New Momentum for Drug Export Bill

Drugs not approved in the U.S. can't be shipped out of the country, but that may change

For the past several years, the pharmaceutical industry has tried unsuccessfully to abolish a federal law that bars the export of drugs which have not been approved for use in the United States. The prohibition, which has been in place for more than 4 decades, has been viewed as an important deterrent to the dumping of unsafe drugs in developing countries. For a number of largely economic reasons, the industry might now succeed in persuading Congress to allow export in certain circumstances. New support for a change is being provided by biotechnology companies and the mood of protectionism on Capitol Hill.

In October, Senator Orrin Hatch (R–Utah), chairman of the Labor and Human Resources Committee, reintroduced a bill that would significantly loosen the current prohibition, while also providing, he says, even stronger safeguards than earlier versions to prevent the indiscriminate sale of unapproved drugs in Third World countries.

Under current law, a drug not approved for use here cannot be shipped even to countries with sophisticated regulatory agencies, such as West Germany and Britain, even if the drug has been approved there. This is unjustified paternalism in the view of Hatch and the pharmaceutical industry.

They say that as a result of the law, American companies must either give up the market to foreign competitors or build plants overseas to supply these drugs, draining investment capital and jobs from the American economy. Hatch and the Pharmaceutical Manufacturers Association say that if the ban were lifted, American companies could generate 12,000 more jobs in the United States and up to $500 million more in revenues. Hatch has made these arguments before, but this year they seem to hold more sway given congressional interest in protecting American industry.

The other factor that gives the issue more momentum is that biotechnology companies back the bill. They assert that the prohibition hurts them too. Senator Edward Kennedy (D–Mass.), the ranking minority member of the committee, previously has opposed lifting the prohibition, but now agrees to the concept of the bill, according to a staff aide. Several genetic engineering companies, some of which are located in the Boston area, have urged Kennedy to support the bill, the aide says.

The biotechnology companies, particularly Genentech, contend that the export ban could erode American genetic engineering know-how. Few of the young biotech firms can afford to build plants overseas, for instance, to produce drugs not yet approved here. So to market abroad, they might have to give a foreign partner in Europe or Japan the recipe to manufacture the drug. According to a Genentech representative, a West German company agreed to sign on as a manufacturing and marketing partner only after Genentech said it would hand over the genetically engineered microorganism that produces a specific drug. George Rathmann, president of Amgen, says that letting another company have such an organism is "giving away the store" because of the scientific information that can be derived from the microbe itself.

Hatch's bill sets up three categories of countries that could or could not receive unapproved drugs. No drug that has been banned or suspended for use by FDA could be shipped anywhere overseas. It would allow the export of a drug not sanctioned by FDA provided that the recipient country has approved the drug and has adequate regulatory authority. Several European nations, Japan, and Canada fall into this category. A second group of countries could receive unapproved drugs made in the United States from a country on the first list if it is approved by the first list country. The last category could receive unapproved drugs if the substances will be used to treat tropical diseases.

But Hatch has only cited a handful of examples in which companies say they were forced to produce drugs abroad because of the ban. In the worst case, Merck in 1977 spent $30 million to build a plant in England to produce a drug not approved by FDA. American Cyanamid spent $11 million, and Abbott Laboratories invested $4 million, to manufacture overseas. A Hatch aide said that a comprehensive list has not been drawn up that totals the amount of money invested overseas and the number of top-selling drugs that have led companies to build abroad. "We're past that point," he said.

There are other factors that influence a company's decision to site a plant overseas, according to David Bodde, assistant director of natural resources and commerce at the Congressional Budget Office. The considerations that go into building a plant overseas "are extraordinarily complex," and include foreign tax incentives, and cheaper labor. Bruce Brennan of the Pharmaceutical Manufacturers Association acknowledges that most large drug companies already have plants overseas partly because most other governments require a local presence for clinical testing and to gain drug approval.

Canceling the export ban may not significantly help American companies in Japan, which has a comparable market to Europe, and whose own companies are regarded as serious competitors to American firms. Japan has all sorts of nontariff trade barriers in place that make it difficult for an American company to obtain approval for a drug.

The biotechnology companies fear that they will have to transfer too much technology to overseas partners. Yet the Genentech representative notes that "in a majority of Genentech's licensing agreements, not much technology has been traded away." In general, most American biotech companies are now striking agreements to license products, not technology.

Investment opportunities abroad attract biotech firms too. Damon Biotech of Cambridge, Massachusetts, last month broke ground in Scotland for a new plant, its first overseas. Foreign investors raised $40 million for the new subsidiary, while Damon put up $3 million.

The key hurdle in Congress right now is whether Hatch and Kennedy can agree to specific legislative language. Markup has been canceled twice now because Kennedy is not satisfied that the safeguards are strong enough against sales of unapproved and unsafe drugs in developing countries. One key problem is how FDA would enforce the law if a drug were improperly shipped from one country to another. Committee markup is now scheduled for 19 November. If and when the bill passes the Senate, it will then have to meet the approval of Henry Waxman (D–Calif.), who is chairman of the health and environment subcommittee and in the past has opposed the abolition of the export ban.

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