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GOVERNMENT

FDA initiative targets safe use of medicines

The agency is seeking physicians' input on how to reduce overdoses from opioids, acetaminophen and over-the-counter drugs.

By KEVIN B. O'REILLY, *amednews* staff. Posted Nov. 29, 2010.

The Food and Drug Administration is seeking insight from doctors and others in health care on how best to prevent the harms associated with misuse of medications.

As part of its "Safe Use Initiative," the FDA is targeting injection safety as well as overdoses from opioids, acetaminophen and over-the-counter drugs. The FDA held a two-day workshop in November in Silver Spring, Md., asking physicians for their ideas.

Opioid abuse is of particular concern. Emergency department visits related to misuse of opioids more than doubled between 2004 and 2008, rising from an estimated 144,644 to 305,885, according to a Centers for Disease Control and Prevention report issued in June. Fatal poisonings from opioid overdoses tripled to nearly 14,000 from 1999 to 2006, the CDC said last year.

"Physicians can make a huge impact on opioids," said Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research. "It's really in the prescribing community that they can modify their habits and can educate their patients."

The FDA is still considering how to proceed on a Risk Evaluation and Mitigation Strategy for long-acting and extended-release opioids. An FDA proposal requiring opioid manufacturers to boost efforts to educate physicians and patients was rejected as too lenient by an advisory panel in July. Many panel members said physicians should be required to take continuing medical education courses on pain medicine before prescribing opioids.

The agency also is working with drugmakers on changing packaging to reduce the risk of accidental overdoses.

"We see children getting into certain products because they look attractive and they overdose on them, and we see older people getting confused and taking too many products containing acetaminophen," Dr. Woodcock said. "When you're dealing with a hydra-headed problem like this, it requires many parties working together -- it's not one simple regulatory solution."

This content was published online only.

ADDITIONAL INFORMATION:**WEBLINK**

Food and Drug Administration's Safe Drug Initiative (www.fda.gov/drugs/drugsafety/ucm187806.htm)

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