Institutional Corruption of Pharmaceuticals

Risky Drugs: Why The FDA Cannot Be Trusted

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A forthcoming article for the special issue of the Journal of Law, Medicine and Ethics (JLME), edited by Marc Rodwin and supported by the Edmond J. Safra Center for Ethics, presents evidence that about 90 percent of all new drugs approved by the FDA over the past 30 years are little or no more effective for patients than existing drugs.

All of them may be better than indirect measures or placebos, but most are no better for patients than previous drugs approved as better against these measures. The few superior drugs make important contributions to the growing medicine chest of effective drugs.

The bar for "safe" is equally low, and over the past 30 years, approved drugs have caused an epidemic of harmful side effects, even when properly prescribed. Every week, about 53,000 excess hospitalizations and about 2400 excess deaths occur in the United States among people taking properly prescribed drugs to be healthier. One in every five drugs approved ends up causing serious harm, while one in ten provide substantial benefit compared to existing, established drugs. This is the opposite of what people want or expect from the FDA.

Prescription drugs are the 4th leading cause of death. Deaths and hospitalizations from over-dosing, errors, or recreational drug use would increase this total. American patients also suffer from about 80 million mild side effects a year, such as aches and pains, digestive discomforts, sleepiness or mild dizziness.

The forthcoming article in JLME also presents systematic, quantitative evidence that since the industry started making large contributions to the FDA for reviewing its drugs, as it makes large contributions to Congressmen who have promoted this substitution for publicly funded regulation, the FDA has sped up the review process with the result that drugs approved are significantly more likely to cause serious harm, hospitalizations, and deaths. New FDA policies are likely to increase the epidemic of harms.

http://www.ethics.harvard.edu/lab/blog/312-risky-drugs

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Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs

By Donald W. Light, Joel Lexchin and Jonathan J. Darrow
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Abstract:

Over the past 35 years, patients have suffered from a largely hidden epidemic of side effects

from drugs that usually have few offsetting benefits. The pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they are tested, and how medical knowledge is created. Since 1906, heavy commercial influence has compromised Congressional legislation to protect the public from unsafe drugs. The authorization of user fees in 1992 has turned drug companies into the FDA's prime clients, deepening the regulatory and cultural capture of the agency. Industry has demanded shorter average review times and, with less time to thoroughly review evidence, increased hospitalizations and deaths have resulted. Meeting the needs of the drug companies has taken priority over meeting the needs of patients. Unless this corruption of regulatory intent is reversed, the situation will continue to deteriorate. We offer practical suggestions including: separating the funding of clinical trials from their conduct, analysis, and publication: independent FDA leadership; full public funding for all FDA activities; measures to discourage R&D on drugs with few if any new clinical benefits; and the creation of a National Drug Safety Board.

Restoring Institutional Integrity for Safer Drugs

Many concerned experts have suggested ways to reduce conflicts of interest and improve the safety and effectiveness of drugs.

First, while research companies play important roles in discovering and developing superior drugs, they should play no role in testing them. Over the years, expert bodies and prominent scientists have called for an independent institute to test drugs because commercial trials were so poor, biased, and conflicted. Yet this bedrock reform has never been accomplished, as the industry's lobbying of Congress and its contributions to Congressional campaigns have soared.

Second, the FDA needs new leadership to restore public trust and build a new culture focused on safety through enforcement of its existing rules. Hearings through the 1960s and 1970s documented how frequently the FDA fails to adhere to its own rules and protocols.

Third, user fees must end and the FDA must be entirely funded by taxpayers-as-consumers. The FDA should be entirely clear about whom it serves.

Fourth, while approval criteria should allow for a sufficient number of therapeutically equivalent drugs in a class to give clinicians a range of choices, they should also require patient-relevant evidence of superiority. Non-inferiority trials should be allowed only if one can ethically justify entering patients into a trial in which there can be no benefit for them. All adverse events, including those occurring among subjects who drop out, must be reported with follow-up for two years.

Fifth, Congress needs to restore trust by creating a National Drug Safety Board with adequate powers, funds, and mandates to independently investigate and report on drug safety issues. The creation of this board would support the position that all data related to how drugs and vaccines affect people are a public good and that access to this data is a human right. Both the inadequacy of pre-approval safety testing and the lack of systematic post-approval monitoring need urgent attention.

None of this is likely to happen until third-party payers, politicians, and the people decide they want to stop paying so much for so many drugs of little value and then for treating the millions harmed by those drugs. Nor is it likely until the campaign to restore institutional integrity to Congress through funding elections by the 99 percent, rather than by the one percent, is successful.

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2282014

Comment:

By Don McCanne, M.D.

Millions of people are being harmed by drugs, many of which have only negligible therapeutic value, and tens of thousands are dying. We need much greater government oversight of pharmaceuticals, certainly more than that which currently is being provided by the FDA.