



1. This paragraph contains plaintiffs' characterization of the nature of plaintiffs' action to which no response is required.

2. The first sentence contains plaintiffs' characterization of the law, to which no response is required; to the extent a response is deemed necessary, defendants respectfully refer the Court to the relevant provisions of the Social Security Act. As to the second sentence, defendants admit that plaintiffs' exclusions were based on their convictions for misdemeanor misbranding under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 333(a)(1); the remainder of the second sentence contains plaintiffs' characterization of the law to which no response is required. As to the third sentence, defendants admit that the plaintiffs' misdemeanor charges were based on the Food, Drug, and Cosmetic Act's "responsible corporate officer" doctrine and deny the remaining factual allegations; to the extent the third sentence contains plaintiffs' characterization of the law, no response is required. The fourth sentence consists of plaintiffs' characterizations of the Administrative Record, which contains, among other things, hearing and sentencing transcripts, plaintiffs' and Purdue Pharma's plea agreements, and the Agreed Statement of Facts on which those pleas are based, all pertaining to plaintiffs' underlying criminal convictions, and the Court's decision in U.S. ex. rel. Purdue Frederick Co. Inc., 495 F. Supp. 2d 569 (W.D. Va. 2007), which speak for themselves; defendants deny any allegations regarding the Administrative Record and the Court's decision that are inconsistent with their contents. Defendants admits the fifth sentence and affirmatively states that, to the best of defendant's knowledge and belief, plaintiffs are the first pharmaceutical company executives convicted under the "responsible corporate officer doctrine" for misbranding violations of the Food, Drug, and Cosmetics Act since 42 U.S.C. § 1320a-7(b)(1) and (b)(3) were enacted, and that defendants have excluded other individuals for analogous misdemeanors.

3. This paragraph contains factual allegations, which defendants deny; recitations of statutes, which speak for themselves; and legal conclusions, to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the Social Security Act, deny any allegations inconsistent with the Social Security Act, and otherwise deny paragraph 3.

4. Defendants admit the first sentence. Defendants lack sufficient knowledge or information to confirm or deny the factual allegations in the second sentence and therefore deny.

5. Defendants admit the first sentence. As to the second and third sentences, defendants admit that plaintiff Goldenheim resides in Massachusetts; defendants lack sufficient knowledge or information to confirm or deny the remaining factual allegations and therefore deny.

6. Defendants admit the first sentence. Defendants lack sufficient knowledge or information to confirm or deny the factual allegations in the second sentence and therefore deny.

7. Admit.

8. Defendants admit and affirmatively state that this is an appeal of a final decision by defendant, in her official capacity as Secretary, upon review of a decision by the Inspector General, and therefore naming the Inspector General as a defendant in this action is neither necessary nor appropriate.

9-10. These paragraphs set forth plaintiffs' assertion of jurisdiction and venue, and are thus legal conclusions to which no response is required. Defendants affirmatively state that this Court has jurisdiction over this action only to the extent that jurisdiction exists under 42 U.S.C. § 1320a-7(f), which incorporates by reference 42 U.S.C. § 405(g).

11. Defendants admit that Purdue Frederick developed and originally marketed OxyContin, and that in 1995 the Food and Drug Administration approved OxyContin, an opioid analgesic, for treatment of moderate to severe pain “where use of an opioid analgesic is appropriate for more than a few days.” Defendants lack sufficient knowledge or information regarding the relationship between Purdue Pharma and Purdue Frederick to form an opinion and on that basis deny. Defendants deny the remaining factual allegations.

12. Admit.

13. Defendants admit the first sentence. The second sentence consists of plaintiffs’ characterization of the Agreed Statement of Facts, which speaks for itself; defendants deny any allegations regarding the Agreed Statement of Facts that are inconsistent with its contents.

14.-16. These paragraphs consist of plaintiffs’ characterizations of the Administrative Record and the Court’s decision in U.S. ex. rel. Purdue Frederick Co. Inc., 495 F. Supp. 2d 569 (W.D. Va. 2007), which speak for themselves; defendants deny any allegations regarding the Administrative Record and the Court’s decision that are inconsistent with their contents.

17. This paragraph consists of plaintiffs’ characterization of the Agreed Statement of Fact, which speaks for itself; defendants deny any allegations regarding the Agreed Statement of Facts that are inconsistent with its contents.

18. As to the first sentence of this paragraph, defendants admit that as part of a global resolution of the investigation, plaintiffs entered pleas to misdemeanor charges of misbranding based on the Agreed Statement of Facts, and otherwise denies. The remaining two sentences are legal conclusions to which no response is required.

19. The first sentence consists of a legal conclusion to which no response is required. To the extent a response is deemed necessary, defendants respectfully refer the Court to the

Food, Drug, and Cosmetics Act and deny any allegations inconsistent with its contents. The second sentence consists of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents.

20. This paragraph consists in part of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents. The remainder of this paragraph consists of legal conclusions, to which no response is required.

21. This paragraph consists of plaintiffs' characterization of the Agreed Statement of Fact, which speaks for itself; defendants deny any allegations regarding the Agreed Statement of Facts that are inconsistent with its contents.

22. This paragraph consists in part of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents.

23.-24 These paragraphs consist in part of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents. The remainder of these paragraphs consist of legal conclusions, to which no response is necessary.

25. This paragraph consists in part of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents.

26. Defendants admit and affirmatively state that the Inspector General considered the reasons and contentions set forth in plaintiffs' written submission to the Inspector General when making the initial exclusion decision.

27. This paragraph consists of plaintiffs' characterizations of the Inspector General's March 31, 2008 letters to plaintiffs, which speak for themselves; defendants deny all allegations that are inconsistent with the text of these letters.

28. The first two sentences consist of legal conclusions and recitations of statutes to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to 42 U.S.C. § 1320a-7(b)(1) and (b)(3) and deny all allegations that are inconsistent with the statute's contents. Defendants admit the third sentence.

29. The first sentence consists of legal conclusions and recitations of statutes to which no response is required. To the extent a further response is deemed necessary, defendant refers the Court to 42 U.S.C. §§ 1320a-7(a)(a)(6) and (a)(8) and denies all allegations that are inconsistent with the statute's contents. Defendants deny the second sentence.

30. The first sentence consists of plaintiffs' characterization of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents. Defendants lack sufficient knowledge or information to confirm or deny the factual allegations in the second and third sentences and therefore deny. As to the fourth sentence, defendants admit that plaintiff Udell has been Vice President and Chief Legal Officer of Purdue Pharma and Purdue Frederick, and now serves Purdue Pharma and Purdue Frederick as a consultant, and otherwise deny.

31. Defendants admit the first sentence. The second sentence consists in part of plaintiffs' characterization of the Court's decision in Friedman et al v. Leavitt, 1:08-cv-00586

(D.D.C. 2008), which speaks for itself; defendants deny any allegations that are inconsistent with the Court's decision. As to the factual allegations in the second sentence, defendants deny that the Court granted plaintiffs preliminary injunctive relief and affirmatively state that the Court granted plaintiffs a temporary restraining order without argument or briefing from the Inspector General and then imposed a stay based on the consent of the parties in order to permit briefing on plaintiffs' motion for a preliminary injunction.

32. Defendants admit the first sentence. As to the second sentence, defendants admit that plaintiffs contested the fact and length of their exclusions; the remainder of the second sentence is plaintiffs' characterization of the basis for their appeal, for which the best evidence is the Administrative Record of that appeal and the Administrative Record speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents. The third sentence consists of plaintiffs' characterization of the Departmental Appeals Board's August 31, 2009 decision, which is defendant Sebelius's final decision and which speaks for itself; defendants deny any inconsistent allegations. Defendants admit the fourth and fifth sentences, and affirmatively state that 42 U.S.C. §§ 405(g) and 1320a-7(f) provide plaintiffs with the opportunity for review by the federal courts of defendant's final decision.

To the extent that plaintiffs re-allege and incorporate all the preceding paragraphs in the paragraphs that follow, defendants refer the Court to their response to those specific preceding paragraphs.

33. This paragraph contains plaintiffs' characterization of the law, to which no response is required. To the extent a further response is deemed necessary, defendants

respectfully refer the Court to the relevant provisions of the Administrative Procedure Act and the Social Security Act and deny all allegations that are inconsistent with their contents.

34. Defendants admit that Defendant Sebelius has excluded plaintiffs under sections 1128 (b)(1) and 1128(b)(3) of the Social Security Act, as codified at 42 U.S.C. § 1320a-7(b)(1) and (b)(3), based on plaintiffs' convictions for misdemeanor offenses under sections 331(a) and 333(a)(1) of the Food, Drug, and Cosmetic Act, and otherwise denies.

35.-36. Deny.

37. This paragraph consists of a legal conclusion to which no response is required. To the extent an answer is deemed necessary, defendants deny and affirmatively state that 42 U.S.C. § 1320a-7(f) provides plaintiffs with a remedy through the appeal of defendant's final decision to federal district court.

38. Defendants lack sufficient knowledge or information to confirm or deny and therefore deny.

To the extent that plaintiffs re-allege and incorporate all the preceding paragraphs in the paragraphs that follow, defendants refers the Court to their response to those specific preceding paragraphs.

39. This paragraph consists of plaintiffs' characterization of the law, to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the relevant provisions of the Administrative Procedure Act and deny all inconsistent allegations.

40. Defendants admit that protecting federal funds and program beneficiaries and deterring health care fraud are remedial purposes of the exclusion statute and affirmatively states that she excluded plaintiffs for 12 years in furtherance of these remedial purposes.



41. This paragraph consists of plaintiffs' characterization of the Agreed Statement of Facts, which speaks for itself; defendants deny any allegations regarding the Agreed Statement of Facts that are inconsistent with its contents.

42-45. Deny.

46. This paragraph consists of a legal conclusion to which no response is required. To the extent an answer is deemed necessary, defendants deny and affirmatively state that 42 U.S.C. § 1320a-7(f) provides plaintiffs with a remedy through the appeal of defendant's final decision to federal district court.

47. Defendants are without sufficient knowledge to admit or deny and therefore deny.

To the extent that plaintiffs re-allege and incorporate all the preceding paragraphs in the paragraphs that follow, defendants refer the Court to their response to those specific preceding paragraphs.

48. This paragraph consists of plaintiffs' characterization of the law, to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the relevant provisions of the Administrative Procedure Act and deny all inconsistent allegations.

49. Defendants admit only insofar as defendant has promulgated regulations under the authority delegated to her by 42 U.S.C. § 1320a-7(c)(3)(D) to determine the lawful period of exclusion necessary to promote the remedial purposes of the exclusion and affirmatively states that those regulations were applied to determine the length of plaintiffs' exclusions.

50. Defendants admit that protecting federal funds and program beneficiaries and deterring health care fraud are remedial purposes of the exclusion statute.

51. The first sentence consists of plaintiffs' characterizations of their convictions and the Agreed Statement of Facts, which speak for themselves; defendants deny any allegations inconsistent with the contents of plaintiffs' convictions and the Agreed Statement of Facts. The second sentence consists of plaintiffs' characterization of the law, to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the relevant provision of the Food, Drug, and Cosmetics Act and deny all allegations inconsistent with its contents.

52-55. Deny.

56. Defendants deny the first sentence. The second sentence consists of conclusions of law and recitations of statutes, to which no response is required. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the relevant provisions of the Social Security Act and deny all inconsistent allegations.

57. This paragraph consists of plaintiffs' characterization of HHS's regulations, which speak for themselves. To the extent a further response is deemed necessary, defendants respectfully refer the Court to the relevant provisions of the Code of Federal Regulations and deny all inconsistent allegations.

58. This paragraph consists of plaintiffs' characterization of the Departmental Appeals Board's August 31, 2009 decision, which is defendant's final decision and which speaks for itself. Defendants respectfully refer the Court to the Departmental Appeals Board's August 31, 2009 decision and deny any inconsistent allegations.

59-60. Deny.

61.-63. These paragraphs consist of plaintiffs' characterizations of the Administrative Record, which speaks for itself; defendants deny any allegations regarding the Administrative Record that are inconsistent with its contents.

64. This paragraph consists of plaintiffs' characterizations of the Administrative Record and the Court's decision in U.S. ex. rel. Purdue Frederick Co. Inc., 495 F. Supp. 2d 569 (W.D. Va. 2007), which speak for themselves; defendants deny any allegations regarding the Administrative Record and the Court's decision that are inconsistent with their contents.

65. Deny.

66. The first sentence consists of plaintiffs' characterization of the Administrative Record and the Court's decision in Friedman et al v. Leavitt, 1:08-cv-00586 (D.D.C. 2008), which speak for themselves; defendants deny any inconsistent allegations. Defendants admit the second sentence. Defendants lack sufficient knowledge or information to confirm or deny the third sentence and therefore deny.

67. Deny.

68. Defendants deny and affirmatively state that defendant Sebelius considered the relevant aggravating and mitigating factors under her regulations when deciding the length of plaintiffs' exclusions.

69. This paragraph consists in part of legal conclusions to which no response is required. Defendants deny the factual allegations.

70. Defendants deny and affirmatively state that defendant Sebelius considered the relevant aggravating and mitigating factors under her regulations when deciding the length of plaintiffs' exclusions.

71. This paragraph consists of a legal conclusion to which no response is required. To the extent an answer is deemed necessary, defendants deny and affirmatively state that 42 U.S.C. § 1320a-7(f) provides plaintiffs with a remedy through the appeal of defendant Sebelius's final decision to federal district court.

72. Defendants lack sufficient knowledge to admit or deny and therefore deny.

The balance of the Complaint consists of plaintiffs' prayer for relief to which no response is necessary. Defendants deny that plaintiffs are entitled to the relief requested, or to any relief whatsoever.

Defendants hereby deny all allegations not expressly admitted or denied.

/s/  
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