In Opposition to Liberty: We Need a "Sovereign" to Govern Drug Claims

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Hobbes had it right. The 17th-century political philosopher explained that civilization requires individuals to willingly transfer some of their freedom to a Sovereign who can use that power to organize society through the consent of the governed (1). Without this basic tradeoff, Hobbes argued, existence would be a struggle of "all against all," resulting in life that is "solitary, poor, nasty, brutish, and short." Hobbes' work helped inspire the Declaration of Independence and the Constitution. Now the latter document is being used to threaten a central aspect of medical practice that is rooted in this "consent-of-the-governed" concept.

During the summer of 2015, the U.S. Food and Drug Administration (FDA) plans to hold a public meeting to discuss whether its restrictions on what drug manufacturers can claim about their products improperly infringes the liberty of those companies (2). This revision of current standards is advocated by the pharmaceutical, biotechnology, and device industries, as well as those with libertarian philosophies who contend that the government should regulate very little of anything. The marketplace, they argue, will sort out which products work and are safe. Outright fraudulent claims would still be prohibited (even in this brave new world a drugmaker could not claim its product confers immortality), but short of that, advocates argue that most kinds of "scientific evidence" should be grounds to promote both new and old products, regardless of whether the FDA agrees.

In my decades of practice as an internist, I have taken comfort that drugs on the market were there because their manufacturers had provided the FDA with at least some evidence that they worked and that their known risks were depicted in the product labeling. I did not need to review on my own all of the available evidence about efficacy and safety for each drug I prescribed. Even if I had the time and acumen to do so—and what busy practitioner has hundreds of hours to assess each new medication?—I knew that the FDA had additional thousands of details about these drugs I could never see, because they were the private property of the companies that had paid for the clinical trials.

Hobbes made his case by referring back to a theoretical "state of nature" that existed before consent-of-the-governed societies came together. We, too, had a prescription drug "state of nature" not so long ago. The FDA's power to require efficacy data dates back only to the 1960s; the thalidomide tragedy of that era convinced Congress to give the FDA new authority to ensure that useless or minimally effective products, or those with unacceptable safety problems, could not come into use. The agency then assessed thousands of drugs on the market to weed out the many that were ineffective, dangerous, or both (3). Thus, the summer of 2015 could mark the beginning of a step back to the pre-1960s era for prescription drugs.

The proposals under discussion fly in the face of much of what we know about rigorously evaluating clinical interventions. First, they would allow companies to short-circuit the need for a review of the totality of the available data (including those secret proprietary files), permitting them to present clinicians with cherry-picked studies that may look good in isolation but could be methodologically inadequate or fail to present a balanced picture of a drug's benefits and risks (4). A second problem is the unreliability of "clinical experience" measures, such as "observational studies, registries, and therapeutic use" as well as guidelines (5), to assess efficacy, as is advocated in pending legislation (6). Yet all of these measures would become fair game for companies seeking to promote their products to us. Noncommercial services, such as those that provide academic detailing (7), could try to provide some balance for clinicians, but they could be swamped by the drug industry's unchained promotional leviathan.

Besides looking at our past to assess the possible effect of these proposed changes, we can also see present evidence of how this approach might play out. In the 1990s, the "dietary supplements" industry extricated itself from the constraints of FDA evaluation, making possible the cacophony of ludicrous unregulated and often phony claims that now contaminate the airways, print media, and cyberspace. Anyone who likes the concept of useless over-the-counter nostrums advertised to "promote immunologic health" or "support brain function" will love the proposed new rules for prescription drug promotion.

As a prescriber, I have been willing to give up my freedom to prescribe any chemical I choose to patients, and I am willing to have drug manufacturers give up some of their right to tell me whatever they may want me to hear. For all of us (including patients) to hand over some liberties to a Hobbesian Sovereign, such as the FDA, offers a different kind of freedom—knowing that the medications we use are probably, at least as a first approximation, reasonably safe and have some evidence that they work. After all, the often-maligned agency usually does its work accurately and efficiently (8). Rather than representing an infringement of companies' inherent rights as "citizens," maintaining our current standards for promotional statements can keep us from sinking back into an "all against all" state of

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poorly founded drug claims and understated risks. Yielding to the pressure to do otherwise would risk making our patients' lives more poor, nasty, brutish, and short than they have a right to expect.

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