than 600 corporations and 250 not-for-profit organizations. "All in all, the guidance is well done and doesn't stifle innovation," said Collins, who is senior director of mHIMSS, the society's mobile initiative. "They're not looking at the entire universe of health apps. They are looking at those that if they don't work right, patients will be harmed."

The FDA will not expect manufacturers to submit premarket review applications or to register and list mobile apps that

- Help users self-manage their disease or condition without providing specific treatment suggestions.
- Provide users simple tools to organize and track their health information.
- Provide easy access to information related to health conditions or treatments.
- Help patients document, show, or communicate potential medical conditions to health care professionals.
- Automate simple tasks for health care professionals.
- Enable patients or health care professionals to interact with personal health records or electronic health record systems.

The FDA's mobile medical apps policy also does not regulate the sale or general use of smartphones or tablets and does not consider mobile platform manufacturers to be medical device manufacturers just because their mobile platforms could be used to run mobile medical apps regulated by the FDA.

Further clarity as to how the federal government will regulate apps and other health information technology (IT) is expected in January, when the Department of Health and Human Services (HHS) Secretary is required, per the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, to "post a report that contains a proposed strategy and recommendations on a risk-based regulatory framework regarding health IT, including mobile apps, that promotes innovation, protects patient safety, and avoids regulatory duplication."

A special FDASIA committee issued a report September 4 with specific recommendations for the HHS secretary to consider when making the regulatory framework (http://tinyurl.com/q7nhntr). One of the committee's recommendations calls for not making health IT subject to FDA premarket requirements unless it is a medical device accessory or contains information to assist a health professional when making a high-risk clinical decision. The committee also recommended better postmarket surveillance of health IT, which should be transparent and include reports from users and vendors. ■

Dietary Supplement Linked to Cases of Acute Hepatitis

Bridget M. Kuehn, MSJ

A dietary supplement marketed as a weight loss and bodybuilding aid has been linked to dozens of cases of acute hepatitis and at least 1 death in Hawaii, according to national and state public health authorities.

News of a cluster of nonviral hepatitis cases in Hawaii broke September 26, when the state's health department alerted residents of cases of liver inflammation and liver failure linked to use of dietary supplements for weight loss or bodybuilding. By October 8, both the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) had issued alerts linking the cases to a product called OxyElite Pro, which is sold nationwide by a Texas-based manufacturer. All 3 agencies were warning individuals to avoid using this supplement until further information is available.

At press time, 29 cases of liver inflammation or liver failure, including 11 that required hospitalization, 2 liver transplants, and 1 death, had been reported to the Hawaii Department of Health. Twenty-four of the 29 affected individuals reported using OxyElite Pro before becoming ill.

The CDC's investigation identified several individuals from other states who had developed hepatitis after taking OxyElite Pro or other supplements but had not yet concluded whether it was a national problem. Clinicians treating patients with signs of liver injury are advised to ask about supplement use and report any potential cases to local authorities and to the FDA's MedWatch program (http://1usa.gov/gk6jeU). ■

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Are Camels the Coronavirus Culprit?

Dromedary camels may be the source of human infections with a new coronavirus responsible for at least 94 confirmed cases and 46 deaths.

After some patients recalled having contact with livestock, researchers gathered blood samples from cattle, sheep, goats, and dromedary camels from several countries to test for antibodies to Middle East respiratory syndrome coronavirus (MERS-CoV). Of the 160 cattle, sheep, and goats tested, none had the antibodies. However, all 50 dromedaries in Oman and 15 of 150 dromedaries in Spain did have MERS-CoV antibodies.
http://jama.md/1h2293N

Little Support for Treating Sex Abusers

Evidence from studies evaluating the effectiveness of interventions intended to prevent sexual predators from abusing children is weak, according to a recent study.

Researchers analyzed findings from 8 studies that examined various interventions. Their analysis showed that evidence on the benefits and risks of cognitive behavioral treatment is inconclusive. No studies with minimal quality standards were found for pharmacological treatments or for interventions directed toward those who hadn't sexually abused children but were at a higher risk of doing so. One study found weak evidence that family and community-based therapy focused on environmental factors may keep adolescent sexual offenders from reoffending.
http://jama.md/136LyLj

Another Compounding Pharmacy Recall

Bacterial infections in 15 patients who received drug infusions made by a Texas compounding pharmacy prompted a nationwide recall of the company's products.

The US Food and Drug Administration (FDA) implicated infusions of calcium gluconate produced by Specialty Compounding, of Cedar Park, Texas. The patients' infections were caused by the bacterium *Rhodococcus equi,* which was present in cultures of drug samples. The company recalled all of its sterile products. Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research, said contaminated injectable drugs can result in life-threatening infections.
http://jama.md/11ZNulY

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