FDA Goes Global

FDA Consumer magazine
The Centennial Edition / January-February 2006

By Murray M. Lumpkin, M.D., and Lawrence Bachorik, Ph.D.

Not so long ago, the Food and Drug Administration's public health mission was confined largely within the borders of the United States. It was a time when most FDA-regulated products were grown, produced, studied, and manufactured here at home. At that time, the FDA's international work focused primarily on protecting Americans from potentially risky products from abroad.

The FDA's more formal involvement in international affairs began some 40 years ago, with one or two staff members who handled foreign inquiries and visitors to the FDA, as occasionally a representative of a foreign government would call the FDA to ask about a U.S. regulatory requirement or to request a tour of an FDA facility.

In 1979, the International Affairs Staff was formed in the Office of the Commissioner as the first organized FDA effort to cooperate internationally with and reach out to foreign counterparts. A year later, the World Health Organization and the FDA played host for the first International Conference of Drug Regulatory Authorities.

Now, scarcely a day goes by without the FDA having intensive formal and informal interactions with our foreign counterparts. The FDA's international programs have grown in breadth and depth, and its experts are called on to direct, manage, and coordinate the growing body of international work across the agency.

Why Go Global?

One might ask why the FDA, a domestic regulatory agency, needs to be involved so intensely internationally. The reasons are many.

The first, and fundamental, reason is the globalization of items and issues that affect our public health positively and negatively. As we continue to evolve into a global society, it is clear that public health, and the science that supports it, knows no borders. Whether working to foster innovation in product development, investigating a potential health risk from a product, or addressing an emerging new disease, the concerns, challenges, and needs are shared by public health officials and the public around the world.

The second reason is that the industries whose products the FDA regulates have in great numbers achieved "global" status and impact. Multinational companies have become increasingly common. Both generic and innovator pharmaceutical products are manufactured in many countries around the world for the U.S. market. For example, plasma derivatives, such as blood-clotting agents, are made from human blood that may have been collected in the United States and undergo final processing in Europe. Similarly, medical devices have many national origins,

and food arrives in the United States from virtually all continents.

Third, the increasingly international nature of scientific research and the nearly instantaneous availability of information worldwide have contributed to this globalization. In the mid-20th century, U.S. pharmaceutical firms primarily tested their products in the United States. Now, multinational drug companies test their products in places and in people around the world and use those data to support marketing applications both in the United States and in other countries. With the revolution in information technology, data acquisition and sharing have become easier than ever. As a result, regulatory agencies have had to make their marketing application review processes more compatible and efficient.

As the industries the FDA oversees have become global, many regulatory systems around the world have become increasingly competent and sophisticated. Some have modeled themselves on the United States and the FDA, which maintains its very strong position as a world leader in the regulatory promotion and protection of public health. Others, however, have evolved along alternative paths and have found different innovative approaches to consumer protection. This means that the FDA has had to find new ways to work with a variety of international counterparts.

The fourth, and final, factor that has demanded that the FDA assume a greater international role has been the mushrooming of international trade in the products FDA regulates. The North American Free Trade Agreement (NAFTA) in 1993 and the establishment of the World Trade Organization in 1995, for example, have given a greater impetus to international commerce.

As a result, the United States is importing more FDA-regulated products than ever. In 1991, about 1.5 million discrete shipments of imported FDA-regulated products entered the United States. That total skyrocketed to nearly 12 million in 2004, and an estimated 14.4 million last year. Imported food accounts for nearly two-thirds of the total imports, and medical devices and radiological health products make up more than one-fifth. As more free trade agreements are being negotiated, the FDA has become the face and the voice of public health in these trade negotiations. Some may wonder whether the FDA, as a science-based regulatory agency--and not a trade-promoting agency--has a legitimate role to play in the world of international trade. The answer is now a resounding "Yes." The FDA must assure that the public health protections Americans demand are indeed maintained while fostering wider, freer trade on a global scale.

Rising to Meet the Challenges of Globalization

How can the FDA continue to protect and promote the public health in this global marketplace?

Good public health protection demands more than a solid inspection program to manage imports. Faced with this unprecedented increase in products from abroad, the FDA has relied on two primary strategies for helping to assure the quality of these products: harmonization of standards through multilateral fora, and two-party (bilateral) agreements with other nations.

In general, the FDA and other nations have entered into harmonization initiatives to assure product quality while at the same time conserving scarce human and financial resources and

improving the efficiency of their operations. When nations can agree on scientific standards for establishing the safety, effectiveness, and manufacturing quality of pharmaceutical products, or on standards that help ensure that high-quality medical devices are produced, everyone wins.

As useful as they are, these harmonization efforts sometimes do not address specific national needs. That is when the FDA and its international counterparts find it mutually beneficial to enter into one-on-one agreements that allow them to share information sooner and work more closely together to solve specific problems.

The FDA of 2006 is not the same as that of 1906 or even 1976. Influenced by such factors as globalization, the information revolution, and increased trade, the FDA has by necessity and choice become a premier player and leader in the international arena on challenging and emerging public health issues.

Murray M. Lumpkin, M.D., is the FDA's deputy commissioner for international and special programs;

Lawrence Bachorik, Ph.D., is the FDA's senior advisor for international policy and communications.