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### US PRESCRIPTION-MEDICATION OVERDOSES INCREASING

A study in the American Journal of Preventive Medicine showed that hospitalizations for poisonings by opiates, tranquilizers and sedatives has jumped 65 percent from 1999 to 2006 a number that is almost twice that of all other medicines. The CDC reports that unintentional poisoning deaths are second only to motor vehicle deaths for unintentional injury in the United States and the number has been increasing since 1992.

### FDA CHANGES OPINION ON NEW HEPARIN POTENCY ASSAY

On Oct 2009 the FDA issued an alert notifying clinicians to consider the potential need to adjust heparin doses to make up for the decrease in potency, which was expected to be about 10% due to new USP standards for heparin anticoagulant activity. Based the evaluation of a number of studies, the FDA has now concluded that a 10% decrease in heparin dose, a consequence of not increasing a dose to counterbalance the lower activity of heparin, may not show up in a patients aPTT or activated clotting time. The agency, did however, name three clinical conditions that may warrant adjustments in heparin dosage and more extensive monitoring to compensate for the 10% decrease in potency.

- extracorporeal membrane oxygenation in pediatric patients
- cardiopulmonary bypass
- treatment or prevention of life-threatening thrombosis.

### DATES SET FOR PHASE OUT OF MDIs THAT CONTAIN OZONE-DEPLETING CFCs

The FDA announced that in accordance with longstanding U.S. obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer, seven metered dose inhalers used to treat asthma and chronic obstructive pulmonary disease (COPD) will be removed from the US market place. These inhalers contain ozone-depleting chlorofluorocarbons (CFCs) which act as propellants to move medication out of the MDI.

CFCs are harmful because they deplete the ozone layer miles above the earth that absorb some of the sun's harmful ultraviolet rays. The United States has banned the general use of CFCs in consumer aerosols for decades and has eliminated the productions of CFCs since January 1, 1996, except for limited uses such as MDIs. Bans on products containing CFCs began in the late 1970s. The affected products, and their phase-out dates, include:

Inhaler	Last date to be manufactured/sold or dispensed
Tilade (nedocromil)	June 14 <sup>th</sup> 2010
Alupent Inhaler Aerosol (metaproterenol)	June 14 <sup>th</sup> 2010
Azmacort Inhalation (triamcinolone)	Dec 31, 2010
Intal Inhaler (cromolyn)	Dec 31, 2010
Aerobid inhaler (flunisolide)	June 30, 2011
Combivent Inhalation Aerosol	Dec 31, 2013
Maxair Autohaler (pirbuterol)	Dec 31, 2013

During the transition the FDA wants to ensure that patient have access to safe and effective alternative medications to treat their COPD. Patients using inhalers scheduled to be phased out need to talk to their health care professionals about switching to one of the several alternative treatments currently available.<sup>(1)</sup>

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## Drugs That May Cause Ototoxicity

- Amphotericin B
- Capreomycin
- Chloroquine
- Ethacrynic Acid
- Azithromycin
- Amikacin
- Bumetamide
- Carboplatin
- Furosemide
- NSAIDS (all)
- Gentamicin
- Neomycin
- Tobramycin
- Cyproheptadine
- Hydroxychloroquine
- Quinine
- Vancomycin
- Minocycline
- Oral contraceptives

## FDA ADDS WARNINGS ABOUT LIVER INJURY TO PROPYLTHIOURACIL'S LABEL (Medication Guide Now Required)

The FDA has finished a review of 40 years worth of adverse events and has identified 23 cases of serious liver injury in adults who were treated with propylthiouracil (PTU) and 11 cases in children. In all, 13 of the adults and two of the children died. Five adults and seven children required a liver transplant.

The FDA stated that PTU and methimazole are the only drugs approved for the treatment of hyperthyroidism. The FDA has identified five cases of severe liver disease with methimazole three of them fatal associated with methimazole use. But has no reports of liver injury in pediatric patients.

PTU is now considered a second line therapy for treatment of hyperthyroidism. It is to be used in patients who cannot tolerate methimazole and are not candidates for radioactive iodine therapy or surgery. PTU is preferred over methimazole in women during the first 12 weeks of pregnancy, because craniofacial malformations and other congenital malformations have been associated with methimazole use in early pregnancy.

The agency now requires that a Medication Guide be distributed with every filled prescription for PTU. This guide contains detailed information about symptoms of liver disease and other issues associated with the drugs use that should be discussed with a health care provider.

<http://www.fda.gov/Safety/MedWatch><sup>(2)</sup>

## FROM THE DIRECTOR'S DESK



## SOURCES

1. REF; [FDA.gov/Newsevents/newsroom/PressAnnouncements](http://FDA.gov/Newsevents/newsroom/PressAnnouncements)
2. REF; FDA Drug Safety communication – April 21, 2010