Remedying Pharmaceutical Industry Regulation

by Alison Coppelman

Richard A. Epstein, James Parker Hall Distinguished Service Professor of Law, has taught at the Law School since 1972. In his recent book, Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovations, Professor Epstein examines the current legal and regulatory challenges facing the pharmaceutical industry. Ultimately, he concludes that in order to ensure continued innovation and maximum efficiency in the development of pharmaceutical drugs, regulatory and judicial involvement in all facets of the process should be minimized.

Alison Coppelman: The ongoing litigation over the prescription drug Vioxx has been highly publicized. What about the ongoing lawsuits involving a similar drug, Celebrex, and the nearly 5,000 lawsuits brought against Wyeth over the effects of Prempro and Premarin, the menopause hormone replacement drugs?

Richard Epstein: The risk of suit is always present. The prime targets for litigation are drugs that are given broadly for non-critical care uses, like Vioxx. If you have a drug that is only used in surgery, only administered in hospitals, only done by physicians, people are very reluctant to sue in those cases. But the exposure is far greater with these widespread blockbuster drugs that are extremely important to people. There is still nothing to replace Bendectin, which has been off the market now for about twenty years. Nobody will make a drug to deal with nausea in pregnant women, because once that drug is marketed, every birth defect—and there are always birth defects—could be treated as attributable to that drug, for the causation is unobservable and thus subject to dispute. In the Bendectin case, the defendants actually won the litigation in the long run. But the litigation fees exceeded the total revenues from the drug’s sales, and it’s not a winning proposition. One of the Vioxx cases that I thought was particularly weak from the plaintiff’s side was a case called Humeston coming out of New Jersey. The first time it went for the defendant. Then, another jury comes in, and a sixty-one-year-old man who suffered a heart attack from which he recovered is given $18 million in actual damages where there are so many alternative reasons why that attack could have taken place. This outcome is almost surreal.

AC: At one point you question whether it’s possible to “salvage something from the wreckage of a broken torts system.” Is it possible?

RE: It’s always possible. The only thing that will end the tort problem, in my judgment, is to give the FDA warnings conclusive power with respect to all lawsuits that are based upon insufficient warning or over-promotion. I don’t know whether that’s attainable politically. It has been done in a number of states, including Michigan. But the politics are tricky, for lots of people in Michigan want to repeal the statutory defense because they’re saying, “Why should every plaintiff in every other state be able to sue if we can’t? We pay for Vioxx, and if all the money from a lawsuit goes to people in Ohio and Kansas, we’re shortchanged.” This interstate prisoner’s dilemma game set up a very powerful dynamic, so it’s going to take some federal action to correct the underlying situation.

AC: In recent years, the Senate has attempted to introduce legislation to regulate the pricing of pharmaceutical drugs, and the District of Columbia recently passed the Prescription Drug Excessive Pricing Act of 2005, only to have it rendered invalid by the district court. Do you foresee the successful passage of price control legislation at some point in the near future, whether on the national or the local level?

RE: Pricing regulation could spell financial death for the industry, so any price fixing scheme will be subject to prompt challenges the moment it is put into place for a
myriad of constitutional reasons. But if the scheme in question is imposed by Congress, and it's done on a national level, there's a long tradition in this country of sustaining price controls, even when not used to control monopoly profits. The monopoly issue, moreover, is always very difficult to handle with respect to pharmaceutical patents, because all patents are, in some sense, a monopoly. I'm the only one who can make Celebrex if I have the Celebrex patent. But, on the other hand, there are the drugs in the same class that are competitive with mine, so it's not as though the legal monopoly translates into an economic monopoly. You can have all multiple varieties of one drug that are in competition with one another, even though they're not perfectly fungible. There are six different kinds of statins out there in the market—Lipitor, Crestor, etc. I don't think pricing regulation legislation could override the Bush veto, and the success of Medicare Part D may blunt the efforts in that direction. But it is hard to be sure.

**AC:** As far as the patent policy debate goes, you outline potential solutions but note, “any solution to this dilemma is strictly second-best.” What changes, if any, would you make to current patent policy?

**RE:** My view on the patent policy is that I would make no fundamental changes in the current structure, although I would extend the useful patent life by giving a greater credit to the company for the time a drug is lost in the FDA. I think the effective useful life of 8 or 9 years, which is becoming the norm, is too short. That goes against the grain, but given the cost of putting things through, I can't see how it goes otherwise. One of the things we know is that with new medicines, small differences in molecular structure can make a huge difference in body absorption and response. So even if you just tinker with one or two radicals on a molecule, there is no reason to assume that the new drug will be the same as the older drug or an obvious extension of it. If they were functionally the same, no one would care about a fresh round of clinical trials. But we have those trials because we want people to find and test the “me-too” drugs.

On a different front, I think compulsory licensing is immensely dangerous. In virtue of the fact that the government is calling the shots, it is always going to lowball the compensation, which in turn is going to kill future innovation. Selective compulsory licensing also has its real disadvantages. It would mean that the licensed drug would be in competition with unlicensed ones, such that the first goes out to the consumer at a much lower price than the second, which would distort the market.

**AC:** A lot has changed since the book was published in October. What are your thoughts on some of the more recent developments that pertain to the regulation of the pharmaceutical industry?

**RE:** The amount of new material that keeps coming out in this field is just unbelievable. The book has been out for six months and although I think the basic principles hold up, recent events have really changed, almost daily, the political landscape. I was somewhat pleasantly surprised by the relative public acceptance of competition under Medicare Part D, relative to proposals to have the government step into a key role on negotiation. I think that the VA is no longer the ideal by which most Americans measure the soundness of the health system. Choice matters, and people are willing to pay for it.

Richard Epstein

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