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By [Caleb Groos \(https://www.findlaw.com/company/our-team.html\)](https://www.findlaw.com/company/our-team.html) on September 02, 2009 11:16 AM

Drugmaker Pfizer Inc. and one of its subsidiaries agreed to pay \$2.3 billion to settle civil and criminal charges regarding its marketing of the drug Bextra. As part of the settlement, Pfizer pled guilty to a felony violation of the Food, Drug, and Cosmetic Act for marketing the drug with the intent to deceive and mislead the public.

The criminal portion of the fine is the largest fine ever levied by the United States government, breaking the previous record set by drugmaker Eli Lilly and Company with its illegal campaign for the drug Zyprexa just last January.

## Problematic Off-Label Marketing Practices

Like the Zyprexa case, the criminal charges against Pfizer come from "off-label marketing" of its drug Bextra, an anti-inflammatory used for the treatment of arthritis and menstrual cramps. Pfizer yanked Bextra from the shelves in 2005 after the FDA found an increased risk of heart attack and stroke (<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/cox-2-selective-includes-bextra-celebrex-and-vioxx-and-non-selective-non-steroidal-anti-inflammatory>), from usage, along with other potentially serious side effects.

Off-label *marketing* refers to the illegal practice of marketing a drug approved by the Food and Drug Administration (FDA) for uses other than what the FDA approves it for. This is different from "off-label *use*" (<https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>), which is the legal practice of a doctor prescribing a drug for a different use than the FDA granted approval for. If a drugmaker wants to market a drug for a new use, which brings with it new revenue streams (<https://www.findlaw.com/legalblogs/consumer-protection/drug-ads-abilify-fda-approval/>), it must seek additional FDA approval.

While in this case, Bextra came off the shelf because of unrelated dangers, it does not mean that every drug subject to illegal off-label marketing claims is dangerous. To gain FDA approval, drugs and vaccines undergo rigorous clinical trials heavily scrutinized by both the drugmakers and regulatory bodies like the FDA and similar agencies in other countries.

According to the Department of Justice (<https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>) (DOJ), Pfizer marketed Bextra for a variety of uses and dosage sizes, including post-operative pain for joint replacement patients, that the FDA had already refused to approve due to safety concerns.

## A Punitive Fine

The criminal fine against Pfizer is \$1.195 billion, with another \$105 million to be paid by its subsidiary Pharmacia & Upjohn Company Inc. Whistleblower suits filed in Massachusetts, Pennsylvania, and Kentucky triggered the federal investigation.


According to the DOJ, the size of Pfizer's fine came in part because of the company's duplicitous dealings with federal prosecutors. As one U.S. attorney put it: "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws."

In addition to the honor of largest criminal fine of any type from the feds ever (according to the DOJ), Pfizer will also pay the largest civil fraud settlement, \$1 billion, ever forced on a pharmaceutical company in the U.S.

## Related Resources:

- [Find a Lawyer Near You Who Handles Dangerous and Defective Drug Lawsuits](https://lawyers.findlaw.com/lawyer/practice/drugs-medical-devices) (<https://lawyers.findlaw.com/lawyer/practice/drugs-medical-devices>) (FindLaw's Lawyer Directory)
- [Push is on to end prescription drug ads targeting consumers](https://www.usatoday.com/money/advertising/adtrack/2009-08-09-adtrack-prescription-drug-ads_N.htm) ([https://www.usatoday.com/money/advertising/adtrack/2009-08-09-adtrack-prescription-drug-ads\\_N.htm](https://www.usatoday.com/money/advertising/adtrack/2009-08-09-adtrack-prescription-drug-ads_N.htm)) (USA Today)
- [Document Details Plan to Promote Costly Drug Lexapro](https://www.nytimes.com/2009/09/02/business/02drug.html) (<https://www.nytimes.com/2009/09/02/business/02drug.html>) (NY Times)
- [The Changing Landscape of Pharmaceutical Marketing](http://blogs.wsj.com/health/2009/07/20/the-changing-landscape-of-pharmaceutical-marketing/) (<http://blogs.wsj.com/health/2009/07/20/the-changing-landscape-of-pharmaceutical-marketing/>) (Wall Street Journal Health Blog)

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