Give the FDA Expanded Powers

Currently, the Agency Has No Authority to Embargo Unsafe Food, Drugs, And Cosmetics; No Authority to Inspect Records of Food Facilities; No Authority to Assess Civil Penalties.

By Rep. Henry Waxman

Imagine the following scene: An official from the Food and Drug Administration is inspecting a food processing plant. He finds a batch of canned mushrooms that looks suspicious; he is concerned about possible contamination with botulism, a deadly poison.

He reviews his options. If this were a heart valve or other medical device facility, he could order the suspect product embargoed for 20 days, enough time to request a court order so that the product could be destroyed or made safe.

In the case of food products, there is no embargo authority. Instead, if the food processor doesn't cooperate — and they don't always cooperate — the inspector's only option is to obtain assistance from the state.

Although it is odd for the federal official to have to rely on state authorities to enforce the Federal Food, Drug and Cosmetic Act, help from state officials is essential to solving the immediate problem of the cans in the plant (as it would be in a drug or cosmetic facility).

But where did those mushrooms come from? To find out, the inspector has to look at shipping records. This would be no problem if the culprit were a prescription drug. Again, the FDA has no authority to inspect the records of food facilities (or facilities where cosmetics and most medical devices are produced). What about the mushrooms that have already been distributed? In the case of a medical device, the agency could rely on its recall authority. Again, no such luck for foods (or for drugs and cosmetics).

How did we get to this sorry state of affairs? The answer lies in the age of the FDA's current law, enacted more than 50 years ago.

What about the investigation that follows, to determine whether to punish the responsible parties?

A subpoena for relevant documents could be issued if the investigation were being conducted by almost any other agency, including the Department of Agriculture, EPA, FTC, CPSC, NHTSA, OSHA, or IRS. Again the FDA has no subpoena authority (except in limited cases for medical devices).

Once the investigation is complete, the FDA must decide what penalty to impose. Criminal penalties are always an option, but they are not always appropriate. What about civil penalties? Again, administrative civil penalties would be an option if this were a violation of the medical device law, but not for other products regulated by the agency.

How did we get to this sorry state of affairs? How did an agency that regulates products that account for 25 cents of every dollar spent in this country end up with such weak and inconsistent enforcement authorities? The answer lies in the age of the FDA's current law, which was enacted more than 50 years ago.

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As a result, the agency does not have authorities that would routinely be given to a regulatory agency today. Where specific issues have been addressed (such as in the case of the Medical Device Amendments of 1976 and 1991), the agency's authorities have been updated, but unfortunately only in a piecemeal fashion.

To modernize the FDA's enforcement authorities, Rep. John Dingell (D-Mich) and I have introduced the Food, Drug, Cosmetic, and Device Enforcement Amendments of 1991. The key provisions of those amendments would give the FDA the following authorities:

- Embargo of products where the inspector has reason to believe that the product violates the Act, under the same circumstances as are now applicable to medical devices;
- Record inspection authority for food and cosmetics, under the same circumstances as are now applicable to drugs and medical devices;
- Recall of products that violate the Act where the defect presents a significant risk to public health;
- Subpoena authority comparable to the authority given to other administrative agencies;
- Authority to assess civil penalties for violations of the Act;
- Authority to destroy imported products that threaten the public health; and
- Authority to carry firearms when investigating serious criminal activity, such as diversion of steroid drugs.

Our bill follows the recommendations of various commissions that have recently reviewed the FDA's operations and authorities.

It is closely tailored to a bill that was drafted by the FDA and approved by Health and Human Services Secretary Louis Sullivan, although the Administration has not yet submitted legislation or taken a position on it.

Photo courtesy Food and Drug Administration

An FDA inspector on the job at an ice cream plant. If the inspector finds a possibly contaminated batch at the plant, the FDA itself lacks the power to embargo the food. "The inspector's only option," writes Rep. Henry Waxman, "is to obtain assistance from the state."

For many years the Food and Drug Administration has been a weak agency that has declined to enforce the law or to issue regulations in a timely manner. It made little sense to talk about additional enforcement tools, when the Agency expressed so little interest in enforcing the basic laws on the books.

Today the FDA has a new Commissioner, Dr. David Kessler, who is committed to simple law enforcement — that is, establishing clear rules; warning companies that are not in compliance; and bringing enforcement actions in court when companies refuse to comply. But Dr. Kessler is hampered by current law.

The lack of subpoena, embargo, and inspection authorities results in inefficiencies.

The agency can take the action needed to protect the public health, but only in a round-about way.

The lack of civil penalties means that the agency is forced to choose between criminal penalties or nothing. This can result in penalties being too harsh or too easy. And the lack of recall authority and the authority to destroy dangerous, imported products threatens the public health.

The time has come to bring the Food and Drug Administration into the 1990s. The Food, Drug, Cosmetic, and Device Enforcement Act of 1991 would go a long way toward achieving that goal.

Rep. Henry Waxman (D-Calif) is chairman of the health and the environment subcommittee of the Energy and Commerce Committee, which has jurisdiction over the Food and Drug Administration.