DOWN ON THE PHARMA: HOW GREEN-LIGHTING GENERICS CAN BE A GAME-CHANGER AGAINST OFF-LABEL MARKETING BY BRAND-NAME OFFENDERS

Sean J. Quinn

ABSTRACT

In July, 2012, pharmaceutical giant GlaxoSmithKline ("GSK") agreed to pay $3 billion in fines and plead guilty to marketing drugs for unapproved uses. It was the largest healthcare fraud settlement in U.S. history. The government alleged that from January 1999 to December 2003, GSK promoted Wellbutrin SR to treat sexual dysfunction and weight loss even though the Food and Drug Administration only approved the drug to treat depression. Specifically, a Department of Justice investigation found that GSK used lavish vacations and lump sums of cash to entice medical professionals, including radio and television personality Dr. Drew Pinsky, to prescribe the drug for off-label uses. The government also alleged that GSK instructed its sales force to promote the antidepressant to physicians as the "happy, horny, skinny drug," as Wellbutrin sales skyrocketed 34 percent from 2000 to 2001.

This off-label marketing has made the pharmaceutical industry the biggest defrauder of the federal government. The practice is not only deceptive but also disastrous for federal healthcare programs. While physicians are free to prescribe drugs off-label, drug companies are not allowed to promote those unapproved uses. The practice leads to submission of thousands of fraudulent claims into Medicare and Medicaid. Taxpayers, of course, foot the bill.

The government tried to use this landmark settlement to make an example out of GSK. However, it only exemplified the futility of monetary fines. These penalties are merely seen as the cost of doing business. Moreover, federal prosecutors have been reluctant to use perhaps

their most powerful tool, individual exclusion, on big pharma executives, who actually oversee these deceptive practices.

This Note argues a fresh approach to both punish and deter brand-name, off-label offenders. It calls for amendments to the Federal Food, Drug, and Cosmetic Act, the statute that regulates off-label promotion. Specifically, it aims to define the term "truthful speech" to prevent First Amendment claims from pharmaceutical giants. Further, it introduces the idea of earlier entry of generic drugs into the marketplace to obliterate brand-name profits and provide cheaper drugs to patients, ultimately saving taxpayers billions in federal healthcare dollars.