining whether they needed Serostim.
 43. Commencing in or about June, 1997, and continuing thereafter, Defendant **SERONO LABS** forwarded to its sales representatives copies of various training materials prepared by RJL and by others for the purpose of training **SERONO LABS'** sales representatives in performing BIA tests on humans and in interpreting BIA test results.
 44. In or about June, 1997, Defendant **SERONO LABS** obtained from RJL a "Body Composition Analysis Worksheet" and disseminated it to **SERONO LABS'** representatives for use in interpreting BIA tests and obtaining reimbursement for Serostim from third-party payors.
 45. Commencing in 1997, and continuing thereafter, Defendant **SERONO LABS** required its sales representatives to submit bi-weekly reports to **SERONO LABS'** management showing how many BIA tests the sales representatives performed and how many prescriptions of Serostim were obtained as a result of those BIA tests.
 46. Commencing in 1997, and continuing thereafter, Defendant **SERONO LABS** provided, free of charge, BIA and software devices to physicians and others involved in treating

AIDS patients, and further arranged for the purchase by physicians and others of BIA and software devices at a reduced cost. Defendant **SERONO LABS** also provided training in performing and interpreting BIA tests to physicians and others involved in treating AIDS patients, and arranged for such training to be provided by others.

47. Commencing in 1996, and continuing thereafter, Defendant **SERONO LABS** promoted reliance upon BIA test results by third-party payors, including state Medicaid agencies, for the purpose of determining whether the payors should reimburse for prescriptions of Serostim. Defendant **SERONO LABS** prepared and assisted in the development of guidelines and other written materials recommending that BIA testing be used as a key criterion in determining whether a patient was suffering from AIDS wasting and whether to reimburse for Serostim prescriptions.
48. In or about August, 1997, Defendant **SERONO LABS** executed a written agreement governing the sale by RJI and Liedtke of BIA and computer software devices to **SERONO LABS** and to others known and unknown to the United States Attorney. Pursuant to this agreement, Defendant **SERONO LABS** and RJI agreed that RJI would provide "a specialized, private labelled model [BIA device] for Serono" that included, among other things, "R.J.L.'s Fluid & Nutrition Analysis Clinical Software Program for medical reimbursement," and further agreed to cooperate with RJI "for the development of new software and/or hardware for the diagnosis and monitoring of AIDS Associated Wasting and monitoring treatment with Serostim."
49. Commencing in or about August, 1999, Defendant **SERONO LABS** collaborated with RJI and Liedtke and others known and unknown to the United States Attorney in the creation of the BIA computer software package known as "SomaScan." Defendant

SERONO LABS knew and intended that the SomaScan software computed "ideal" body composition values by comparing the individual subject's BIA test results to a select portion of a database of humans derived from the NHANES database, and that the SomaScan software provided these "ideal" values as precise numerical amounts, rather than as ranges for these values. Defendant **SERONO LABS** expressly directed RJL and Liedtke to eliminate any standard deviation from the SomaScan software in order to identify additional purported candidates for receiving Serostim and to increase sales of Serostim.

50. Commencing in or about August, 1999, Defendant **SERONO LABS** received various versions of the SomaScan software from RJL, created copies of the computer software, and affixed labels to this software that identified it as SomaScan software and bore the name "Serono."
51. Commencing in or about September, 1999, Defendant **SERONO LABS** disseminated the SomaScan software to its sales representatives and to others known and unknown to the United States Attorney for use in measuring body cell mass, diagnosing AIDS wasting in humans who were potential candidates for receiving Serostim, and promoting sales of Serostim.
52. Commencing in or about September, 1999, Defendant **SERONO LABS** prepared and disseminated training materials regarding the SomaScan software, provided training to sales representatives and to others known and unknown to the United States Attorney in the use of the software, and established a "Hotline" that users of the SomaScan software could telephone to obtain guidance in using the software.

53. Commencing in or about September, 1999, RJL, acting at the direction of Defendant **SERONO LABS**, prepared and posted a website which provided information and training regarding the use of the SomaScan software.
54. Commencing in or about October, 1999, and continuing thereafter, Defendant **SERONO LABS** initiated an assessment of the validity of the SomaScan software after receiving complaints that the SomaScan software was flawed and that BIA tests performed using the SomaScan software showed individuals to have AIDS wasting who were not in fact wasting.
55. Commencing in or about February, 2000, Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including RJL and Liedtke, evaluated the possible use by Defendant **SERONO LABS** of versions of RJL computer software known as Cyprus. Pursuant to directions from Defendant **SERONO LABS**, RJL and Liedtke created the version of the Cyprus software known as Cyprus 1.2 Condensed for use by Defendant **SERONO LABS** and others known and unknown to the United States Attorney.
56. In or about September, 2000, Defendant **SERONO LABS** decided to withdraw the SomaScan software from use by its representatives. In place of the SomaScan software, Defendant **SERONO LABS** decided to disseminate to the Cyprus 1.2 Condensed software to **SERONO LABS**' sales representatives and others known and unknown to the United States Attorney for use in purportedly measuring body cell mass, diagnosing AIDS wasting in humans who were potential candidates for receiving Serostim, and promoting sales of Serostim.

57. Commencing in or about September, 2000, and continuing until at least January 2002, the exact dates being unknown to the United States Attorney, Defendant **SERONO LABS** disseminated the Cyprus 1.2 Condensed BIA software to others known and unknown to the United States Attorney for use in purportedly measuring body cell mass and diagnosing AIDS wasting in humans who were potential candidates for receiving the drug, and promoting sales of Serostim.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

(CONSPIRACY TO OFFER TO PAY ILLEGAL REMUNERATION)

At all times material to this Information, unless otherwise alleged:

PRELIMINARY ALLEGATIONS

58. The allegations of Paragraphs 1-7 and 26-30 are incorporated herein as though fully set forth.

Corporate Organization of the Serostim Business Unit

59. From 1996 through in or about September, 2000, the business unit within Defendant **SERONO LABS** that was responsible for selling Serostim in the United States was known as Metabolic & Immune Therapy ("M&IT"). Following a corporate reorganization in or about September, 2000, the business unit responsible for selling Serostim in the United States was known as Metabolic Endocrinology of North America ("MENA").
60. In March of 1999, the top management of M&IT included, among others: John Bruens (hereinafter referred to as "Bruens"), the Vice-President of Marketing for M&IT, who worked out of Defendant **SERONO LABS'** headquarters in Massachusetts and reported directly to X, an executive in M&IT (hereinafter "Executive X"), and Mary Stewart (hereinafter referred to as "Stewart"), the Vice- President of Sales of M&IT, who worked out of Defendant **SERONO LABS'** headquarters in Massachusetts and reported directly to Executive X.
61. In March of 1999, the M&IT sales force was divided into six sales Regions each led by a Regional Director: the Northeast Region (Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State); the New York

Region (New York City and its environs); the Southeast Region (Florida, Louisiana, Mississippi, Alabama and Texas); the Central Region (Illinois, Wisconsin, Missouri, Arkansas, Oklahoma, Kentucky, Michigan, Minnesota, North Dakota, South Dakota, Nebraska, Iowa and Indiana); the Mid-Atlantic Region (Maryland, Delaware, Georgia, North Carolina, South Carolina, Ohio, West Virginia, and parts of Pennsylvania); and the Western Region (California, Oregon, Washington, Arizona, and Colorado).

62. In March of 1999, the Regional Sales Directors for Defendant **SERONO LABS** included, among others: Melissa Vaughn (hereinafter referred to as "Vaughn"), the Regional Director of Sales for the Southeast Region, who reported directly to Stewart and supervised sales representatives (known within Defendant **SERONO LABS** as "clinical consultants") in Florida, Louisiana, Mississippi, Alabama and Texas; Marc Sirockman (hereinafter referred to as "Sirockman"), the Regional Director of Sales for the Northeast Region, who reported directly to Stewart and supervised clinical consultants in Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State; and Adam Stupak (hereinafter referred to as "Stupak"), the Regional Director of Sales in the New York Region, who reported directly to Stewart and supervised clinical consultants in New York City.

The Medicaid Program in New York, New Jersey, and Florida

63. At all times relevant hereto, the States of New York, New Jersey and Florida, were among the states that had Medicaid programs receiving federal funding. From 1997 through 1999, Medicaid claims for Serostim in New York were over \$53 million; in New Jersey were over \$12 million; and in Florida were over \$25 million.

64. Drs. RL, P, DC, AC, O, G and W were each Medicaid providers who provided care and treatment for Medicaid-eligible patients who were HIV-positive or suffering from AIDS. Drs. RL and P were located in and treated patients in Florida; Drs. DC and AC were located in and treated patients in New Jersey; and Drs. O, G and W were located in and treated patients in New York. Each of these physicians prescribed Serostim from time to time to patients who were Medicaid program beneficiaries

The Conspiracy

65. Commencing on or about March 1, 1999, and continuing thereafter until in or about December of 1999, the exact dates being unknown to the United States Attorney, in the District of Massachusetts and elsewhere, Defendant

SERONO LABS

and others known and unknown to the United States Attorney, including John Bruens, Mary Stewart, Melissa Vaughn, Marc Sirockman, and Executive X, knowingly and willfully combined, conspired, and agreed to commit an offense against the United States, to wit, 42 U.S.C. § 1320a-7b(b)(2)(A), by knowingly and willfully offering and paying remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce them to refer individuals, including Medicaid patients, to pharmacies for the furnishing of the drug Serostim, for which payments were made in whole and in part under state Medicaid programs.

Purpose of the Conspiracy

66. It was the purpose of this conspiracy that Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including Bruens, Stewart, Vaughn, Sirockman, and Executive X, targeted physicians who were high prescribers of Serostim

or who were generally regarded as “thought leaders” and offered certain of these physicians financial incentives in order to obtain the number of prescriptions that would advance a sales goal of increasing sales by \$6,000,000, which was to be accomplished by offering an all-expenses paid trip for each physician and a guest to the 3rd International Conference on Nutrition and HIV Infection held in Cannes, France from April 22-25, 1999 (hereinafter referred to as the “Cannes Conference”) in return for the physicians writing additional prescriptions of Serostim.

Means and Manner of the Conspiracy

67. It was a part of the conspiracy that Defendant **SERONO LABS** and Executive X, Bruens, and Stewart devised a plan called the “\$6m-6 Day Plan,” which had as an objective to target top prescribing Serostim physicians and top “thought leader” physicians in the AIDS/HIV medical community and then induce the targeted physicians to write more prescriptions by offering as an inducement an all-expenses paid trip to the Cannes Conference, which was organized to include new data on advances in the treatment of nutritional aspects of HIV disease, including but not limited to the effects of protease inhibitors on body composition, metabolism and hormone systems.
68. It was a further part of the conspiracy that Defendant **SERONO LABS** and Executive X, Bruens, and Stewart, summoned the six Regional Directors of M&IT, including Vaughn, Sirockman, and Stupak, to an emergency meeting at the Boston Harbor Hotel on March 1, 1999. At this meeting, which included other M&IT personnel, Executive X, Bruens, and Stewart told the six Regional Directors that they were falling short of their sales goals for Serostim. Executive X, Bruens and Stewart also advised the

Regional Directors that they needed to “dig their way out” of this fiscal crisis and informed the Regional Directors of the “\$6m-6 Day Plan.”

69. It was a further part of the conspiracy that, to effectuate the objectives of the “\$6m-6 Day Plan,” Defendant **SERONO LABS** and others known and unknown to the United States Attorney agreed to offer to selected physicians an all-expenses paid trip to the Cannes Conference in return for the physicians writing additional prescriptions of Serostim for patients. Although this target number of prescriptions per physician changed over time, the “\$6m-6 Day Plan,” as originally explained by Bruens and Stewart, was intended to increase total sales of Serostim by more than \$6,000,000 within six (6) days.
70. It was a further part of the conspiracy that Defendant **SERONO LABS** and Executive X, Bruens, and Stewart required each Regional Director, including Vaughn, Sirockman, and Stupak, to report daily to Defendant **SERONO LABS**’ headquarters in Massachusetts the number of Serostim prescriptions that they obtained during the sales push, including those prescriptions obtained from the key physicians who were targeted and offered the opportunity to attend the Cannes Conference.
71. It was a further part of the conspiracy that Defendant **SERONO LABS** and others known and unknown to the United States Attorney, including Bruens, Stewart, Vaughn, Sirockman, and Stupak, offered and caused to be offered to selected physicians the opportunity to attend the Cannes Conference with a guest with all expenses paid by Defendant **SERONO LABS** in return for the physicians writing additional prescriptions of Serostim.

72. It was a further part of the conspiracy that, in exchange for the physicians writing additional Serostim prescriptions, Executive X, Bruens, Stewart, Vaughn, Sirockman, and Stupak and others known and unknown to the United States Attorney caused Defendant **SERONO LABS** to pay, and Defendant **SERONO LABS** did in fact pay, for the travel expenses of the physicians and their guests who actually attended the Cannes Conference.
73. It was a further part of the conspiracy that, in exchange for the physicians' Serostim prescriptions, Executive X, Bruens, Stewart, Vaughn, Sirockman, Stupak, and others known and unknown to the United States Attorney caused Defendant **SERONO LABS** to pay, and Defendant **SERONO LABS** did in fact pay, thousands of dollars for the hotel accommodations, some meals, and entertainment for the physicians and their guests while they were at the Cannes Conference.
74. It was a further part of the conspiracy that Bruens and others known and unknown to the United States Attorney authorized and caused Defendant **SERONO LABS** to provide, and Defendant **SERONO LABS** did in fact provide, a variety of personal gifts to the physicians and their guests who attended the Cannes Conference.
75. It was a further part of the conspiracy that, after certain physicians rejected the Cannes offer, Defendant **SERONO LABS** and other known and unknown to the United States Attorney advised certain of the physicians who had already been offered the all-expenses trip to the Cannes Conference that they would subsequently be asked to speak on behalf of Defendant **SERONO LABS** about the issues presented at the conference and about Serostim, and Defendant **SERONO LABS** paid these physicians separately for these speaking engagements.

Overt Acts

In furtherance of this conspiracy, and to effect the objects thereof, Defendant **SERONO LABS**, acting through Executive X, Bruens, Stewart, Vaughn, Sirockman, Stupak, and others known and unknown to the United States Attorney, engaged in the following overt acts, among others, in the District of Massachusetts and elsewhere:

76. On March 1, 1999, Executive X, together with Bruens and Stewart, met with the six Regional Directors, including Vaughn, Sirockman, and Stupak, and other M&IT employees at the Boston Harbor Hotel and advised them of the proposed plan of Defendant **SERONO LABS** to offer selected physicians an all-expenses paid trip to the Cannes Conference in return for additional prescriptions of Serostim.
77. On or about March 2, 1999, Vaughn, Sirockman, Stupak, and others known and unknown to the United States Attorney, telephoned and sent e-mails to their respective sales forces passing forward the directions of Bruens and Stewart and advising their respective sales forces of Defendant **SERONO LABS'** "\$6m-6 Day" sales plan and the plan to offer the Cannes trip to certain physicians.
78. On or about March 2 or 3, 1999, Vaughn, Sirockman, Stupak, and others known and unknown to the United States Attorney, left Boston to return to their respective regions to implement the plan of Defendant **SERONO LABS** that was agreed upon at the Boston Harbor Hotel.

The Florida Physicians

The Offers to Drs. RL and P

79. Between on or about March 1 and on or about March 3, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, Vaughn and others known and unknown to the

United States Attorney, caused a co-conspirator who was a **SERONO LABS** clinical consultant to visit Dr. RL, a physician in Florida who treated HIV positive and AIDS patients, and to offer Dr. RL the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.

80. Between on or about March 1, 1999 and on or about March 3, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, Vaughn, and others known and unknown to the United States Attorney, caused a co-conspirator who was a **SERONO LABS** clinical consultant to visit the office of Dr. P, a physician in Florida who treated HIV positive and AIDS patients, and to offer Dr. P the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.
81. On or about March 3, 1999, Vaughn, after learning that at least one doctor had reacted negatively to the offer of the Cannes trip in return for additional Serostim prescriptions, sent a voice-mail to Bruens, Stewart, Sirockman, Stupak and to others known and unknown to the United States Attorney, in which she stated that at least one doctor told a **SERONO LABS** clinical consultant that this program was "unethical and the very thing that the FDA looks for . . ." and further advised the recipients of the voice-mail that "I just wanted to let you know that we won't be doing this program in the south."
82. On or about March 4, 1999, as part of the reporting required by Defendant **SERONO LABS** for the "\$6m - 6 Day Plan," Vaughn reported via e-mail to Executive X, Bruens, Stewart, and to others known and unknown to the United States Attorney, that Dr. P had written one (1) Serostim prescription on March 3, 1999, and that Dr. P had written seven (7) Serostim prescriptions on March 4, 1999.

83. On or about March 13, 1999, Vaughn advised Bruens that Dr. P would attend the Cannes Conference and would need business-class airline tickets. On or about April 8, 1999, Bruens directed an employee in Norwell, Massachusetts, to charge \$7,846.64 on a corporate credit card of Defendant **SERONO LABS** to cover the cost of Dr. P's round trip airfare, which had been booked by the travel agency for Defendant **SERONO LABS**. Thereafter, Defendant **SERONO LABS** paid for this credit card charge.

The New Jersey Doctors

The Offer to Dr. DC

84. In or about March 1999, the exact dates being unknown, Defendant **SERONO LABS**, acting through Bruens, Stewart, Sirockman, and others known and unknown to the United States Attorney, caused a co-conspirator who was a clinical consultant employed by Defendant **SERONO LABS** to visit the office of Dr. DC, a physician in New Jersey who treated HIV positive and AIDS patients, and to offer Dr. DC the all-expenses paid trip to the Cannes Conference in return for gaining clinical experience with at least thirty (30) Serostim patients before Dr. DC could attend the conference.

The Offer to Dr. AC

85. In or about March 1999, the exact dates being unknown, Defendant **SERONO LABS**, acting through Bruens, Stewart, and others known and unknown to the United States Attorney, caused Sirockman to contact Dr. AC, a physician in New Jersey who treated HIV positive and AIDS patients, and to offer to him the all-expenses paid trip to the Cannes Conference in return for writing of additional prescriptions of Serostim.

86. On or about April 15, 1999, Defendant **SERONO LABS**, acting through various co-conspirators, including Bruens, Stewart, and Sirockman, and others known and

unknown to the United States Attorney, caused Dr. AC to receive a check in the amount of \$4,000 for airline tickets.

87. On or about April 25, 1999, Sirockman, using his corporate expense account for Defendant **SERONO LABS**, paid for Dr. AC's transportation in a private limo service for Dr. AC's return to his residence from an airport in New York after the Cannes Conference. Thereafter, Defendant **SERONO LABS** paid for this charge.

The New York Doctors

88. Between on or about March 1, 1999 and on or about March 4, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, and others known and unknown to the United States Attorney, caused Stupak to visit the office of Dr. O, a physician in New York City who treated HIV positive and AIDS patients, and to offer Dr. O the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.
89. Between on or about March 1, 1999 and on or about March 4, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, and others known and unknown to the United States Attorney, caused Stupak to visit the office of Dr. G, a physician in New York City who treated HIV positive and AIDS patients, and to offer Dr G the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.
90. Between on or about March 1, 1999 and on or about March 4, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, and others known and unknown to the United States Attorney, caused Stupak to visit the office of Dr. W, a physician in New York City who treated HIV positive and AIDS patients, and to offer Dr W the all-

expenses paid trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

91. On or about April 15, 1999, Defendant **SERONO LABS**, acting through Bruens, Stewart, Stupak, and others known and unknown to the United States Attorney, caused a \$4,000 check for airline tickets to be issued to Dr. W, who had accepted the offer for the all-expenses paid trip to the Cannes Conference.

All in violation of Title 18 United States Code, Section 371.

MICHAEL J. SULLIVAN
United States Attorney

By:

MARY ELIZABETH CARMODY
Assistant U.S. Attorney
U. S. Attorney's Office
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3290

PETER D. KEISLER
Assistant Attorney General
United States Department of Justice

EUGENE M. THIROLF
Director
Office of Consumer Litigation

By:

SONDRA L. MILLS
SUZETTE SMIKLE
Trial Attorneys
United States Department of Justice
Office of Consumer Litigation,
P.O. Box 386
Washington, D.C. 20044
(202) 616-2375