



The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

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BREAKING NEWS ALERT

340B and Medicaid Benefit From Lilly Settlement

Eli Lilly will refund 340B-covered entities more than \$750,000 to settle an off-label marketing case involving the anti-psychotic drug Zyprexa, the U.S. Department of Justice announced Jan. 15. The Indiana-based drug maker will also pay affected state Medicaid programs more than \$361 million to settle similar claims.

The total settlement, \$1.42 billion, is the largest amount paid by a single defendant in Justice Department history, and the second major off-label marketing case in which 340B entities are compensated. Less than four months ago, federal prosecutors settled a similar False Claims Act case with Cephalon that netted 340B entities \$1.86 million.

Eli Lilly has agreed to mail out checks to affected Public Health Service entities within 60 days of the U.S. District Court accepting the company's guilty plea to criminal charges. The plea hearing is scheduled for Jan. 30. By cashing the check, 340B-covered entities and others covered under the deal will release Eli Lilly from liability.

According to federal prosecutors, Eli Lilly created marketing material and trained its sales force to promote Zyprexa for off-label uses, despite a warning from the Food and Drug Administration. The company began marketing the drug to nursing home and primary care doctors in 1999 for ailments it was never approved for, such as dementia, depression and sleep disorders. This, prosecutors say, posed risks to patients.

"Today's disclosures should send a clear message to those doing business with the government that they will be held accountable for their decisions and actions that have an adverse impact on health care programs such as Medicare and Medicaid," Special Agent-in-Charge Patrick Doyle of the U.S. Health and Human Services' Office of Inspector General said in a statement Thursday.

Eli Lilly noted in a press release that it has been cooperating in the government's investigation for the past four years and that while it accepted the misdemeanor guilty charge, it does not admit to the allegations in the civil allegations.

"We deeply regret the past actions covered by the misdemeanor plea," John C. Lechleiter, the company's chief executive was quoted as saying. "At Lilly we take seriously our responsibilities to abide by all the laws governing our business practices, and we realize that we have tremendous responsibility to the patients and healthcare professionals we serve."

For more information, read the:

- Justice Department press release -
<http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf>
- Eli Lilly press release -
<http://newsroom.lilly.com/releasedetail.cfm?ReleaseID=359242>
- Settlement Agreement -
<http://www.usdoj.gov/usao/pae/News/Pr/2009/jan/lillysignedsettlementagreement.pdf>