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,[1] 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. This will increase costs for insurers but increase revenues for providers.

This evidence indicates why we can no longer trust the FDA to carry out its historic mission to protect the public from harmful and ineffective drugs. Strong public demand that government "do something" about periodic drug disasters has played a central role in developing the FDA.[2] Yet close, constant contact by companies with FDA staff and officials has contributed to vague, minimal criteria of what "safe" and "effective" mean. The FDA routinely approves scores of new minor variations each year, with minimal evidence about risks of harm. Then very effective mass marketing takes over, and the FDA devotes only a small percent of its budget to protect physicians or patients from

receiving biased or untruthful information.[3,4] The further corruption of medical knowledge through company-funded teams that craft the published literature to overstate benefits and understate harms, unmonitored by the FDA, leaves good physicians with corrupted knowledge.[5,6] Patients are the innocent victims.

Although it now embraces the industry rhetoric about "breakthrough" and "life-saving" innovation, the FDA in effect serves as the re-generator of patent-protected high prices for minor drugs in each disease group, as their therapeutic equivalents lose patent protection. The billions spent on promoting them results in the Inverse Benefit Law: the more widely most drugs are marketed, the more diluted become their benefits but more widespread become their risks of harm.

The FDA also legitimates industry efforts to lower and widen criteria prescribing drugs, known by critics as "the selling of sickness." Regulations conveniently prohibit the FDA from comparing the effectiveness of new drugs or from assessing their cost-effectiveness. Only the United States allows companies to charge what they like and raise prices annually on last year's drugs, without regard to their added value.[7]

Now the FDA is going even further. The New England Journal of Medicine has published, without comment, proposals by two senior figures from the FDA to loosen criteria drugs that allege to prevent Alzheimer's disease by treating it at an early stage.[8] The authors seem unaware of how their views about Alzheimer's and the role of the FDA incorporate the language and rationale of marketing executives for the industry. First, they use the word "disease" to refer to a hypothetical "early-stage Alzheimer's disease" that supposedly exists "before the earliest symptoms of Alzheimer's disease are apparent." Notice that phrasing assumes that the earliest symptoms will become apparent, when in fact it's only a hypothetical model for claiming that cognitive lapses like not remembering where you put something or what you were going to say are signs of incipient Altzheimer's disease. The proposed looser criteria would legitimate drugs as "safe and effective" that have little or no evidence of being effective and expose millions to risks of harmful side effects.

No proven biomarkers or clinical symptoms exist, the FDA officials note, but nevertheless they advocate accelerated approval to allow "drugs that address an unmet medical need." What "unmet need"? None exists. This market-making language by officials who are charged with protecting the public from unsafe drugs moves us towards the 19-century hucksterism of peddling cures of questionable benefits and hidden risks of harm, only now fully certified by the modern FDA.[9]