Sending Unapproved Drugs Abroad

As this column is being written, legislation is being debated in Congress that would allow United States pharmaceutical manufacturers to export drugs that have not been approved for use in this country.

The issue is a highly controversial one with very vocal opponents, as well as proponents, each stirring up considerable public interest in the issue and support for their respective positions. As just one example, several prominent lay newspapers, including the *New York Times* and the *Washington Post*, have published editorials opposing such legislation.

Those opposed generally make the argument that Americans would create "a double standard"; namely, drugs that have not been shown to be sufficiently safe and effective for marketing in the United States and for use by Americans would be sanctioned for export and use by people living in other lands.

Admittedly, that argument appears appealing and persuasive on purely moral or ethical grounds. Political foes who would wish to cast the United States in a bad light undoubtedly could have a field day playing it to their best advantage. Moreover, there is some unfortunate past history—many, many years ago—when unscrupulous manufacturers did use the export market to "dump" substandard batches of deteriorated or otherwise unsuitable drug products.

However, the legislation that is presently under consideration does seem to have provisions that would adequately safeguard foreign consumers from products of inferior quality. Hence, the basic difference today is not one of manufacturing quality, but rather the degree of proof of safety and effectiveness. Put another way, it revolves around the inherent features of the drug entity rather than characteristics of the dosage form or the drug product. And again even in this regard, the present legislation would only permit export to (*a*) countries having a well-regarded drug regulatory agency that could make a valid judgement as to the suitability of the imported drug for that country's population given the specific circumstances involved or (*b*) other countries only if at least one country having a well-regarded drug regulatory agency has approved the drug. No export would be allowed if any agency throughout the world that is comparable to the U.S. Food and Drug Administration had banned or withdrawn the drug on the grounds of its safety or efficacy.

Unfortunately, in presenting their arguments, the major proponents of the legislation have consistently emphasized only the economic considerations involved. They point out, and correctly so, that under current law American manufacturers can establish plants abroad to produce, sell, and distribute the very drugs that they now are prohibited from producing in their U.S. plants to export for exactly the same purpose. The proponents further note that this serves to send abroad investment capital, jobs, and income that otherwise would benefit the U.S. and its citizens. Jobs are lost, the balance of trade is upset, and technology is drained away.

Editor's Note: Dr. Feldmann's editorials are an expression of personal opinion and do not necessarily reflect views or policies of APhA. The editorials are intended to be provocative and to stimulate thinking. Readers having reactions, either pro or con, are invited to submit them for publication in the *Open Forum* section.

These points are all quite valid. However, they neglect to address what is, in our opinion, the most persuasive argument. Specifically, many drugs needed in other parts of the world are intended to treat conditions for which there is virtually no American market and, hence, there is no reason whatsoever for the drug company to expend the time, effort, and expense of seeking U.S. approval.

For example, in late September, a prominent American pharmaceutical firm presented the results of three clinical studies at a session of the XI International Congress for Tropical Medicine and Malaria in Calgary, Canada. The studies involved clinical investigations that were conducted in close collaboration with the World Health Organization.

Based simply on the news releases prepared for the professional press announcing those reports, the results were dramatic and represent a potential public health breakthrough that would greatly benefit a very significant portion of the world's population—virtually none of whom reside in the U.S.

Specifically, a single oral dose of a new antiparasitic drug (identified as "ivermectin") was found to be a highly promising agent for the treatment of the tropical disease known as onchocerciasis or "river blindness."

An estimated 40 million people in Africa, Central and South America, and Yemen in the Middle East are currently afflicted with this disease. Its victims not only suffer blindness, but a whole host of other seriously debilitating conditions. A tiny blackfly which breeds in fast-moving streams carries the developing larvae of the worm that causes onchocerciasis and is the reason why the disease is referred to as "river blindness."

But, according to all three of the studies reported at the International Congress, a single oral dose of ivermectin reduced to near zero in skin snip samples the numbers of microfilariae or tiny worm larvae which cause the disease. And the drug's side effects or toxicity was nominal at most.

It strikes us as not only ironic, but virtually a social injustice, that current American law prevents the American drug manufacturer—that discovered and developed this drug in its U.S. laboratories—from producing and exporting the drug from its U.S. plants for foreign markets. It is now prohibited from doing so because the drug is not approved in the U.S. and, with no incidence of "river blindness" in the U.S., it is a safe assumption that the drug will not be subjected to the very costly and time-consuming process involved in seeking such approval.

Consequently, recognizing the surface arguments that can be cited in opposing the present legislation to relax the prohibition on exporting of American produced drugs not approved in the U.S., it is our belief that the greater good would be served by passage of such legislation.

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