IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA GAINESVILLE DIVISION

UNITED STATES OF AMERICA

v.

ONA M. COLASANTE

_____/

SEALED INDICTMENT

1:14CR10 MW/GRJ

THE GRAND JURY CHARGES:

COUNTS ONE THROUGH ONE HUNDRED NINETY-NINE

A. INTRODUCTION

At all times material to this Indictment:

1. The defendant, **ONA M. COLASANTE**, was a physician licensed by the State of Florida. **COLASANTE** possessed medical license number ME63062.

2. Between on or about October 7, 1998, and in or about March 2009, the defendant, **ONA M. COLASANTE**, owned and operated Hawthorne Medical Center, PA ("the Hawthorne Center"), located in Hawthorne, Florida. In or about March 2009, **COLASANTE** sold the Hawthorne Center to PM.

3. Between on or about January 21, 2010, and in or about January 2013, the defendant, **ONA M. COLASANTE**, owned and operated Colasante Clinic, PA ("the Colasante Clinic"), in Gainesville, Florida.

4. On or about January 27, 2010, the defendant, **ONA M. COLASANTE**, opened checking account ending in 8171 in the name of the Colasante Clinic at Merchants and Southern Bank ("M&S Bank") in Gainesville, Florida, a financial

institution, the deposits of which were insured by the Federal Deposit Insurance Corporation, and **COLASANTE** had sole signatory authority on the account.

5. The defendant, **ONA M. COLASANTE**, caused health care benefit programs to be billed for benefits, items, and services, provided to patients of the Colasante Clinic and the Hawthorne Center.

6. The defendant, **ONA M. COLASANTE**, caused claims to be submitted for payment to various health care benefit programs. These claims for payment were submitted for patients purportedly seen and medical services purportedly provided by the Colasante Clinic and the Hawthorne Center. The claims were submitted to a third-party company, and the third-party company submitted the claims to the health care benefit programs.

7. The term "health care benefit program" as defined in Title 18, United States Code, Section 24, means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

8a. The Medicare program was a federal government insurance program for paying certain hospital and medical expenses for persons qualified under the plan, usually for those 65 or older, for individuals entitled to Social Security disability payments for two years or more, and people with end-stage renal disease regardless of income. The Centers for Medicare and Medicaid Services ("CMS") was a federal agency within the United States Department of Health and Human Services ("HHS"), which administered

the Medicare program through its contractors. The hospital benefits were Part A, and the medical expense portion was Part B. Part A benefits covered inpatient services and limited amounts of long-term care. Part B benefits covered outpatient services, diagnostic tests, images, and drug injections. Medicare was established under Title 18 of the Social Security Act of 1965 and became effective on July 1, 1966. First Coast Service Options, Inc. ("First Coast Service Options"), was the fiscal agent that processed the claims and maintained the records for the Medicare program in Florida. First Coast Service Options was located in Jacksonville, Florida. Medicare was funded by federal tax dollars. Provider participation in the Medicare program was voluntary. A participating provider was a person, organization, or institution with a valid participation agreement who or which would: (1) provide the service, (2) submit the claim, and (3) accept as payment in full the amount paid by the program.

8b. Each provider that became a certified Medicare provider was issued a manual or provided with online access to regulations outlining participation requirements and guidelines. To receive Medicare reimbursement for covered services set forth in the manual, the provider filled out either a UB-92 Claim Form for Part A or a Form CMS-1500 "Health Insurance Claim Form" for Part B. This form was either mailed or electronically submitted to First Coast Service Options. When a provider submitted a claim to Medicare, it included information such as the beneficiary's name and address, Medicare number, the date and type of service provided, the place of service, the procedure code, the diagnosis code, the amount billed, and other relevant medical information. One of the critical conditions for any payment was that the service had been

provided for a legitimate, medically necessary purpose. Once a claim was approved, payment was either mailed to the provider or electronically transferred to the provider.

8c. Medicare's policies and rules precluded reimbursement of a provider for drugs that were not approved by the United States Food and Drug Administration ("FDA"), unless CMS provided otherwise.

8d. The defendant, **ONA M. COLASANTE**, was an authorized provider under the Medicare program. On or about March 15, 2000, **COLASANTE** obtained Medicare provider number K1983 for the Hawthorne Center. On or about May 11, 2009, the Hawthorne Center's Medicare provider number was transferred to the Hawthorne Center's new owner. On or about February 3, 2010, **COLASANTE** obtained Medicare provider number CW019 for the Colasante Clinic. On or about the same date, **COLASANTE** also obtained Medicare provider number 18622V for herself as an individual provider.

9a. The Medicaid system was designed under the Social Security Act (Title 42, United States Code, Chapter 7) for the payment of medical costs associated with the treatment of indigent patients. The Medicaid system was administered by each state individually, but was funded in part with federal funds. HHS provided federal funding to the State of Florida Medicaid System, which was administered by the Florida Agency for Health Care Administration ("AHCA"). AHCA in turn contracted with a fiscal intermediary designated to serve as the paying agent. The fiscal intermediary received, adjudicated, and paid Medicaid claims submitted by Medicaid participating providers, and reimbursed medically necessary services performed, ordered, or supervised by a

licensed physician based upon an established fee schedule. Florida physicians and other health care providers submitted Medicaid claims for payment via mail and electronic submission on a Form CMS-1500.

9b. A Medicaid provider had a responsibility to present claims that were true and accurate and for goods and services that, among other things were: (a) actually furnished to the beneficiary; (b) medically necessary and covered by Medicaid; (c) in compliance with applicable Medicaid rules, regulations, handbooks, and federal and state laws; and (d) documented by records made at the time the goods and services were provided, that demonstrated the medical necessity for the goods and services. Pursuant to the aforementioned, Medicaid's rules, regulations, and handbook precluded the reimbursement of a provider for drugs that were not approved by FDA. Once a claim was adjudicated, payment was either mailed to the provider or electronically transferred to the provider.

9c. The defendant, **ONA M. COLASANTE**, was an authorized provider of physician services under the Florida Medicaid program. On or about October 13, 2000, **COLASANTE** obtained Medicaid provider number 259804301 for the Hawthorne Center. On or about October 12, 2005, **COLASANTE** surrendered Medicaid provider number 259804301. On or about February 26, 2010, **COLASANTE** obtained Medicaid provider number 001883000 for the Colasante Clinic.

10a. Blue Cross Blue Shield of Florida, Inc. ("Blue Cross"), with its headquarters in Jacksonville, Florida, was a company that provided health insurance to beneficiaries and issued payments to providers for covered medical services. Blue

Cross's policies precluded reimbursement by a provider for drugs that were not approved by the FDA.

10b. The defendant, **ONA M. COLASANTE**, was an authorized provider for Blue Cross at the Colasante Clinic and the Hawthorne Center.

11. Medicare, Medicaid, and Blue Cross were health care benefit programs as defined in Title 18, United States Code, Section 24, and operated health care public and private plans and contracts affecting commerce under which medical benefits, items, and services were provided to individuals.

12. Health care providers submitted claims to health care benefit programs using standardized codes to describe the diagnosis and the procedures for which payment was sought. With respect to diagnoses, providers used the codes established in the International Classification of Diseases Manual ("ICD-9-CM"). With respect to procedures for which payment was sought, providers used the codes established in the Physicians' Current Procedural Terminology code book ("CPT") and the Health Care Financing Administration Common Procedural Code System code book ("HCPCS").

13. The FDA was the federal agency within HHS responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs were safe and effective for their intended uses and had labeling that contained true and accurate information. The FDA's responsibilities included regulating the manufacturing and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs. The FDA carried out its responsibilities

by enforcing the Food, Drug and Cosmetic Act ("FD&C Act"), Title 21, United States Code, Chapter 9, and other pertinent laws and regulations.

14. The FD&C Act defined a "drug" to include, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; articles (other than food) intended to affect the structure or any function of the body of humans; and articles intended for use as a component of any such articles. Title 21, United States Code, Section 321(g)(1).

15. Prescription drugs were drugs that, because of their toxicity and other potential for harmful effects, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. Title 21, United States Code, Section 353(b)(1)(A). A drug was also a prescription drug if the FDA required it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. Title 21, United States Code, Section 353(b)(1)(B).

16. A drug was considered a "new drug" if it was "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." Title 21, United States Code, Section 321(p)(1). New drugs required an FDA-approved new drug application ("NDA") before they could lawfully be introduced into interstate commerce. Title 21, United States Code, Sections 331(d) and 355.

17. An approved NDA authorized a drug company to manufacture and distribute only the exact drug described in the application. The manufacturing had to occur only at the facilities authorized under the approved NDA; the drug had to bear only the FDA-approved package insert and all labeling information required under federal law; and the drug had to be intended only for the uses prescribed, recommended, or suggested in the approved labeling.

18. Drugs approved for foreign markets often would be unapproved drugs under United States law even if chemically identical to the FDA-approved version. Foreign drugs may have different labeling (including different warnings, dosage recommendations, and indications for use) and may have been manufactured at a location other than the location approved in the FDA approval process.

19. The FD&C Act defined "label" as a display of written, printed, or graphic matter upon the immediate container of any article. Title 21, United States Code, Section 321(k). The FD&C Act provided that any "word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper,...of the retail package of such article, or is easily legible through the outside container or wrapper." Title 21, United States Code, Section 321(k).

20. The FD&C Act defined "labeling" as all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article. Title 21, United States Code, Section 321(m).

21. A drug was "misbranded" if, among other things, its labeling (a) did not bear adequate directions for use, or (b) was not likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Title 21, United States Code, Section 352.

22. For all drugs distributed in the United States, all words, statements, and other information on the label or labeling required by the FD&C Act must appear in the English language. Title 21, Code of Federal Regulations, Part 201.15(c)(1).

23. Bayer Healthcare Pharmaceuticals, Inc. ("Bayer"), was the manufacturer of Mirena® ("Mirena"). Mirena was a drug-releasing Intrauterine Device ("IUD") used for contraception and manufactured in Finland. The only version of Mirena approved by the FDA for distribution, within the United States, was approved on or about December 6, 2000, in NDA number 21-225, and assigned National Drug Code ("NDC") number 50419-421. The FDA-approved Mirena label and labeling was written in the English language and bore the NDC number. Bayer also manufactured a non-FDA-approved product known as Mirena for distribution in countries other than the United States.

24. Novartis Pharmaceutical Corporation ("Novartis") was the manufacturer of Reclast® ("Reclast"). Reclast was a drug manufactured in Switzerland and Austria by Novartis for the treatment of osteoporosis. The only version of Reclast approved by the FDA for distribution, within the United States, was approved on or about August 17, 2007, in NDA number 22-080, and assigned NDC number 0078-0435-61. Novartis also manufactured a non-FDA-approved version known as Aclasta for distribution in countries other than the United States.

25. Genetech, Inc. ("Genetech"), was the manufacturer of Boniva® ("Boniva"), a drug used in the treatment of osteoporosis. On or about May 16, 2003, the tablet form of Boniva, ibandronate sodium, was approved by the FDA for distribution within the United States, in NDA number 21-455. On or about January 6, 2006, the FDA approved injectable Boniva for distribution within the United States, in NDA number 21-858 and assigned NDC number 0004-0191. As of on or about May 22, 2013, there was no "generic" form of injectable Boniva or ibandronate sodium approved by the FDA for distribution in the United States.

B. THE SCHEME

It was part of this scheme to defraud that:

1. The defendant, **ONA M. COLASANTE**, while operating the Hawthorne Center and the Colasante Clinic, ordered and performed, and caused others to order and perform, medically unnecessary tests and procedures on patients covered by health care benefit programs, including, among others, Medicare, Medicaid, and Blue Cross. These medically unnecessary tests and procedures included, among others, hearing tests, breathing tests, urinalysis drug screens, colposcopies, ultrasounds, x-rays, mini-mental exams, stress tests, B-12 injections, and other injections.

2. The defendant, **ONA M. COLASANTE**, used and caused others to use a computerized billing program that assigned false and fictitious diagnosis codes to claims submitted to health care benefit programs that resulted in health care benefit programs reimbursing claims for medically unnecessary tests and procedures.

3. The defendant, **ONA M. COLASANTE**, submitted and caused to be submitted fraudulent claims for services and procedures to health care benefit programs that were never rendered or provided to the patient. These services included, among others, ethanol and substance abuse counseling, tobacco cessation counseling, and self-care management training.

4. The defendant, **ONA M. COLASANTE**, directed one or more employees of the Colasante Clinic to order less expensive non-FDA-approved drugs and devices from "Getcanadiandrugs.com" and "Northwestpharmacy.com," pharmacies in Canada and other locations outside the United States.

5. The defendant, **ONA M. COLASANTE**, purchased, and caused to be purchased, the non-FDA-approved drugs and devices, including, but not limited to, Mirena, Aclasta, Idrofos 3, and T-Safe CU 200B/380A ("T-Safe") (collectively "non-FDA-approved drugs and devices").

6. The defendant, **ONA M. COLASANTE**, purchased the non-FDA-approved drugs and devices using money held in the Colasante Clinic's M&S Bank account ending in 8171.

7. The non-FDA-approved drugs and devices were shipped to the Colasante Clinic. The non-FDA-approved drugs and devices were kept and maintained separate from the FDA-approved drugs in the Colasante Clinic.

8. The defendant, **ONA M. COLASANTE**, administered, and caused others to administer, the non-FDA-approved drugs and devices to patients of the Colasante Clinic.

9. The defendant, **ONA M. COLASANTE**, failed to inform patients that they were being administered and receiving non-FDA-approved drugs.

10. The defendant, **ONA M. COLASANTE**, submitted, and caused to be submitted, to Medicare, Medicaid, Blue Cross, and other health care benefit programs fraudulent and misleading claims for charges related to the administration of the non-FDA-approved drugs and devices, and fraudulently failed to disclose the fact that these drugs and devices had not been approved by the FDA.

11. The defendant, **ONA M. COLASANTE**, caused misbranded drugs to be introduced and delivered for introduction and delivery into interstate commerce, that is, the defendant purchased from foreign sources, and administered to patients at the Colasante Clinic, non-FDA-approved drugs and devices, which were misbranded in that:

a. failing to prominently and conspicuously, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, bear all words, statements, and other information required by law to appear on the label and labeling, in that the labeling was not in the English language, within the meaning of Title 21, United States Code, Section 352(c);

b. they did not bear the symbol "Rx only" pursuant to Title 21, United States Code, Section 353(b)(4);

c. they did not bear adequate directions for use, within the meaning of Title 21, United States Code, Section 352(f); and

d. they came from a foreign drug establishment and were not annually listed with the FDA by that establishment as drugs that were being manufactured for

commercial distribution in the United States at that drug establishment as required by Title 21, United States Code, Sections 352(o) and 360(j).

12. The defendant, **ONA M. COLASANTE**, caused unapproved new drugs, within the meaning of Title 21, United States Codes, Section 321(p)(1), to be introduced and delivered for introduction and delivery into interstate commerce in that these drugs were not the subject of approved marketing or investigation applications on file with the FDA as required by Title 21, United States Code, Section 355(a).

13. By the conduct described in this section, the defendant, **ONA M. COLASANTE**, fraudulently caused health care benefit programs to remit payments to bank accounts controlled by Colasante, including the Colasante Clinic's M&S Bank account ending in 8171, to which the defendant was not entitled.

C. EXECUTION OF THE SCHEME

For the purpose of executing this scheme to defraud, the defendant, **ONA M. COLASANTE**, caused fraudulent claims to be submitted to health care benefit programs as set forth below:

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
1	3/2/10	5/26/10	VC	Medicare	False Diagnosis and Medically Unnecessary	$154.00
2	3/12/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
3	3/15/10	6/24/10	FH	Medicare	Services Not Rendered	$80.00
4	3/15/10	6/24/10	FH	Medicare	False Diagnosis and Services Not Rendered	$220.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
5	3/15/10	6/24/10	FH	Medicare	False Diagnosis and Services Not Rendered	$225.00
6	3/19/10	5/6/10	BC	Medicare	Non-FDA-Approved Drug	$846.00
7	3/19/10	5/6/10	GW	Medicare	Non-FDA-Approved Drug	$2,230.00
8	3/22/10	3/25/11	JC	Medicare	False Diagnosis and Services Not Rendered	$67.00
9	4/14/10	5/6/10	SR	Medicare	Non-FDA-Approved Drug	$846.00
10	4/15/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
11	4/16/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
12	4/16/10	5/6/10	CB	Medicare	False Diagnosis and Services Not Rendered	$50.00
13	4/22/10	3/25/11	JC	Medicare	False Diagnosis and Services Not Rendered	$67.00
14	4/28/10	5/12/10	JC	Medicare	Non-FDA-Approved Drug	$846.00
15	4/30/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
16	4/30/10	5/12/10	CB	Medicare	Non-FDA-Approved Drug	$2,230.00
17	5/5/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
18	5/9/10	5/18/10	FH	Medicare	Non-FDA-Approved Drug	$846.00
19	5/12/10	3/25/11	JC	Medicare	False Diagnosis and Services Not Rendered	$67.00
20	5/18/10	5/25/10	BE	Medicare	Non-FDA-Approved Drug	$846.00
21	5/24/10	3/24/11	MN	Blue Cross	False Diagnosis and Services Not Rendered	$67.00
22	5/25/10	6/1/10	TB	Medicaid	False Diagnosis and Medically Unnecessary	$42.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
23	5/25/10	6/1/10	TB	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
24	5/29/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
25	6/1/10	6/10/10	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
26	6/2/10	6/9/10	LA	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
27	6/2/10	6/9/10	LA	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
28	6/2/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
29	6/10/10	3/24/11	MN	Blue Cross	False Diagnosis and Services Not Rendered	$67.00
30	6/18/10	6/29/10	VC	Medicare	Non-FDA-Approved Drug	$846.00
31	6/19/10	6/29/10	BC	Medicare	Non-FDA-Approved Drug	$846.00
32	6/25/10	3/25/11	JC	Medicare	False Diagnosis and Services Not Rendered	$67.00
33	6/30/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
34	6/30/10	7/13/10	VH	Medicare	Non-FDA-Approved Drug	$846.00
35	7/2/10	7/13/10	AB	Medicare	False Diagnosis and Services Not Rendered	$225.00
36	7/2/10	7/13/10	AB	Medicare	False Diagnosis and Services Not Rendered	$220.00
37	7/3/10	6/20/11	LL	Medicare	False Diagnosis and Services Not Rendered	$67.00
38	7/14/10	7/26/10	SR	Medicare	Non-FDA-Approved Drug	$846.00
39	7/15/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
40	7/21/10	8/2/10	GW	Medicare	False Diagnosis and Medically Unnecessary	$154.00
41	7/22/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
42	7/22/10	8/2/10	PG	Medicare	Non-FDA-Approved Drug	$2,230.00
43	7/26/10	8/6/10	AB	Medicare	Non-FDA-Approved Drug	$846.00
44	7/29/10	8/6/10	JC	Medicare	Non-FDA-Approved Drug	$846.00
45	7/30/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
46	8/5/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
47	8/5/10	8/18/10	VC	Medicare	False Diagnosis and Services Not Rendered	$30.00
48	8/5/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
49	8/10/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
50	8/12/10	8/20/10	CB	Medicare	False Diagnosis and Services Not Rendered	$30.00
51	8/27/10	9/1/10	BE	Medicare	Non-FDA-Approved Drug	$846.00
52	8/31/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
53	9/9/10	9/13/10	EB	Blue Cross	False Diagnosis and Medically Unnecessary	$30.00
54	9/9/10	9/13/10	EB	Blue Cross	False Diagnosis and Medically Unnecessary	$42.00
55	9/14/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
56	9/16/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
57	9/17/10	9/30/10	AM	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
58	9/17/10	9/30/10	AM	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
59	9/17/10	9/30/10	AM	Medicaid	False Diagnosis and Medically Unnecessary	$64.00
60	9/20/10	10/4/10	AS	Medicare	Non-FDA-Approved Drug	$846.00
61	9/21/10	9/27/10	VC	Medicare	Non-FDA-Approved Drug	$846.00
62	9/22/10	9/30/10	BC	Medicare	Non-FDA-Approved Drug	$846.00
63	9/23/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
64	9/27/10	11/5/10	SK	Blue Cross	False Diagnosis and Medically Unnecessary	$30.00
65	9/27/10	11/20/10	SK	Blue Cross	False Diagnosis and Medically Unnecessary	$181.00
66	9/30/10	10/7/10	VH	Medicare	Non-FDA-Approved Drug	$846.00
67	10/4/10	10/11/10	HS	Medicare	False Diagnosis and Services Not Rendered	$30.00
68	10/6/10	11/24/10	JB	Medicare	False Diagnosis and Services Not Rendered	$220.00
69	10/6/10	11/24/10	JB	Medicare	False Diagnosis and Services Not Rendered	$225.00
70	10/6/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
71	10/6/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
72	10/6/10	10/11/10	VC	Medicare	Services Not Rendered	$60.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
73	10/7/10	10/13/10	BC	Medicare	False Diagnosis and Medically Unnecessary	$154.00
74	10/7/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
75	10/7/10	10/13/10	VC	Medicare	Services Not Rendered	$60.00
76	10/8/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
77	10/8/10	10/14/10	VC	Medicare	Services Not Rendered	$60.00
78	10/11/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
79	10/11/10	3/24/11	MN	Blue Cross	False Diagnosis and Services Not Rendered	$67.00
80	10/14/10	10/20/10	VC	Medicare	Non-FDA-Approved Drug	$2,230.00
81	10/14/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
82	10/14/10	10/20/10	SR	Medicare	Non-FDA-Approved Drug	$846.00
83	10/19/10	10/27/10	BC	Medicare	Services Not Rendered	$60.00
84	10/20/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
85	10/20/10	4/28/11	WL	Medicare	False Diagnosis and Services Not Rendered	$67.00
86	10/20/10	10/27/10	AS	Medicare	Non-FDA-Approved Drug	$846.00
87	10/26/10	11/15/10	EB	Blue Cross	False Diagnosis and Services Not Rendered	$220.00
88	10/26/10	11/15/10	EB	Blue Cross	False Diagnosis and Services Not Rendered	$225.00
89	10/26/10	11/3/10	AB	Medicare	Non-FDA-Approved Drug	$846.00
90	10/27/10	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$136.00
91	10/27/10	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$30.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
92	10/29/10	11/8/10	JC	Medicare	Non-FDA-Approved Drug	$846.00
93	11/8/10	11/19/10	EG	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
94	11/8/10	11/19/10	EG	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
95	11/8/10	11/19/10	KH	Medicaid	False Diagnosis and Medically Unnecessary	$64.00
96	11/8/10	11/19/10	KH	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
97	11/8/10	11/19/10	KH	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
98	11/9/10	11/17/10	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
99	11/10/10	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$67.00
100	11/12/10	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
101	11/17/10	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
102	11/17/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
103	11/19/10	6/13/11	TG	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
104	11/19/10	6/13/11	TG	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
105	11/20/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
106	11/20/10	11/30/10	CB	Medicare	False Diagnosis and Services Not Rendered	$30.00
107	11/23/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
108	11/27/10	12/3/10	JH	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
109	11/27/10	12/3/10	JH	Medicaid	False Diagnosis and Medically Unnecessary	$64.00
110	12/1/10	12/8/10	SK	Blue Cross	Non-FDA-Approved Drug	$2,230.00
111	12/8/10	12/16/10	GR	Medicare	Non-FDA-Approved Drug	$846.00
112	12/14/10	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$67.00
113	12/14/10	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$30.00
114	12/22/10	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
115	12/24/10	4/28/11	WL	Medicare	False Diagnosis and Services Not Rendered	$67.00
116	12/29/10	5/2/11	DD	Medicare	False Diagnosis and Services Not Rendered	$67.00
117	12/31/10	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
118	1/3/11	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
119	1/3/11	5/2/11	DD	Medicare	False Diagnosis and Services Not Rendered	$67.00
120	1/5/11	4/11/11	ML	Medicare	False Diagnosis and Services Not Rendered	$67.00
121	1/7/11	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
122	1/12/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
123	1/12/11	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$67.00
124	1/12/11	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$30.00
125	1/12/11	1/21/11	AS	Medicare	Non-FDA-Approved Drug	$846.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
126	1/13/11	1/25/11	JG	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
127	1/13/11	1/25/11	JG	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
128	1/15/11	1/25/11	DG	Medicaid	False Diagnosis and Medically Unnecessary	$40.00
129	1/18/11	6/2/11	EE	Medicare	False Diagnosis and Services Not Rendered	$67.00
130	1/19/11	1/27/11	BC	Medicare	Non-FDA-Approved Drug	$846.00
131	1/24/11	2/2/11	EE	Medicare	Non-FDA-Approved Drug	$2,230.00
132	1/25/11	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
133	1/26/11	2/2/11	AB	Medicare	Non-FDA-Approved Drug	$846.00
134	1/28/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
135	1/29/11	2/3/11	JC	Medicare	Non-FDA-Approved Drug	$846.00
136	2/4/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
137	2/4/11	2/16/11	IF	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
138	2/4/11	2/16/11	IF	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
139	2/7/11	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
140	2/11/11	6/20/11	LL	Medicare	False Diagnosis and Services Not Rendered	$67.00
141	2/14/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
142	2/15/11	2/19/11	LA	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
143	2/15/11	2/19/11	LA	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
144	2/16/11	3/25/11	CB	Medicare	False Diagnosis and Services Not Rendered	$67.00
145	2/17/11	2/23/11	CB	Medicare	False Diagnosis and Services Not Rendered	$30.00
146	2/17/11	3/25/11	JC	Medicare	False Diagnosis and Services Not Rendered	$67.00
147	2/22/11	3/2/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
148	2/24/11	3/2/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
149	2/25/11	3/8/11	LT	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
150	2/25/11	3/8/11	LT	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
151	2/26/11	3/7/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
152	3/1/11	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
153	3/3/11	3/10/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
154	3/4/11	3/10/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
155	3/10/11	3/25/11	VC	Medicare	Non-FDA-Approved Drug	$846.00
156	3/10/11	5/6/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
157	3/10/11	3/25/11	VC	Medicare	Services Not Rendered	$60.00
158	3/15/11	3/25/11	MB	Medicaid	False Diagnosis and Medically Unnecessary	$154.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
159	3/15/11	3/25/11	BC	Medicare	Services Not Rendered	$60.00
160	3/16/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
161	3/16/11	12/20/11	IF	Medicaid	Non-FDA-Approved Drug	$800.00
162	3/16/11	3/29/11	GI	Blue Cross	Non-FDA-Approved Drug	$800.00
163	3/21/11	3/30/11	GW	Medicare	Non-FDA-Approved Drug	$2,230.00
164	3/21/11	6/4/11	DW	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
165	3/21/11	6/4/11	DW	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
166	3/23/11	4/7/11	CB	Medicare	False Diagnosis and Services Not Rendered	$30.00
167	3/23/11	5/2/11	PG	Medicare	False Diagnosis and Services Not Rendered	$67.00
168	3/23/11	12/20/11	HS	Medicaid	Non-FDA-Approved Drug	$800.00
169	3/24/11	4/7/11	EL	Blue Cross	Non-FDA-Approved Drug	$800.00
170	3/24/11	4/7/11	GV	Blue Cross	Non-FDA-Approved Drug	$800.00
171	3/25/11	6/4/11	DW	Medicaid	False Diagnosis and Medically Unnecessary	$154.00
172	3/25/11	6/4/11	DW	Medicaid	False Diagnosis and Medically Unnecessary	$210.00
173	3/28/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
174	3/31/11	6/7/11	CA	Medicare	False Diagnosis and Services Not Rendered	$67.00
175	3/31/11	4/8/11	CR	Blue Cross	Non-FDA-Approved Drug	$800.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
176	4/1/11	4/11/11	LC	Medicare	False Diagnosis and Services Not Rendered	$30.00
177	4/12/11	4/21/11	AS	Medicare	Non-FDA-Approved Drug	$846.00
178	4/12/11	5/6/11	AS	Medicare	False Diagnosis and Services Not Rendered	$67.00
179	4/18/11	6/7/11	RB	Medicare	False Diagnosis and Services Not Rendered	$67.00
180	4/18/11	5/6/11	RB	Medicare	False Diagnosis and Services Not Rendered	$30.00
181	4/20/11	5/2/11	VC	Medicare	False Diagnosis and Services Not Rendered	$30.00
182	4/21/11	5/6/11	BC	Medicare	Non-FDA-Approved Drug	$846.00
183	4/21/11	5/12/11	LL	Blue Cross	Non-FDA-Approved Drug	$800.00
184	4/26/11	5/6/11	AB	Medicare	Non-FDA-Approved Drug	$846.00
185	4/26/11	5/9/11	CS	Blue Cross	Non-FDA-Approved Drug	$800.00
186	4/29/11	5/9/11	JC	Medicare	Non-FDA-Approved Drug	$846.00
187	5/2/11	5/9/11	CB	Medicare	Non-FDA-Approved Drug	$2,230.00
188	5/2/11	5/9/11	CB	Medicare	Services Not Rendered	$60.00
189	5/2/11	5/11/11	EE	Medicare	False Diagnosis and Service Not Rendered	$67.00
190	5/3/11	5/10/11	AB	Medicare	False Diagnosis and Medically Unnecessary	$45.00
191	5/6/11	5/19/11	VH	Medicare	Non-FDA-Approved Drug	$846.00
192	5/17/11	12/20/11	MV	Medicaid	Non-FDA-Approved Drug	$800.00
193	6/7/11	6/20/11	RB	Medicare	False Diagnosis and Services Not Rendered	$30.00

COUNT	OFFICE VISIT DATE	BILLING DATE	PATIENT INITIALS	HEALTH CARE BENEFIT PROGRAM	FALSITY OF CLAIM	AMOUNT CLAIMED
194	6/9/11	7/18/11	MM	Medicaid	False Diagnosis and Medically Unnecessary	$42.00
195	6/9/11	7/18/11	MM	Medicaid	False Diagnosis and Medically Unnecessary	$30.00
196	6/9/11	7/18/11	MM	Medicaid	False Diagnosis and Medically Unnecessary	$181.00
197	6/13/11	7/19/11	RB	Medicare	False Diagnosis and Services Not Rendered	$30.00
198	6/14/11	7/19/11	VC	Medicare	False Diagnosis and Services Not Rendered	$67.00
199	6/14/11	7/19/11	VC	Medicare	False Diagnosis and Services Not Rendered	$30.00

In violation of Title 18, United States Code, Sections 1347 and 2.

COUNT TWO HUNDRED

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery for introduction into interstate commerce of a drug, by purchasing non-FDA-approved

Mirena from foreign sources, that was misbranded, within the meaning of the FD&C Act, in one or more of the following ways:

1. failing to prominently and conspicuously, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, bear all words, statements, and other information required by law to appear on the label and labeling, in that the labeling was not in the English language, within the meaning of Title 21, United States Code, Section 352(c);

2. failing to bear adequate directions for use, within the meaning of Title 21, United States Code, Section 352(f); and

3. failing to bear the symbol "Rx only" as required by Title 21, United States Code, Section 353(b)(4).

In violation of Title 21, United States Code, Section 331(a), 333(a)(2), 352(c), 352(f), and 353(b)(4), and Title 18, United States Code, Section 2.

COUNT TWO HUNDRED ONE

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery, for introduction into interstate commerce of a drug, by purchasing non-FDA-approved Aclasta from foreign sources, that was misbranded, within the meaning of the FD&C Act, in one or more of the following ways:

1. failing to bear the symbol "Rx only" as required by Title 21, United States Code, Section 353(b)(4);

2. failing to bear adequate directions for use, within the meaning of Title 21, United States Code, Section 352(f); and

3. the drug came from a foreign drug establishment and that drug was not annually listed with the FDA by that establishment as one of the drugs that was being manufactured for commercial distribution in the United States at that drug establishment as required by Title 21, United States Code, Sections 352(o) and 360(j).

In violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(f), 352(o), 353(b)(4), and 360(j), and Title 18, United States Code, Section 2.

COUNT TWO HUNDRED TWO

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery for introduction into interstate commerce of a drug, by purchasing non-FDA-approved Idrofos 3 from foreign sources that was misbranded, within the meaning of the FD&C Act, in one or more of the following ways:

1. failing to bear the symbol "Rx only" as required by Title 21, United States Code, Section 353(b)(4);

2. failing to bear adequate directions for use, within the meaning of Title 21, United States Code, Section 352(f); and

3. the drug came from a foreign drug establishment and that drug was not annually listed with the FDA by that establishment as one of the drugs that was being manufactured for commercial distribution in the United States at that drug establishment as required by Title 21, United States Code, Sections 352(o) and 360(j).

In violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(f), 352(o), 353(b)(4), and 360(j), and Title 18, United States Code, Section 2.

COUNT TWO HUNDRED THREE

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery for introduction into interstate commerce of a drug, namely, Aclasta, from foreign sources, which was an unapproved new drug within the meaning of Title 21, United States Code, Section 321(p)(1), in that it was not the subject of an approved marketing or investigation application on file with the FDA as required by Title 21, United States Code, Section 355(a).

In violation of Title 21, United States Code, Sections 331(d), 333(a)(2), and 355, and Title 18, United States Code, Section 2.

COUNT TWO HUNDRED FOUR

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery for introduction into interstate commerce of a drug, namely, Idrofos 3, from foreign sources, which was an unapproved new drug within the meaning of Title 21, United States Code, Section 321(p)(1), in that it was not the subject of an approved marketing or investigation application on file with the FDA as required by Title 21, United States Code, Section 355(a).

In violation of Title 21, United States Code, Sections 331(d), 333(a)(2), and 355, and Title 18, United States Code, Section 2.

COUNT TWO HUNDRED FIVE

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

Between on or about February 1, 2010, and on or about June 16, 2011, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

with the intent to defraud and mislead, did cause the introduction and delivery for introduction into interstate commerce of a drug, namely, T-Safe, from foreign sources, which was an unapproved new drug within the meaning of Title 21, United States Code, Section 321(p)(1), in that it was not the subject of an approved marketing or investigation

application on file with the FDA as required by Title 21, United States Code, Section 355(a).

In violation of Title 21, United States Code, Sections 331(d), 333(a)(2), and 355, and Title 18, United States Code, Section 2.

COUNTS TWO HUNDRED SIX THROUGH TWO HUNDRED TEN

A. INTRODUCTION

The allegations contained in paragraphs A1 through A25 and B1 through B13 of Counts One through One Hundred Ninety-Nine are incorporated by reference as if fully set forth herein.

B. THE CHARGE

On or about the dates listed below, in the Northern District of Florida, and elsewhere, the defendant,

ONA M. COLASANTE,

did knowingly engage and attempt to engage in a monetary transaction by, through, and to a financial institution, affecting interstate and foreign commerce, in criminally derived property of a value greater than $10,000, namely, the withdrawal and transfer of funds and monetary instruments, as identified below, such property having been derived from a specified unlawful activity, that is, health care fraud, in violation of Title 18, United States Code, Section 1347:

COUNT	DATE	PAYEE	AMOUNT
206	11/16/10	Northwest Pharmacy	$15,940.00
207	1/5/11	Northwest Pharmacy	$15,424.25
208	3/15/11	GCD Panama Inc.	$12,199.90
209	3/29/11	GCD Panama Inc.	$11,298.90
210	3/29/11	Northwest Pharmacy	$23,599.65

In violation of Title 18, United States Code, Sections 1957 and 2.

CRIMINAL FORFEITURE

The allegations contained in Counts One through Two Hundred Ten of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures to the United States pursuant to the provisions of Title 18, United States Code, Sections 982(a)(1) and 982(a)(7).

Upon the conviction of the violations alleged in Counts One through Two Hundred Ten of this Indictment, the defendant,

ONA M. COLASANTE,

shall forfeit to the United States, pursuant to Title 18, United States Code, Sections 982(a)(1) and 982(a)(7), any and all property, real or personal, involved in the aforementioned offenses and all property, constituting, derived from, or traceable to such violations, including the medical license of the defendant, **ONA M. COLASANTE**, medical license number ME63062.

If any of the property described above as being subject to forfeiture pursuant to Counts One through Two Hundred Ten of the Indictment, as a result of any act or omission of any defendant:

i. cannot be located upon the exercise of due diligence;

ii. has been transferred or sold to, or deposited with, a third person;

iii. has been placed beyond the jurisdiction of this Court;

iv. has been substantially diminished in value; or

v. has been commingled with other property that cannot be divided without difficulty,

the United States shall be entitled to forfeiture of substitute property up to the value of the property subject to forfeiture under the provisions of Title 21, United States Code, Section 853(p), which is incorporated by reference in Title 18, United States Code, Section 982.

Redacted

PAMELA C. MARSH
United States Attorney

TIFFANY H. EGGERS
Assistant United States Attorney