Mercatus Reports

The Mercatus Center at George Mason University is an education, research, and outreach organization that works with scholars, policy experts, and government officials to bridge academic theory and real-world practice. The center's Regulatory Studies Program works within the university setting to improve the state of knowledge and debate about regulations and their impact on society. More information about the center can be found on the Web at www.mercatus.org. For the latest federal regulatory developments, visit www.regradar.org.

Pizza Identity Rule

STATUS: USDA analyzing public comment.

In 1970, the United States Department of Agriculture Food Safety Inspection Service (FSIS) instituted requirements for the composition of pizzas that contain some form of meat. According to the standards, a non-sausage meat pizza must be a bread-based product with tomato sauce, cheese, and a topping containing cooked meat made from not less that 15 percent of raw meat. A sausage pizza must have a bread base, contain tomato sauce and cheese, and have a sausage topping of not less that 12 percent of cooked sausage or 10 percent of a dry sausage. In establishing those definitions, the FSIS claimed that it was protecting consumers from "economic deception."

The FSIS has recently decided to remove the meat and sausage pizza identity standards. Instead, the agency will permit pizza makers to reduce their meat content to two-percent cooked or three-percent raw meat – the general level that all products designated as "meat products" must meet. As the Mercatus public interest comment on the proposed rule noted, the change would enable frozen pizza makers to produce potentially healthier pizzas with lower fat and cholesterol content.

New Source Review

STATUS: EPA conducting review as part of new "comprehensive strategy."

In May of 2001, the National Energy Policy Development Group (NEPDG) recommended that federal officials conduct a careful review and analysis of New Source Review (NSR) regulations. The regulations require that, prior to construction, major new and refurbished air pollution emission sources (typically power plants and refineries) receive Environmental Protection Agency certification that they will meet stringent air quality regulations. The regulations are not enforced against older plants that are not retooled. (See "Rationalizing Air Pollution," p. 13.)

NSR critics charge that the regulations discourage firms from modernizing or replacing outdated, heavily polluting plants because, even though the new or renovated plants would emit less pollution, they still may not pass the rigorous review requirements. With that criticism in mind and in the wake of the recent California energy crisis, NEPDG requested that the EPA administrator, together with the secretary of energy and officials from other agencies, examine NSR to determine its effect on "investment in new utility and refinery generation capacity, energy efficiency, and environmental protection."

EPA subsequently announced that it would not produce a specific study of NSR, but would include a review of the regulations in a soon-to-be-released comprehensive strategy to reduce air pollution and protect public health.

As a recent Mercatus public interest comment on NSR noted, EPA has the opportunity to allow oil refiners and power generators to improve capacity, energy efficiency, reliability, and environmental performance. To do that, the agency should decouple the NSR process from firms' investment decisions by requiring that lower emissions rates be achieved at a fixed time after a modification has been made. What is more, EPA could increase the flexibility of the NSR system by expanding emissions trading programs.

ILLUSTRATIONS BY KEVIN TUMA (2)

Particulate Matter

STATUS: EPA preparing for review.

The Clean Air Act requires that national ambient air quality standards for particulate matter be reviewed every five years. In July of 1997, the EPA published a final rule revising the national ambient air quality standards for fine particulate matter. That requirement is due for review this year.

EPA currently is developing a Criteria Document (CD) to assess relevant scientific information. The agency's Office of Air Quality Planning and Standards will also prepare a staff paper that will evaluate the policy implications of the key studies and scientific information contained in the CD and additional technical analyses. The paper will identify critical elements that EPA staffers believe should be considered in reviewing the standards. Once the review is completed, EPA will propose to revise or reaffirm the existing standards and will request public comment on the proposal.

Total Maximum Daily Load

STATUS: EPA analyzing public comment.

In July of 2000, EPA issued new Total Maximum Daily Load (TMDL) regulations for pollutants discharged into waterways. Under the regulations, states must determine the maximum daily amounts of various pollutants that can be discharged into a waterway without harming its recreational, drinking water, and agricultural value. The states must then act to ensure that those daily loads are not exceeded. (See "The Trouble with TMDLs," *Regulation*, Spring 2001.)

Critics immediately charged that the regulations are both prescriptive and open-ended, and that they leave states with little flexibility and substantial responsibility. The lack of knowledge about the extent of water quality problems and the very local nature of water quality issues caused states to object to the broad federal authority asserted in the TMDL rule. In response, Congress delayed implementation of the regulations by failing to appropriate funding for their execution.

In response to those concerns, EPA issued a draft report in August of 2001 on the expected costs of the TMDL program. The agency has compiled detailed estimates of the costs of developing and implementing TMDLs (ranging from $986 million to $4.4 billion per year), but critics claim that the estimates are not reliable measures of what the real costs of the program will be. EPA is now collecting public comments on the report.

The difficulties EPA has had in estimating the costs of the TMDL rule highlight the essential problem with setting national standards for what are fundamentally local problems. Considering that the entire Clean Water Act, as currently enforced, has been estimated by EPA to cost $14 billion per year, the incremental costs from the TMDL program could result in increases of anywhere from seven to 30 percent each year. Those higher costs could result in little, if any, improvement in water quality.

Environmental Electronic Reporting

STATUS: EPA analyzing public comment.

The Government Paperwork Elimination Act of 1998 required all agencies to offer options for electronic reporting and record keeping by October of 2003. To comply with that mandate, EPA released the Cross Media Electronic Reporting and Record-Keeping Rule (CROMERRR).

CROMERRR seeks to permit states and regulated entities to submit electronic documents or maintain electronic records in order to comply with the reporting or record keeping aspects of environmental laws and regulations. EPA maintains that the rule must be instituted in order to dismantle existing regulatory obstacles to electronic reporting and record keeping, and that the rule is optional. The agency claims that it "will not require the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records."

Regulated entities disagree, however. They argue that the actual language of the rule indicates that it is mandatory — any entity that keeps some form of an electronic record must submit all necessary data in electronic form, whether it has the capacity to do so or not. Furthermore, they argue that EPA has significantly underestimated the costs of CROMERRR, while not sufficiently supporting its claims of benefits deriving from the rule. Additionally, the record-keeping provision raises difficult questions about the technological feasibility of the rule.

EPA is currently examining public comments on CROMERRR.

Drug Re-importation's No-Win Solution

By Jonathan Klick
The Mercatus Center

With midterm elections only a few months away, lawmakers once again are talking about implementing a prescription drug plan for seniors. But, with the economy stalled and increased military spending dominating the budget for the near future, it will be difficult to add such a huge expenditure to an already precarious Medicare system. Instead, some members of Congress will once again call for the allowance of drug "re-importation" — enabling pharmaceutical wholesalers and retailers to purchase prescription drugs from other countries where pharmaceutical companies sell drugs to retailers at lower prices in exchange for guarantees that the drugs will not be resold abroad.

The drug re-importation issue last emerged during the waning days of the Clinton administration and the opening days of the Bush presidency. However, both administrations decided not to back the idea because, apparently, they were persuaded that re-importation would circumvent the Food and Drug Administration's efforts to protect American consumers from dangerous or ineffective drugs and poor labeling standards.

To re-importation supporters in Congress, those concerns paled in comparison to the opportunity for America's seniors to get their medications from abroad at prices as much as 50 percent less than those charged in U.S. pharmacies. The supporters insist that legislation passed late in 2000 and signed by President Bill Clinton (but never implemented) ensure safety through careful tracking of pharmaceuticals, including assurances that the drugs have passed FDA scrutiny. News footage of elderly Americans, prescriptions in hand, boarding buses bound for Canada in search of bargain medicines reinforced the claim of supporters that re-importation represents a no-lose solution to the problem of rising drug costs.

WRONG ON BOTH SIDES

Sadly, both the supporters and detractors of drug re-importation are wrong on the issue. Re-imported drugs are likely to be just as safe as domestically produced and sold pharmaceuticals because they come from the same sources. What is more, even in the absence of FDA regulation, drug makers would face huge incentives to provide effective and safe products. Their reputations, and bottom lines, would be destroyed if they acted otherwise.

But, even with assurances regarding the safety of re-imported drugs, re-importation will most certainly not help consumers. The pharmaceutical industry is characterized by very large fixed costs (in the form of research and development expenditures and the costs of product testing) and very low incremental costs of production. That is, once a drug is developed and tested, an individual unit of it can generally be produced for mere pennies. If drug companies expected only to cover their per unit cost of producing the pharmaceutical, there would be absolutely no incentive to invest the enormous resources needed to develop new products. Profits, then, are the driving force behind technological progress in the pharmaceutical industry. As the expectation of profits grows, more progress will be made. Allowing re-importation will definitely cut drug companies' profits and, more than likely, will not result in a reduction in cost to American consumers.

Price discrimination The ban on wholesale and retail re-importation allows drug manufacturers to engage in price discrimination. That is, they can charge different groups of consumers different prices depending on how much they value the product. In the case of pharmaceutical companies, that means charging a relatively high price in the United States where incomes and demand are relatively high, while charging a lower price in Canada. As long as the price charged in Canada is above the incremental cost of production for the drug, the company profits from the sale.

The scenario is similar to the pricing schemes used by movie theaters, which also face large fixed costs and small incremental costs. Theaters charge a high price in the evenings, not because it costs more to show a movie after dusk, but because the market will bear a higher price in the evening. Because the incremental cost of showing the movie in the afternoon is low, the theater will have matinee showings, even if the afternoon crowd is not willing or able to pay the evening price.

Those afternoon viewers, with relatively low demands for movies, benefit by getting the same movie for a lower price. The interesting thing, however, is that the evening viewers also benefit from this arrangement because the theater's large fixed costs are now spread among more moviegoers. In a very real way, evening patrons pay a lower price than they otherwise would have been charged if the theaters did not have matinee shows and earn additional revenue. Similarly, U.S. pharmaceutical prices would be higher if the drug companies did not offer the same medicines abroad for lower prices.

Foreign aid Also, from the perspective of countries where pharmaceuticals are sold at lower prices, the discounts they receive from drug manufacturers represent a tremendous

Jonathan Klick is a Robert A. Levy Fellow in Law and Liberty at the George Mason University School of Law and a research fellow at the Mercatus Center. He can be contacted by e-mail at jklick@gmu.edu.

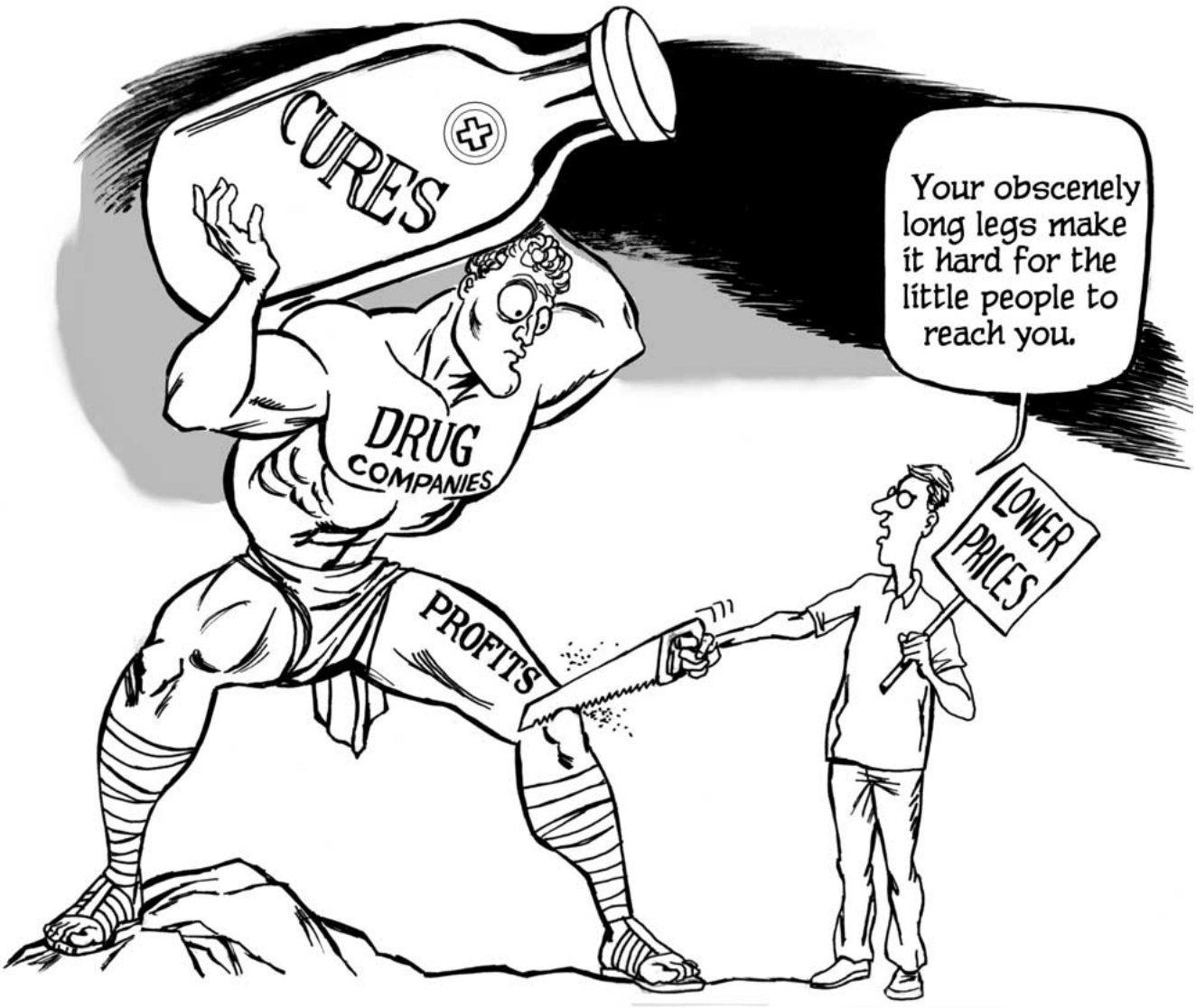

ILLUSTRATION BY KEVIN TUMA

form of foreign aid. Drugs used to fight HIV/AIDS in Africa cost only a fraction of their U.S. list price. For example, according to the Campaign for Access to Essential Medicines (a group that is generally critical of drug manufacturers), one dose of the anti-viral regimen AZT + 3TC in South Africa costs only 15 percent of what a similar dose would cost at U.S. wholesale prices. Given the monumental proportions of the AIDS crisis in Africa, those discounts are invaluable in terms of reducing the personal suffering and public health epidemic that the disease represents.

NO-WIN SITUATION

If widespread re-importation were allowed, those price differences would be eliminated. For those supporting re-importation, that is exactly the point; with equivalent Canadian and American prices, U.S. consumers supposedly would be better off. But closing the price gap does not necessarily entail that U.S. prices would drop significantly. Rather, it is likely that manufacturers would limit quantities sold in Canada, causing Canadian prices to rise toward the American levels. In the short run, American consumers would see relatively small cost savings due to re-importation, but Canadian consumers would face higher effective prices. Canadians, in turn, would buy smaller amounts of the drugs, leading to declining profits for the manufacturers. So, instead of the no-lose situation envisioned by the champions of re-importation, we would likely be left with a situation where everyone loses.

The long-term ramifications are even bleaker. Lower returns would lead to less research, which, in turn, would lead to fewer new drugs developed in the future. A large portion of the improvements in health witnessed during the last half-century can be attributed directly to the development of new pharmaceuticals. Econometric research by Columbia Business School professor Frank Lichtenberg suggests that, during the periods 1970-1980 and 1980-1991, new drugs increased life expectancy by about one percent per year, and a $15 billion increase in drug research leads to a savings of 1.6 million life-years per year. Those life-years represent $27 billion in increased economic production annually.

Thus, re-importation of drugs would harm Americans because it would stifle technological progress and its attendant health benefits. Unfortunately, that argument does not play nearly as well on the evening news as tape of busloads of old folks heading for bargains in Canada. R