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## **Support Sanders Amendment to Curtail Pharmaceutical Fraud, Hold Violators Accountable**

- **The pharmaceutical industry is now the biggest defrauder of the federal government under the False Claims Act (FCA).** The pharmaceutical industry has greatly overtaken the defense industry in recent years as the biggest defrauder of the federal government, paying \$2.2 billion in FCA penalties in FY 2011 alone.<sup>1</sup>
- **Over the past two decades (1991-2011), pharmaceutical companies have been forced to pay at least \$23 billion in civil and criminal penalties** in 214 settlements with the federal and state governments resolving myriad violations under the FCA and other laws. Three-fourths of the settlements have occurred in just the past five years.<sup>2</sup>
- **The practice of illegal off-label promotion of pharmaceuticals is responsible for the largest amount of financial penalties levied by the federal government.** This practice is often prosecuted as a criminal offense because of the potential for serious adverse health effects in patients from such activities.
- **The fraud endangers the public health.** The illegal marketing of pharmaceuticals for indications not approved by the Food and Drug Administration (FDA) bypasses the FDA's critical review process whereby the benefits and risks of a drug for each indication are fully evaluated prior to approval. As a consequence, many patients prescribed off-label medications are needlessly exposed to dangerous risks that outweigh any benefit. Just a few months ago, in November 2011, Merck pled guilty to illegally promoting the dangerous painkiller, Vioxx, for almost three years for rheumatoid arthritis before FDA approval for this indication.<sup>3</sup> Vioxx was later removed from the market for causing fatal heart attacks.
- **The fraud costs taxpayers dearly.** Deliberately overcharging state health programs, mainly Medicaid fraud, has been the most common violation against state governments. In one case, a jury found a Pfizer, Inc. subsidiary guilty of 1,440,000 counts of Medicaid pricing fraud in Wisconsin, costing state and federal taxpayers \$7 million, due to the manipulation of the average wholesale price (AWP) by the pharmaceutical company.<sup>4</sup>

- **Without the help of whistleblowers, much of this fraud would remain hidden from public view.** From 2001 through 2010, cases initiated by whistleblowers were responsible for 59 percent of federal pharmaceutical settlements and 67 percent of taxpayer dollars recovered by the federal government.
- **Current penalties are too small to deter unlawful behavior, which, as a consequence, has almost certainly become a business model for the pharmaceutical industry.** The \$23 billion in financial penalties paid by all pharmaceutical companies in the 21 years from 1991-2011 constitute just over half the \$43 billion in profits made by the ten largest pharmaceutical companies in a single year, 2010.<sup>5</sup>
- **The profits generated, in part, through unlawful activity dwarf current penalties.** In 2004, a Pfizer, Inc. subsidiary pled guilty to off-label promotion of Neurontin, an anti-seizure medication, and paid \$430 million in civil and criminal penalties for the conduct.<sup>6</sup> By contrast, sales of Neurontin in a single year, 2002, reached \$2.27 billion, 94% of which were from off-label indications.<sup>7</sup> The company admitted to promoting the drug despite knowing that it was proven ineffective for many of these indications.<sup>8</sup>
- **Company heads are rarely held accountable.** Only a handful of pharmaceutical executives have been successfully prosecuted for overseeing this fraudulent activity, and only one has been sentenced to prison (for only 30 days).<sup>9</sup>

### **The Solution: Sanders Amendment**

- **The Sanders amendment would add a critical tool to the federal government's enforcement efforts.** The amendment would rescind exclusivity rights for a pharmaceutical product granted under the Food, Drug & Cosmetic Act (FDCA), if the company marketing that product has been found, or admits to, engaging in unlawful activity involving the drug.
- **Unlike existing enforcement actions, the amendment would serve as an effective deterrent.** Removing the exclusivity for the drug involved in unlawful activity will undoubtedly change the cost-benefit equation for pharmaceutical companies engaging in fraud. Companies will no longer treat the penalties for unlawful conduct as merely a part of doing business.

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<sup>1</sup> U.S. Department of Justice. Justice Department Recovers \$3 Billion in False Claims Act Cases in Fiscal Year 2011. December 19, 2011. Available at: <http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html>

<sup>2</sup> Unpublished data compiled by Public Citizen covering the years 1991-2011, which updates a previous report that covered the 1991-2010 period. **Unless otherwise noted, the information in this fact sheet is based on the 2010**

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**Public Citizen report:** Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010. December 16, 2010. Available at: [www.citizen.org/hrg1924](http://www.citizen.org/hrg1924)

<sup>3</sup> U.S. Department of Justice. U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx. November 22, 2011. <http://www.justice.gov/opa/pr/2011/November/11-civ-1524.html>

<sup>4</sup> Wisconsin Department of Justice. Jury Finds Pharmacia Committed Fraud On Wisconsin Medicaid Program; Van Hollen's Department Of Justice Wins State \$9 Million. February 17, 2009. Available at: [http://www.doj.state.wi.us/absolutenm/templates/template\\_share.aspx?articleid=1076&zoneid=3](http://www.doj.state.wi.us/absolutenm/templates/template_share.aspx?articleid=1076&zoneid=3); Pharmacia has been a subsidiary of Pfizer since 2003. Available at: [http://www.pfizer.com/about/history/pfizer\\_pharmacia.jsp](http://www.pfizer.com/about/history/pfizer_pharmacia.jsp)

<sup>5</sup> CNN Money: Fortune 500 Pharmaceuticals. Issue Date: May 23, 2011. Available at: <http://money.cnn.com/magazines/fortune/fortune500/2011/industries/21/index.html>

<sup>6</sup> U.S. Department of Justice. Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion. May 13, 2004. Available at: [http://www.justice.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm)

<sup>7</sup> Evans D. When Drug Makers' Profits Outweigh Penalties. Washington Post. March 21, 2010. Available at: <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/19/AR2010031905578.html>

<sup>8</sup> U.S. Department of Justice. Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion. May 13, 2004. Available at: [http://www.justice.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm)

<sup>9</sup> According to Bloomberg, "since 2007, prosecutors have won convictions of three top executives at Purdue Pharma LP who pleaded guilty to misdemeanor charges of misbranding the painkiller OxyContin; former Intermune Inc. Chief Executive Officer W. Scott Harkonen; four Synthes Inc. executives [a medical device, not a pharmaceutical company]; and former KV Pharmaceutical Co. CEO Marc Hermelin." The article is incorrect in stating that the longest prison term was nine months. This nine month sentence for Scott Harkonen was actually for house arrest, not prison time. Marc Hermelin was sentenced to 30 days in prison. Voreacos D. and Lawrence J. Health Care Prosecution Losses Mar U.S. Marketing Probe. Bloomberg. March 14, 2012. Available at: <http://www.bloomberg.com/news/2012-03-14/health-care-prosecution-losses-mar-u-s-marketing-probe.html>; and for the Scott Harkonen case: Gullo K. Intermune Ex-CEO Harkonen Sentenced to Home Confinement in Fraud Case. Bloomberg. April 14, 2011. Accessed on May 10, 2012. <http://www.bloomberg.com/news/2011-04-14/intermune-ex-ceo-harkonen-given-home-confinement-over-2002-press-release.html>