UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA	)	No. 03CR0126
	)	Violations: Title 18, United
v.	)	States Code, Sections 2
	)	371,1001 1341,and 1343, and
	)	Title 21 United States Code,
	)	Sections 331(a) and 333(a)(1)
ROSS A. CAPUTO,	)	
ROBERT M. RILEY,	)	
MARK E. SCHMITT, and	)	
MARILYN M. LYNCH	)	

MAGISTRATE JUDGE BROWN

COUNT ONE

The SPECIAL FEBRUARY 2002-1 GRAND JURY charges:

1. At all times relevant to this indictment:

a. The United States Food and Drug Administration ("FDA")was an agency of the United States government entrusted with responsibility for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans were safe and effective for their intended uses and that the labeling of such devices bore true and accurate information. Pursuant to this statutory mandate, FDA regulated the manufacture, labeling, and shipment in interstate commerce of any such devices.

b. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §§ 301-397, the "FDCA"), and pursuant to Title 21, United States Code §321(h)the term "device" included "an instrument, apparatus, implant, machine . . . or other similar or related article . . . which is . . . intended for use in . . . the

treatment or prevention of disease, in man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

c. Pursuant to the FDCA, every manufacturer of a new device had to obtain "clearance" or "approval" from the FDA prior to marketing its device.

d. All devices marketed via interstate commerce in the United States fell into one of three regulatory classes under the FDCA. Class III devices were subject to the most stringent regulatory requirements, Class I devices to the least stringent, and Class II devices to requirements that fell in between. The classification assigned to each device was determined by the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of that device in its intended use.

e. Devices that were not in commercial distribution prior to May 28, 1976, when the Medical Device Amendments to the FDCA became effective, were automatically assigned to Class III by operation of law. Such Class III devices could not be legally marketed in the United States until the manufacturer had submitted to the FDA a pre-market approval application ("PMA") and the FDA had approved that application. The FDA would not approve a PMA unless the information in the PMA provided the FDA with reasonable assurance

that the device was safe and effective when used according to its labeling.

f. As an alternative to submitting a PMA, a manufacturer of a new Class III device could also seek to demonstrate to the FDA that its device should be classified into Class I or Class II or that it was substantially equivalent to a legally marketed device for which pre-market approval was not required. A manufacturer which sought a determination of "substantial equivalence" could submit to the FDA "pre-market notification" (also known as a "510(K)") no later than ninety days before the manufacturer intended to introduce the device into interstate commerce. If FDA made a finding of "substantial equivalence" based on the manufacturer's pre-market notification, the device was then "cleared" for marketing and could be marketed in a manner consistent with the pre-market notification cleared by the FDA.

g. Approval of a PMA and clearance of a pre-market notification were separate routes for obtaining FDA's permission to market a medical device. Initially, each new device was subject to both pre-market approval and pre-market notification. However, if a PMA was approved by the FDA, pre-market notification was no longer necessary. Similarly if a particular device was classified as either Class I or Class II by the FDA, through clearance of a pre-market notification, approval of a PMA for that device was no longer required. Until a device obtained either one or the other

form of permission, it could not be distributed in intestate commerce.

h. A manufacturer which intended to modify a device that had been cleared by FDA pursuant to a "510(K)" pre-market notification was required to file a new 510(K) pre-market notification if the proposed change could significantly affect the safety or the effectiveness of the device.

i. A Class III device was "adulterated" if it was required to have an approved PMA and did not have an approved PMA in effect.

j. A medical device was "misbranded" if the manufacturer of a device had failed to provide the FDA with pre-market notification ninety days prior to introducing the device into interstate commerce.

k. Introduction of an adulterated or misbranded medical device into interstate commerce was prohibited by law.

2. At times material to this indictment:

a. AbTox, Inc. ("AbTox") was a business corporation organized under the law of the State of Delaware, with its principal place of business located at Mundelein, in the Northern District of Illinois.

b. Defendant ROSS A. CAPUTO was the President and Chief Executive Officer of AbTox. He was also the President of a related company called Pharmaceutical Systems, Inc. ("PSI"), also located in Mundelein, which was engaged in laboratory and consulting work.

c. Defendant ROBERT M. RILEY was employed first by PSI as a consultant and then by AbTox as Vice President of Regulatory Affairs.

d. Defendant MARK E. SCHMITT was employed by AbTox as Director of Marketing, and later as Vice President of Sales.

e. Defendant MARILYN M. LYNCH was employed by AbTox in various positions, and from 1996 through 1998 as Director of Clinical Services.

f. AbTox was in the business of manufacturing and selling a sterilizer for medical instruments known as the Plazlyte Sterilization system. This device purported to sterilize at low temperature medical instruments placed in a sterilization chamber into which a mixture of gases, including peracetic acid and hydrogen peroxide among others, flowed through an electromagnetic field to create a gas plasma. The sterilizer distributed by AbTox was not in commercial distribution prior to May 28, 1976, and the model actually marketed by AbTox was a Class III device within the meaning of the FDCA.

g. A sterilizer different than the sterilizer actually marketed, containing different engineering and design characteristics and different gas concentrations ("the cleared device"), was cleared by the FDA pursuant to pre-market notification. The FDA found that, if manufactured with the engineering characteristics and gas concentrations described in

AbTox's pre-market notification and used for the uses described in AbTox's submission, the cleared device was substantially equivalent to sterilization in ethylene oxide, a process in commercial distribution prior to August 28, 1976, and that the sterilizer therefore constituted a Class II device, subject to special controls necessary to provide adequate assurance of safety and effectiveness. The model cleared by the FDA was cleared only for sterilization of stainless steel surgical instruments, without hinges or lumens, packaged as described in the pre-market notification submitted by AbTox.

h. At no time was the cleared device actually marketed or sold by AbTox, or intended to be marketed or sold.

i. The sterilizer actually promoted and distributed by AbTox (Model ABT 1.0) was never the subject of an approved PMA or cleared 510(K) pre-market notification, although either approval or clearance by the FDA was necessary to distribute it under the FDCA. Moreover, at no time was a PMA for the model actually distributed by AbTox ever submitted to the FDA, and, during most of the time in which the sterilizer was marketed, no 510(K) pre-market notification for it was actually pending with the FDA. Therefore at all times the Model ABT 1.0 Plazlyte sterilizer manufactured, promoted, and distributed by AbTox was an adulterated device, and during the time when no 510(K) pre-market notification was pending,

a misbranded device. Adulterated and misbranded devices could not be lawfully introduced into interstate commerce.

3. Between the approximate dates of August 11, 1994, and July 22, 1998, at Mundelein, in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, together with others both known and unknown to the Grand Jury, agreed, combined, and conspired to defraud the United States and its agencies by:

a. impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the United States were safe and effective for their intended uses and that the labeling of such devices bore true and accurate information; and

b. offering for sale, and selling, to the Department of Veterans Affairs (VA) and other agencies of the United States Government, including the Department of Defense and the Indian Health Service, for use in their hospitals, an adulterated and misbranded device, the AbTox Plazlyte sterilizer model ABT 1.0, that had not received either pre-market approval or pre-market clearance from the FDA.

4. It was part of the conspiracy that defendants ROSS A. CAPUTO and ROBERT M. RILEY submitted to the FDA a pre-market notification for a different and smaller sterilizer that they did not intend to market and that in fact was not marketable. In so doing, they concealed from the FDA that AbTox in fact intended to market a different sterilizer than the submitted device, which had a larger sterilizer chamber, a different gas concentration, a different sterilant distribution system, and other differences in engineering and design.

5. It was further part of the conspiracy that defendants ROSS A. CAPUTO and ROBERT M. RILEY submitted to the FDA a pre-market notification falsely representing that AbTox would market the Plazlyte sterilizer for the sole intended use of sterilizing flat stainless steel surgical instruments; which were instruments without hinges or lumens (tubes).

6. It was further part of the conspiracy that after AbTox received a warning letter from the FDA directing AbTox not to market the Plazlyte sterilizer for uses other than the cleared use of sterilizing flat stainless steel surgical instruments, for the purpose of lulling the FDA, defendant ROBERT RILEY falsely assured the FDA in writing that AbTox would neither promote nor support validation studies by AbTox's hospital customers to justify use of the Plazlyte sterilizer by AbTox's customers to sterilize medical

instruments other than those in the limited class of instruments for which it had been cleared.

7. It was further part of the conspiracy that, despite defendant RILEY'S assurances, defendants ROSS A. CAPUTO, ROBERT M. RILEY, MARK E. SCHMITT, and MARILYN M. LYNCH marketed the AbTox Plazlyte sterilizer by promoting and encouraging use of the sterilizer by customers to sterilize materials and medical instruments which had not been cleared by the FDA, and in packaging which had not been cleared by the FDA, by doing, and causing others to do, the following:

a. representing both to customers and employees of AbTox that the Plazlyte sterilizer was a general purpose sterilizer;

b. representing both to customers and employees of AbTox that anything that could be sterilized in an ethylene oxide sterilizer, which was in fact a general purpose sterilizer, could also be sterilized in the AbTox Plazlyte sterilizer;

c. representing to both customers and employees that the AbTox Plazlyte sterilizer could be used to replace sterilization by ethylene oxide, even though ethylene oxide was commonly used by hospitals to sterilize medical instruments and materials that were not cleared by the FDA for processing in the AbTox Plazlyte sterilizer;

d. offering discounts to customers and prospective customers who agreed to "trade-in" their ethylene oxide sterilizer

or other sterilizer for the AbTox Plazlyte sterilizer, thereby encouraging use of the AbTox Plazlyte sterilizer for uses not cleared by the FDA;

e. preparing and distributing to customers and prospective customers both printed and video taped promotional materials which stated and implied that the AbTox Plazlyte sterilizer could be used to sterilize instruments and materials other than those for which it was cleared by the FDA;

f. encouraging and requesting customers and prospective customers to contact hospitals which the defendants knew were using the Plazlyte sterilizer to process instruments and materials for which the AbTox sterilizer was not cleared by the FDA;

g. encouraging hospitals that had already purchased the AbTox Plazlyte sterilizer to use the unit to process instruments and materials for which the unit was not cleared by the FDA, and to serve as references to other prospective purchasers of the AbTox Plazlyte sterilizer;

h. offering discounts to hospitals that purchased the AbTox Plazlyte sterilizer, if they would agree to serve as reference sites which other prospective purchasers could tour in order to witness use of the sterilizer to process medical instruments and materials other than those cleared by the FDA;

i. encouraging customers and prospective customers to conduct or obtain so-called "validation studies," which would

purport to establish the effectiveness of the AbTox Plazlyte sterilizer for uses other than those cleared by the FDA;

j. referring customers and prospective customers to PSI, a related company controlled by defendant ROSS A. CAPUTO, as a provider of validation studies for the AbTox Plazlyte sterilizer;

k. arranging, in some cases, to have AbTox pay the cost of validation studies commissioned by customers and prospective customers in connection with their purchase of an AbTox Plazlyte sterilizer;

l. arranging, in some cases, that PSI would not charge for performing a validation study for an AbTox customer;

m. offering what they called a "label copy" discount to offset the cost to a customer of obtaining a validation study to support uncleared uses of the AbTox Plazlyte sterilizer;

n. offering to indemnify customers for damage done by the AbTox Plazlyte sterilizer to medical instruments processed in it, including instruments not cleared by the FDA for processing in the sterilizer;

o. seeking to persuade manufacturers of medical instruments to support and approve processing of the instruments they manufactured in the AbTox Plazlyte sterilizer, even though processing of such instruments had not been cleared by the FDA; and

p. sending "clinical specialists," who were typically registered nurses, to hospitals to perform so-called "instrument

audits" in order to identify medical instruments owned by the hospital which purportedly could be processed in the AbTox Plazlyte sterilizer, even though such instruments were not in a class of instruments which the Plazlyte sterilizer was cleared to process.

8. It was further part of the conspiracy that defendants ROSS A. CAPUTO and ROBERT M. RILEY lulled the FDA by submitting to it purported "510(k)" pre-market notifications for the uncleared AbTox Plazlyte sterilizer model ABT 1.0, with expanded uses, even though AbTox was already marketing the uncleared model and was already promoting the uncleared uses.

9. It was further part of the conspiracy that defendants ROSS A. CAPUTO and ROBERT M. RILEY withheld from the FDA adverse testing results relating to a change in the length of the sterilization cycle for which AbTox sought approval in a 510(k) pre-market notification.

10. It was further part of the conspiracy that AbTox employees acting under the direction and with the approval of defendants ROSS A. CAPUTO, ROBERT M. RILEY, MARK E. SCHMITT, and MARILYN M. LYNCH deceived customers and potential customers into believing that the sterilizer AbTox manufactured, promoted, and distributed had been cleared by the FDA, and in so doing submitted to customers and employees of AbTox copies of the clearance letter issued by the FDA to AbTox, dated December 22, 1994, as well as a modified version of that letter, without explaining that the

clearance letter related to a different sterilizer than the one AbTox was marketing, thereby misleading customers and employees to believe that the sterilizer that AbTox actually promoted and distributed had been cleared by the FDA, when in fact such sterilizer had been neither approved nor cleared by the FDA.

11. It was further part of the conspiracy that by means of the conduct described above, Abtox sold in the United States approximately 160 AbTox Plazlyte Model ABT 1.0 sterilizers, at prices averaging between $75,000 and $115,000 each, all contrary to the FDCA and the regulations and directives of the FDA, thereby impeding, impairing and defeating the mission of the FDA to protect the health and safety of the public, and to exercise its lawful functions.

12. It was further part of the conspiracy that defendant ROSS A. CAPUTO, ROBERT M. RILEY, MARK E. SCHMITT, and MARILYN M. LYNCH, and Abtox employees working with the defendants' knowledge and at their direction, promoted the sale of the AbTox Plazlyte Sterilizer model ABT 1.0 to the VA, and misled the VA to believe that the device had been cleared by the FDA, even though they knew that the VA would not knowingly purchase a sterilizer which was neither cleared nor approved by the FDA.

13. It was further part of the conspiracy that on or about December 20, 1996 and again on March 17, 1998, defendant MARK E. SCHMITT, acting on behalf of AbTox, signed a Federal Supply

Schedule (FSS) which was in effect a nationwide contract with the VA, authorizing all VA hospitals to buy the AbTox Plazlyte Sterilizer. As part of the FSS, AbTox, by defendant SCHMITT, agreed that AbTox would not offer to the VA a device which had not received full pre-market approval by the FDA, and further agreed that AbTox would comply with the FDCA.

14. Despite knowing that the AbTox Plazlyte Model ABT 1.0 Sterilizer had received neither pre-market clearance nor approval from the FDA, and that it was marketed in a manner which violated the FDCA, the defendants successfully marketed and sold to the VA, at a cost exceeding approximately $1,200,000, approximately twelve such sterilizers, which were adulterated and misbranded.

15. It was further part of the conspiracy that in order to lull the FDA, and to conceal the nature of the acts performed as part of the conspiracy, during the month of February, 1998, defendants ROBERT M. RILEY, MARK E. SCHMITT, and MARILYN M. LYNCH knowingly made a series of false statements to an investigator for the FDA, in which they concealed their knowledge that the AbTox Plazlyte Sterilizer was marketed and promoted by AbTox for purposes other than those cleared by the FDA.

16. It was also part of the conspiracy that, in order to effect the object of the conspiracy, the defendants did and committed in the Northern District of Illinois, the following overt acts:

a. On or about September 5, 1997, defendant ROSS A. CAPUTO, flew from O'Hare Airport, Chicago, Illinois, to Des Moines, Iowa, in order to make a sales presentation to Mary Greely Medical Center in Ames, Iowa;

b. On or about October 30, 1997, defendant MARK E. SCHMITT, approved sale of an Abtox Plazlyte Sterilizer to Swedish Medical Center, in Seattle, Washington;

c. On or about November 26, 1997, defendant MARK E. SCHMITT approved sale of an AbTox Plazlyte Sterilizer to Flagler Hospital, St. Augustine, Florida;

d. On or about January 13, 1998, defendant MARK E. SCHMITT approved sale of an AbTox Plazlyte Sterilizer to Barnes Jewish Children's Hospital, in St. Louis, Missouri;

e. On or about January 20, 1998, defendant MARK E. SCHMITT approved sale of an Abtox Plazlyte Sterilizer to Riverview Hospital, Noblesville, Indiana;

f. On or about January 29, 1998, defendant MARILYN M. LYNCH traveled from Illinois to the John Cochran VA Center in St. Louis, Missouri;

g. On or about February 12, 1998, defendant ROBERT M. RILEY had a conversation with an investigator for the FDA;

h. On or about February 19, 1998, defendant MARK E. SCHMITT had a conversation with an investigator for the FDA;

i. On or about February 19, 1998, defendant MARILYN M. LYNCH had a conversation with an investigator for the FDA.

j. On or about March 2, 1998, defendant MARK E. SCHMITT approved sale of an Abtox Plazlyte Sterilizer to Rockdale Hospital, in Conyers, Georgia;

In violation of Title 18, United States Code, Section 371.

COUNT TWO

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 and 2 of Count One of this indictment are incorporated and realleged as though fully set forth herein.

2. Between the approximate date of August 11, 1994 and July 22, 1998, at Mundelein, in the Northern District of Illinois,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, devised and intended to devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses, representations, promises, and omissions.

3. It was part of the scheme that the defendants and employees acting with their approval and at their direction, contacted hospitals in the United States in order to market and offer for sale the AbTox Plazlyte model ABT 1.0 Sterilizer.

4. It was further part of the scheme that the defendants and their agents falsely represented to the hospitals that the AbTox Plazlyte model ABT 1.0 Sterilizer had received 510(k) pre-market clearance from the FDA, while knowing that such sterilizers had not in fact received such clearance.

5. It was further part of the scheme that the defendants and their agents supported their false representations by providing copies, and in some cases altered copies, of a clearance letter from the FDA, which they in fact knew related not to the sterilizer

they were marketing and offering for sale, but to a different and smaller model with different design and engineering characteristics, and a different gas concentration, which unit Abtox did not offer for sale.

6. By means of their materially false and misleading representations the defendants succeeded in selling in excess of approximately 160 unapproved and uncleared sterilizers to hospitals in the United States, thereby causing their customers a loss in excess of approximately $16,000,000.

7. On or about September 8, 1997, at Buffalo Grove, in the Northern District of Illinois, Eastern Division, and elsewhere,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the aforesaid scheme, and attempting to do so, knowingly caused to be delivered by mail, according to the directions thereon, an envelope addressed to Abtox, Inc. at P. O. Box 7263, Buffalo Grove, Illinois 60089, containing a United States Treasury check, number N2444363, payable to Abtox, Inc. in the amount of $100,400;

In violation of Title 18, United States Code, Sections 1341 and 2.

COUNT THREE

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as though fully set forth herein.

2. On or about October 28, 1997, at Buffalo Grove, in the Northern District of Illinois, Eastern Division,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the aforesaid scheme, and attempting to do so, knowingly caused to be delivered by mail, according to the directions thereon, an envelope addressed to Abtox, Inc. at P.O. Box 7263, Buffalo Grove, Illinois 60089, containing a United States Treasury check, number 5793315, dated October 28, 1997, in the amount of $200,800;

In violation of Title 18, United States Code, Sections 1341 and 2.

COUNT FOUR

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as though fully set forth herein.

2. On or about December 2, 1997, at Mundelein, in the Northern District of Illinois, Eastern Division,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the aforesaid scheme, and attempting to do so, knowingly caused to be placed in an authorized depository for mail matter, to be delivered by the Postal Service, a letter dated December 2, 1997, signed by an employee of Abtox, Inc., announcing an impending price increase for the Abtox Plazlyte sterilizer, effective January 1, 1998;

In violation of Title 18, United States Code, Sections 1341 and 2.

COUNT FIVE

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraph 1 through 6 of Count Two of this indictment are incorporated and realleged as though as full set further herein.

2. On or about February 2, 1998, at Mundelein, in the Northern District of Illinois, Eastern Division,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing aforesaid scheme, and attempting to do so, knowingly caused to be delivered by mail, according to the directions thereon, a letter dated February 2, 1998, signed by an employee of the St. Joseph Hospital, Denver, Colorado, informing AbTox of the hospital's acceptance of an offer to trade in its existing ethlene oxide sterilizer in exchange for $20,000 in consumable materials to be used with the AbTox Plazlyte sterilizer;

In violation of Title 18, United States Code, Sections 1341 and 2.

COUNT SIX

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as though fully set forth herein.

2. On or about December 8, 1997, at Mundelein, in the Northern District of Illinois, Eastern Division, and elsewhere,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the scheme described above, knowingly caused to be transmitted by means of wire communication, in interstate commerce between Illinois and Minnesota, certain writings, signs, and signals, namely: a facsimile transmission of a letter dated December 8, 1997, signed by an employee of Abtox, Inc., addressed to an employee of Fairview Hospital in Minneapolis, Minnesota, containing a price quotation for purchase of an Abtox Plazlyte sterilizer;

In violation of Title 18, United States Code, Sections 1343 and 2.

COUNT SEVEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as though fully set forth herein.

2. On or about December 16, 1997, in the Northern District of Illinois, Eastern Division, and elsewhere,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the scheme described above, knowingly caused to be transmitted in interstate commerce between Illinois and Texas, certain writings, signs, and signals, namely: a facsimile transmission of a letter dated December 16, 1997, signed by an employee of AbTox, addressed to Guadalupe Valley Hospital in Sequin, Texas, a letter recommending the Abtox Plazlyte sterilizer as an alternative to ethylene oxide and offering a discount for trade-in of the hospital's ethylene oxide sterilizer;

In violation of Title 18, United States Code, Sections 1343 and 2.

COUNT EIGHT

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as through fully set forth herein.

2. On or about December 30, 1997, at Mundelein, in the Northern District of Illinois, Eastern division,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the scheme described above, knowingly caused to be transmitted in interstate commerce, between Arizona and Illinois, certain signs and signals, namely: a cover sheet and purchase order for an AbTox Plazlyte Sterilizer System, to be purchased by University Medical Center, Tucson, Arizona;

In violation of Title 18, United States Code, Sections 1343 and 2.

COUNT NINE

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

1. Paragraphs 1 through 6 of Count Two of this indictment are incorporated and realleged as through fully set forth herein.

2. On or about January 27, 1998, at Mundelein, in the Northern District of Illinois, Eastern division,

ROSS A. CAPUTO and
ROBERT M. RILEY,

defendants herein, for the purpose of executing the scheme described above, knowingly caused to be transmitted in interstate commerce, between Ohio and Illinois, certain writings, signs, and signals, namely: an order placed by Grandview Hospital, Dayton, Ohio, for a service agreement for its AbTox Plazlyte Sterilizer;

In violation of Title 18, United States Code, Sections 1343 and 2.

COUNT TEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about February 12, 1998, at Mundelein, in the Northern District of Illinois,

ROBERT M. RILEY,

defendant herein, in a matter within the jurisdiction of the Food and Drug Administration (FDA), an agency of the executive branch of the Government of the United States, knowingly and willfully falsified and concealed a material fact, and made a materially false, fictitious, and fraudulent statement and representation, in that he denied to an investigator for the FDA that any AbTox employee to his knowledge had promoted the Plazlyte sterilizer for sterilization of devices other than those labeled in the operator's manual, or that to his knowledge any AbTox employee had distributed promotional literature stating that the Plazlyte system had been built to replace ethylene oxide, or had made oral statements to that effect;

In violation of Title 18, United States Code, Section 1001.

COUNT ELEVEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about February 19, 1998, at Mundelein, in the Northern District of Illinois,

MARILYN M. LYNCH,

defendant herein, in a matter within the jurisdiction of the Food and Drug Administration ("FDA"), an agency of the executive branch of the Government of the United States, knowingly and willfully falsified and concealed a material fact, and made a materially false, fictitious, and fraudulent statement and representation, in that she denied to an investigator for the FDA that (1) she or any other AbTox employee to her knowledge had promoted the Plazlyte sterilizer for sterilization of devices other than those labeled in the operator's manual; (2) that she had ever stated that the Plazlyte system had greater capabilities than it was labeled for;(3) that she or any other AbTox employee to her knowledge had ever represented to a customer that packing material other than that approved by the FDA could be used in the Plazlyte system; (4) that she or any other AbTox employee to her knowledge had ever claimed that the Plazlyte system had been built to replace ethylene oxide; and (5) that she or any other AbTox employee to her knowledge had given out validation information to customers;

In violation of Title 18, United States Code, Section 1001.

COUNT TWELVE

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about February 19, 1998, at Mundelein, in the Northern District of Illinois,

MARK E. SCHMITT,

defendant herein, in a matter within the jurisdiction of the Food and Drug Administration ("FDA"), an agency of the executive branch of the Government of the United States, knowingly and willfully falsified and concealed a material fact, and made a materially false, fictitious, and fraudulent statement and representation, in that he denied to an investigator for the FDA that he was unaware of any AbTox employee promoting the Plazlyte sterilizer for sterilization of devices other than those labeled in the operator's manual;

In violation of Title 18, United States Code, Section 1001.

COUNT THIRTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about October 22, 1997, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely an AbTox Plazlyte sterilizer, Model ABT 1.0, sold to Mary Greely Medical Center, in Ames, Iowa;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT FOURTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about October 30, 1997, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, caused to be introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely three AbTox Plazlyte sterilizers, Model ABT 1.0, sold to Swedish Medical Center, Seattle, Washington;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT FIFTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about December 5, 1997, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, caused to be introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely two AbTox Plazlyte sterilizers, Model ABT 1.0, sold to St. Joseph Hospital, Denver, Colorado;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT SIXTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about December 31, 1997, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein caused to be, introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely an AbTox Plazlyte sterilizer, Model ABT 1.0, sold to St. Elizabeth Medical Center, Edgewood, Kentucky;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT SEVENTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about December 31, 1997, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, caused to be introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely an AbTox Plazlyte sterilizer, Model ABT 1.0, sold to University Medical Center, Tucson, Arizona;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT EIGHTEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about January 22, 1998, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, caused to be introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely an AbTox Plazlyte sterilizer, Model ABT 1.0, sold to Riverview Hospital, Noblesville, Indiana;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

COUNT NINETEEN

The SPECIAL FEBRUARY 2002-1 GRAND JURY further charges:

On or about March 26, 1998, at Mundelein in the Northern District of Illinois, and elsewhere,

ROSS A. CAPUTO,
ROBERT M. RILEY,
MARK E. SCHMITT, and
MARILYN M. LYNCH,

defendants herein, caused to be introduced, and delivered for introduction, into interstate commerce an adulterated and misbranded device, namely an AbTox Plazlyte sterilizer, Model ABT 1.0, leased to Mercy Hospital, Nampa, Idaho;

In violation of Title 21, United States Code, Sections 331 (a) and 333(a)(1).

A TRUE BILL:

FOREPERSON

UNITED STATES ATTORNEY

No. _____

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA

vs.

MARILYN M. LYNCH, ROSS A. CAPUTO,
MARK E. SCHMITT and ROBERT RILEY

I N D I C T M E N T

Violations: Title 18, United States Code,
Sections 2,371,1001, 1341, 1343 and
Title 21 331(a) and 333(a)(1)

A true bill,

_____
Foreman

Filed in open court this 4th day
of February, A.D. 2003

MICHAEL W. DOBBINS,
By: Ameleda Saccomanto
Clerk

Bail, $ _____