Report calls for better U.S. efforts to fight counterfeit drugs

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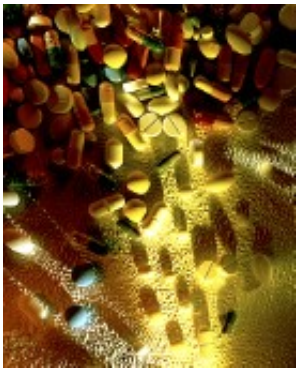

Institute of Medicine panel says international cooperation also needed to combat public health threat.

(HealthDay)—Aiming to reduce the global threat of counterfeit drugs, a new Institute of Medicine report also recommends changes in the United States that include a mandatory drug-tracking system and tighter licensing rules for drug wholesalers.

The potential dangers of counterfeit drugs are many, the expert panel noted.

In 2012, the U.S. Food and Drug Administration issued warnings more than once about fake doses of the injectable cancer drug Avastin (bevacizumab).

The scope of the problem is even bigger in developing parts of the world. One 2011 investigation revealed that falsified or substandard drugs have been sold in at least 124 countries.

"We have a rampant problem with malaria medications, tuberculosis medications and others, particularly in low- and middle-income countries, and we know it's increasing," said Lawrence Gostin, chair of the committee that prepared the report, which was released Wednesday. The Institute of Medicine (IOM) is a nonprofit organization that gives expert, evidence-based advice on public health issues to policy makers and health professionals.

Experts say the health consequences of counterfeit drugs depend to a great degree on the disease a particular medication is used to treat.

In a worst-case scenario, a "bad" cancer drug could rob a small child with curable leukemia of the chance to be cured, said Dr. Otis Brawley, chief medical officer of the American Cancer Society, who stressed that the chances of getting substandard cancer drugs, especially in a physician's office or hospital, is quite small.

Meanwhile, antibiotics that have been diluted could actually foster antibiotic-resistant bacteria and push a malaria or tuberculosis outbreak far beyond the borders of a particular country in Africa or Asia, he added.

The problem is that this hugely profitable business is vastly splintered and there is essentially no global regulatory system to combat it; there are not even consistent definitions among countries for terms such as "substandard" and "falsified."

The word "counterfeit," for instance, is often bandied about to describe drugs that have no active ingredient or have been diluted or otherwise

violated and don't meet regulatory standards. Under patent law, however, it has a very narrow meaning.

"We don't have common shared definitions. We don't have any global tracking and tracing. All of the reports by INTERPOL [International Criminal Police Organization] are anecdotal. Nobody coordinates with one another," said Gostin, professor of global health law at Georgetown University Law Center and director of the World Health Organization (WHO) Collaborating Center on Public Health Law and Human Rights, both in Washington, D.C. "As a result, we have fragmented, inconsistent data, and our report is designed to fix all of that."

The report's most ambitious recommendation, said Gostin, is asking WHO to begin a global code of practice that would create standard definitions, introduce track-and-trace systems and improve regulatory structures and capabilities all over the world.

The report also calls on the U.S. Food and Drug Administration, which sponsored the report, to act as the leader in the United States and set standards for other countries to follow.

The task is a daunting one.

"The business [of selling substandard/falsified drugs] is more profitable than the illicit drug trade," said Gostin. "It's bringing the same kinds of cartels and illegal behavior and trafficking of these medications, and it's extremely sophisticated."

Drug tampering can occur at any point in an incredibly complex supply chain. As Gostin said, "at the raw materials stage, at the manufacturing stage and even when you have good-quality drugs, they are being transported and can be delivered by the illicit trade and then diluted."

The drugs can end up in doctors' offices, but often are purchased via the Internet or in local black markets. There's no duty to report "fake" drugs, and they're often impossible to detect, he added.

"We had people show us two different drugs in two different packages. We're a sophisticated [scientific] committee, and we couldn't tell the difference," Gostin noted.

The unanswered question is whether such immense changes can be made.

In a statement released Wednesday, FDA Commissioner Dr. Margaret Hamburg commended the IOM for its recommendations.

She said her agency is currently "transforming from a predominantly domestically focused agency to one that is fully prepared to help ensure product safety and quality within a globalized world."

"In this context, many of the IOM recommendations support actions and efforts already underway at the FDA," Hamburg added, "including advancing technology, strengthening global regulatory capacity, strengthening surveillance, developing science-based standards and engaging in global dialogue."

Gostin conceded that the recommendations were also likely to benefit international pharmaceutical companies that sell legitimate drugs, but "that's not our purpose. Our purpose is to make sure that people, when they're taking medications, can have some confidence that the medication will work and won't poison them."

More information: The World Health Organization has more on substandard drugs.