



Curbing Drug-Company Abuses: Are Fines Enough?

Written On June 2, 2010 By Bob Kraft

That's the headline of a recent Time Magazine article. The question is whether relatively small fines (relative to drug company profits) are any real deterrent to continued false marketing practices. The article is a good read. Here are the opening paragraphs: In late April, when the Justice Department announced its deal with AstraZeneca for the pharmaceutical company to pay a \$520 million fine, as a result of the off-label marketing of its blockbuster antipsychotic drug Seroquel, Justice officials called it a "historic settlement." Attorney General Eric Holder, Health and Human Services Secretary Kathleen Sebelius and the head of the Food and Drug Administration held a press conference, trumpeting it as part of the Administration's "top priority" fight against health care fraud. It was the largest ever civil-only fine imposed by the U.S. government for an off-label marketing offense — the promotion of the drug for uses not approved because it has not been shown safe, necessary and effective.

Seroquel had FDA approval for use in short-term treatment of schizophrenia and acute bipolar 1, but according to Justice's complaint the company aggressively marketed the drug "as a long-term cure-all for a broad spectrum of psychiatric maladies, including ... aggression and agitation in children" even though clinical studies have sometimes shown "serious and debilitating side effects," particularly among the elderly and

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children. Seroquel is typically prescribed by psychiatrists, but was being marketed to general medical practitioners, including staff at nursing homes, veterans hospitals and prisons, and to neighborhood pediatricians, making patients “guinea pigs in an unsupervised drug test,” according to a prosecutor.

The company denied the allegations but agreed to settle to “avoid the delay, uncertainty, inconvenience, and expense of protracted litigation.” That kind of outcome is not uncommon. A conviction in court can be crippling to companies. The government too has an interest in avoiding expensive court fights, particularly if it feels it can gain future compliance through fines and corporate integrity agreements [CIAs] that allow it to guide and monitor companies’ compliance efforts.

But critics are starting to question these settlements, pointing out that even such large fines have yet to make a serious dent in recurring marketing abuses. AstraZeneca’s fine represented just 16.5% of revenue earned from Seroquel during the years its off-label marketing was ongoing — \$8.6 billion in the U.S. between 2001 and 2006. Just how much of this was due to improper marketing is unclear, but considering the limited primary market and the widespread use of the drug, it was bound to have been significant.

Since companies can roll the costs of such fines into future drug prices, the penalties become just another cost of doing business. That means Americans get whammied twice. The first involves hundreds of millions of dollars in unnecessary reimbursements paid out by Medicare and Medicaid for drugs that were surreptitiously being promoted for unapproved uses. “Health care fraud is not only illegal, it drives up the cost of medical care for all of us,” noted Tony West, who directs Justice’s civil division.