Department of Justice

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WARNER-LAMBERT TO PAY $430 MILLION TO RESOLVE CRIMINAL & CIVIL HEALTH CARE LIABILITY RELATING TO OFF-LABEL PROMOTION

WASHINGTON, D.C. – American pharmaceutical manufacturer Warner-Lambert has agreed to plead guilty and pay more than $430 million to resolve criminal charges and civil liabilities in connection with its Parke-Davis division's illegal and fraudulent promotion of unapproved uses for one of its drug products, Associate Attorney General Robert D. McCallum, Jr. and Massachusetts U.S. Attorney Michael J. Sullivan announced today. The drug Neurontin was approved by the Food and Drug Administration in December 1993 solely for adjunctive or supplemental anti-seizure use by epilepsy patients.

Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses - any use not specified in an application and approved by FDA.

However, Warner-Lambert's strategic marketing plans, as well as other evidence, show that Neurontin was aggressively marketed to treat a wide array of ailments for which the drug was not approved. The company promoted Neurontin for the treatment of bipolar mental disorder, various pain disorders, Amyotrophic Lateral Sclerosis (ALS, a degenerative nerve disease commonly referred to as Lou Gehrig's Disease), attention deficit disorder, migraine, drug and alcohol withdrawal seizures, restless leg syndrome, and as a first-line monotherapy treatment for epilepsy (using Neurontin alone, rather than in addition to another drug).

"The Department of Justice is committed to rooting out and prosecuting health care fraud," said Associate Attorney General Robert McCallum. "It is of paramount importance that the Department use every legal tool at its disposal to assure the health and safety of the consumers of America's health care system, and to pursue companies and individuals that steal

from the taxpayers and inflict suffering on patients and families. The Department's commitment to effective health care fraud enforcement is driven by a mandate that wrongdoers be brought to justice, to deter conduct which threatens the safety and welfare of all Americans, and the need to protect the resources of the Medicare Trust Fund, state Medicaid programs, and other government health programs."

Warner-Lambert promoted Neurontin even when scientific studies had shown it was not effective. For example, the company promoted Neurontin as effective for use as the sole drug (monotherapy) for epileptic seizures, even after solo use had been specifically rejected by the FDA. Similarly, the pharmaceutical company falsely promoted Neurontin as effective for treating bipolar disease, even when a scientific study demonstrated that a placebo worked as well or better than the drug.

"This illegal and fraudulent promotion scheme corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk," stated U.S. Attorney Michael Sullivan. "This scheme deprived federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals -- judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor. The pharmaceutical industry will not be allowed to profit from such conduct nor subject the poor, the elderly and other persons insured by state and federal health care programs to experimental drug uses which have not been determined to be safe and effective."

As a consequence of the unlawful promotion scheme, patients who received the drug for unapproved and unproven uses had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Warner-Lambert. Potential problems that can arise from off-label use without the benefit of careful FDA oversight include the occurrence of unforeseen adverse effects because the drug was not studied in the type of patient it is being used for off-label and the appropriate dosage and course of treatment have not been established.

"The plea agreement and settlement announced today marks the end of an exemplary effort to use all of the appropriate anti-fraud weapons available to us in a concerted manner to

send clear and unequivocal messages to the pharmaceutical industry," said Assistant Attorney General Peter D. Keisler. "To insure a just result, we in the Civil Division will vigilantly join our tools for fighting fraud on consumers with those available to remedy fraud on the federal health care programs."

Warner-Lambert used a number of tactics to achieve its marketing goals, including encouraging sales representatives to provide one-on-one sales pitches to physicians about off-label uses of Neurontin without prior inquiry by doctors. The company's agents also made false or misleading statements to health care professionals regarding Neurontin's efficacy and whether it had been approved by the FDA for the off-label uses. Warner-Lambert also utilized "Medical Liaisons," who represented themselves (often falsely) as scientific experts in a particular disease, to promote off-label uses for Neurontin.

Warner-Lambert paid doctors to attend so-called "consultants meetings" in which physicians received a fee for attending expensive dinners or conferences during which presentations about off-label uses of Neurontin were made. These events included lavish weekends and trips to Florida, the 1996 Atlanta Olympics and Hawaii. There was little or no significant consulting provided by the physicians.

The pharmaceutical company implemented numerous teleconferences in which physicians were recruited by sales representatives to call into a pre-arranged number where they would listen to a doctor or a Warner-Lambert employee speak about an off-label use of Neurontin.
The company also sponsored purportedly "independent medical education" events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants.

Warner-Lambert misled the medical community beforehand about the content, as well as the lack of independence from the company's influence, of many of these educational events. In at least one instance, when unfavorable remarks were proposed by a speaker, Warner-Lambert offset the negative impact by "planting" people in the audience to ask questions highlighting the benefits of the drug.

Warner-Lambert paid physicians to allow a sales representative to accompany the physician while he or she saw patients, with the representative offering advice regarding the patient's treatment which was biased towards the use of Neurontin.

These tactics were part of a widespread, coordinated national effort to implement an off-label marketing plan. At the same time, Warner-Lambert decided not to seek FDA approval for any of the new uses because it was concerned that approval for any of the non-epilepsy uses would allow generic competitors of Neurontin, which was expected to go off-patent soon, to compete with a "son of Neurontin" drug that Warner-Lambert hoped to have approved by the FDA for both epilepsy and non-epilepsy uses.

Neurontin was launched into the marketplace in February of 1994; from mid-1995 to at least 2001, the growth of off-label sales was tremendous. While not all of these sales were the consequence of Warner-Lambert's illegal marketing, the marketing scheme was very successful in increasing Neurontin prescriptions for unapproved uses.

The state Medicaid programs were harmed by Warner-Lambert's aggressive promotion for off-label uses in numerous ways. The conduct caused doctors to write prescriptions for Medicaid patients when those medications were not eligible for Medicaid reimbursement in that the prescriptions were fraudulently obtained through false statements to doctors and by payment of illegal kickbacks, including so called "consulting fees" and trips for physicians.

The investigation was commenced in the District of Massachusetts when a former medical liaison for Warner-Lambert, Dr. David Franklin, filed a suit on behalf of the U.S. government. Private individuals like Dr. Franklin are allowed to file whistleblower suits under the federal False Claims Act to bring the United States information about wrongdoing. If the United States is successful in resolving or litigating the whistleblower's claims, the whistleblower may share in part of the recovery. As a part of today's resolution, Dr. Franklin will receive approximately $24.64 million of the civil recovery.

"Today's settlement demonstrates the government's continued scrutiny of sales and marketing practices by the pharmaceutical industry to ensure that those who do business with our programs act properly," said Acting Principal Deputy Inspector General Dara Corrigan for the Department of Health and Human Services, Office of Inspector General. "Our programs cannot

afford the abuses we have seen by drug companies against our beneficiaries and the American taxpayers."

"The Health Care Fraud Squad in the Boston Office of the FBI is committed to weeding out fraud and corruption within our health care system," stated Special Agent in Charge Kenneth W. Kaiser of the Boston Office of the FBI. "Our agents will continue to work diligently along with other law enforcement agencies to protect Medicare and Medicaid from fraud and abuse to ensure that our most vulnerable citizens will continue to have health care coverage."

"This settlement achieves the goals of placing the welfare of our veterans first," stated Bruce Sackman, Special Agent in Charge of the Northeast Field Office of the Office of Inspector General for Department of Veterans Affairs. "Parke-Davis directly promoted off-label drug uses to Veterans Affairs physicians and pharmacists on a nationwide basis, in direct violation of FDA laws. From 1994 to 2002, sales of Neurontin to the Department of Veterans Affairs jumped from $287,000 to $43.2 million. These sales, in part, directly reflect the impact of Parke-Davis' illegal marketing techniques. Hopefully, this settlement will serve as a deterrent to other firms thinking of engaging in this practice. The Department of Veterans Affairs will remain vigilant in its efforts to prevent illegal activities such as this in the future."

"We believe that this settlement goes a long way to protecting Americans against unlawful and inappropriate conduct by pharmaceutical companies," stated Mark B. McClellan, M.D., Ph.D., Administrator of the Centers for Medicare & Medicaid Services. "It sends a strong message in advance of implementation of the Medicare prescription drug benefit that our first priority will be protecting beneficiaries and the programs that serve them."

"Today's action is a result of the close cooperation between the Department of Justice and FDA in investigating this matter and seeking appropriate redress for it," said Acting FDA Commissioner, Dr. Lester M. Crawford. "These fines and penalties demonstrate that there is a strong system in place for ensuring that companies comply with the laws that safeguard Americans."

The global agreement includes the following components:

(a) Warner-Lambert has agreed to plead guilty to two counts of violating the Food, Drug & Cosmetic Act with regard to its misbranding of Neurontin by failing to provide adequate

directions for use and by introduction into interstate commerce of an unapproved new drug. Warner-Lambert has, as punishment for these offenses, agreed to pay a $240 million criminal fine, the second largest criminal fine ever imposed in a health care fraud prosecution. The Plea Agreement between the United States and Warner-Lambert specifically states that Warner-Lambert's criminal conduct caused losses of $150 million and that the violations are felonies as a consequence of Warner-Lambert's prior Food, Drug & Cosmetic Act conviction.

(b) Warner-Lambert has agreed to settle its federal civil False Claims Act liabilities and to pay the United States $83.6 million, plus interest, in civil damages for losses suffered by the federal portion of the Medicaid program as a result of Warner-Lambert's fraudulent drug promotion and marketing misconduct.

(c) Warner-Lambert has agreed to settle its civil liabilities to the fifty states and the District of Columbia in an amount of $68.4 million, plus interest, for losses the state Medicaid programs suffered as a result of Warner-Lambert's fraudulent drug promotion and marketing misconduct.

(d) Warner-Lambert has agreed to settle its civil liabilities to the fifty states and the District of Columbia in an amount of $38 million, plus interest, for harm caused to consumers and to fund a remediation program to address the effects of Warner-Lambert's improper marketing scheme. This part of the global settlement agreement was negotiated by the Consumer Protection divisions of the fifty State Attorneys General.

(e) Pfizer Inc, Warner-Lambert's parent company, has agreed to comply with the terms of a corporate compliance program, which will ensure that the changes Pfizer Inc made after acquiring Warner-Lambert in June 2000, are effective in training and supervising its marketing and sales staff, and ensures that any future off-label marketing conduct is detected and corrected on a timely basis. In addition, Warner-Lambert agreed to an injunction by a state court against continuing the improper conduct that was the subject of the States' Consumer Protection Divisions investigation.

Pfizer Inc, the owner of Warner-Lambert since June of 2000, has also agreed to institute a compliance program. The charged conduct occurred prior to the acquisition.

The case was handled by Assistant U.S. Attorneys Thomas E. Kanwit and Sara M. Bloom of the U.S. Attorney's Office for the District of Massachusetts, and by Trial Attorney Jill Furman of the Justice Department Office of Consumer Litigation. Assisting in the investigation were Jonathan Diesenhaus and Stanley Alderson of the Department of Justice's Civil Fraud section. 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 and the Consumer Protection Divisions of the States Attorneys General. The investigation was conducted by the Federal Bureau of Investigation, the Veteran's Administration's Office of Criminal Investigations, the Office of Criminal Investigations for the Food and Drug Administration and the Office of Inspector General for the Department of Health and Human Services.

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