The United States Attorney's Office

Eastern District of New York

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United States Attorney's Office
Eastern District of New York

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FOR IMMEDIATE RELEASE **April 05, 2006**

PRESS RELEASE

PSYCHIATRIST CHARGED WITH CONSPIRACY TO ILLEGALLY MARKET THE PRESCRIPTION MEDICATION XYREM, ALSO KNOWN AS "GHB," FOR UNAPPROVED MEDICAL USES ON BEHALF OF ITS MANUFACTURER

Nationwide Scheme Also Sought Unlawful Reimbursements from Public and Private Health Insurers

An indictment was returned today in U.S. District Court in Brooklyn, New York, charging the defendant PETER GLEASON, a psychiatrist, with federal crimes arising from his participation in a nationwide scheme to unlawfully promote the medication Xyrem, also known as sodium oxybate and gamma-hydroxybutyrate ("GHB"), to prescribing physicians for non-approved medical purposes and concealing those purposes from health insurers. The indictment further alleges that the defendant was paid tens of thousands of dollars by Xyrem's manufacturer in furtherance of this scheme. Specifically, GLEASON was charged with introducing a misbranded drug into interstate commerce, health care fraud, and conspiracy to commit those offenses.

The indictment was announced by **ROSLYNN R. MAUSKOPF,** United States Attorney for the Eastern District of New York, **KIM A. RICE,** Special Agent-in-Charge, U.S. Food and Drug Administration, Office of Criminal Investigations, Washington Metro Field Office, and **MARK J. MERSHON**, Assistant Director-in-Charge, Federal Bureau of Investigation, New York Field Office, and is the culmination of a year-long undercover investigation that included the use of a cooperating witness who recorded his conversations with GLEASON, as well as GLEASON's presentations to prescribing physicians at continuing education programs and promotional events sponsored by Xyrem's manufacturer.

According to the indictment, the active ingredient in Xyrem is GHB, a powerful and fast-acting central nervous system depressant that has been subject to abuse as a recreational drug and is classified

by the federal government as a "date rape" drug. Xyrem is capable of inducing sleep very quickly and causing serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. Abuse of the drug can cause additional serious medical problems, including seizures, coma, and death, and can also lead to dependence and severe withdrawal symptoms. Xyrem's dangers are set forth in a "black box" warning, which is the most serious warning placed in the labeling of a prescription medication.

Federal law makes it a crime for anyone to introduce a drug into interstate commerce for a medical use or "indication" that is not approved by the U.S. Food and Drug Administration ("FDA"). According to the indictment, Xyrem is only approved for two medical indications, the treatment of cataplexy, a condition characterized by weak or paralyzed muscles associated with the sleep disorder known as narcolepsy, and the treatment of excessive daytime sleepiness ("EDS") in narcolepsy patients. The indictment charges GLEASON with conspiring with employees of Xyrem's manufacturer to market Xyrem for a range of unapproved or "off-label" indications, including fatigue, chronic pain, weight loss, EDS not associated with narcolepsy, depression, bipolar disorders, fibromyalgia (a disorder causing muscle pain and fatigue), insomnia, and movement disorders such as Parkinson's disease.

As alleged in the indictment and a previously filed complaint, Xyrem's manufacturer, Orphan Medical, Inc. ("Orphan"), relied on GLEASON to give lectures around the country promoting Xyrem to physicians for "off-label" indications and paid GLEASON tens of thousands of dollars for such speaking engagements. In 2004 alone, GLEASON spoke at over 100 events and was paid more than $70,000. GLEASON was allegedly in high demand by Orphan sales representatives because of his proven ability to generate "off-label" sales of Xyrem in their respective sales territories. The indictment charges that GLEASON engaged in deceptive and misleading behavior in promoting Xyrem by, among other things, suggesting to physicians that GHB was not a "date rape" drug, and that Xyrem was safe for very young children when, in fact, the drug's labeling stated that Xyrem had not been proven safe and effective for people under the age of 16. The indictment also charges that GLEASON conspired with Orphan employees to defraud public and private health insurance plans by concealing, and advising prescribing physicians to conceal, evidence that Xyrem prescriptions were being filled for "off-label" indications that generally were not reimbursable.

"Illegal marketing of prescription medications for unauthorized medical uses is a serious and increasingly widespread crime that we are committed to prosecuting," stated United States Attorney **MAUSKOPF**. "This case is particularly troubling, not only because it involves the marketing of a medication containing GHB, a dangerous substance with a long history of abuse, but because those marketing activities were furthered by a psychiatrist who, for financial gain, willingly used his professional status to promote the use of the medication at the expense of patient health and to urge other physicians to conceal those unauthorized uses from health insurers." Ms. **MAUSKOPF** thanked the Department of Health and Human Services, Office of Inspector General, for its assistance in this matter and emphasized that the investigation is continuing.

FDA Special Agent-in-Charge RICE stated, "The FDA does not tolerate the marketing of products that use deceptive and untruthful claims to lure consumers into potentially dangerous situations."

FBI Assistant Director-in-Charge **MERSHON** stated, "Apparently motivated solely by greed, someone whose moral and professional obligation was patient well-being engaged in a pattern of promoting unproven and even unsafe uses of a potentially dangerous drug. That a psychiatrist would engage in conduct indistinguishable from a carnival snake-oil salesman is appalling."

If convicted, GLEASON faces the following maximum sentence: conspiracy to introduce a misbranded drug into interstate commerce -- five years incarceration, conspiracy to commit health care fraud -- 10 years incarceration, introducing a misbranded drug into interstate commerce -- three years incarceration, and health care fraud -- 10 years incarceration. On each count of conviction the defendant also faces a maximum fine of $250,000. In addition, the indictment seeks a forfeiture judgment against the defendant of any and all property constituting or derived from proceeds traceable to his offenses.

The government's case is being prosecuted by Assistant United States Attorneys Geoffrey Kaiser, Paul Kaufman, and Margot Schoenborn.

The Defendant:

PETER GLEASON

DOB: 4/1/1953

RF:MEC:mec
F.#2006R00646

DLF

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- - - - - - - - - - - - - - - - - - -X

UNITED STATES OF AMERICA

- against -

PETER GLEASON,

Defendant.

- - - - - - - - - - - - - - - - - - -X

SUPERSEDING
MISDEMEANOR
INFORMATION

Cr. No. 06-229 (S-2) (ENV)
(T. 21, U.S.C., §§ 331(a) and 333(a)(1); T. 18, U.S.C., §§ 3551 et seq.)

THE UNITED STATES ATTORNEY CHARGES:

INTRODUCTION

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

The Defendant, Orphan and Xyrem

1. Orphan Medical, Inc. ("Orphan") was a Delaware corporation with its headquarters and principal place of business located in Minnetonka, Minnesota. Orphan was a specialty pharmaceutical company focused primarily on the development of drugs to treat pain, sleep disorders and central nervous system ("CNS") disorders.

2. Orphan's lead product was Xyrem, also known as sodium oxybate or gamma-hydroxybutyrate ("GHB"), which was first approved by the U.S. Food and Drug Administration ("FDA") in July 2002 to treat patients with narcolepsy who experience episodes of cataplexy, a condition associated with weak or paralyzed muscles

(the "First Medical Indication"). Subsequently, in November 2005, FDA approved Xyrem to treat excessive daytime sleepiness ("EDS") in patients with narcolepsy, a neurological disorder caused by the brain's inability to regulate sleep-wake cycles normally (the "Second Medical Indication"). A "medical indication" refers to the use of a drug for treating a particular medical condition. Xyrem was not approved by FDA for any medical indications other than the First Medical Indication and the Second Medical Indication.

3. The active ingredient in Xyrem was GHB, a powerful and fast-acting CNS depressant that was subject to abuse as a recreational drug. Xyrem was capable of inducing sleep very quickly and causing serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting and sleepwalking. Abuse of the drug could cause additional serious medical problems, including seizures, coma and death, and could also lead to dependence, craving for the drug and severe withdrawal symptoms. Overdosing on Xyrem could cause, among other things, seizures, a slow heart rate and coma. Xyrem's dangers were set forth in a "black box" warning, which is the most serious warning placed in the labeling of a prescription medication. The labeling also stated that the drug's safety and efficacy were not established in patients under 16 years of age,

and that it was important to keep the drug away from children. The labeling further indicated that there was only "very limited" experience with the drug in elderly patients.

4. Distribution of Xyrem was tightly restricted due to safety concerns associated with use of the drug. In the Controlled Substances Act ("CSA"), Xyrem was designated a Schedule III Controlled Substance for medical use, meaning that it could not be sold, distributed or provided to anyone other than for its prescribed use. The illicit use of Xyrem was subject to penalties under Schedule I, the most restrictive schedule of the CSA.

The Food, Drug and Cosmetic Act

5. Congress enacted the Federal Food, Drug and Cosmetic Act ("FDCA"), set forth at 21 U.S.C. §§ 301 et seq., to protect the public from, among other things, drugs that were misbranded or not proven to be safe and effective for their intended uses.

6. Section 331(a) of Title 21, United States Code, prohibited the introduction or causing the introduction into interstate commerce of any drug that was misbranded.

7. Pursuant to Title 21, United States Code, Sections 352(a) and 352(f), a drug was deemed to be misbranded if, among other things, the drug's labeling was false or misleading, did not contain adequate directions for the drug's use or adequate

warnings against its use where such use could be dangerous to the user's health. Any uses claimed for a drug that were not approved by FDA as safe and effective, and thus not included in the drug's approved labeling, were known as "off-label" indications or uses. A drug that was marketed to the public for an "off-label" indication or use did not contain "adequate directions for use" because such an "off-label" indication or use and related information were not included in the FDA-approved labeling for the drug.

The Defendant's Promotion
of Xyrem For "Off-Label" Uses

8. In or about and between 2003 and 2006, the defendant PETER GLEASON, who was a licensed psychiatrist, was paid by Orphan to promote Xyrem to physicians for "off-label" indications. During speaking engagements with groups of physicians and in meetings with individual physicians, GLEASON promoted Xyrem for "off-label" indications that included fibromyalgia, weight loss, excessive daytime sleepiness not associated with narcolepsy, insomnia and chronic fatigue. GLEASON was in high demand by Orphan's sales representatives to promote Xyrem because his presentations frequently resulted in increased sales of Xyrem. In total, Orphan paid GLEASON tens of thousands of dollars for these "off-label" presentations.

MISBRANDING

9. In or about and between 2003 and 2006, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant PETER GLEASON did knowingly and intentionally introduce into interstate commerce, and cause the introduction into interstate commerce of, a drug, to wit: Xyrem, that was misbranded within the meaning of 21 U.S.C. § 352(f), in that the defendant was marketing Xyrem for medical indications that were not approved by FDA when, as the defendant then and there well knew and believed, Xyrem's labeling lacked adequate directions for such uses and adequate warnings against such uses where such uses could be dangerous to the user's health.

(Title 21, United States Code, Sections 331(a) and 333(a)(1); Title 18, United States Code, Sections 3551 et seq.)

BENTON J. CAMPBELL
UNITED STATES ATTORNEY
EASTERN DISTRICT OF NEW YORK

BY: [signature]
ACTING UNITED STATES ATTORNEY
PURSUANT TO 28 C.F.R. 0.136

SIR:

PLEASE TAKE NOTICE that the within will be presented for settlement and signature to the Clerk of the United States District Court in his office at the U.S. Courthouse, **271 Cadman Plaza East Brooklyn, New York** _____

_____

Dated: Brooklyn, New York
_____, 2006

United States Attorney,
Attorney for _____

To: _____

_____

_____

Attorney for _____

SIR:

PLEASE TAKE NOTICE that the within is a true copy of _____ Duly entered herein on the _____ day of _____, in the office of the Clerk of the Eastern District of

New York,
Dated: Brooklyn, New York
_____, 2006

United States Attorney,
Attorney for _____

To:

_____

_____

_____

Attorney for _____

Criminal Action No.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

vs.

PETER GLEASON,

Defendant.

SUPERSEDING MISDEMEANOR INFORMATION

BENTON J. CAMPBELL
United States Attorney
271 Cadman Plaza East
Brooklyn, New York 11201
Mailing Address:
271 Cadman Plaza East
Brooklyn, New York 11201

Due Service of a copy of the within _____ is hereby admitted.

Dated: _____, 2006

_____

Attorney for _____

Martin E. Coffey
Assistant U.S. Attorney
(718) 254-6157

D&F

US MAGISTRATE JUDGE CHERYL L. POLLAK DATE: 8/8/08

TIME SPENT: 21 min

CRIMINAL CAUSE FOR PLEADING

DOCKET NO. 06 CR 229 (ENV)

DEFENDANT'S NAME : Peter Gleason

__ custody X bail

DEFENSE COUNSEL : Michael Weil

__ CJA __ Retained X Legal Aid

A.U.S.A. : Martin Coffey DEPUTY CLERK : E. Huters

TICK # : 12:47 - 1:08 OTHER : _____

INTERPRETER : (Language - n/a)

X CASE CALLED. __ DEFENDANT'S FIRST APPEARANCE

DFT: X SWORN __ ARRAIGNED X INFORMED OF RIGHTS

X WAIVES TRIAL BEFORE DISTRICT COURT

__ WAIVER OF INDICTMENT EXECUTED FOR THE DEFENDANT.

X INFORMATION FILED. (superseding misdemeanor) __ SUPERSEDING INDICTMENT FILED.

__ DEFENDANT FAILED TO APPEAR, BENCH WARRANT ISSUED.

X DEFENDANT ENTERS **GUILTY PLEA** TO COUNT _____

OF THE: X (Superseding) INFORMATION __ (Superseding) INDICTMENT.

X COURT FINDS BASIS FOR THE PLEA.

__ SENTENCING TO BE SET BY PROBATION DEPARTMENT.

X SENTENCING DATE ~~SET FOR~~ to be set by case manager.

__ DEFENDANT ENTERS **NOT GUILTY PLEA** TO ALL COUNTS.

X BAIL CONTINUED FOR THE DEFENDANT.

__ DEFENDANT CONTINUED IN CUSTODY.

__ CASE ADJOURNED TO _____ FOR _____.