

Is it time to regulate the pharmaceutical industry?

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Wisconsin is among the state governments that have set up Web sites instructing their citizens in how to import prescription drugs from Canada. Although the US Food and Drug Administration (FDA) says such importations are illegal, it has taken no action to stop this. The states respond that their citizens are the ones importing the drugs—not the states per se. So to protect them, the states have inspected some Canadian sources for quality and an absence of counterfeit drugs.

Also, the senior drug plan for Medicare recipients has a provision prohibiting our government from negotiating drug prices. The lack of such restrictions in Canada is why drug prices there are more reasonable.

When public utilities such as telephone companies, gas companies, or electric companies became natural monopolies, public service commissions were set up to ensure efficient pricing in the public interest and also to ensure reasonable profits for the utilities. The entire pharmaceutical industry has drifted into various practices that have made the industry de facto monopolistic, in spite of the fact that there are numerous competing

corporations. The following policies explain why that is so.

1. Since physicians prescribe the drugs and the patients pay for them, the logic of a self-regulating market is broken as soon as some drugs became available by prescription only.
2. Patents are granted one chemical entity at a time, so competition motivates that pharmaceutical research be diverted to imitation of successful chemical structures. A very small modification of a chemical structure permits an entirely new patent as if the new structure were an innovative “breakthrough” drug. The unnecessary costs of the development, safety testing, and marketing of six or so “me too” drugs per breakthrough drug are borne by the public with no choice except occasionally to ask if a generic drug is available. There are many examples of a drug company developing a new product to compete with one of its own existing drugs because the original patent is about to run out, such as Valium replacing Librium and, more recently, Nexium replacing Prilosec.
3. Direct advertising of prescription drugs to the public has been permitted for the last few years with considerable consequences. The most obvious is vastly increased marketing costs, again

borne by the public. Marketing to physicians continues unabated. From the physician’s point of view, any time spent discussing an advertisement the patient may have seen is likely to detract from time available for discussing the main reasons for the visit. Patients have asked me for the “purple pill” without even knowing what it is for. Gradually it has dawned on me that the ads don’t always mention the uses of the pill to avoid having to list side effects in the ad.

4. We need competent research comparing competing medications head-to-head for effectiveness. Most clinical research on drug effectiveness is paid for by the industry. Supporting direct comparisons of medications results in an approximately 50% chance of enhancing the reputation of the competing product instead of benefiting the sponsor. There have been a few scandals from attempts to suppress the results in such instances.

For all of these reasons, it makes sense to regulate the prescription drug industry like a public utility. Surprisingly, this is doable. Corporations are chartered by the states, and these charters could and can be revoked. But many legislative changes would have to take place before such regulation could happen.

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- Reverse corporate personhood as a constitutionally provided privilege. This may not be absolutely essential to achieve our goal of regulating the pharmaceutical industry, but it would go a long way toward ensuring success.
- Support campaign finance reform even if it takes public financing of elections—a bargain compared to trying to compete financially with corporate fat cats as a private citizen of merely adequate wealth.
- Praise the pharmaceutical indus-

try, including naming worthy companies. For example, of all the companies still producing vaccines, only three—Aventis-Pasteur, SmithKlineGlaxo, and Merck—deserve our praise in this regard. The others terminated production without so much as notifying public health authorities or the companies still producing vaccines so that they could ratchet up their production. Some basic vaccines like tetanus have had to be rationed in recent years. Once these steps are taken, ad-

visers knowledgeable about drugs, medical research, and politics can figure out how to further regulate the pharmaceutical industry. Retired experts such as FDA administrators, National Institute of Health (NIH) administrators, and medical school faculty can craft the restrictions on industry so they have a minimum of unintended consequences.

Wouldn't this be a more rational approach to high prescription drug costs than forcing desperate citizens to buy their medicine from a foreign country?

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