

Tracking System Needed to Fight Fake Drugs

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WASHINGTON (AP) — Fighting the problem of fake drugs will require creating a national drug-tracking system, the Institute of Medicine said Wednesday.

The call for putting medications through a chain of custody like U.S. courts require for evidence in a trial comes a week after the Food and Drug Administration warned doctors, for the third time in about a year, that it discovered a counterfeit batch of the cancer drug Avastin that lacked the real tumor-killing ingredient.

Fake and substandard drugs have become an increasing concern as U.S. pharmaceutical companies move more of their manufacturing overseas. The risk made headlines in 2008 when U.S. patients died from a contaminated blood thinner imported from China.

The Institute of Medicine report made clear that this is a global problem that requires an international response, with developing countries especially at risk from phony medications. Drug-resistant tuberculosis, for example, is fueled in part by watered-down medications sold in many poor countries.

"There can be nothing worse than for a patient to take a medication that either doesn't work or poisons the patient," said Lawrence O. Gostin, a professor of health law at Georgetown University who led the IOM committee that studied how to combat the growing problem.

A mandatory drug-tracking system could use some form of barcodes or electronic tags to verify that a medication and the ingredients used to make it are authentic at every step, from the manufacturing of the active ingredient all the way to the pharmacy, he said. His committee examined fakes so sophisticated that health experts couldn't tell the difference between the packaging of the FDA-approved product and the look-alike.

"It's unreliable unless you know where it's been and can secure each point in the supply chain," Gostin said.

Patient safety advocates have pushed for that kind of tracking system for years, but attempts to include it in FDA drug-safety legislation last summer failed.

The report also concluded that:

—The World Health Organization should develop an international code of practice that sets guidelines for monitoring, regulation and law enforcement to crack down on fake drugs.

—States should step up licensing requirements for the wholesalers and distributors

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who get a drug from its manufacturer to the pharmacy, hospital or doctor's office.

—Internet pharmacies are a particularly weak link because fraudulent sites can mimic legitimate ones. The report urged wider promotion of the National Association of Boards of Pharmacy's online accreditation program as a tool to help consumers spot trustworthy sites.

FDA Commissioner Margaret Hamburg didn't comment on the tracking system proposal but the agency already had begun some steps to better address the issue, including improving surveillance.

The Institute of Medicine is an independent organization that advises the government on health matters.

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