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In the News

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In The News

No Standards to Test for Drugs in Water

Until recently, the government and physicians advised consumers to flush expired pharmaceuticals down the toilet. However, experts now note that this recommendation was ill-advised. Recent studies have shown that this practice has resulted in the prevalence of medications, such as antibiotics, anti-convulsants, mood stabilizers, and sex hormones in the nation's water supply. Despite this phenomenon, the Environmental Protection Agency (EPA) does not require utility companies to test for the presence of pharmaceuticals in the water supply. Due to the lack of regulations, many communities do not test for the presence of drugs in drinking water, and most fail to inform their customers when these pollutants are detected. Experts express concern that these pollutants potentially threaten the health of humans, wildlife, and the natural environment.

In response, the U.S. Senate has scheduled hearings to address these concerns, however, many cities plan to take action before rulings are made in the federal government. In response to growing public outcry about the issue, the pharmaceutical industry has teamed up with the U.S. Fish and Wildlife Service to devise a strategy to inform Americans about ways in which to dispose of unused pharmaceutical products. Experts emphasize the need for the EPA to expand the list of contaminants for which utilities are required to test to include pharmaceuticals.

Heparin Contamination Raises Questions About the Safety of U.S. Drug Supply

Contamination of the blood thinner heparin, which led to drugmaker Baxter to recall its heparin in early in 2008, has been linked to the source of the supply in Chinese workshops. The associated deaths are estimated to include more than 60 people and the contamination is spread among all manufacturers of the drug. The recall raises questions about drug regulation in an increasingly global market, when drug supply originates from provinces that do not fall under the jurisdiction of the FDA's Good Manufacturing Practices. Indeed, China's State Food and Drug Agency responded to the contamination by releasing a notice requiring producers of heparin to obtain their supplies only from registered suppliers. Questions about the FDA's capacity to adequately inspect the United States' food and drug supply first arose in 2007 after spinach was contaminated in California, and will undoubtedly continue to be a concern for policymakers.

Celebrity Confidentiality Breaches in Health Care Records

With a public apology, the UCLA Medical Center in Los Angeles, California has promised to work closely with state health officials to investigate privacy breaches of over 30 high profile patients, including Britney Spears, Farrah Fawcett, and California first lady Maria Shriver. More than several employees have been implicated, disciplined, or fired for snooping into the electronic health records of celebrity patients in violation of state and federal laws, including thirteen individuals who were involved in probing into Britney Spears's medical file. At least one employee may face criminal charges under the Health Insurance Portability Accountability Act of 1996 (HIPAA). Questions have arisen regarding the time lapse between when the hospital became aware of the breaches and when it notified the celebrities. This breech has reinvigorated discussions about the possibility of strengthening state and federal medical privacy laws.

FDA To Issue Decision on the Safety of Cough and Cold Medications for Children

The over-the-counter drug industry is awaiting a decision from the Food and Drug Administration (FDA) as to whether it will allow the continued marketing of cough and cold medicines to children under the age of six. The FDA has issued two public health advisories since August 2007, warning that, "serious and potentially life-threatening side effects" can occur from use of the products. The adverse effects include death, convulsions, rapid heart rate, and decreased level of consciousness. The FDA recommends that the products not be given to children under two years of age "unless given specific directions to do so by a healthcare provider."

Prior to the FDA's Nonprescriptions Drugs Advisory Committee public meeting, the makers of oral infant cough and cold medicines sold under the Dimetapp, PediaCare, Robitussin, Tylenol, and Triaminic brands voluntarily recalled their products from store shelves.

As the industry awaits the final decision, stakeholders are debating whether labeling changes are an adequate solution, or whether the products should be removed from the market altogether. A Citizen's Petition filed with the FDA by several health professionals in early 2007 requests that the agency require nonprescription cough medications be labeled with the following statement: "(a) These products have not been found to be safe or effective in children under six years of age for treatment of cough and cold. (b) These products should not be used for the treatment of cough and cold in children under six years of age."

The Consumer Healthcare Products Association (CHPA), a trade group representing the nonprescription drug industry, has told the media that entirely removing these products from the market could have negative consequences, cautioning that if cough and cold medications are not available for children, parents may give their children adult medication and attempt to adjust the dosages. One study revealed that 74 percent of parents reported they would use whatever medication they had around the house to treat their children. Rather than eliminating all children's over-the-counter cough and cold products from the market, CHPA advocates for keeping the products on the market and educating parents on administering medicines to their children in safe and proper doses.

The Citizen's Petition asserts that the FDA has never formally concluded that the medications are "generally recognized as safe and effective" for the pediatric population. The agency has acknowledged that there is a paucity of data about the safety and efficacy of pediatric cold medications.

Funding to Develop Blood Substitute

As the blood-donor shortage in the United States worsens, demand for a suitable blood substitute increases. Aside from the shortages, problems with traditional blood transfusion include transfusion-transmitted diseases, the problems and expense of collecting and storing donated human blood, and the demand for compatibility testing.

According to estimates by the World Health Organization, there are not enough blood donations to meet the worldwide need of 100 million units (45 million liters) per year. Thus, a viable blood substitute could save the lives of millions, and has practical applications in military, homeland security, emergency medicine, and traumatic brain injury. "Creating an effective substitute for human blood has been an elusive dream for many decades," says Dr. Jan Simoni, associate research professor in Texas Tech Health Sciences Center's surgery department and HemoBioTech Inc.'s acting vice president for research and development.

To this end, the Office of Naval Research has awarded four grants to the Virginia Commonwealth University Reanimation Engineering Shock Center (VCURES) for research using the blood substitute Oxycite. VCURES is Virginia Commonwealth University's critical injury and illness research group. The $3.5 million funding will be used to support studies which focus on the use of Oxycite in decompression sickness, embolisms, traumatic brain injury, and blast injuries.

Bridget Behling and Rebecca L. Wolf contributed to this column.