

Proposition 79 Will Hamper Development of New Drugs

By Michael A. S. Newman

The economist and social philosopher Thorstein Veblen quipped that "invention is the mother of necessity." This would be hard to deny in our gadget-driven age. Those of us who believe we cannot live without the Internet, e-mail, BlackBerrys, Palm Pilots or MP3 players forget that, 30 years ago, none of those marvels existed, and no one missed them.

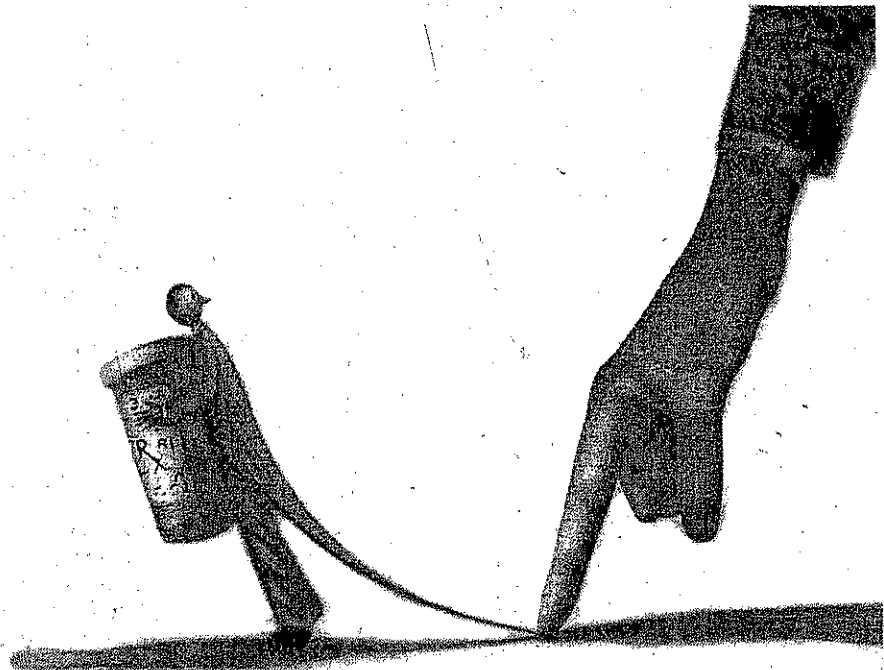
Nowhere is Veblen's witticism truer than in the area of medicine. Understandably, those who have a disease regard a newly discovered medicine as a necessity. Based on the idea that no person should be deprived of a "necessity," consumer advocates argue that government should act to lower the prices of drugs artificially, to allow more people to purchase them.

Ironically, in so doing, consumer advocates are trying to make "necessity" the enemy of invention. Profit is what encourages inventors to invent; it is what justifies companies' spending years on research and development. By hindering profits, the forcible lowering of prices will hamper the discovery of new drugs. Prohibiting the very pursuit of profit and encouraging private lawyers to sue on this basis will deter invention still more.

That is what Proposition 79, an initiative on the Nov. 8 ballot, effectively threatens to do. Among other things, the initiative makes it illegal for the manufacturers, distributors or labelers of prescription drugs to "profiteer."

What does it mean to "profiteer" on a prescription drug? The initiative provides no clear definition. It defines "profiteering" as (a) demanding an "unconscionable price"; (b) exacting prices "that lead to any unjust or unreasonable profit"; (c) discriminating "unreasonably" against any person in the sale, exchange, distribution or handling of prescription drugs; or (d) intentionally "prevent[ing], limit[ing], lessen[ing] or restrict[ing]" the sale or distribution of prescription drugs in "retaliation" against Proposition 79.

These definitions provide no guidelines; they merely provoke more questions. What is an "unconscionable" price? What is an "unreasonable" profit? What does it mean to discriminate "unreasonably"? How will the manufacturer, distributor or labeler of a drug know whether it is acting in violation of the law?



Apparently, the answers to all of these questions are left to the fact-finder in some future litigation, based on that fact-finder's personal assessment of what is unreasonable and unconscionable. In short, the producers and sellers of drugs will have no way of knowing whether they are in compliance with the law.

In its vagueness, Proposition 79 is worse even than a price ceiling, which, although profoundly disruptive of the market, at least allows the seller to know whether he or she is complying with the law. Attempting to comply with the anti-profiteering provisions of Proposition 79, in contrast, will be like walking through a minefield blindfolded.

As a reasonable response to Proposition 79, the manufacturers, distributors and labelers of prescription drugs will have every incentive to limit their sales in California. The drafters of Proposition 79 appear to have anticipated this, because the initiative awkwardly attempts to hold its victims' feet to the fire. It prohibits the sellers of a prescription drug from "prevent[ing], limit[ing], lessen[ing], or restrict[ing]" the sale or distribution of their products in "retaliation" against the Proposition 79.

Arguably, this provision makes it illegal to pull a drug from the market if Proposition 79 renders the sale of that drug economically disadvantageous or

too risky. The right enjoyed by virtually every person who sells something — to withdraw a product that does not render a profit — would be denied the seller of prescription drugs. Sellers would effectively become slaves of the state, fearful that any action taken to withdraw a product from the market would be perceived as "retaliation" for Proposition 79.

To add to this mess, Proposition 79, if passed, will foment a rash of lawsuits. The initiative would give any person "acting on behalf of the general public" the right to sue for a violation of Proposition 79. The effect of this would be to unleash countless shakedown lawsuits. Plaintiffs' attorneys would be able to file claims on behalf of the "general public" without being required to locate a single person harmed by the alleged illegal practice.

Only last year, in November, the state's voters, tired of the rash of unmeritorious lawsuits aimed at businesses, passed Proposition 64, which provided that lawsuits for unfair competition could be brought only by those injured by an alleged unfair practice. Proposition 79 is a blatant attempt to reverse Proposition 64 in the context of prescription drug sales. The free hand given to bounty-hunting plaintiffs' counsel, combined with the vagueness and malleability of the law, will ensure virtually limitless litigation.

Moreover, Proposition 79 establishes a

regimen that would require pharmaceutical companies to provide discounts to state residents whose annual incomes do not exceed 400 percent of the federal poverty level. Nine of the initiative's 10 pages are taken up describing the complicated process of administering this regimen. Companies that decline to offer such discounts would not be able to participate in Medi-Cal. A Medi-Cal doctor would not be permitted to prescribe drugs produced by such companies without obtaining prior approval of the state.

The establishment of mandatory discounts suffers from the same shortsighted view as the rest of the initiative. It assumes, mistakenly, that pressuring companies to sell drugs at a lower price will have no detrimental affect on the future availability of drugs. (Another initiative on November's ballot, Proposition 78, would establish a system for voluntary prescription drug discounts.)

Proposition 79 will limit the availability of prescription drugs to Medi-Cal patients, the portion of the population presumably in greatest need. Although the initiative provides that drugs without a "therapeutic equivalent" are not to be excluded from Medi-Cal, the fact remains that Medi-Cal doctors will be constrained in their ability to prescribe what they think are the best medications in each situation. In this way, hapless Medi-Cal patients will become pawns in a governmental attempt to coerce manufacturers.

Moreover, some question whether Proposition 79 will be enforceable in light of the federal laws relating to Medi-Cal, but that is an issue for another article.

In its tacit assumption that the state can legislatively force inventors and sellers to provide necessary products to consumers, Proposition 79 runs contrary to the principle that the best means of encouraging invention is with the promise of profit, not the fear of punishment. The Framers of the Constitution understood this. For this reason, the Constitution provides for patent and copyright protection "to promote the progress of science and useful arts."

Where invention is thus encouraged and protected, James Madison explained in "The Federalist Papers," "[t]he public good fully coincides ... with the claims of individuals." The public enjoys the benefit of the new invention or discovery; the inventor enjoys the fruits of his or her labor. Proposition 79, to the contrary, not only hinders profit but also transforms the pursuit of profit into a violation of the law.

In penalizing profit, Proposition 79 will discourage invention. This is especially true if other states, looking to trailblazing California for guidance, adopt ordinances similar to Proposition 79. The develop-

ment of new drugs in particular requires an enormous investment of time and money. It typically takes 10-to-15 years for a pharmaceutical company to develop a new drug. According to a study conducted by Tufts University, the average cost to develop a new drug is \$802 million. Allowing the producers of drugs to charge market prices for their products justifies the enormous investment of time and expense in their development. Penalizing the charging of such prices will chill the development of new drugs.

The chilling effect will be even worse where the sellers and manufacturers receive no real guidelines to help them determine what constitutes "profiteering," and where the only certainty is that they will be sued.

The threat of litigation has a negative effect on the availability of drugs. Consider the flu vaccine shortage of 2004. Only two manufacturers in the world produce flu vaccines. Thus, contamination in a single plant led to the shortage, which affected millions. Why were there only two manufacturers? Part of the answer has to do with the fact that huge liability awards have frightened manufacturers out of the vaccine market.

Another example of the power of litigation to hamper the availability of drugs is the withdrawal of Bendectin, a drug for morning sickness at one point used in 40 percent of pregnancies in the United States. A series of lawsuits launched in the 1980s alleged that Bendectin caused birth defects. As Dr. Paul A. Offit wrote in *The Wall Street Journal*, Merrell Dow, the manufacturer of Bendectin, won 17 of 22 lawsuits but spent \$100 million in defense and awards.

When the company stopped making Bendectin, a spokesman explained, "We wouldn't bring Bendectin back if we won every lawsuit." Whether Bendectin in fact caused birth defects was irrelevant. The cost of litigation had driven the product from the market.

Chief Justice John Marshall observed that "the power to tax is the power to destroy." He could have said the same thing, with even greater truth, about the power to sue.

Proposition 79, with its vague parameters and its provisions allowing any lawyer to make war on the purveyors of prescription drugs, is an unwise initiative that will do exactly what it purports to prevent. In the guise of punishing profiteering and providing discounts for prescription drugs, it will stifle the public's access to new drugs.

California will learn, like the greedy farmer in the fable, that cutting open the goose ends the production of golden eggs.

Michael A.S. Newman is a litigation associate in the Los Angeles office of Barger & Wolen.