

United States Attorney's Office

District of New Jersey

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Par Pharmaceutical Companies Inc. Pleads guilty, Admits Misbranding of Megace® Es

FOR IMMEDIATE RELEASE

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Par Pharmaceutical Companies Inc. Pleads guilty, Admits Misbranding of Megace® Es Agrees to Pay \$45M to Resolve Criminal and Civil Investigations

NEWARK, N.J. – New Jersey-based Par Pharmaceutical Companies Inc. (“Par”) pleaded guilty in federal court today and agreed to pay \$45 million to resolve its criminal and civil liability in the company’s promotion of its prescription drug Megace® ES for uses not approved as safe and effective by the Food and Drug Administration (FDA) and not covered by federal health care programs, the Justice Department announced.

Chief Executive Officer Paul V. Campanelli pleaded guilty on behalf of Par before U.S. Magistrate Judge Madeline Cox Arleo earlier today in Newark federal court. Judge Arleo imposed sentence today, fining Par \$18 million and ordering \$4.5 million in criminal forfeiture. Par also agreed to pay \$22.5 million to resolve its civil liability.

“The FDA requires drug makers to go through a stringent approval process before new drugs – or new uses for existing drugs – are made available to doctors and their patients,” U.S. Attorney Paul J. Fishman said. “Today, Par admitted that it chose to ignore that process in pursuit of more sales and greater profits. It is paying the price for its choice.”

“Today’s resolution emphasizes the importance of the U.S. government’s coordinated efforts to combat health care fraud. We expect companies to make honest, lawful claims about the drugs they sell. We will be vigorous in our enforcement efforts when they break the law, to ensure that they are held accountable,” said Stuart F. Delery, Principal Deputy Assistant Attorney General for the Justice Department’s Civil Division.

“Individual accountability of Par's board and executives is required under the comprehensive five-year integrity agreement OIG has with the company,” said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. “For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales representatives may not be paid incentive compensation for the drug involved in the case, or successor branded versions of that drug.”

“The public has been well served by this investigation and the FDA commends the efforts of the U.S. Attorney's Office in New Jersey, the Department of Justice and the other law enforcement agencies that worked with us to vigorously pursue this matter,” said Mark Dragonetti, Special Agent In Charge of the FDA's Office of Criminal Investigation's New York Field Office. “Today's settlement demonstrates the FDA's continued commitment to target companies that disregard the safeguards of the drug approval process and promote drugs for uses before they have been proven to be safe and effective.”

Par pleaded guilty to an Information charging it with a criminal misdemeanor for misbranding Megace® ES in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”). Megace® ES, a megestrol acetate drug product, was approved by the FDA to treat anorexia, cachexia, or other significant weight loss suffered by patients with AIDS (the “AIDS Indication”). The Megace® ES distributed nationwide by Par was criminally misbranded because its FDA-approved labeling lacked adequate directions for use in the treatment of non-AIDS-related geriatric wasting, a use that was intended by Par but never approved by the FDA. The FDCA requires companies such as Par to specify the intended uses of a product in an application to the FDA. Once approved, a drug may not be distributed in interstate commerce for unapproved or “off-label” uses until the company receives FDA approval for the new intended uses. In addition to the criminal fine and forfeiture, the plea agreement mandates that Par implement several compliance measures and annually provide the U.S. Attorney’s Office with a sworn certification from its chief executive officer that the company has not unlawfully marketed any of its pharmaceutical products.

The civil settlement agreement requires Par to pay \$22.5 million to the federal government and various states to resolve claims arising from its off-label marketing. The civil settlement resolves allegations that Par, by promoting the sale and use of Megace® ES for uses that were not FDA-approved and not covered by Federal health care programs, caused false claims to be submitted to these programs. The United States further alleged that Par deliberately and improperly targeted sales to elderly nursing home residents with weight loss, whether or not such patients suffered from AIDS, and launched a long-term care sales force to market to this population. During this marketing campaign, Par was allegedly aware of adverse side effects associated with the use of megestrol acetate in elderly patients, including an increased risk of deep vein thrombosis, toxic reactions in elderly patients with impaired renal function, and mortality. The United States alleged that Par made unsubstantiated and misleading representations about the superiority of Megace® ES over generic megestrol acetate for elderly patients to encourage providers to switch patients from generic megestrol acetate to Megace® ES, despite having conducted no well-controlled studies to support a claim of greater efficacy for Megace® ES. Except as admitted in the plea agreement, the claims settled by the civil settlement agreement are allegations only, and there has been no determination of liability as to those claims.

In addition to the criminal and civil resolutions, Par also agreed to enter into a five-year Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services (“HHS-OIG”) that requires enhanced accountability, increased transparency, and wide-ranging monitoring activities conducted by both internal and independent external reviewers.

The plea agreement and CIA include provisions that require Par to implement changes to the way it does business. The plea agreement and CIA prohibit Par from providing compensation to sales representatives or their managers based on the volume of sale of Megace ES, and in the CIA, based on the volume of Megace ES and any branded successor megestrol acetate drug. Under the CIA, Par is also required to change its executive compensation program to permit the company to recoup annual bonuses from covered executives if they, or their subordinates, engage in significant misconduct.

The settlement resolves three lawsuits filed under the whistleblower provisions of the False Claims Act, which permit private parties to file suit on behalf of the United States and obtain a portion of the government’s recovery. The civil lawsuits were filed in the District of New Jersey and are captioned *U.S. ex rel. McKeen and Combs v. Par Pharmaceutical, et al.*, *U.S. ex rel. Thompson v. Par Pharmaceutical, et al.*, and *U.S. ex rel. Elliott & Lundstrom v. Bristol-Myers Squibb, Par Pharmaceutical, et al.* As part of today’s resolution, relators McKeen and Combs will receive \$4.4 million.

This resolution is part of the government’s emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than \$10.2 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department’s total recoveries in False Claims Act cases since January 2009 are over \$14.1 billion.

History of Megace® ES and Par’s Failed Attempts to Obtain FDA Approval of a Geriatric Wasting Indication for Megace® ES

According to the Information, a drug named Megace® OS – a predecessor to Megace® ES – was approved by the FDA in 1993 for the AIDS Indication. Between 2002 and 2005, Par’s market research showed that practitioners prescribed Megace® OS [1](#) for uses that were inconsistent with the approved labeling, including geriatric weight loss, and that the overwhelming majority of Megace® OS prescriptions were written for such off-label uses.

In 2002, Par first approached the FDA and discussed the company’s plan to seek approval of a new formulation of Megace® OS as a treatment option for geriatric patients with malnutrition. Par did not thereafter seek approval for that patient population. Instead, in June 2004, Par relied on the Megace® OS safety and effectiveness data in seeking approval for Megace® ES for the AIDS indication, i.e., the same indication as Megace® OS. Less than two months after the FDA approved Megace® ES for the AIDS indication, Par requested a meeting with the FDA to discuss Par’s intent to seek approval of

Megace® ES for certain non-AIDS geriatric patients. Par never sought approval for that patient population, nor did Par ever conduct drug trials in the geriatric population.

Par's "Conversion" Strategy, False Superiority Claims, and Promotion of Megace® ES for Geriatric Wasting

Despite knowing that Megace® ES had a limited market for its approved use, Par set aggressive sales goals for the product launch. After failing to attain these goals, Par adopted and implemented a marketing strategy designed to promote Megace® ES to geriatric wasting patients – the same population Par had twice discussed with the FDA. Par devised sales call panels which required Par sales representatives to market Megace® ES in nursing homes, as well as to practitioners who treated geriatric patients. These call panels identified physicians with the highest number of Megace® OS prescriptions as the top targets to “convert” from the old Megace® OS to Par’s Megace® ES product. Some Par sales managers required that their subordinates visit 10 to 15 nursing homes a week to promote Megace® ES, and told them there would be possible employment consequences, including termination, if they did not promote Megace® ES in nursing homes.

While targeting an audience of health care practitioners that treated the elderly or geriatric population, Par promoted Megace® ES by making false and/or misleading claims that Megace® ES was superior to Megace® OS, including:

1. Despite having no clinical support for the claim, Par sales representatives promoted Megace® ES as more effective than Megace® OS;
2. Despite having no clinical support for the claim, Par sales representatives claimed that Megace® ES worked faster and was more effective than other products, and used the phrase “speed and ease” to promote Megace® ES;
3. Par sales representatives were taught to try and “flip” a nursing home by asking the homes to convert all Megace® OS patients in the nursing home to Megace® ES, despite knowing that the nursing homes contained very few, if any, AIDS patients and the requested patients would therefore be using the product for off-label purposes;
4. Par trained and directed its sales force to minimize or eliminate mentioning altogether the FDA-approved indication for Megace® ES during promotional sales calls, so as to draw as little attention as possible to the fact that Megace® ES was not approved for geriatric wasting; and
5. Par managers trained, directed, and encouraged their sales representatives to ask health care practitioners for patient information protected by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), so that the representatives could request that certain patients who were using Megace® OS be switched to Megace® ES.

U.S. Attorney Fishman said the corporate guilty plea, the civil settlement, and the corporate integrity agreement are the culmination of a multi-year investigation conducted jointly by special agents from HHS-OIG, under the direction of Special Agent in Charge Tom O’Donnell, special agents from FDA-OIG, under the direction of Special Agent in Charge Mark Dragonetti, and criminal investigators and paralegals with the U.S. Attorney’s Office.

U.S. Attorney Fishman thanked the Defense Criminal Investigative Service; the Office of Personnel Management-Office of Inspector General; the Department of Veterans’ Affairs Office of Inspector General; and TRICARE Program Integrity for assisting in the investigation. He also thanked the National Association of Medicaid Fraud Control Units (NAMFCU), with assistance from the Medicaid Fraud Control Unit of the Ohio Attorney General’s Office for their help in coordinating the settlements with the various states.

The government is represented in the prosecution of the criminal case by Assistant U.S. Attorney Joseph Mack of the U.S. Attorney’s Office Health Care and Government Fraud Unit and Special Assistant U.S. Attorney Shannon M. Singleton from the FDA’s Office of Chief Counsel. Paralegals Jeffrey Skonieczny and Doug Minotti with the U.S. Attorney’s Office and Trial Attorney David Frank of the Department of Justice’s Consumer Protection Branch assisted on the criminal side of the case. The government is represented in the civil settlement by Assistant U.S. Attorney David Dauheimer and Trial Attorney Eva Gunasekera from the Department of Justice’s Commercial Litigation Branch. The corporate integrity agreement was

negotiated by Christina McGarvey and Gregory Lindquist from the Department of Health and Human Service's Office of Inspector General.

U.S. Attorney Fishman reorganized the health care fraud practice at the U.S. Attorney's Office, District of New Jersey, including creating a stand-alone Health Care and Government Fraud Unit, which handles both criminal and civil investigations and prosecutions of health care fraud offenses. Since 2010, the Office has recovered more than \$500 million in health care fraud and government fraud settlements, judgments, fines, restitution, and forfeiture under the False Claims Act, the Food, Drug and Cosmetic Act, and other statutes.

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Defense counsel: John N. Nassikas Esq., Washington, D.C.

1 The original Megace[®] OS product was sold by Bristol Myers Squibb ("BMS") from approximately 1993 until 2001. Since on or about July 25, 2001, the FDA approved five different generic versions of BMS's Megace[®] OS product. As used herein, the term "Megace[®] OS" refers not only to BMS's branded Megace[®] OS product, but also to the five generic versions approved by the FDA.

[Par Pharmaceutical Information](#)

[Par Pharmaceutical Plea Agreement](#)