JM/SS:2008R00799

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Criminal No. 13-
v.	:	
PAR PHARMACEUTICAL COMPANIES, INC.	:	21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1)

INFORMATION

The United States Attorney for the District of New Jersey charges:

THE DEFENDANT

At all times relevant to this Information, unless otherwise alleged:

1. Defendant **PAR PHARMACEUTICAL COMPANIES, INC.** was a publicly traded company (NYSE ticker symbol PRX) headquartered in Woodcliff Lake, New Jersey and was the holding company for Par Pharmaceutical, Inc., a wholly owned subsidiary (collectively referred to as "PAR"). PAR was engaged in, among other things, the development, manufacture, promotion and sale of pharmaceutical drugs intended for human use. PAR distributed its pharmaceutical drugs throughout the United States, including in New Jersey. PAR operated through two different divisions: (a) a generic drug division, Par Pharmaceutical; and (b) a branded division which, as explained more fully below, was initially named the "Proprietary Products Division," and was eventually re-named Strativa Pharmaceuticals ("Strativa").

2. From in or about July 2005 through on or about September 27, 2007, PAR marketed, promoted, and sold Megace® ES, a prescription drug approved for use in patients with

acquired immunodeficiency syndrome ("AIDS") and indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with acquired immunodeficiency syndrome (the "AIDS Indication"). During this time period, PAR's Proprietary Products Division promoted and sold Megace® ES throughout the United States, including in New Jersey.

3. On or about September 28, 2007, PAR renamed its Proprietary Products Division as Strativa. From on or about September 28, 2007 through and including 2009, PAR marketed, promoted, and sold Megace® ES throughout the United States, including in New Jersey, through Strativa.

The FDA and FDCA

4. The Food and 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, and Cosmetic Act ("FDCA"), codified at Title 21, United States Code, Section 301, *et seq.*, and ensuring, among other things, that drugs intended for use in humans were safe and effective for each of their intended uses and that the labeling of such drugs bore true, complete, and accurate information.

5. The FDCA, along with its implementing regulations, required that, with certain exceptions not relevant here, before a new drug could legally be introduced into interstate commerce, a sponsor of a new drug submit and obtain approval of a New Drug Application.

6. FDA required that a New Drug Application identify all of the proposed uses of the drug intended by that sponsor, together with the proposed labeling for those uses, and data, generated in adequate and well-controlled clinical trials, that demonstrated to FDA's satisfaction that the drug would be safe and effective for those intended uses. 21 U.S.C. §§ 331(d) and

355(b).

7. Until FDA both found sufficient evidence of the drug's safety and efficacy for the uses proposed by the sponsor and approved the application, including the proposed labeling, the FDCA prohibited the sponsor from introducing the new drug into interstate commerce. 21 U.S.C. § 355(a). Only after FDA approved the application was the sponsor permitted by law to promote and market the drug, and then only for the medical conditions of use specified in the approved labeling. Any uses that were not approved by FDA, and therefore not included in the drug's approved label, were known as "unapproved uses" or "off-label uses."

8. Under the FDCA, if the sponsor of a drug wanted to market that drug for an unapproved or off-label use, the sponsor first was required to submit to FDA each additional proposed use, together with evidence, in the form of adequate and well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for each additional proposed use. The sponsor could not label or promote the drug for any new intended use without the prior approval of FDA.

9. Under the FDCA, a "prescription drug" was (a) a drug intended for use by people that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (b) a drug which FDA required to be administered under the professional supervision of a practitioner licensed by law to administer such drug as a condition of FDA approving the drug to be placed on the market. 21 U.S.C. § 353(b)(1)(A) and (B).

10. Under the FDCA, a drug was misbranded if its labeling did not contain "adequate

directions for use." 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the purposes for which the drug was intended. 21 C.F.R. § 201.5. A prescription drug, by definition, could not bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner, see 21 U.S.C. § 353(b)(1), but an FDA-approved prescription drug, bearing the FDA-approved labeling, could be exempt from the adequate-directions-for-use requirement if it was marketed for an FDA-approved use, see 21 C.F.R. § 201.100. A prescription drug that was marketed for non-approved, off-label uses would not qualify for this exemption and therefore would be misbranded. Id.

11. The FDCA prohibited the introduction or delivery for introduction into interstate commerce, or the causing thereof, of a misbranded drug. 21 U.S.C. § 331(a).

FDA APPROVAL OF MEGACE® ES

12. On or about September 10, 1993, FDA approved a New Drug Application filed by Bristol Myers Squibb ("BMS") for megestrol acetate oral suspension, which had a branded name of Megace® OS, for the treatment of the AIDS Indication. BMS's Megace® OS New Drug Application was supported by safety and effectiveness clinical trials conducted in AIDS patients.

13. Since on or about July 25, 2001, FDA has approved five different generic versions of BMS's Megace® OS product, all of which were approved and labeled only for the AIDS Indication. "Megace® OS," as used hereinafter, refers not only to BMS's branded Megace® OS product, but also to the five generic megestrol acetate oral suspension products.

14. In or about January 2002, PAR began actively developing a new formulation of Megace® OS that utilized nanocrystalization technology. As explained below, PAR eventually

named this formulation "Megace® ES." PAR's nanocrystalized version of Megace® OS is hereinafter referred to as Megace® ES.

15. On or about August 28, 2002, PAR met with FDA to discuss, among other things, PAR's plan to seek approval of Megace® ES for the AIDS Indication via FDA's 505(b)(2)/New Drug Application ("New Drug Application") process, whereby PAR would rely on the safety and efficacy data submitted previously by BMS in support of BMS's Megace® OS New Drug Application. At this meeting, PAR also informed FDA that it was considering Megace® ES as a treatment option for geriatric patients with malnutrition. In response, FDA informed PAR that improvements in body weight gain and body composition would not be sufficient for PAR to obtain an indication for anorexia, cachexia or an unexplained significant weight loss in the geriatric population (the "Geriatric Indication"), and instead, the primary endpoint of a clinical trial to support the Geriatric Indication must be some validated measure of functional performance where a clinically important difference has been established.

16. On or about June 29, 2004, PAR submitted its 505(b)(2) New Drug Application for Megace® ES to FDA for the AIDS Indication. In its 505(b)(2) New Drug Application for Megace® ES, PAR relied on the safety and effectiveness data previously submitted by BMS in support of the Megace® OS New Drug Application. PAR also submitted bioavailability and bioequivalence study data comparing Megace® ES with Megace® OS, which data demonstrated that Megace® ES and Megace® OS had the same bioavailability when patients took the drugs with food, but Megace® ES had an increased bioavailability over Megace® OS when patients took the drugs without food, *i.e.*, on an empty stomach. PAR did not, however, submit adequate and sufficient clinical trial data demonstrating that the increased bioavailability of Megace® ES

in the unfed state led to any increase in the efficacy of Megace® ES over Megace® OS.

17. On or about July 5, 2005, FDA approved PAR's 505(b)(2) New Drug Application for Megace® ES, 125mg/mL, for the AIDS Indication, *i.e.*, for use in the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with AIDS.

18. Less than two months later, on or about August 19, 2005, PAR submitted a meeting request to FDA to discuss, among other things, PAR's proposed investigational plan to seek approval of Megace® ES for the Geriatric Indication. PAR proposed one randomized, double-blind, placebo-controlled trial to support the safety and efficacy of Megace® ES for the Geriatric Indication.

19. On or about September 1, 2005, FDA denied PAR's meeting request. On or about September 2, 2005, an FDA Medical Officer contacted PAR's Senior Director of Regulatory Affairs to discuss PAR's intent to seek approval of Megace® ES for the Geriatric Indication. On that call, FDA informed PAR that in order to obtain approval of Megace® ES for the Geriatric Indication, additional safety data in the non-geriatric adult population would first be required before PAR could then conduct a clinical trial in the geriatric population, given that the geriatric population is inherently prone to several of the Megace® ES-labeled adverse events and precautions, such as suppression of the hypothalamic-pituitary-adrenal axis, osteoporosis, diabetes mellitus, congestive heart failure, and edema. FDA then reiterated its previous statement that changes in weight and body composition alone were not suitable primary efficacy endpoints for the geriatric clinical trials of Megace® ES, and instead, the primary endpoint would need to be a validated measure of functional performance.

20. PAR has never conducted clinical trials of Megace® ES in the geriatric

population.

21. PAR has never filed, nor has FDA ever approved, a New Drug Application for Megace® ES for the Geriatric Indication.

THE LIMITED ON-LABEL MARKET FOR MEGACE® ES

22. From at least in or about 2002 through at least in or about 2005, PAR conducted market research to determine practitioner use of Megace® OS. PAR learned from this market research that practitioners prescribed Megace® OS primarily for the off-label uses of cancer-related cachexia and geriatric weight loss, as opposed to the on-label use of the AIDS Indication, and that therefore the overwhelming majority of Megace® OS prescriptions were for off-label uses. More specifically, PAR learned that of all of the off-label prescribers, geriatricians prescribed Megace® OS for the widest variety of off-label uses.

23. PAR also conducted market research from at least in or about 2002 through at least in or about 2005 to gauge practitioner response to Megace® ES. This market research revealed that the projected use of Megace® ES increased if the new formulation had improved efficacy over Megace® OS.

24. In July 2005, when PAR gained FDA-approval of Megace® ES for the AIDS Indication, the treatment options for HIV positive and AIDS patients, such as highly active antiretroviral therapy ("HAART"), had advanced such that the incidence of AIDS-related weight loss, or AIDS-wasting, had significantly decreased, thus limiting the on-label market for Megace® ES.

PAR'S CREATION OF CALL PANELS AND SALES GOALS

25. Since as early as its 2003 Marketing Plan, PAR made it a top corporate priority to

maximize the sales of Megace® ES. In addition, PAR's early sales projections for Megace® ES assumed that PAR would eventually obtain FDA-approval for the Geriatric Indication.

26. Despite knowing at the time of FDA-approval for the AIDS Indication in July 2005 that the on-label market for Megace® ES was limited, PAR set aggressive sales goals for its initial launch of Megace® ES.

27. Shortly after the initial sales launch of Megace® ES, PAR realized that it would be unable to meet its sales goals for Megace® ES if the current sales trends continued. PAR thereafter adopted and implemented a marketing strategy designed to promote Megace® ES to an off-label population and thereby obtain significant off-label sales of Megace® ES for non-AIDS-related geriatric wasting.

28. At various relevant times, in order to maximize sales, PAR promoted the use of Megace® ES for the treatment of non-AIDS-related geriatric wasting. In order to capitalize on this strategy, PAR created lists of physicians that its sales representatives were expected to call on and provide detail regarding Megace® ES, referred to as sales "call panels," and these sales call panels required sales representatives to promote Megace® ES in long-term care facilities, including nursing homes, for non-AIDS-related geriatric wasting, including nursing homes, as well as to other practitioners who treated geriatric patients. Throughout the relevant time period, members of the PAR sales force knew that they were calling on very few nursing homes that actually had AIDS patients, or health care providers who actually treated AIDS patients.

29. PAR adopted and implemented a promotion strategy whereby PAR sought to "convert" existing Megace® OS prescriptions to Megace® ES prescriptions, without regard to whether Megace® OS had been prescribed to patients for the AIDS Indication. In order

to implement the "conversion strategy," PAR purchased only prescribing data for physicians who were prescribing Megace® OS, including long-term care data that identified physicians prescribing Megace® OS in the long-term care setting, and did not also purchase prescribing data for drugs indicated for the treatment of AIDS, including HAART drugs, despite the fact that Megace® ES was only FDA-approved for the AIDS indication. Thereafter, PAR used only the Megace® OS prescribing data to create its sales call panels. PAR ranked each physician based on the amount of Megace® OS that she or he had prescribed in the past, regardless of whether Megace® OS was being prescribed on- or off-label. The physicians with the highest number of prior Megace® OS prescriptions became the PAR sales representatives' top targets to "convert" all Megace® OS prescriptions to Megace ES prescriptions.

PAR'S INTRODUCTION INTO INTERSTATE COMMERCE OF MEGACE® ES FOR NON-AIDS-RELATED GERIATRIC WASTING

30. While targeting an audience of nursing home practitioners and health care providers who treat the elderly or geriatric population, PAR promoted Megace® ES by making false and/or misleading claims that Megace® ES was superior to Megace® OS through the following methods, among others:

A. Despite knowing since at least 2002 that the overwhelming majority of Megace® OS prescriptions were written for an off-label use, PAR sales representatives were trained and directed to request that healthcare practitioners convert "all Megace® OS patients" to Megace® ES, regardless of their on-label use of Megace® OS, resulting in the Par sales force affirmatively requesting off-label prescriptions of Megace® ES. PAR sales managers and representatives promoting Megace® ES in long-term care facilities referred to the conversion of

all Megace® OS patients in a long-term care facility over to Megace® ES as "bulk conversion" or "flipping a home." Members of the PAR sales team - including sales management - knew that they called on very few, if any, facilities with AIDS patients and very few practitioners that treated AIDS patients. Despite this, PAR continued to promote Megace® ES to this audience and to ask for "full conversion" of all patients on Megace® OS.

B. PAR trained, directed, and encouraged its sales representatives to promote Megace® ES during sales calls as a more effective product than Megace® OS, despite having no adequate and well-controlled clinical trial data to support such a superiority claim. While the FDA-approved label for Megace® ES reflected that Megace® ES was more bioavailable than Megace® OS in the unfed state, PAR never conducted the clinical trials that would be necessary to prove that Megace® ES was more effective than Megace® OS. Despite this lack of supporting data, PAR promoted Megace® ES as having superior clinical efficacy over Megace® OS, and Par's sales force was encouraged and directed to promote superiority in several different ways, including by:

(i) promoting Megace® ES as an "upgrade" over Megace® OS, and asking healthcare practitioners to "upgrade" their Megace® OS patients to Megace® ES;

(ii) falsely claiming that Megace® ES works faster than Megace® OS and that Megace® ES was a more effective medication than its competitors, and using the catchphrase "speed and ease" to promote Megace® ES; and

(iii) making misleading comments to healthcare providers that insinuated the superior efficacy of Megace® ES over Megace® OS, such as "[h]ave you

ever had a patient on the old Megace that did not respond or gained only a pound or two? Let me tell you why that might be ... bioavailability," and further promoting the false concept that Megace® ES worked faster than other drugs.

C. PAR trained, directed, and encouraged its sales force to minimize or eliminate mentioning altogether the FDA-approved indication for Megace® ES during promotional sales calls, in order to draw as little attention as possible to the fact that Megace® ES was only FDA-approved to treat AIDS wasting (i.e., the AIDS Indication), and not geriatric wasting (i.e., the Geriatric Indication). PAR accomplished this through at least two different methods:

(i) on many occasions, instead of providing the indication for Megace® ES, PAR sales representatives were encouraged by their superiors at PAR to omit language in the indication relating to AIDS and to otherwise "wordsmith" their sales presentation so as to minimize the indication, such as by simply telling healthcare practitioners that Megace® ES had the same indication as OS, rather than giving the indication; and

(ii) PAR encouraged its sales force to speak to healthcare providers regarding their patients with "UWL" - an acronym PAR used to mean "unintended weight loss" that was intended to relate to weight loss generally and not to be connected in any way to AIDS-related weight loss. PAR did not require its salespersons to ask if specific practitioners or nursing homes treated AIDS patients but did require the salespersons to inquire about the

number of patients with weight issues, including "UWL." According to at least one senior PAR manager, PAR sales management believed that "UWL" gave PAR a "license to hunt" in the nursing home environment. Members of the PAR sales force were encouraged by PAR to introduce themselves to nursing home personnel as specialists who could deliver information to the nursing home staff regarding how to assess and manage UWL, cachexia, or anorexia in nursing home patients. Sales representatives were then encouraged to falsely promote Megace® ES as the "best UWL product," and to ask specifically healthcare providers about their "UWL patients," and then urge them to switch those patients using Megace® OS to Megace® ES.

D. From in or about July 2006 through in or about January 2009, PAR devised and implemented a compensation structure whereby its representatives were credited only with Megace® ES prescriptions that were written by call panel physicians. The PAR call panels mandated that its sales force promote Megace® ES in nursing homes; in fact, some PAR sales managers required that their sales team visit ten to fifteen nursing homes a week in order to promote Megace® ES, and representatives were told that they would face possible employment consequences, including termination, if they did not promote Megace® ES in nursing homes. In order to incentivize its sales representatives to hew closely to its PAR-established call panels, PAR ranked the performance of its sales representatives based solely on the number of Megace® ES prescriptions written by call panel physicians who were on the sales representatives' call panels, and PAR often paid out bonuses exclusively on the basis of that ranking. PAR also held various sales contests for employees, and the winners of those sales contests were awarded high-

end, lucrative prizes, including, among other things, Rolex watches and trips to Cabo San Lucas. In response to these financial incentives designed to increase the number of Megace® ES prescriptions written by call panel physicians, PAR sales representatives actively requested that physicians convert all Megace® OS patients to Megace® ES, without regard to whether the physicians were prescribing Megace® ES for the AIDS Indication.

E. In furtherance of PAR's conversion strategy to promote and sell Megace® ES, PAR sales managers trained, directed, and encouraged PAR sales representatives to ask health care practitioners for protected patient identifying information so that they could request patients who were using Megace® OS be switched to Megace® ES. To this end, PAR sales representatives asked for patient identifying information, including patient names, medications, and insurance coverage, all information covered by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Multiple PAR sales supervisors not only condoned this practice, but encouraged the practice at sales meetings and praised sales representatives who obtained patient names. In some cases, while in nursing homes promoting Megace® ES, PAR sales representatives explicitly asked for lists of patients, and in other instances, representatives asked nursing home employees - such as those responsible for medicine carts - for access to patient prescription information. On some occasions, PAR sales representatives asked nursing home employees to look through the prescription medications on the medicine cart, and would either write down patient names themselves or ask the nursing home employee to make a note to switch patients receiving Megace® OS to Megace® ES.

31. The conduct described above in paragraph 30 is evidence of Par's objective intent to introduce Megace ES into interstate commerce for use in the treatment of anorexia, cachexia,

or significant unintended weight loss in geriatric patients, who do not also have AIDS, a use that was not approved by the FDA.

COUNT ONE

(Introduction into Interstate Commerce of a Misbranded Drug, 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1))

32. The allegations contained in paragraphs 1 through 30 are realleged and incorporated herein as if set forth in full.

33. Beginning in or about July 2005 and continuing until in or about 2009, in the District of New Jersey and elsewhere,

PAR PHARMACEUTICAL COMPANIES, INC.,

through its subsidiary Par Pharmaceutical Inc.'s branded drug division, that was first called the Proprietary Products Division and that was re-named Strativa Pharmaceuticals, did introduce and deliver for introduction, and cause the introduction or delivery for introduction, into interstate commerce, quantities of Megace® ES, a drug within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g), for an unapproved use, namely the treatment of non-AIDS-related geriatric wasting, which drug was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling for Megace® ES lacked adequate directions for such use.

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

FORFEITURE ALLEGATIONS

1. Upon conviction of the violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) alleged in this Information, defendant

PAR PHARMACEUTICAL COMPANIES, INC.

shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any quantities of Megace® ES which were misbranded when introduced into interstate commerce or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c), and Rule 32.2 of the Federal Rules of Criminal Procedure.

PAUL J. FISHMAN
United States Attorney