FDA Abuses Alternative-Medicine Industry but Is Lax on Drugmakers

Insight on the News
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In the last decade, Americans have embraced alternative medicine in all its forms. According to the National Institutes of Health (NIH), they spent $27 billion on all forms of alternative health care -- more than the total out-of-pocket expenses for hospitalizations. In 1999, Americans laid out $15 billion for herbal remedies alone. Orthodox medicine and its allies in the federal bureaucracy, however, do not share the public's enthusiasm.

In the late 1980s and early 1990s, Federal Drug Administration (FDA) bureaucrats pushed to have dietary supplements, vitamins, herbs and such, subjected to the same exhaustive and costly testing that drugs are supposed to undergo. Supplement manufacturers countered that the requirement would put them out of business. Since they could not be patented, there was no way to recoup the $200 million to $600 million cost of the tests.

Responding to an avalanche of constituent complaints, Congress struck a compromise with the Dietary Supplement Health and Education Act of 1994. The act allowed supplement manufacturers to market their products but prohibited them from claiming the products could treat specific diseases without evidence of "general scientific agreement" to support the claims.

Congress thought it had solved the problem. What it didn't realize was that there was no fury like a bureaucrat scorned. FDA minions soon were out searching for ways to bring dietary supplements under their bureaucratic thumb -- no matter what the intent of the legislators might have been.

The FDA obtained permission to arm its representatives, and soon FDA SWAT teams -- yes SWAT teams -- were raiding herbalists, compounding pharmacists and anyone else who strayed from medical orthodoxy's line.

In 1992, it broke down the door of holistic practitioner Jonathan Wright, an M.D., holding his middle-aged receptionist at gunpoint in a search for illicit vitamins. In August 1998, it raided the offices of 16 compounding pharmacists (pharmacists who make custom formulations for patients), confiscating their confidential patient records and credit-card data, even though their warrants didn't demand such information. In fact, the warrants didn't concern the pharmacists themselves but rather one of their former suppliers.

In May 1998, the FDA went into court against Pharmanex, the manufacturer of Cholestin, a herbal product proven effective in reducing cholesterol, claiming it was a drug, even though it was an extract of red-rice yeast. The FDA pursued its lawsuit without disputing the supplement's effectiveness or safety, even though the company was not making health claims.

Perhaps most amazing was the FDA's refusal to allow supplement manufacturers to make true statements about their products even after a federal court ordered them to do so. In 1999, the U.S. Court of Appeals for the District of Columbia found that the FDA had violated the First Amendment in refusing to allow Durk Pearson and Sandy Shaw to make four health claims:

* that antioxidant vitamins may reduce the risks of certain kinds of cancers;

* that consumption of fiber may reduce the risk of colorectal cancer;

* that omega-3 fatty acids may reduce the risk of coronary artery disease; and

* that 0.8 mg of folic acid in a dietary supplement was more effective in reducing the risk of neural-tube defects than a lower amount in common foods.

Yet, two years after the court ordered the FDA to design regulatory language that would permit Pearson and Shaw to list the health claims on their supplement labels, the FDA still had not issued the new rules.

While the FDA may fight like a lion when dietary supplements are the issue, when multinational pharmaceutical companies are involved, the agency is as timid as a lamb.

Witness the fact that, between 1997 and 2000, the FDA issued some 568 "warning letters" to pharmaceutical companies on issues ranging from false and misleading advertising to substandard manufacturing practices.

Some had multiple violations. Glaxo Wellcome, the pharmaceutical giant, got 30 letters. Schering AG was cited 26 times. Wyeth-Ayerst got 11 warning letters. Often the letters concerned repeated violations of the same rule.

Perhaps the most extreme example of kid-glove handling is the FDA's actions regarding Glaxo-Wellcome's blockbuster flu remedy, Relenza. Relenza was the only drug approved by the FDA after being rejected by an advisory panel. The advisory panel concluded that Relenza didn't work! Yet, Glaxo was allowed to market the drug to an unsuspecting public and generate $400 million in sales.

When Glaxo's claims for Relenza became too much for even its FDA sponsors, a series of warning letters was dispatched, telling the company to stop misleading the public. It took three letters to get the company to act. And what was the punishment for these misleading claims? Nothing! No sanctions, no fines, not even a slap on the wrist.

Clearly, something is seriously wrong. The Constitution guarantees equal protection under the law, but the FDA bureaucrats seem to think that this provision does not apply to them.

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