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UNITED STATES OF AMERICA, ex rel.	:	UNITED STATES DISTRICT COURT
JEFFREY D. FELDSTEIN, M.D.,	:	FOR THE DISTRICT OF NEW JERSEY
	:	
Plaintiff/Relator,	:	Civil Action No. 07-2690 (DMC)(MF)
	:	
v.	:	AMENDED COMPLAINT
	:	AND JURY DEMAND
ORGANON, INC. and SCHERING-	:	
PLOUGH, INC.	:	
	:	
Defendants.	:	
	:	

Plaintiff/Relator Jeffrey D. Feldstein, M.D. (“Dr. Feldstein”), individually and on behalf of the United States of America, by way of Amended Complaint against Defendants Organon, Inc. (“Organon”) and Schering-Plough, Inc. (“Schering”) (collectively, “Defendants”) alleges as follows:

IDENTIFICATION OF THE PARTIES

1. Dr. Feldstein is an individual residing at 505 Binghampton Lane, Livingston, New Jersey.

2. At all times relevant to the Amended Complaint, Organon created, manufactured, distributed, and marketed pharmaceuticals within the United States and abroad.

3. In 2007, Schering, with its principal place of business in Kenilworth, New Jersey, acquired Organon and succeeded to its rights and liabilities.

JURISDICTION AND VENUE

4. Dr. Feldstein, individually and on behalf of the United States of America, seeks relief pursuant to 31 U.S.C. § 3729, *et seq.*, commonly known as the False Claims Act. Pursuant to 28 U.S.C. § 1331, this Court possesses subject matter jurisdiction over this claim because it presents a question of federal law.

5. Venue in the United States District Court for the District of New Jersey is proper pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claims in this litigation occurred in New Jersey. Furthermore, Schering and Organon are subject to personal jurisdiction in New Jersey and are thus considered residents of New Jersey for the purpose of determining venue.

BACKGROUND

6. For many years, Organon expended enormous time, money and resources developing and ultimately obtaining regulatory approval for a neuromuscular blocking agent known as Raplon. Raplon was designed to paralyze a patient's throat area to allow the painless insertion of an endotracheal tube into a patient's trachea. An endotracheal tube is designed to facilitate the administration of oxygen and anesthetic agents to patients during surgical or obstetric procedures.

7. On August 18, 1999, Raplon received regulatory approval from the United States Food and Drug Administration (the “FDA”). Organon subsequently engaged in extensive efforts to market Raplon to physicians in the United States and abroad.

8. Organon hoped that Raplon would be superior to its competitor drugs because it induced paralysis so rapidly. For example, Raplon would paralyze a patient’s bronchial area more quickly than the drug most often used, succinylcholine, an older generic drug that competed with Raplon.

9. Raplon, however, sometimes produced an unexpected serious, and sometimes fatal, side effect which met the definition of a serious adverse event (“SAE”) as set forth in the FDA regulations. Certain individuals would suffer severe respiratory problems and, at times, even, “chest rigidity” after receiving Raplon, nothing like a brief bronchospasm (a condition that occurs when a patient’s bronchial tubes close and prevent breathing.)

10. The SAEs generated by Raplon were unique in their severity when compared with similar drugs of its class. The seriousness of these episodes was described as “like having a clamp over the airway” or “the chest felt like concrete”. These SAEs would cause a patient’s entire thoracic region to contract so completely that it became extremely difficult or impossible for physicians to ventilate patients. In certain instances, physicians were unable to reverse the condition before the patient succumbed from a lack of oxygen.

11. On May 31, 2000, Organon hired Dr. Feldstein to serve as Associate Director of Medical Services for Antithrombotics. During his employment, Dr. Feldstein acquired non-public information concerning the clinical problems associated with Raplon. This included evidence that Organon had knowingly concealed information and made misrepresentations to the FDA during and after the regulatory approval process concerning SAEs caused by Raplon.

12. In early 2001, Organon's Associate Director of Anesthesiology, Dr. Daniel Sack, informed Dr. Feldstein that Raplon had caused numerous SAEs and multiple deaths since its approval. Dr. Sack also disclosed to Dr. Feldstein that he was in possession of a private e-mail suggesting that personnel at Organon knew prior to Raplon's approval by the FDA that Raplon caused SAEs.

13. The e-mail was prepared by Organon's Director of Hospital Products, Dr. Jonathan Deutsch, and sent to Organon's Vice President of Medical Services, Dr. Deborah Shapse, prior to the FDA's approval of Raplon. Dr. Sack discovered the e-mail on Dr. Shapse's laptop computer after Organon had reassigned the laptop to Dr. Sack for his use.

14. The e-mail references an earlier "bronchospasm" e-mail (quote from original) and further states as follows:

"at the Dallas meeting 'bronchospasm' was heatedly discussed by the investigators as a potential problem that needed to be addressed prior to (Raplon's) launch."

A copy of the e-mail is annexed hereto and incorporated herein by reference as Exhibit "A".

15. The e-mail further notes, in pertinent part, as follows:

"My understanding is that Cari is concerned, hence her inclusion in the PIP of a mention that Medical Services needs to have a treatment protocol in place for bronchospasm prior to launch."

16. The e-mail also indicates that "Michael may be correct in not wanting to draw attention to bronchospasm." Upon information and belief, Michael is a reference to Michael Navinsky, Organon's Head of Marketing.

17. Dr. Feldstein also discovered that the reference in the e-mail to the Dallas meeting was a meeting of the investigators involved in Raplon's US Phase III Pivotal trial at which Organon disbursed topline data. During that meeting various investigators were concerned with

Raplon's propensity to cause SAEs in certain patients. The investigators understood that these SAEs were caused by Raplon, even though they had used a double blinded trial, because the investigators never experienced this type of SAE during the many years they had worked with the comparator drug succinylcholine.

18. Dr. Feldstein also discovered that, as a result of the investigators' meeting, in early 1998 a representative from Organon's Clinical Development Department contacted Dr. Carol Hirshman, a Professor of Anesthesiology at Columbia University, and asked her if she could perform a mechanism of action study to determine the cause of the SAEs associated with Raplon. Dr. Hirshman, an expert in these types of studies, indicated that she could and would be able to perform the study, but Organon failed to authorize the study and never discussed the matter with her again.

19. After reviewing other internal, non-public documents and Organon's various submissions to the FDA, Dr. Feldstein concluded that Organon had failed to disclose to the FDA instances and the severity of the SAEs associated with Raplon both before and after obtaining FDA approval. Upon information and belief, Organon's submissions to the FDA contained numerous quantitative and qualitative misrepresentations concerning Raplon's propensity to cause SAEs, which were purposely labeled only as expected and non-life threatening adverse events ("AEs"), such as coughing or wheezing, bronchospasm and other airway symptoms, contrary to the FDA and CFR definitions.

20. Moreover, after receiving FDA approval, Organon never advised doctors or patients of the potential for SAEs in any labeling or package insert and never had a treatment protocol in place prior to launch.

21. The extent of the danger posed by Raplon came to light following its approval by the FDA. In or about August 1999, physicians began reporting instances of SAEs related to Raplon to Organon's safety department. Organon disingenuously suggested that the cause of these SAEs might have been related to the incorrect insertion of endotracheal tubes by physicians when it knew that Raplon was the true cause.

22. Many individuals died from Raplon. Additionally, reports from physicians indicate that Raplon also caused a significant number of non-fatal cases of SAEs in patients which, in turn, led to innumerable surgical delays, cancellations and/or other unnecessary medical expenses associated with treating same.

23. Organon's actions have caused false claims to be submitted to and paid by Medicare and Medicaid, which are agencies of the United States government. Raplon's approval by the FDA was invalid because it was obtained by Organon as a result of a willful failure to disclose and/or through the use of fraudulent and/or deceptive information. Organon, therefore, caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid associated with Raplon they otherwise would not have been able to submit. Moreover, Medicare and Medicaid would not have reimbursed hospitals, physicians and/or patients for the use of Raplon had those agencies known that the FDA approved Raplon without the benefit of adequate disclosures regarding the potential for SAEs. Organon's actions also have caused Medicare and Medicaid to pay for medical costs associated with treating SAEs that never should have been incurred had adequate disclosures been made.

24. Organon never informed the FDA, hospitals, physicians or patients that Raplon posed a serious threat to public health and safety before it unilaterally decided to pull the drug

from the market on or about March 27, 2001. Upon information and belief, Organon removed Raplon from the market to avoid intervention and scrutiny by the FDA.

25. Schering acquired Organon and succeeded to its rights and liabilities.

Accordingly, Schering and Organon are jointly and severally liable for compensating the United States for the damages caused by Organon's actions, and/or inactions.

FIRST COUNT
(Violation of 31 U.S.C. § 3729, et seq.)

26. Dr. Feldstein repeats and realleges all of the allegations of the preceding paragraphs of the Amended Complaint as though fully set forth herein at length.

27. Organon knowingly misrepresented and/or concealed relevant information from the FDA in order to obtain, and subsequently retain, regulatory approval for Raplon.

28. Between August 1999 and March 2001, Organon knowingly failed to warn hospitals, physicians and patients of the dangers posed by Raplon, yet internally developed pharmacoeconomic data on the costs associated with the treatment of same.

29. Organon's actions and/or omissions caused numerous hospitals, physicians and patients to submit false reimbursement claims concerning Raplon to Medicare and Medicaid.

30. Organon's actions and/or omissions also caused numerous hospitals, physicians and patients to submit claims to Medicare and Medicaid for additional medical procedures and treatment relating to SAEs caused by the administration of Raplon. If Organon had not used fraudulent and/or deceptive means to secure regulatory approval for Raplon, the drug would not have been administered to these patients and Medicare and Medicaid would not have been forced to pay for these additional medical procedures and treatment.

31. The False Claims Act requires Organon to compensate the United States of America for all damages caused by its actions, and entitles Dr. Feldstein to receive compensation for his role in prosecuting this suit.

32. Schering acquired Organon and succeeded to its rights and liabilities. Accordingly, Schering and Organon are jointly and severally liable for compensating the United States for the damages caused by Organon's actions and/or inactions, and compensating Dr. Feldstein for his role in prosecuting this suit.

WHEREFORE, Plaintiff/Relator Jeffrey D. Feldstein, M.D., individually and on behalf of the United States of America, demands entry of judgment against Defendants, Organon, Inc. and Schering-Plough, Inc., jointly, severally, and/or in the alternative as follows:

- A. Restitution,
- B. Compensatory damages;
- C. Statutory damages;
- D. Consequential damages;
- E. Punitive damages;
- F. Interest;
- G. Costs of suit;
- H. Reasonable attorneys' fees; and
- I. Such other relief as the Court may deem just and proper under the

circumstances.

DEMAND FOR TRIAL BY JURY

Plaintiff/Relator Jeffrey D. Feldstein, M.D., individually and on behalf of the United States of America, hereby demands a trial by jury on all issues so triable.

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Feldstein, M.D.

By: _____
Steven I. Adler

DATED: April ____, 2008