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PHARMACEUTICAL COMPANY PFIZER, INC. TO PAY $301 MILLION FOR OFF-LABEL DRUG MARKETING

PHILADELPHIA – United States Attorney Michael L. Levy announced today that pharmaceutical manufacturer Pfizer, Inc. has agreed to pay $301 million, plus interest, to resolve civil liabilities for its off label marketing of the anti-psychotic drug, Geodon. This agreement is part of a $2.3 billion global settlement announced today by Assistant United States Attorney General Tony West. The Eastern District of Pennsylvania settled allegations that Pfizer illegally promoted Geodon for a variety of off-label uses, marketed Geodon for ineligible patients, and encouraged inappropriate doses.

Geodon was initially approved by the FDA for the acute manifestations of schizophrenia. FDA later expanded its approval for use in acute bipolar mania. But Pfizer allegedly marketed the drug for use in patients with depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism, and post-traumatic stress disorder, none of which were approved uses for Geodon.

The government alleges that Pfizer also promoted Geodon for use by unapproved patients, including pediatric and adolescent patients, and promoted Geodon for higher dosages than were approved by the FDA. This conduct included direct promotion by Pfizer sales representatives and promotion through the hiring of physicians, or "key opinion leaders", to give promotional talks to other physicians about unapproved uses and dosages of Geodon. Specifically, these talks included encouraging doctors to prescribe the drug for children, and to prescribe the drug at substantially higher than approved dosages.

The government alleges that, as a result, Pfizer caused false and fraudulent claims for Geodon to be submitted to Medicaid, Medicare, and other federal health care programs. Patients who received the drug for unapproved and unproven uses had no assurance about whether their doctors were exercising their independent and fully-informed medical judgement, or were, instead, influenced by Pfizer's misleading statements and/or inducements.

"To address this and other schemes Pfizer committed across the nation, the U.S. Attorneys' Offices and our investigative agency partners from the Eastern Districts of Pennsylvania and Kentucky, the District of Massachusetts and the Department of Justice cast their investigation widely, worked tirelessly to find witnesses and evidence, and together prosecuted what they found,"

said Levy. "The global resolution achieved in this matter was due to these collaborative efforts, which exemplify the U.S. Department of Justice at its best."

As part of its settlement with the United States, Pfizer and its subsidiary, Pharmacia & Upjohn Company, agreed to a plea to criminal charges for off-label promotion of Bextra, as well as the civil settlement of claims involving the off-label promotion of Bextra, Zyvox, and Lyrica. The civil resolution also resolves allegations that Pfizer paid kickbacks to physicians to induce them to prescribe the drugs Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec, in violation of the Federal Anti-Kickback Statute.

These investigations were commenced by the filing of numerous whistleblower lawsuits in several districts around the country, including in this district Kruszewski ex rel U.S. v Pfizer, Inc. Civil Action 07-4106. The federal False Claims Act authorizes private individuals to file such suits, in order to alert the United States about potential wrongdoing. If the United States is successful in resolving or litigating the whistleblower's claims, the whistleblower may share in part of the recovery.

Pfizer has also agreed to comply with the terms of a new and significantly expanded corporate compliance program which seeks to ensure that in the future there are procedures and reviews in place to avoid, or, at a minimum, timely detect such violations.

This resolution is the second this year in the Eastern District of Pennsylvania addressing off-label promotion of an anti-psychotic drug by a pharmaceutical company. The FDA has approved anti-psychotics to treat specific mental health disorders. These drugs, initially approved for the serious disease of schizophrenia, have strong side effects. Off-label use for other conditions can cause similar or more serious adverse effects, such as weight gain, hyperglycemia, diabetes, stroke, or sudden death in the elderly. The FDA has enhanced warnings about these effects in labels for all atypical anti-psychotic medications.

The Geodon matter was handled by Assistant United States Attorneys Marilyn May and Charlene Keller Fullmer of the Eastern District of Pennsylvania and Department of Justice Civil Fraud Attorney Patricia Hanower. The Corporate Integrity Agreement was negotiated by Senior Counsel Mary Riordan in the Office of Counsel to the Inspector General for the Department of Health and Human Services. The states were represented by the National Association of Medicaid Fraud Control Units. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services, the Office of Criminal Investigations for the Food and Drug Administration and the Office of the Inspector General for the United States Postal Service.

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