

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

RECEIVED
JUL 14 1974
U.S. DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
EAST LANSING, MICHIGAN
-M- Hall

UNITED STATES OF AMERICA, ex rel

CIVIL NUMBER

[UNDER SEAL,] and

[UNDER SEAL],

5.00 CV 124

PLAINTIFFS,



Gordon J. Quist
U. S. District Judge

VS.

UNSEALED

[UNDER SEAL],

[UNDER SEAL],

DEFENDANTS.

PLAINTIFFS' ORIGINAL COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE
FALSE CLAIMS ACT

JURY TRIAL DEMANDED

1 UNITED STATES DISTRICT COURT
2 WESTERN DISTRICT OF MICHIGAN

3
4
5
6 UNITED STATES OF AMERICA, *ex rel*
7 RUSSELL E. DINGLE and
8 THOMAS L. REMPFER,

CIVIL NUMBER

9
10 PLAINTIFFS,

11
12 VS.

13
14
15 BIOPORT CORPORATION,
16 ROBERT MYERS,

17
18 DEFENDANTS.
19
20
21
22

23
24 PLAINTIFFS' ORIGINAL COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE
25 FALSE CLAIMS ACT

26
27
28 JURY TRIAL DEMANDED
29
30
31

COMPLAINT

- 1
2 1. This is an action to recover damages and civil penalties on behalf of the United States of
3 America arising from false statements and claims made by defendants Bioport Corporation and
4 Robert C. Myers, in violation of the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.
- 5 2. Beginning in 1990 and continuing through 1998, defendants submitted false statements,
6 records, and claims for payment to the United States in connection with the development and
7 procurement of Anthrax Vaccine Adsorbed for use by the United States Department of Defense
8 ("DOD").
- 9 3. Defendants' false claims followed from the false statements and false records provided by
10 defendant BioPort Corporation and Robert C. Myers during the several contracts between the
11 defendant BioPort Corporation and the United States from 1990 to the present. BioPort
12 Corporation provided an adulterated, and misbranded drug product to the United States, falsely
13 claiming the product as the Food and Drug Administration ("FDA") approved Anthrax
14 Vaccine Adsorbed ("AVA"). As a result of the scheme, the government improperly paid
15 defendants millions of dollars.
- 16 4. Defendant's fraudulent claims for additional monies through modifications to contracts with
17 DOD resulted in the government improperly paying defendants millions of dollars.
- 18 5. The False Claims Act, originally enacted in 1863, was substantially amended by the False
19 Claims Amendments Act of 1986. Congress enacted the amendments to enhance the
20 Government's ability to recover losses resulting from fraud against the United States.
- 21 6. The Act provides that any person who knowingly submits a false or fraudulent claim to the
22 government for payment or approval, is liable for a civil penalty of up to \$10,000 for each such
23 claim, plus three times the amount of the damages sustained by the government. The Act
24 allows any person having information regarding a false or fraudulent claim against the
25 government to bring an action for himself and for the government and to share in any recovery.
26 The complaint is to be filed under seal for up to 60 days (without service on the defendant
27 during that period) to enable the government to conduct its own investigation without the
28 defendant's knowledge and determine whether to join the action.
- 29 7. Based on these provisions, plaintiffs/relators Russell E. Dingle and Thomas L. Rempfer seek to
30 recover damages and civil penalties arising from defendant's presentation of false records,

1 claims, and statements to the United States Government in connection with the various AVA
2 production contracts.

3 PARTIES

4 8. Plaintiff/relator Russell E. Dingle is a resident of East Hartford, Connecticut. Mr. Dingle is
5 currently a member of the United States Air Force Reserve with 18 years of service to the
6 United States. Mr. Dingle became interested in AVA shortly after Secretary of Defense Cohen
7 announced a vaccination policy affecting the 2.4 million members of the United States Military
8 in December 1997. As an Air National Guardsman for Connecticut, Mr. Dingle was assigned
9 to a research team by his commander to investigate the history of the anthrax vaccine and to
10 develop questions as necessary to present to the National Guard Bureau in Washington D.C.
11 Based on that research, Mr. Dingle found evidence that raised serious doubts about the safety
12 and effectiveness of the anthrax vaccine. As a result, Mr. Dingle declined the vaccine and was
13 forced to resign from the Connecticut Air National Guard in April 1999. Mr. Dingle has
14 continued to conduct independent research on AVA from August 1998 through the present.
15 Mr. Dingle, to the best of his recollection and records, has personal knowledge of the
16 allegations contained in this complaint.

17 9. Plaintiff/relator Thomas L. Rempfer is a resident of West Suffield, Connecticut. Mr. Rempfer
18 is currently a member of the United States Air Force Reserve with 17 years of service to the
19 United States. Mr. Rempfer became interested in AVA shortly after Secretary of Defense
20 Cohen announced a vaccination policy affecting 2.4 million members of the United States
21 Military in December 1997. As an Air National Guardsman for Connecticut, Mr. Rempfer was
22 assigned to a research team by his commander to investigate the history of the anthrax vaccine
23 and to develop questions as necessary to present to the National Guard Bureau in Washington
24 D.C. Based on that research, Mr. Rempfer found evidence that raised serious doubts about the
25 safety and effectiveness of the anthrax vaccine. As a result, Mr. Rempfer declined the vaccine
26 and was forced to resign from the Connecticut Air National Guard in March 1999. Mr.
27 Rempfer has continued to conduct independent research on AVA from August 1998 to the
28 present. Mr. Rempfer, to the best of his recollection and records, has personal knowledge of the
29 allegations contained in this complaint.

30 10. Plaintiffs/relators Messrs. Dingle and Rempfer have combined their research to form the basis
31 for the allegations in this complaint.

- 1 11. Defendant BioPort Corporation is a Michigan corporation with its principal place of business
2 in Lansing, Michigan. From the 1970's until 1998, the Department of Defense procured AVA
3 from a facility owned by the state of Michigan. The facility, first known as the Biologic
4 Products Division of the Michigan Department of Public Health and later as the Michigan
5 Biologic Product Institute ("MBPI") was sold to BioPort Corporation in September 1998. The
6 contracts DOD had with the Michigan facility transferred to BioPort Corporation. BioPort
7 Corporation was awarded another multi-million dollar contract for AVA by the DOD shortly
8 after the sale.
- 9 12. Defendant Robert C. Myers, a doctor of Veterinarian Medicine, was the Chief, Division of
10 Biologic Products, for the Michigan facility in 1990 and directly responsible for the production
11 of AVA. Dr. Myers later became the Director for MBPI. Dr. Myers is now Chief Operating
12 Officer for and a principal owner of BioPort Corporation.

13 JURISDICTION AND VENUE

- 14 13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331
15 and 31 U.S.C. § 3732, which confer jurisdiction on this Court for actions brought pursuant to
16 31 U.S.C. §§ 3729 and 3730.
- 17 14. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732 (a),
18 which authorizes nationwide service of process. In addition, one or more of the defendants can
19 be found in, resides in, and/or transacts business in the Eastern District of Michigan.
20 Furthermore, one or more of the acts proscribed by 31 U.S.C. § 3729 occurred in the Eastern
21 District of Michigan.
- 22 15. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because one or more
23 defendants can be found in, resides in, and/or transacts business in the Eastern District of
24 Michigan and because one or more of the acts committed in violation of the False Claims Act
25 occurred in the Eastern District of Michigan.

26 BACKGROUND

- 27 16. AVA was developed in the 1950's and 1960's and licensed by the Division of Biologics,
28 National Institute for Health in 1970 to be manufactured by the Michigan Department of Public
29 Health. This is the only facility in the United States licensed to manufacture AVA. AVA is a
30 biologic product as defined in 42 U.S.C. § 262(i). The Federal Food, Drug, and Cosmetics Act
31 (21 U.S.C. § 301 et seq) applies to a biological product subject to regulation under 42 U.S.C. §

1 262. The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetics
2 Act are set forth in 21 C.F.R. Chapter 9 Food and Drugs. 21 C.F.R. sets forth the requirements
3 for the manufacture, storage, packaging, labeling, etc. of biologic products. 21 U.S.C. § 331
4 identifies acts prohibited under the Federal Food, Drug, and Cosmetics Act (the act).

- 5 17. The United States Department of Defense purchases certain military systems or products on a
6 "sole source" basis. AVA is such a product. MBPI was and BioPort Corporation is the sole
7 license holder and manufacturer of AVA in the United States. MBPI and BioPort Corporation
8 (herein after "BioPort") have been the "sole source" of AVA for the DOD. The DOD has a
9 decades long relationship with BioPort, substantially funding the entire facility in Lansing,
10 Michigan, to include all renovations, expansions and facility improvements and providing
11 government furnished equipment. DOD funding has allowed BioPort to modernize and expand
12 the production capability of AVA. DOD has been the majority customer for AVA over time.
13 DOD is currently the sole customer for AVA produced by BioPort. The Federal Acquisition
14 Regulations apply to sole source contracts with DOD.
- 15 18. BioPort first produced AVA under an Investigational New Drug application (DBS-IND 180) in
16 1966. BioPort filed a license application for the manufacture of Anthrax Protective Antigen,
17 Aluminum Hydroxide Adsorbed in 1967. The specification for manufacture is based on U.S.
18 Patent 3,208,909. The license application references an article published in "Applied
19 Microbiology" that details the production process. The license to manufacture AVA, granted in
20 1970, is made of two parts. One is for the facility, the Establishment License Application
21 (ELA). The second is for the product, the Product License Application (PLA). BioPort
22 produced AVA continuously from its first contract (PH21-68-2064) in 1968 until January 1998
23 when the facility ceased production and was razed.

24 SPECIFIC ALLEGATIONS

- 25 19. BioPort underwent a major expansion in AVA production capacity in 1990. Dr. Myers notified
26 the Center for Biologics Evaluation and Research (CBER) in June 1990 that BioPort would
27 replace the approved fermenter and chill tank on or about 15 August 1990 with a new
28 fermenter. A 9 July 1990 Conversation Record by FDA employee Rebecca Devine to Dr.
29 Myers indicates that he was informed that this would be considered a major change and should
30 be submitted in the form of an ELA amendment.
- 31

- 1 20. A July 1990 Trip Report to the Michigan facility by a member of the U.S. Army Medical
2 Research and Development Command indicates that at least one 100 liter fermenter had been
3 added to the AVA production line and that a recently delivered 100 liter fermenter could be
4 diverted from production of another vaccine to the AVA production line.
- 5 21. A September 1990 Trip Report to the Michigan facility discusses the necessity and the ability
6 to put the recently acquired additional fermenter into AVA production. Also discussed is the
7 total number of fermenters that the facility could hold, i.e. three additional fermenters for a
8 total of four fermenters producing AVA. This Trip Report also indicates that FDA must
9 approve the change in fermenter types from glass-lined to stainless steel and that FDA
10 approval will require developing the definitive data that the product from the stainless steel
11 fermenters is the same as the glass-lined fermenters.
- 12 22. In December 1990, BioPort filed for an amendment to their ELA to include the expanded
13 manufacturing facility. Rather than replacing the original equipment as indicated in the June
14 1990 letter to CBER, the renovation included the addition of two AVA production lines
15 adjacent to the original AVA production line. The renovated facility contained three AVA
16 production lines versus the one production line originally licensed. This ELA amendment
17 request indicates that the renovation had already taken place.
- 18 23. Changes in the manufacturing process are governed by 21 U.S.C § 356a. and 21 C.F.R. §
19 601.12. 21 U.S.C § 356a. classifies a manufacturing change that has substantial potential to
20 adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate
21 to the safety and effectiveness of a drug as a "major" change. 21 U.S.C § 356a. requires that a
22 drug made with a major manufacturing change not be distributed until the Secretary approves
23 the application.
- 24 24. 21 C.F.R. § 601.12 further defines a "major" manufacturing change as any change in the
25 product, production process, quality controls, equipment, facilities, or responsible personnel
26 that has a substantial potential to have an adverse effect on the identity, strength, quality,
27 purity, or potency of the product as they may relate to the safety and effectiveness of the
28 product. These changes include "Changes in the qualitative or quantitative formulation or other
29 specifications as provided in the approved application or in the regulations" (21 C.F.R. §
30 601.12(b)(2)(i)) and "Changes in the virus or adventitious agent removal or inactivation
31 method(s);" (21C.F.R. § 601.12(b)(2)(iii)).

- 1 25. The production line in the original ELA consisted of glass-lined fermenters, a glass-lined chill
2 tank, and sintered glass filters. The two production lines added in 1990 consisted of stainless
3 steel fermenters, stainless steel chill tanks, and low-protein-binding nylon membrane filters.
4 The amendment request, while indicating that stainless steel equipment was being used, failed
5 to identify this as a change in equipment type for the additional production lines. As a result,
6 FDA was unaware of the substantial potential of the amendment request to have an adverse
7 effect on the identity, strength, quality, purity, or potency of the product as they may relate to
8 the safety and effectiveness of the product.
- 9 26. The vaccine manufactured from these three production lines is not the final product. It is a
10 preliminary product called a subplot. Sublots are stored in bulk. When a Lot of AVA is required,
11 BioPort combines a certain amount from several sublots to form the final Lot. This procedure
12 ensures uniformity of vaccine over time. The AVA produced from the sublots after the two
13 production lines were added is different than the originally licensed AVA. According to
14 researchers, the AVA produced after the manufacturing change is more potent than the original
15 approved AVA.
- 16 27. The original licensed vaccine sublots were produced from the only production line. Vaccine
17 produced after 1990 was a combination of the three production lines, mixing the sublots
18 produced by materially different fermenters and chillers. The primary components of the
19 originally approved manufacturing process were glass-lined. The additional production lines
20 employed stainless steel, potentially affecting the qualitative formulation of the sublots and the
21 final Lots. BioPort failed to inform FDA in their ELA amendment request that the equipment
22 type had changed. 21 C.F.R. § 601.12 requires prior approval before the product is distributed
23 after a major manufacturing change.
- 24 28. The original licensed sublots were inactivated by use of a sintered glass filter. The two
25 additional production lines employed a low-protein-binding nylon membrane filter. The
26 sublots, inactivated by different methods, were combined to form final Lots. 21 C.F.R. §
27 610.12(b)(2)(vi) considers a change which may affect product sterility assurance, such as
28 changes in product or component sterilization methods a major change. BioPort failed to
29 inform FDA in their ELA amendment request that the filter type had changed. 21 C.F.R. §
30 601.12 requires prior approval before the product is distributed after a major manufacturing
31 change.

- 1 29. CBER approved the ELA amendment some years later. In 1996, Kenimer Associates
2 conducted an on-site review of the BioPort facility. A final observation in the closing
3 paragraph indicates that as of 26 February 1996 the two fermenters had not been supplemented
4 (i.e. approved through an ELA amendment request). Therefore, BioPort delivered a least one
5 dose of AVA to DOD that was produced after the major manufacturing change had occurred
6 and before the ELA amendment was approved. Every dose delivered since the 1990
7 manufacturing change has occurred without an ELA amendment for the change in filter type.
8 21 C.F.R. § 601.12 requires prior approval before the product is distributed after a major
9 manufacturing change.
- 10 30. 21 U.S.C. § 355 regulates new drugs. 21 U.S.C. § 321 defines a new drug in two ways. The
11 second definition of a new drug is "Any drug (except a new animal drug or an animal feed
12 bearing or containing a new animal drug) the composition of which is such that such drug, as a
13 result of investigations to determine its safety and effectiveness for use under such conditions,
14 has become so recognized, but which has not, otherwise than in such investigations, been used
15 to a material extent or for a material time under such conditions."
- 16 31. AVA met this definition of a new drug in 1990. From 1972 until the Gulf War, BioPort
17 distributed approximately 70,000 doses of AVA in total. The vast majority of this was used in
18 research animals. The use in humans was essentially limited to those conducting that research.
19 Beginning in 1988, DOD contracted for 300,00 doses over five years. Shortly after that, DOD
20 contracted for another 350,000 doses with options for 700,000 more. This vast increase in
21 production and "for use under such conditions...which has not...been used to a material
22 extent" meets the definition of a new drug. . BioPort never sought to approve this new product
23 as a New Drug in accordance with 21 U.S.C. § 355.
- 24 32. The various application processes for a new drug require the submission of the actual patent or
25 patent pending information for the new drug. The original license for AVA is based on U.S.
26 Patent 3,208,909. The two production lines added to the BioPort facility in 1990 did not
27 conform to the patented method for production of AVA. The patent specifically states the use
28 of glass fermenters and sintered glass filters. The two additional production lines use stainless
29 steel fermenters and low-protein-binding nylon membrane filters. The production of vaccine
30 with an un-patented method classifies the vaccine as a different product. A New Drug
31 application was therefore required for the vaccine produced by the additional production lines.

- 1 Without an approved New Drug Application, the drug is unlicensed and unapproved. BioPort
2 never sought to approve this new product as a New Drug in accordance with 21 U.S.C. § 355.
- 3 33. A Reference Standard is used when testing the potency of biologic products. This standard
4 ensures the quality (potency) of the drug over time. 21 C.F.R. § 601.12(b)(2)(i) considers a
5 change to the qualitative or quantitative formulation or other specifications as provided in the
6 approved application as a major change. BioPort changed the Reference Standard in 1991.
7 BioPort failed to apply for the requisite amendments.
- 8 34. 42 U.S.C § 262 Regulation of biological products requires that no person shall introduce or
9 deliver for introduction into interstate commerce any biologic product unless a biologics
10 license is in effect for the biological product. The vaccine produced by BioPort, from the time
11 the additional production lines started until the FDA approved the ELA amendment, was
12 produced without the appropriate biologics license. The vaccine produced in this time frame
13 was distributed to DOD as recently as 1998. Biologic products distributed without the
14 appropriate approved license is prohibited under 42 U.S.C. § 262.
- 15 35. 21 C.F.R. Part 210 contains the Current Good Manufacturing Practice in Manufacturing,
16 Processing, Packing, or Holding of Drugs. 21 C.F.R. § 210.1(b) states that failure to comply
17 with any regulation set forth in this part and in parts 211 through 226 of this chapter shall
18 render such product adulterated under section 505(a)(2)(B) of the Act and that such drug as
19 well as the person responsible for the failure to comply shall be subject to regulatory action.
- 20 36. Biologic products are required to have expiration dates (21 C.F.R. 211.137). The expiration dates,
21 or dating period limitations, for biologic products are listed in 21 C.F.R. § 610.53. 21 C.F.R. §
22 610.53 indicates that the expiration date for AVA is a maximum of three years from the start of
23 the latest valid potency test. On at least one occasion, BioPort redated expired vaccine without
24 an approved stability testing procedure as required by 21 C.F.R. § 211.137. The redated Lots
25 are considered adulterated IAW 21 C.F.R. § 210.1(b). 21 U.S.C. § 331 prohibits the delivery
26 of adulterated products in interstate commerce.
- 27 37. Biologic product labels must conform to 21 C.F.R. § 610.60. A requirement of 21 C.F.R. §
28 610.60 is to indicate the Lot number on the label. 21 C.F.R. § 201.18 states that the lot number
29 on the label of a drug should be capable of yielding the entire manufacturing history of the
30 package. An incorrect lot number may be regarded as causing the article to be misbranded. A
31 misbranded product is considered an adulterated product. On at least occasion BioPort

1 misbranded vials of AVA. 21 U.S.C. § 331 prohibits the delivery of adulterated products and
2 the misbranding of products in interstate commerce.

- 3 38. The Department of Defense contracted with BioPort on at least four occasions from 1988 to the
4 present for AVA; contract DMAD17-88-R-0149 awarded in 1988, contract DMAD17-90-C-
5 0159 awarded in 1990, contract DMAD17-91-C-1139 awarded in 1991, and contract
6 DMAD17-98-C-8052 awarded in 1998.
- 7 39. The term of DMAD17-88-R-0149 was 30 September 1988 to 30 September 1993. The initial
8 value of this contract was 2.19 million dollars. AVA produced in the expanded facility was
9 used to fulfill at least a portion of this contract. The terms for the three other contracts began
10 after the facility expansion in 1990.
- 11 40. DMAD17-90-C-0159 was modified at least five times to include the exercise of options to
12 procure additional AVA. The value of this contract to BioPort was at least 4.66 million dollars
13 at the time of the fifth modification. DMAD17-91-C-1139 was amended/modified at least
14 twenty three times to include the exercise of options to procure additional AVA. The value of
15 this contract to BioPort began at 13.31 million dollars and was at least 33.34 million dollars at
16 the time of the twenty-third modification.
- 17 41. Amendment P30009 exercised the final option for additional AVA in DMAD17-91-C-1139.
18 This amendment, awarded in 1995, was DOD's last production order awarded prior to the
19 facility shutting down in January 1998. The contract term was extended to September 1996 to
20 accommodate the production of this option. Amendment P30012 further extended the contract
21 term to July 1997.
- 22 42. P30022 to DMAD17-91-C-1139 was awarded after the BioPort facility had ceased production
23 of AVA and the building had been shut down. P30022 modified DMAD17-91-C-1139 in
24 March 1998 to cover additional costs for the purpose of renovations to Building 12. Building
25 12 was demolished after BioPort ceased production in January 1998.
- 26 43. P30023 to DMAD17-91-C-1139 was awarded after BioPort had ceased production of AVA
27 and the building had been shut down. P30023 modified DMAD17-91-C-1139 in May 1998 to
28 provide Fiscal Year 1998 dollars for the construction portion of the AVA production suite
29 renovation identified in contract line item number 0001. Contractor line item number 0001 is
30 for remodeling of the existing facilities to manufacture AVA. The facility to manufacture AVA
31 was demolished after BioPort ceased production in January 1998.

1 44. DMAD17-98-C-8052 was awarded in September 1998 with an initial value of 6.25 million
2 dollars. Contract line item number 0001 requires BioPort to provide 790,000 doses of AVA
3 through 31 October 1998. BioPort ceased production in January 1998 and later demolished the
4 facility. BioPort was incapable of producing any AVA at the time this contract was awarded.
5

6 COUNT ONE

7 False Claims Act

8 31 U.S.C. §§ 3927(a)(1) and (a)(2)

9 45. Plaintiffs/relators re-allege and incorporate by reference the allegations made in Paragraphs 1
10 through 44 of this complaint.

11 46. This is a claim for treble damages and forfeitures under the False Claims Act.
12 31U.S.C. §§ 3729-32, as amended.

13 47. Through the acts described in this complaint, defendants failed to comply with the provisions
14 of the Public Health Service regulations. The defendants knowingly concealed material facts,
15 modified their biologic production facility in violation of those provisions, and delivered an
16 unlicensed and unapproved drug product in order to obtain approval of and payment for the
17 various production contracts.

18 48. Through the acts described in this complaint, the defendants knowingly presented and caused
19 to be presented to the United States and its officials an unlicensed and unapproved drug
20 product as the FDA licensed and approved drug product defendants were contracted to
21 produce. The defendants knowingly presented and caused to be presented to the United States
22 and its officials false and fraudulent claims for payment.

23 49. The United States, unaware of the falsity of the claims made and submitted by the defendants,
24 paid money to defendants that it otherwise would not have paid.

25 50. By reason of the payments made by the United States to defendants as a result of their fraud,
26 the United States has suffered many millions of dollars in damages and continues to be
27 damaged.
28
29
30
31

1 an adulterated and misbranded drug product in order to obtain approval of and payment for the
2 various production contracts.

3 59. Through the acts described in this complaint, the defendants knowingly presented and caused
4 to be presented to the United States and its officials an adulterated and misbranded drug
5 product as the FDA licensed and approved drug product defendants were contracted to
6 produce. The defendants knowingly presented and caused to be presented to the United States
7 and its officials false and fraudulent claims for payment.

8 60. The United States, unaware of the falsity of the claims made and submitted by the defendants,
9 paid money to the defendants that it otherwise would not have paid.

10 61. By reason of the payments made by the United States to defendants as a result of their fraud,
11 the United States has suffered many millions of dollars in damages and continues to be
12 damaged.

13
14 COUNT FOUR

15 False Claims Act

16 31 U.S.C. §§ 3927(a)(3)

17 62. Plaintiffs/relators re-allege and incorporate by reference the allegations made in Paragraphs 1
18 through 44 of this complaint.

19 63. This is a claim for treble damages and forfeitures under the False Claims Act,
20 31U.S.C. §§ 3729-32, as amended.

21 64. Through the acts described in this complaint, defendants knowingly presented and caused to be
22 presented to the United States and its officials false and fraudulent claims for payment.

23 65. Through the acts described in this complaint, defendants knowingly conspired to defraud the
24 Government by soliciting for products and services that could no longer be provided, and as a
25 result, getting a false or fraudulent claim approved and paid.

26 66. The United States, unaware of the falsity of the claims made and submitted by the defendants,
27 paid money to the defendants that it otherwise would not have paid.

28 67. By reason of the payments made by the United States to defendants as a result of their fraud,
29 the United States has suffered many millions of dollars in damages and continues to be
30 damaged.

31

COUNT FIVE

False Claims Act

31 U.S.C. §§ 3927(a)(3)

- 1
2
3
4 68. Plaintiffs/relators re-allege and incorporate by reference the allegations made in Paragraphs 1
5 through 67 of this complaint.
- 6 69. This is a claim for treble damages and forfeitures under the False Claims Act,
7 31U.S.C. §§ 3729-32, as amended.
- 8 70. Through the acts described in this complaint, defendants knowingly presented and caused to be
9 presented to the United States and its officials an adulterated, misbranded, unapproved, and
10 unlicensed drug product as the FDA licensed and approved drug product defendants were
11 contracted to produce in violation of the General Standards of the Federal Acquisition
12 Regulations.
- 13 71. Through the acts described in this complaint, defendants knowingly conspired to defraud the
14 Government by soliciting for products and services that could no longer be provided, and as a
15 result, getting a false or fraudulent claim approved and paid in violation of the General
16 Standards of the Federal Acquisition Regulations.
- 17 72. The United States, unaware of the falsity of the claims made and submitted by the defendants,
18 paid money to the defendants that it otherwise would not have paid.
- 19 73. By reason of the payments made by the United States to defendants as a result of their fraud,
20 the United States has suffered many millions of dollars in damages and continues to be
21 damaged.
22
23
24
25
26
27
28
29
30
31

