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SENATOR DORGAN'S BREATHTAKING DRUG BILL

Senator Byron Dorgan (D-ND) introduced S. 2328, "The Pharmaceutical Market Access and Drug Safety Act of 2004", on April 21. Its aim is to lower the prices of prescription drugs for American consumers to make the medicines more affordable. It is similar in many respects to the Pharmaceutical Market Access Act, sometimes called the "Gutknecht bill", which the House passed in July, 2003, in that it would permit the wholesale importation of prescription drugs from Canada, the European Union, and some other industrialized nations where prices are lower than in the United States, and sales to individuals from Canadian pharmacies. The bills would significantly modify current law provisions governing FDA monitoring of the drug approval and manufacturing processes, labeling requirements, and distribution channels, raising questions about the FDA's ability to certify drug safety. Both would eliminate the requirement that the Secretary of Health and Human Services (HHS) certify safety before importation could begin.

The Dorgan bill ... would outlaw several possible production and marketing actions that the pharmaceutical industry might adopt to restrict the availability abroad of drugs that could be imported or reimported to the United States.

The Dorgan bill goes well beyond the earlier legislative proposal in that it would outlaw several possible production and marketing actions that the pharmaceutical industry might adopt to restrict the availability abroad of drugs that could be imported or reimported to the United States. These additional features of the Dorgan bill raise serious Constitutional, economic, and safety questions. The bill would surely reduce the funds available for research and development of new drugs, and would injure future consumers. There are alternative, superior means of guaranteeing access to prescription drugs to those who cannot now afford them, methods that would not have the serious side effects of the Dorgan approach.

Safety concerns

This paper is primarily concerned with the economic and property rights aspects of the Dorgan bill, but a few words about safety and truth in advertising are in order. One safety concern with more liberal drug importation is that drugs could enter the country that are not up to U.S. standards of safety or effectiveness, have not been handled properly (e.g. refrigerated, as is required for injectable drugs such as insulin), or are actual counterfeits.

The Dorgan bill would repeal the Prescription Drug Marketing Act, which forbids the reimportation of U.S.-produced FDA-approved drugs that have been exported (and that have therefore left the country and the control of the U.S. manufacturer, such that neither the company nor the FDA can vouch for their safe handling or identity). But it also permits the importation of foreign versions of FDA-approved drugs that have never been within the U.S. system. In short, it should be admitted that, under Dorgan, there would be no guarantee that imported drugs are bioequivalent to FDA-approved drugs. There would also be less FDA supervision of manufacturing methods and labeling,

and less FDA oversight of handling and distribution, than is required under current law. The Dorgan bill would also waive many consumer protections provided by the Federal Food, Drug, and Cosmetic Act.

As noted, the Dorgan bill permits importation of both FDA-approved drugs and foreign versions of those same drugs. Under the Dorgan bill, an imported drug would be presumed to meet FDA standards (i.e., to be the same as the FDA-approved version) if its labeling states that it has the same active ingredients, route of administration, dosage form, and strength as an FDA-approved drug, if it is made by the same or for the same person that manufactures the FDA-approved drug, and if it meets chain of custody and related requirements. This would still leave room for important variations in other characteristics of the imported drug which may be necessary to comply with the regulatory requirements of the foreign nation in which it is sold, but which, if they were introduced in an FDA-approved product, would require the FDA's prior approval. These variations could mean the foreign drug is not bioequivalent to the FDA-approved drug. The bill orders that the foreign drug would nonetheless be labeled and presumed identical to the U.S.-produced product.

The Dorgan bill...would effectively give foreign exporters and domestic importers the right to demand that manufacturers produce and sell proprietary products to them at prices determined by foreign laws and regulations...This is forced production and forced sale, or in other words, forced trade.

The imports would be exempt from certain U.S. packaging safety rules (including child-proofing). Drugs could be imported that had not been approved by the country from which they were shipped. They could be transshipped from other permitted countries, many of which place transshipped drugs under less stringent regulations than drugs intended for domestic consumption.

The bill imposes a one percent tariff on imported drugs to pay for FDA implementation. This amount appears to be too small to handle the likely expense of reviewing registrations submitted by importers and exporters, reviewing and approving "notices" (translated foreign marketing applications) required from manufacturers, and monitoring imports for compliance as the bill requires. And, as noted, the bill would take away the power of the Secretary of HHS to block imports if he does not feel that it can be done safely, which means that even if the FDA has difficulty with its inspection process, the drugs may still be brought into the country.

These concerns are all real, but some are perhaps more serious than others. No reputable global drug company would deliberately mishandle, adulterate, or mislabel a drug, or sell ineffective or unsafe drugs anywhere in the world. In exchange for lower prices, customers may be willing to take the risk that variations in design and manufacturing methods permitted or required by different governments do not affect efficacy. Some customers may be happy to do without child safety packaging, even if it goes against national policy.

Of more concern is that reduced inspection and oversight by the FDA would open the door to counterfeit drugs and mislabeled or mishandled drugs shipped under forged records by disreputable middlemen without the knowledge of the registered or otherwise accredited exporters and importers. In any case, customers should be aware of the dangers, and the government should not be making implicit claims of equivalent safety by imposing identical labeling on drugs that may contain different ingredients, may be manufactured differently, may not be bioequivalent, and were certainly manufactured and distributed under different regulatory regimes. Finally, it seems inadvisable to strike the Secretary's authority to ban imports over legitimate safety concerns.

Features to overcome resistance to importation by the industry

There are two major economic-related concerns relating to the Dorgan bill. One has to do with the industry-specific consequences of reducing the incentive to invest in the development of new drugs, which will also have health and safety effects on consumers. The second has to do with the bill's violation of the broader principles of private property rights and patent protection, which have implications for all innovators and all industries.

This mandating of what a company must do with its patented knowledge, physical plant, and work force is very close to a "taking" of private property... It is surely an erosion of the benefits of patent protection.

Under the earlier Gutknecht bill, companies could preserve much of their patent protection by limiting sales to foreign cut-price exporters of prescription drugs to the United States. Companies that did not want to have their domestic pricing structures undercut by imports might limit supplies in foreign countries to the amounts normally consumed there, and they might seek to enforce contractual marketing agreements that prohibit foreign wholesalers and pharmacies from selling into the United States.

The Dorgan bill would try to thwart such reactions by the pharmaceutical industry by insisting that companies make unlimited supplies of lower cost foreign drugs readily available to U.S. users. The bill would outlaw efforts by drug companies to restrict foreign sales, declaring such actions to be unfair trade practices subject to legal penalties under the Clayton Act. Any drug company operating in the United Sates, whether U.S. or foreign headquartered, would be subject to pricing and sales rules.

Pharmaceutical manufacturers would be required to sell drugs to any foreign exporter to the United States at the same (lowest) price they sell to other buyers in that exporter's foreign country. That is, they would have to sell for the controlled price set by the foreign government. They could not restrict supply to that exporter, or refuse to do business with it, or require any commitment that the drugs not be sold in the United States. Although the manufacturer would have to accept the lower foreign controlled price for the drug, there is no requirement that the exporter who obtains the lower price must pass the cost savings on to the U.S. buyers, such as pharmacies, U.S. wholesalers, or individuals buying over the internet or by mail.

Pharmaceutical manufacturers that produce product in the United States for U.S. customers, or import their own foreign production into the United States for sale here, would be required to sell to any registered U.S. importer (pharmacy or wholesaler) at the same (lowest) price they charge to other U.S. buyers who do not import. That is, they could not punish U.S. drug buyers that import some of their products at reduced foreign prices by charging them more for other products produced in the United States. They could not limit quantities to the importers, nor refuse to deal with them.

These provisions would effectively give foreign exporters and domestic importers the right to demand that manufacturers produce and sell proprietary products to them at prices determined by foreign laws and regulations, even when such deliveries are not in the interest of the companies. This is forced production and forced sale, or in other words, forced trade.

It is not clear how the government could enforce these rules. In theory, all foreign sales of drugs bound for the United States would have to be at the same lowest price available to other buyers in the country of sale. All sales in the foreign country would have to be monitored in order to know what the appropriate price would be. Any new government regulation or negotiated discount that altered the price for any foreign purchasing agency

could trigger revisions in all other ongoing contracts. To monitor and coordinate the prices set by every contract in a changing market would be an impossible task. For the companies, avoiding violations would be a compliance nightmare. For the government, finding violations would be a regulatory nightmare.

The courts have ruled that patents give the holders the right to sell or not to sell their proprietary products at any given price, and to deal with or not to deal with any given buyer. U.S. issued patents are not subject to forced licensing. The Dorgan bill sweeps this patent protection away for the pharmaceutical industry.

Taking control from firms and taking resources from research

This mandating of what a company must do with its patented knowledge, physical plant, and work force is very close to a "taking" of private property, both real and intellectual. It is surely an erosion of the benefits of patent protection. The bill would sharply reduce the returns on research and interfere with drug development.

Pharmaceutical research is a risky business. The rate of return to the industry is not out of line, on a risk-adjusted basis, with that of other expanding industries, and is essential to attract additional capital into this opportunity-rich field of research. The pharmaceutical industry reinvests a larger share of its revenues in R&D than most other industries, and must continue to do so if it is to develop new medicines for the future at the rates the public has come to expect.

The total cost of developing a new prescription medicine is estimated to be $802 million, on average. When one adds in the expensive follow-up studies that the FDA often requires, the price tag hits $897 million, on average.[1] It does not take a rocket scientist to deduce that pharmaceutical companies need to charge high price for new drugs in the first few years after the drugs are introduced — when the drugs are under patent protection — in order to recover the enormous costs of the research efforts. If the United States imports foreign price controls by way of the Dorgan bill, the predictable result is that drug research efforts will plummet.

The companies must earn enough to cover the marginal and fixed costs of production of the medications that gain approval for sale, including the fixed R&D costs (both for the drugs that make it to market and the dead-ends that must be explored to find the winners) incurred in inventing the products. That total return must include a normal return to the capital tied up in the process (cost of capital) or the industry will not be able to attract capital to the industry. The Congressional Office of Technology Assessment looked at the returns earned by "new chemical entities" introduced in the United States between 1981 and 1983. The study estimated that "excess returns over R&D costs would be eliminated if the annual revenue per compound was reduced by 4.3 percent over the product's life."[2]

The development of new drugs would be slowed, and in some cases eliminated. Over time, tens of millions of people would suffer reduced quality and length of life.

If the Dorgan bill were to reduce U.S. drug revenues significantly, it would eliminate the margin of return that is driving the expansion of the industry through retained earnings, would wipe out the margin for dividends or additional interest payments (blocking the issue of new share or debt to fund expansion), and would eat heavily into the R&D budgets of the industry.

Lower returns would sharply reduce the industry's ability to attract and employ capital. The development of new drugs would be slowed, and in some cases eliminated. Over time, tens of millions of people would suffer reduced quality and length of life.

The devastating effect that price controls have on new drug development can be seen abroad. In

1988, for instance, U.S. drug companies developed 19 of the 50 top-selling pharmaceuticals worldwide, while foreign companies developed 31. By 1998, however, U.S. companies developed 33 of the 50 top-selling pharmaceuticals. In the area of biotechnology, U.S. manufacturers developed 14 of the 15 top-selling drugs in 2001. The United States is the last major developed nation largely free of pharmaceutical price controls.[3]

The Constitution authorizes patents to promote progress

The Constitution of the United States, Article, 1, Section 8, Clause 8, gives the Federal Government the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries." Patent protection was important in fostering innovation and industry in the new nation, and has since helped the United States to become the world's scientific and economic leader.

The Dorgan bill is clearly open to challenge on the grounds that it constitutes a de facto taking of intellectual and physical property.

According to M.I.T. *Technology Review*, "The benefits of patenting inventions have not changed much since U.S. patent number one was issued in 1790 to Samuel Hopkins, who developed a process for making potash, a chemical ingredient essential to glass, soap, and gunpowder. The patent allowed Hopkins to disseminate his technology without giving it away: he sold five-year licenses for $200. Hopkins's process became the industry standard, and the United States became a leading producer of potash until the 1860s."[4]

Note the important point in the Technology Review paragraph about the dissemination of technology. Patents do not restrict the use of technology, they enhance it. Patents allow inventors to benefit from their discoveries without having to keep the processes secret. Through licensing, inventors can obtain a reward for their work even as they make the technology available for widespread use, expanding output and employment throughout the country, and making the product widely available. In the case of pharmaceuticals, the patenting process involves a clear presentation of the formula and production process for the drug, which makes the technology transparent and readily available to generic competitors when the patent expires.

The web site of the United States Patent and Trademark Office (USPTO) states: "Under this system of protection, American industry has flourished. New products have been invented, new uses for old ones discovered, and employment opportunities created for millions of Americans. The strength and vitality of the U.S. economy depends directly on effective mechanisms that protect new ideas and investments in innovation and creativity. The continued demand for patents and trademarks underscores the ingenuity of American inventors and entrepreneurs. The USPTO is at the cutting edge of the Nation's technological progress and achievement." This is an eloquent statement in defense of the economic importance of property rights in general and intellectual property rights in particular.

Assault on patents attacks the Bill of Rights

The Fifth Amendment to the Constitution provides that no person shall "be deprived of life liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation."

Patents are property, as are the intellectual property they protect and the facilities and earnings of the businesses who build on the protected discoveries. Taking private property without paying for it cannot be due process, regardless of what Act the Congress adopts.

Former Food and Drug Administration Commissioner Mark McClellan spoke out on the relationship between price controls and patent protection at an international conference on generic medicine in Cancun, Mexico in 2003. He said, "In many ways, the economic consequences of overly strict price controls on drugs are no different than violating the patent directly through compulsory licensing to make copies of the drug. Either way, there isn't likely to be a fair payment on the value of the new patented product."[5]

There is no free lunch for the public or for the Congress in imposing price controls on the pharmaceutical industry. Allowing research to falter would impose the costs of unnecessary illness and early mortality ... on unsuspecting patients.

The current value of any piece of property equals the present value of its expected future earnings. Seizing or debasing the earnings of a piece of property reduces its value. The Dorgan bill is clearly open to challenge on the grounds that it constitutes a de facto taking of intellectual and physical property.

The challenge might not be successful, of course. Federal, state and local courts have twisted and debased the words of the Fifth Amendment over time. They have allowed Federal agencies and local governments to restrict property use to such an extent that the affected property loses most of its economic value. These restrictions constitute a "taking" of the property in every sense short of an outright seizure of title.

In the case of the Dorgan bill, however, the takings case may be too clear for the courts to ignore. This is because the bill mandates not only the price at which the product must be sold (the controlled foreign price), but also the quantity that must be supplied (whatever the customers demand for shipment to the United States). These features of the bill virtually take over control of foreign manufacturing facilities, demanding that they fill orders for shipment to the United States ahead of any foreign-directed sales and without regard for the capacity of the facilities. The Dorgan bill is therefore reminiscent of the attempted take-over of the United States Steel industry by President Truman. The Supreme Court ruled against the President in the 1952 Steel Seizure Cases that such takeovers were illegal.

Furthermore, most of the drug manufacturing plants targeted by the Dorgan bill are located abroad. If the government cannot take over domestic manufacturing facilities, there is even less of a case for the Congress to seize effective control of manufacturing facilities in foreign countries.

Furthermore, foreign governments might react adversely to Congress's meddling with production and sales of drugs in foreign countries, especially if it resulted in massive diversion of drugs made for foreign consumers to the United States. Canada, for example, has a population about 11 percent that of the United States, a GDP less than 9 percent of that of the United States, and spends about 5 percent as much on drugs. Any large scale purchases of drugs for the U.S. market in Canada could drain that country of its drug output or normal supplies.

Defying the Declaration

The Declaration of Independence is not the law of the land, but it reflects the feelings of the founding fathers and of most Americans alive today. It states that "all men are created equal, that they are endowed by their Creator with certain inalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness..." and "That whenever any Form of Government becomes destructive of these ends, it is the Right of the People to alter or to abolish it, and to institute new Government, ... as to them shall seem most likely to effect their Safety and Happiness."

Curtailing drug development, as the Dorgan bill would do, would sacrifice the length and quality of

life, safety, and happiness of multitudes of citizens now alive and of generations yet unborn. The courts have ruled that laws are not necessarily unconstitutional just because they are foolish. But it must surely be counter to the basic purpose of government as laid out in the Declaration to enact laws that jeopardize the lives, health and happiness of tens of millions of people.

Less harmful alternatives for making drugs available to the poor

There is a legitimate concern that low income Americans may not be able to afford full-priced drugs. There are two possible prescriptions for this social disorder. One, the Dorgan approach, is effectively to import foreign price controls and drive down the price of drugs for all consumers. It has the side effect of curbing development of new drugs and injuring tens of millions of future patients. The other possible policy prescription is to assist people with low income to buy their medicines at market prices, maintaining the flow of research money and medical breakthroughs. This could be accomplished with "drug stamps" akin to food stamps, or by attaching federal or state assistance to discount cards, as is being done with the $600 grant attached to the senior discount cards provided under the 2003 prescriptions drug benefit. People in need will be given access to existing drugs, while the revenues needed to discover and develop new medicines will continue to flow.

(In addition, if there were safe steps the government could take to reduce the regulatory costs of bringing drugs to market, prices would be lower without curtailing the incentive to develop new drugs. In fact, such steps to reduce needless costs should be taken regardless of any other issues concerning the affordability of medication.)

Alternatively ... the government would have to ... make up for the lost research money and the lost incentive to innovate ... supplying just as much money to the industry through grants or tax breaks as would have been the case if people had been helped to purchase drugs at market prices to begin with.

If there are two effective medicines that can cure a disease, but one has life threatening side effects and the other has none, which should the doctor prescribe? If he chooses the one with side effects, he should be sued for malpractice or even lose his license. Unfortunately, in the political arena, people may not see the connection between the policy and the resulting damage. Alternatively, they may not care, because the savings to them are immediate, and the damage falls on their children and grandchildren.

Replacing the lost research money

Congress clearly would like to be credited for enabling everyone to have access to drugs regardless of their incomes and for making drugs less expensive. However, achieving universal coverage by giving federal assistance to the poor and by giving drugs to all seniors via Medicare would impose a huge cost on the federal budget, and would reduce funds available for other federal spending programs. It is no wonder, then, that Congress finds it appealing to shift the costs onto the drug companies. The disadvantage of that approach is that the companies would have to curtail the search for new medications. In many cases, of course, it would be better to curtail other federal spending than to curtail drug research, but that is not the reward structure facing the Congress.

There is no free lunch for the public or for the Congress in imposing price controls on the pharmaceutical industry. Allowing research to falter would impose the costs of unnecessary illness and early mortality in some random manner on unsuspecting patients. The costs would be unpredictable and unattributed, but very real.

Alternatively, to keep the research effort from shrinking, the government would have to devise

alternative sources of funding and reward to make up for the lost research money and the lost incentive to innovate. That would mean supplying just as much money to the industry through grants or tax breaks as would have been the case if people had been helped to purchase drugs at market prices to begin with. It would require enhanced R&D tax credits, or beefed-up tax deductions or federal matching funds for R&D outlays.

If government goes the tax break or subsidy route, the decisions about what research to pursue should have to be left to the companies. The federal incentives should be entitlements, available for whatever research the companies feel is cost effective, that is, likely to lead to new drugs whose benefits match the costs. The danger is that federal money would be redirected by bureaucrats or politicians according to political pressures rather than technical prospects and market valuations. We would end up spending more and getting less.

Conclusion

The Dorgan bill is breathtaking in its scope, shifting the production and marketing decisions of an entire industry from producers to middlemen and agencies of foreign governments, and charging the FDA with monitoring far more activity in the United States and abroad than it is currently capable of handling.

The Dorgan bill is a breathtaking assault on patent protection and property rights. It eliminates the value of patents via the back door, ducking an up front debate on the appropriate length of patent protection and making no acknowledgement of the trade-off between that protection and the availability of new medicines.

The Dorgan bill is breathtaking in its audacious effort to wish away a basic law of economics and markets, which is that reducing the returns to any activity will result in the reduction of that activity.

The Dorgan bill is breath-taking in the most literal and serious sense. By preventing or delaying the development of new life-saving and life-lengthening medications, it will literally and prematurely take the breath of life away from tens of millions of people in the years ahead.

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Endnotes

1. See Tufts Center for the Study of Drug Development, "Postmarketing Studies Becoming Essential to New Drug Development in the U.S., According to Tufts CSDD," News Release, July 6, 2004, accessed on the Internet at http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=44.

2. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards, 1992*, page 22.

3. John E. Calfee, "International Pharmaceutical Pricing; Price Controls Discourage Innovation," Testimony before Senate Committee on Finance; Joint Committee on International Trade, April 27, 2004, accessed on the Internet at http://www.aei.org/include/news_print.asp?newsID=20476.

4. "Patents ’04," M.I.T *Technology Review*, 107,4 (2004): 65.

5. McClellan, Mark, "Speech before First International Colloquium on Generic Medicine", Sept. 25, 2003, U.S. Food and Drug Administration, http://www.fda.gov/oc/speeches/2003/genericdrug0925.html.