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April 24, 2012

The Honorable Tom Harkin
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Michael B. Enzi
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions
379A Russell Senate Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

We are writing in strong support of Senator Bernie Sanders' first amendment to the Prescription Drug User Fee Act (PDUFA) package, introduced today, concerning pharmaceutical fraud (Sanders/Amendment #1). The amendment would rescind exclusivity rights granted under the federal Food, Drug, and Cosmetic Act (FD&C Act) for any future pharmaceutical product, if the company marketing the product has been found, or admits to, engaging in unlawful activity involving the drug.

Such an amendment has never been more necessary. Over the past two decades, the pharmaceutical industry has emerged as the biggest defrauder of the federal government under the False Claims Act (FCA), and has paid \$23 billion¹ to the federal and state governments in settlements resolving myriad civil and criminal violations under the FCA and other laws. The illegal activities encompass a wide variety of violations, including off-label promotion, deliberate overcharging of Medicare and Medicaid, kickbacks to physicians to prescribe a drug, and other offenses.

These actions have cost the taxpayers dearly while putting the public safety at risk. The illegal marketing of pharmaceuticals for indications not approved by the Food and Drug Administration (FDA) is a dangerous practice, as it bypasses the FDA's critical review process whereby the benefits and risks of a drug for each indication are fully evaluated prior to approval. And in an era of increasing budget deficits, companies continue to engage in pricing fraud of already

overstretched Medicare and Medicaid programs, unlawfully enriching themselves on taxpayer funds without any consequences severe enough to deter future unlawful behavior.

Despite a recent increase in federal settlements, the financial penalties handed down are so small relative to industry profits that the companies simply factor them into the cost of doing business.² In addition, prosecution of companies rarely involves holding executives individually responsible, with company heads almost always escaping without punishment for overseeing this fraudulent activity.

The proposed amendment would add a critical tool to the federal government's enforcement efforts. It would immediately put companies on alert that any further unlawful activity will incur serious consequences, thus serving as an effective deterrent to such activity. While we support the amendment in its entirety, we believe that it should also cover violations of the criminal provisions of the FCA under 18 U.S.C. § 287, in addition to the civil provisions already covered in the amendment.

The Sanders amendment simply holds fully accountable those companies that refuse to play by the rules, endangering patients and defrauding taxpayers. Pharmaceutical companies already generate enormous profits through government-granted data exclusivity rights. This amendment would make those exclusivities contingent on a company following the letter of the law. This is hardly a radical proposition, and must be adopted to help put an end to the ongoing fraud perpetrated by the pharmaceutical industry against the American taxpayer.

Thank you,



Sammy Almashat, M.D., M.P.H.
Researcher
Public Citizen's Health Research Group



Sidney Wolfe, M.D.
Director
Public Citizen's Health Research Group

Cc: Ashley Cottingham, Sophie Kasimow, and Meagan Reed (all Sen. Sanders' staffers)

¹ Unpublished data compiled by Public Citizen covering the years 1991-2011, which updates a previous report that covered the 1991-2010 period: Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010. December 16, 2010. Available at: www.citizen.org/hrg1924

² Since 1991, financial penalties paid by all pharmaceutical companies have totaled only \$23 billion, just a little over half the profits made by the ten largest pharmaceutical companies in a single year (2010). CNN Money: Fortune 500 Pharmaceuticals. Issue Date: May 23, 2011. Available at: <http://money.cnn.com/magazines/fortune/fortune500/2011/industries/21/index.html>