UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	**CRIMINAL NO.** 10-10147
)	
)	**VIOLATIONS:**
)	**21 U.S.C. §§331(a), 333(a)(1) and 352(f)(1)**
)	**(distribution of a misbranded drug;**
)	**inadequate directions for use)**
v.)	
ORTHO-MCNEIL)	
PHARMACEUTICAL, LLC,)	
Defendant.)	

FILED
IN CLERKS OFFICE
2010 APR 29 A 11: 12
U.S. DISTRICT COURT
DISTRICT OF MASS.

INFORMATION

The United States Attorney charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

1. **ORTHO-MCNEIL PHARMACEUTICAL, LLC**, formerly known as Ortho-McNeil Pharmaceutical, Inc., ("**ORTHO**") was a Delaware corporation with its principal place of business in Raritan, New Jersey. It was a subsidiary of Johnson & Johnson, a Delaware corporation with its principal place of business in New Brunswick, New Jersey, with publicly traded shares listed on the New York Stock Exchange (ticker symbol: JNJ).

Background

2. **ORTHO** was engaged in, among other things, the development, manufacture, promotion, sale and interstate distribution of prescription drugs intended for human use in the United States. **ORTHO** distributed prescription drugs or directed the distribution of prescription

drugs to all fifty states and the District of Columbia.

The FDA and the FDCA

3. The United States Food & Drug Administration ("FDA") was the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug & Cosmetic Act ("FDCA") and ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bears true and accurate information.

4. The FDCA prohibited causing the delivery for introduction into interstate commerce of new drugs that are not approved for use by the FDA or drugs that are misbranded.

5. The FDCA and its implementing regulations required that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug must submit a New Drug Application ("NDA").

6. The FDCA required that the NDA include proposed labeling for the proposed intended uses of the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in adequate and well-controlled clinical investigations that demonstrated that the drug would be safe and effective when used in accordance with the proposed labeling.

7. An NDA sponsor was not permitted to promote or market the drug until it had an approved NDA, including approval for the proposed labeling. Moreover, if approved, the sponsor was permitted to promote and market the drug only for the medical conditions of use and dosages specified in the approved labeling. Uses not approved by the FDA, including dosages not approved in the drug's approved labeling, were known as "unapproved"or "off-label" uses.

8. The FDCA, and its implementing regulations, required the sponsor to file a new NDA, or amend the existing NDA, in order to label or promote a drug for uses and dosages different from the conditions for use and dosage specified in the approved labeling. The new or amended NDA must include a description of the newly proposed indications for use and evidence, in adequate and well-controlled clinical investigations, sufficient to demonstrate that the drug will be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA, or supplement, could the sponsor promote the drug for the new intended use.

9. The FDCA provided that a drug was misbranded if, among other things, "its labeling is false or misleading in any particular." The FDCA also provided that a drug is misbranded if, among other things, the labeling does not contain adequate directions for use. As the phrase was used in the FDCA, adequate directions for use could not be written for medical indications or uses for which the drug had not been proven to be safe and effective through adequate and well-controlled clinical investigations.

10. The FDCA prohibited, among other things, the distribution in interstate commerce of a misbranded drug.

The Topamax Approval Process

11. In or about 1994, as amended on June 27, 1996, **ORTHO** submitted an NDA for approval of a drug called Topamax (also known by the chemical name topiramate), which was a new drug within the meaning of 21 U.S.C. §321(p) and 21 C.F.R. §310.3(h)(4) and (5). In that application, **ORTHO** sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. On or about December 24, 1996, the FDA approved Topamax for that specific use

only. This approved use for Topamax will be referred to throughout this Information as the "Approved Use." Because **ORTHO** had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Topamax for any such uses, Topamax was not approved for any use or condition other than the Approved Use. Further, Topamax was not exempt, pursuant to 21 U.S.C. §355(i), from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

12. From at least January of 2001 through in or about November of 2003, unapproved uses for Topamax included bipolar disorder, mood disorder, drug and alcohol dependence, and essential tremor, among other uses. These and other unapproved uses for Topamax will be collectively referred to herein as "Unapproved Uses."

13. **ORTHO** did not file a new NDA seeking FDA approval for any Unapproved Uses during the time period addressed in this Information.

14. However, **ORTHO** promoted Topamax to psychiatrists and other physicians for certain Unapproved Uses through a program known as the Doctor For A Day Program.

The Doctor For A Day Program

15. The Doctor For A Day Program was coordinated and approved by **ORTHO** management, and paid for by **ORTHO**. As part of the Doctor for A Day Program, a physician joined an **ORTHO** sales representative on a series of sales calls to physicians and made lunch and/or dinner presentations to a group of physicians on the attributes of Topamax. One of **ORTHO's** managers described the program as follows to one of his colleagues: "We currently run doc for a day program with our Topamax brand. Essentially, a clinician takes a full day out

of their practice, hence the cost of honorarium. The rep schedules a luncheon with their biggest practice and then coordinates field calls in the morning and afternoon with the MD accompanying them on their field day."

16. The **ORTHO** Doctor For A Day Program was promotional, and in some instances imparted off-label promotional messages to physicians. Some of the **ORTHO** sales representatives told doctors, in the presence of one particular Doctor For A Day, that "he can talk to you about things I can't talk to you about."

17. Payments for the **ORTHO** Doctor For A Day program were often made out of a Topamax Target Marketing Account. The fee for a Doctor For A Day ranged between $1,500 and $3,000 plus expenses.

18. An e-mail to **ORTHO's** National Sales Manager described the physicians participating in the Doctor For A Day program as functioning like "sales reps" who would be "paraded from office to office. . ."

19. **ORTHO**'s sales representatives who used the Doctor For A Day Program sometimes prepared Return on Investment ("ROI") forms. Generally, the ROI was positive (on average in excess of 4x), including in the areas of Unapproved Uses.

20. Most of **ORTHO's** sales calls made during the Doctor For A Day Program were unsolicited.

21. One **ORTHO** sales representative touted in writing to **ORTHO** management, in or about September 2001, that "[t]he physicians seem to be responding well [to the visit by the Doctor For A Day]. Many have dabbled in off label areas . . ."

22. Another **ORTHO** sales representative touted in writing to **ORTHO** management, on

or about November 2001, after a visit by a Doctor For A Day (Dr. O): "I tried to have him see doctors that were medium to hi volume that had very low to no topamax usage. All of the doctors committed to trying it [Topamax] for at least one of the areas that he spoke about." Some of these areas included certain Unapproved Uses.

23. **ORTHO** used a number of different doctors as Doctors For A Day. One of the most heavily used was Dr. O, a general neurologist with an interest in using Topamax for a variety of off-label uses, including essential tremor. **ORTHO** used Dr. O as a Doctor For a Day approximately 200 times in many states throughout the country and paid him in excess of $500,000 for his efforts.

24. On March 11, 2003, Dr. O, as part of the Doctor For A Day Program, made sales visits with an **ORTHO** sales representative to two psychiatrists, among other physicians, and promoted Topamax for certain Unapproved Uses.

25. In the course of **ORTHO's** use of Dr. O as part of the Doctor For A Day Program, **ORTHO** used him to promote Topamax to psychiatrists and at psychiatric institutions for certain Unapproved Uses.

26. During **ORTHO's** use of Dr. O as a Doctor For A Day, Dr. O made dosing suggestions for Topamax to physicians, including 100-400 mg for tremor, an off-label use. Some **ORTHO** sales representatives made dosing cards with these off-label dosing suggestions so that they could refer to these cards on sales calls when Dr. O was not with them.

27. **ORTHO** also used other Doctors For A Day, including a headache specialist, Dr. L, who visited many psychiatrists on sales calls with Topamax representatives.

28. **ORTHO** also used two physicians who were trained as both neurologists and

psychiatrists, both of whom were practicing psychiatrists, Dr. A and Dr. J, as Doctors For A Day. **ORTHO** used these Doctors For A Day to promote Topamax, including to psychiatrists, for certain Unapproved Uses.

29. Dr. A accompanied **ORTHO** sales representatives on a number of sales calls to psychiatrists and touted its use for mood stabilization and certain other Unapproved Uses. Dr. A provided Topamax dosing suggestions to physicians during the Doctor For A Day Program for a number of psychiatric related conditions.

30. In 2002, an **ORTHO** sales representative visited a psychiatrist in Worcester, Massachusetts with Dr. O, a Doctor For A Day, who told the psychiatrist in Worcester that Topamax was effective for treating bipolar disorder.

31. **ORTHO** noted in March 2002 in evaluating Dr. J that his best use is in "nonepilepsy use of Topamax," an interesting comment when epilepsy was the only area in which Topamax was FDA approved. After a particular Doctor For A Day Program involving Dr. J, **ORTHO** also noted that after Dr. J had spoken to a psychiatrist, "[b]ased on his [Dr. J's] presentation, she will start to use Topamax."

32. On March 18, 2001, **ORTHO** conducted a Doctor For A Day Program in Massachusetts using Dr. O, one of several Doctor For A Day Programs conducted by **ORTHO** in Massachusetts.

33. On numerous occasions in 2001, 2002 and 2003, **ORTHO** distributed a shipment of Topamax from outside of Massachusetts to Massachusetts.

COUNT ONE

(Distribution of a Misbranded Drug: Inadequate Directions for Use 21 U.S.C. §§331(a), 333(a)(1) & 352(f)(1))

34. The allegations in paragraphs 1 through 33 are realleged and incorporated by reference herein.

35. Beginning as early as January 2001, and continuing thereafter until in or about November 2003, in the District of Massachusetts and elsewhere, the defendant,

ORTHO-MCNEIL PHARMACEUTICAL, LLC

did, through its Doctor For A Day Program, introduce and cause the introduction into interstate commerce, directly and indirectly, into Massachusetts and elsewhere, quantities of Topamax, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321(g), which was approved for use for the treatment of epilepsy, for other unapproved uses, which was misbranded within the meaning of 21 U.S.C.§352(f)(1), in that Topamax's labeling lacked adequate direction for such uses.

All in violation of 21 U.S.C. §§331(a), 333(a)(1), and 352(f)(1).

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

By: 
JEREMY M. STERNBERG
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ASSISTANT U.S. ATTORNEYS

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DEPUTY DIRECTOR
OFFICE OF CONSUMER LITIGATION

JS 45 (5/97) - (Revised USAO MA 11/15/05)

Criminal Case Cover Sheet **U.S. District Court - District of Massachusetts**

Place of Offense: Massachusetts **Category No.** III **Investigating Agency** VA-OIG, FDA-OCI, FBI

City Boston **Related Case Information:** 10-10147

County Suffolk Superseding Ind./ Inf. _____ Case No. _____

Same Defendant _____ New Defendant _____

Magistrate Judge Case Number _____

Search Warrant Case Number _____

R 20/R 40 from District of _____

Defendant Information:

Defendant Name Ortho-McNeil Pharmaceutical, LLC Juvenile ☐ Yes ☒ No

Alias Name _____

Address Raritan, New Jersey

Birth date (Year only): _____ SSN (last 4 #): _____ Sex __ Race: _____ Nationality: _____

Defense Counsel if known: Chris Wray (King & Spalding) **Address:** 1700 Pennsylvania Ave., N.W. Washington, D.C. 20006

Bar Number: _____

U.S. Attorney Information:

AUSA Jeremy Sternberg **Bar Number if applicable** 556566

Interpreter: ☐ Yes ☒ No **List language and/or dialect:** _____

Victims: ☐ Yes ☒ No **If Yes, are there multiple crime victims under 18 U.S.C. §3771(d)(2)** ☐ Yes ☐ No

Matter to be SEALED: ☐ Yes ☒ No

☐ Warrant Requested ☒ Regular Process ☐ In Custody

Location Status:

Arrest Date: _____

☐ Already in Federal Custody as _____ in _____.

☐ Already in State Custody _____ ☐ Serving Sentence ☐ Awaiting Trial

☐ On Pretrial Release: Ordered by _____ on _____

Charging Document: ☐ Complaint ☒ Information ☐ Indictment

Total # of Counts: ☐ Petty _____ ☒ Misdemeanor 1 ☐ Felony _____

Continue on Page 2 for Entry of U.S.C. Citations

☒ **I hereby certify that the case numbers of any prior proceedings before a Magistrate Judge are accurately set forth above.**

Date: 4-29-10 **Signature of AUSA:** _____

District Court Case Number (To be filled in by deputy clerk): _____

Name of Defendant Ortho-McNeil Pharmaceutical, LLC.

U.S.C. Citations

	Index Key/Code	Description of Offense Charged	Count Numbers
Set 1	21 U.S.C. §§331(a), 333(a)(1)	misbranding: inadequate directions for use	One
Set 2			
Set 3			
Set 4			
Set 5			
Set 6			
Set 7			
Set 8			
Set 9			
Set 10			
Set 11			
Set 12			
Set 13			
Set 14			
Set 15			

ADDITIONAL INFORMATION: