Letter to the Editor: The Pundit Speaks

By Randolph M. Howes, M.D., Ph.D.
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"Drug Manufacturer's Risky Practices"

Previously, I have said, "Pharmaceutical companies have egregiously participated in one hundred years of sleazy practices and continue to do so." According to a 2013 article in the Journal of Law, Medicine and Ethics (JLME), here is the heart of the problem: about 350 people die daily from drug reactions or 128,000 per year. Pharmaceutical companies hide, ignore, or misrepresent evidence about new drugs; distort the medical literature; and misrepresent products to prescribing physicians. There appears to be an epidemic of harmful allowable Food and Drug Administration (FDA) approved drugs, which have scarce benefits to any patients. A 2018 report shows that Nuplazid, a drug for hallucinations and delusions associated with Parkinson's disease, failed two clinical trials. In a third trial, under a revised standard for measuring its effect, it showed minimal benefit. Overall, more patients died or had serious side effects on Nuplazid than after receiving no treatment. Also, patients on Uloric, a gout drug, suffered more heart attacks, strokes and heart failure in two out of three trials than did their counterparts on standard or no medication. Uloric's manufacturer reported last November that patients on the drug were 34 percent more likely to die from heart disease than people taking an alternative gout medication. And since the FDA fast-tracked approval of Nuplazid and it went on the market in 2016 at a price of $24,000 a year, there have been 6,800 reports of adverse events for patients on the drug, including 887 deaths as of this past March 31. The FDA is increasingly green-lighting expensive drugs despite dangerous or little-known side effects and inconclusive evidence that they curb or cure disease. Once widely assailed for moving slowly, today the FDA reviews and approves drugs faster than any other regulatory agency in the world. As patients (or their insurers) shell out tens or hundreds of thousands of dollars for unproven drugs, manufacturers reap a windfall. Drug companies continuously analyze thousands of compounds. Of five thousand compounds tested, approximately five will appear promising enough to induce the company to file an Investigational New Drug Application (IND). The entire process is lengthy, bringing total drug development and approval (that is, the IND and NDA stages) to approximately nine years. President Trump has encouraged the FDA to give patients faster access to drugs. Faster reviews mean that the FDA often approves drugs despite limited information.

In the America that I love, drug company corruption results annually in up to 2.7 million hospitalized Americans with serious adverse drug reactions. Drug safety and testing are paramount, unless we are willing to serve as human guinea pigs. The public must demand integrity and safety from rampant drug company corruption. Big Pharma can cause big mistrust.

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