

Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa

\$515 Million Criminal Fine Is Largest Individual Corporate Criminal Fine in History; Civil Settlement up to \$800 Million

Pharmaceutical giant Eli Lilly and Company has agreed to plead guilty and pay \$1.415 billion for promoting its drug Zyprexa as an "off-label" treatment for dementia, including Alzheimer's dementia, in elderly people when those uses were not approved by the Food and Drug Administration (FDA), the Department of Justice announced January 15, 2009. The global settlement and the civil and criminal prosecutions that it arises from highlights the growing emphasis that U.S. regulators are placing on aggressive enforcement of federal and state laws regulating the marketing and referral practices of pharmaceutical, durable medical equipment and other health industry organizations.

According to the announcement, Eli Lilly agreed to enter a global resolution with the United States to resolve criminal and civil allegations that it promoted its antipsychotic drug Zyprexa for uses not approved by the FDA. Eli Lilly's guilty plea and sentence is not final until accepted by the U.S. District Court. Under this global settlement agreement: Eli Lilly:

- Will forfeit assets of \$100 million and pay a criminal fine of \$515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.
- Will pay Eli Lilly will also pay up to \$800 million in a civil settlement with the federal government and the states. to resolve civil allegations originally brought in four separate lawsuits under the qui tam provisions of the federal False Claims Act. The federal share of the civil settlement amount is \$438 million. Under the terms of the civil settlement, Eli Lilly will pay up to \$361 million to those states that opt to participate in the agreement.
- Signed a plea agreement admitting its guilt to a misdemeanor criminal charge.
- Signed a civil settlement to resolve civil claims that by marketing Zyprexa for unapproved uses, it caused false claims for payment to be submitted to federal insurance programs such as Medicaid, TRICARE and the Federal Employee Health Benefits Program, none of which provided coverage for such off-label uses.

The Food, Drug, and Cosmetic Act (FDCA) requires that a company specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.

The global settlement resolves charges that Eli Lilly violated the FDCA by promoting Zyprexa as a treatment for agitation, aggression, hostility, dementia, Alzheimer's dementia, depression and generalized sleep disorder when it was not approved by the FDA for those uses.

You can review the Department of Justice announcement for additional details at <http://www.usdoj.gov/opa/pr/2009/January/09-civ-038.html>.

About Cynthia Marcotte Stamer

Cynthia Marcotte Stamer, J.D. has extensive experience advising, and representing health care providers, health plans, healthcare clearinghouses and other clients about HIPAA and other regulatory compliance, public policy, human resources, technology, privacy, licensing and credentialing, contracting, and other risk management and operational concerns. Her clients include hospitals, physicians, clinics, IPAs, PHOs, skilled nursing facilities, assisted living and home health, rehabilitation, imaging and other diagnostic services providers, DME, physician practice management companies and other

management services organizations, health care technology, payers, employers, public health, school and other health involved governmental entities, and other health industry clients.

Recognized in the International Who's Who of Professionals and bearing the Martindale Hubble (the highest) AV-Rating, Ms. Stamer is a highly regarded legal advisor and consultant, known for her practical, direct problem-solving approach to helping clients.

Immediate Past Chair of the American Bar Association (ABA) Health Law Section Managed Care & Insurance Interest Group, Ms. Stamer also

applies her extensive industry experience in numerous professional and industry leadership roles. In addition to her ABA Health Law Section involvement, Ms. Stamer serves on the editorial advisory boards of and is a contributing author for the Bureau of National Affairs and other publications, served as the Compliance Committee Chair and a member of the Board of the National Kidney Foundation of North Texas Board of Directors, serves on the continuing education and conference planning committees of the ABA Joint Committee On Employee Benefits (JCEB), the HFMA Lone Star Chapter, TAHFA, the IRS TEGE Advisory

Council, and numerous other health industry groups. She also is the past-president of the Alliance for Health Care Excellence, and founder of its Health Care Heroes and Patient Empowerment Programs. She also is active in numerous other industry organizations including the American Health Lawyers Association, the Medical Group Management Association, the Alliance for Healthcare Excellence, the Dallas Bar Association Health Law Section.

Ms. Stamer also is a widely published author and highly sought-after speaker nationally and internationally sought out for her strategic knowledge and insights on operational and technical health care risk management and operational concerns. She frequently

conducts workshops and other training activities on health care compliance and risk management concerns. A recurring author for various other health industry publications, Ms. Stamer's insights have been quoted by the Wall Street Journal, the Bureau of National Affairs (BNA), HIPAA Comply, Private Payer News, Modern Health Care, Managed Healthcare Executive, Health Leaders, Caring for The Elderly Magazine, For The Record, the Dallas Morning News, Spencer Publications, the Dallas Business Journal, the Houston Business Journal, and a various other national and local publications. Ms Stamer is the author of 100s of publications on health plan and health industry matters including numerous highly regarded works

published by the American Bar Association, Aspen Publishers, BNA, the American Health Lawyers Association, the Medical Group Management Association, Government Institutes, Inc., Decision Health, Loreman, Spencer Publications, and others.

For more information about Ms. Stamer, a listing of selected publications and other health industry links, information about workshops and other training and other health industry information and resources or other details about Cynthia Marcotte Stamer, P.C. and Glast, Phillips & Murray, P.C., see CynthiaStamer.com or contact Ms. Stamer.

Important Notices Regarding This Communication

We hope that this information is useful to you. You can register to receive future updates and information about upcoming programs, access other publications by Ms. Stamer and other helpful resources or additional information about Ms. Stamer and/or Glast, Phillips & Murray, P.C., at CynthiaStamer.com or by contacting Ms. Stamer directly. If you or someone else you know would like to receive future Alerts or other information about developments, publications or programs, please be sure that we have your current contact information – including your preferred e-mail. Interested persons can register or update their contact information by providing that information to us through registration on our website at www.cynthiastamer.com or via telephone, fax or e-mail. If you have questions or concerns about the matters discussed in this publication or other health care or health industry related matters, wish to obtain information about arranging for training or presentations by Ms. Stamer, wish to suggest a topic for a future program or publication, or wish to request other information or materials, contact Ms. Stamer using the contact information set

forth below. If you would prefer not to receive these updates, please send a reply e-mail with "Remove" in the subject line to cstamer@solutionslawyer.net.

ABOUT THIS COMMUNICATION. This publication is provided by Solutions Law Press™ for general informational and educational purposes to clients and other interested persons. Neither its distribution to any party nor any statement or information it contains is intended to or shall be construed as establishing an attorney-client relationship or to constitute legal advice. Readers also are cautioned that the information in this publication may not apply to all situations. Consequently, readers must not rely upon this publication or information it contains as a substitute for competent individualized legal advice about the specific circumstances of the reader. If you have received this publication in error or do not wish to receive these in the future, please notify us of your preferences to the attention of Ms. Stamer via email, fax, regular mail or telephone.

HOW TO CONTACT US. You can reach us by writing, telephoning or e-

mailing Cynthia Marcotte Stamer, P.C., Member, Glast, Phillips & Murray, P.C., 2200 One Galleria Tower, 13355 Noel Road, LB 48, Dallas, Texas 75240, Telephone (972) 419-7188, E-mail cstamer@solutionslawyer.net.

CIRCULAR 230 NOTICE: The following disclaimer is included to comply with and in response to U.S. Treasury Department Circular 230 Regulations. ANY STATEMENTS CONTAINED HEREIN ARE NOT INTENDED OR WRITTEN BY THE WRITER TO BE USED, AND NOTHING CONTAINED HEREIN CAN BE USED BY YOU OR ANY OTHER PERSON, FOR THE PURPOSE OF (1) AVOIDING PENALTIES THAT MAY BE IMPOSED UNDER FEDERAL TAX LAW, OR (2) PROMOTING, MARKETING OR RECOMMENDING TO ANOTHER PARTY ANY TAX-RELATED TRANSACTION OR MATTER ADDRESSED HEREIN.