

Pharmaceutical Fraud Whistleblower NEWS

Immediate Release

Tuesday March 5, 2013

McInnis Law
Timothy J. McInnis, Esq.
521 Fifth Avenue, 17th Floor
New York, NY 10175-0038
212-292-4573 – 917-903-9424
www.WhistleblowerLegal.com
TMcInnis@McInnis-Law.com

Drug To Improve Appetite in HIV and Cancer Patients Aggressively
Off-Label Marketed For Nursing Home, Even Hospice, Patients According to
Complaint Unsealed With Federal, State Whistleblower Settlements
Totaling More Than \$22.5 Million by Par Pharmaceuticals

Illegal Sales Tactics for Megace ES Represented “Substantial Portion”
of Drug’s Sales Over Three Years; One NJ Nursing Home Prescribed 6,900 Doses In
Five Months to Patients All of Whom Were HIV-Free,
According to Unsealed Complaint and Settlement Agreements

Death, Deep Vein Thrombosis, and Toxic Reactions Leading to
Impaired Kidney Function Were Side Effects in Elderly Yet Drug Manufacturer
Created Separate Nursing Home Sales Force to Off-Label the Drug, According to
NYC-Based National Qui Tam Whistleblowers’ Attorney Timothy J. McInnis, Esq.

(NEWARK, NJ) –For at least four years, drug manufacturer Par Pharmaceutical
Companies, Inc., and its subsidiary Par Pharmaceuticals, Inc. (together “Par”) risked the
lives of senior citizens across the U.S., by illegally off-label marketing to the elderly
Megace ES, a prescription approved only to help HIV and cancer patients gain weight by
increasing their appetite, qui tam whistleblowers’ attorney Timothy J. McInnis announced.

After FDA approval of Megace ES in 2005, Par staffed a new highly aggressive outside
sales force to push the drug for nursing home patients without HIV or cancer, even
hospice patients, subjecting all to dangerous, even deadly side effects, according to
documents unsealed with the drug manufacturer’s parent company’s \$22.5 million plus
interest settlement of federal and state False Claims Act violations.

Par’s civil settlement with the U.S. and Medicaid participating states followed the
pharmaceutical corporation’s guilty plea in U.S. District Court to a misdemeanor
information charging it with introducing into interstate commerce a misbranded drug,
Megace® ES, in violation of the Federal Food, Drug and Cosmetic Act. The Woodcliff
Lake, New Jersey-based drug manufacturer also paid a criminal fine.

(More)

Drug representatives in Par's new Megace ES marketing force used unapproved marketing materials and had no studies to back up their claims that the drug could be used to address weight loss in seniors not afflicted with HIV or cancer. Physicians they detailed also were told that undiagnosed HIV was "underreported" in nursing home populations and the danger to those for whom it was not indicated was "downplayed," according to the Complaint, filed by McInnis in 2008 on behalf of two whistleblowers who were appalled at the illegal marketing blitzkrieg.

For example, In one 250-bed New Jersey nursing home physicians prescribed 6,900 doses of Megace ES over a five -month period when not one case of HIV was present in the facility, according to the complaint which listed five nursing homes in Brooklyn and nearby New Jersey with approximately 1,330 beds and zero percent of HIV that were targeted by Par.

"Par's Megace ES marketing to hospice physicians represents the ultimate in off-label insanity," McInnis said. "Patients are admitted to hospices when their conditions are terminal, where medical staff helps them die in peace and dignity. Par, instead, saw them as an opportunity for easy money."

In addition to death, Megace ES's dangerous side effects in the elderly include deep vein thrombosis, toxic reaction and impaired kidney function, according to the Complaint and settlement agreement..

The drug manufacturer's off label tactics included misleading unsubstantiated claims that the Par product was superior to the generic version of the drug, megestrol acetate, when it had no well-controlled studies to back up those claims, the Settlement Agreement stated.

In settling with the United States Par also agreed to dismiss with prejudice two court actions, including a preemptive civil suit it filed in U.S. District Court for the District of Columbia, in which it claimed its First Amendment right to discuss off-label use of drugs with physicians was being restrained by the FDA. The suit was filed only after federal agents issued subpoenas to the company in 2009, after McInnis filed the whistleblower complaint. Par also agreed to a Corporate Integrity Agreement with the U,S. Department of Health and Human Services Office of Inspector General.

The relators' share of the recovery from the settlement , approximately \$4.5 million, will be shared by McInnis's two clients, who were the first to file their qui tam suit, and two other individuals whose claims were lodged later.

(More)

Under the False Claims Act, Qui Tam actions allow private citizens with knowledge of fraud to help the Government recover ill-gotten gains and additional civil penalties. The FCA allows the Government to collect up to three times the amount it was defrauded, in addition to civil penalties from \$5,500 to \$11,000 per false claim.

McInnis is a former federal prosecutor with offices in New York City who concentrates his practice on federal and state FCAs and its Qui Tam whistleblower provisions.

The United States is represented in the Par case by the U.S. Attorney's Office for the District of New Jersey, Paul J. Fishman, U.S. Attorney, and Assistant U.S. Attorney David E. Dauenheimer, of the office's Civil Division; as well as by U.S. Department of Justice Civil Division Trial Attorneys Eva U. Gunasekera and Edward Crooke. The relators' allegations were investigated by Special Agents of the Office of the Inspector General for the U.S. Department of Health and Human Services.

The Par case was assigned to United States District Court Judge Stanley R. Chesler, in Newark.

Docket Number, U.S. District Court, Newark, NJ: Civil Action No. 08-3624 (SRC).

###

Contacts:

Timothy J. McInnis, Esq.
McInnis Law
212-292-4573
TMcInnis@McInnis-Law.com

Unable to reach Mr. McInnis?
Richard Lavinthal at PRforLAW, LLC may be able to help
Call 202-596-1176
PRexpert@PRforLAW.com

This news release and any related filed documents are to be posted in the "Successful Cases" Section of WhistleblowerLegal.com and PRforLAW.com.

-30-