

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Shuren Introduces New Guidelines for Device Trials

FDA Device Chief Jeffrey Shuren has introduced new guidelines for FDA device reviewers to use in conducting evaluations of clinical trial designs. Under the new guidelines, reviewers will not approve device studies for “pivotal” product assessments if the experiment’s protocols are not likely to produce clear conclusions to guide the approvals. Shuren has stated that the new guidelines will protect patients from unnecessary risks during trials and will help to ensure that the approved trials produce meaningful results. Industry, however, has expressed concern that the new guidelines could create confusion surrounding the approval process and threaten the availability of capital. Industry is also questioning whether the agency has sufficient resources to implement the new guidelines successfully.

FDA Considering Criminal Penalties Against J&J Unit

The FDA’s principal deputy commissioner, Dr. Joshua M. Sharfstein, indicated at a House Committee [hearing](#) last week that [the agency is considering taking additional action](#) against Johnson & Johnson’s [McNeil Consumer Healthcare unit](#), including [potential criminal penalties](#). Another focus during the hearing was on the warning letter the FDA sent to Perrigo, a manufacturer of generic children’s medicines, for [manufacturing violations](#) which included [pieces of metal](#) found in ibuprofen tablets.

Dorgan May Introduce Reimportation Amendment in Food Safety Bill

Reports are indicating that Sen. Byron Dorgan, who has indicated that he intends to introduce an amendment to the food safety bill that would allow for the reimportation of drugs, is encountering opposition from Representative John Dingell, who has stated that he opposes the amendment.

Minnesota Lawmakers Urge FDA to Proceed Cautiously with 510(k) Reforms

Senator Amy Klobuchar and Representative Erik Paulsen sent a letter to FDA Commissioner Margaret Hamburg, stating that they are concerned that potential changes to the 510(k) process could negatively impact Minnesota’s medical device industry. The lawmakers noted their worry that reforms to the process could increase the time, cost, and risk associated with device approvals.

Some Calling for Uniform Regulation of Generic Test Kits

Stakeholders are calling for the FDA to release a guidance clarifying its stance on diagnostic tests, and to make clear whether the agency plans to establish the same standard for tests performed in laboratories and those sold for home use. The debate over the regulation of at-home genetic test kits has sparked the interest of the leadership of the House Energy and Commerce Committee, which last week sent letters to three genetic test makers asking them about their tests and storage practices.

White House Unveils New Form of Spending Veto

The Obama Administration has unveiled a new plan to cut discretionary spending from agency budgets under which the President would have the authority to make reductions to specific spending levels through a rescission package associated with a particular bill. Congress would then have 25 days to give the cuts an up or down vote. Although the line item veto was deemed unconstitutional in the 1990s, the Obama administration has indicated that this plan would not offend the Constitution, as Congress remains involved in the process.

Agency News

The FDA has indicated that the supply of Thyrogen will be [temporarily limited](#).

In a recent letter to the FDA, Senator Harkin asked whether the agency needs additional authority to allow it to compel companies to initiate recalls. The comment, coming at the heels of a similar request by Rep. Rosa DeLauro for information on the agency's recall authority has some in the industry wondering whether the issue may reappear during next year's user fee reauthorization. The FDA, though stopping short of directly requesting mandatory recall authority at a recent House hearing, pointed to the pending food safety bill, which does give the agency mandatory recall authority, as instructive on drug issues.

A coalition consisting of stakeholders interested in creating policies to govern the FDA's approval process for mobile health products has been formed in response to FDA device chief Jeffery Shuren's plea to industry to help the agency draft guidance documents on particular issues. The coalition will focus on creating a guidance for FDA policies for cellular phone applications and devices that incorporate broadband transfers.

The Federal Trade Commission has again delayed enforcement of its 'red flags' rule, extending it through Dec. 31, 2010. Reports are indicating that Congress is considering legislation that would exempt physician, attorney, and accounting offices with fewer than 20 employees from having to comply with the regulation's requirements.

Republicans have indicated that they [intend to push back](#) against President Obama's nomination of Dr. Donald Berwick as CMS administrator.

At a recent FDA workshop to discuss the agency's Infusion Pump Improvement Initiative, stakeholders noted that, while enacting stricter pre-market requirements on external infusion pumps could lead to fewer recalls, it also stands to significantly slow market entry for safer pump designs.

CDRH has stated that, as part of its pilot program for home-use devices, it will request that manufacturers and distributors of devices cleared for home use voluntarily submit their labeling for posting on an online portal.

Publications

The FDA has published its [list of Premarket Approvals](#) (PMA), Product Development Protocols (PDP), Supplement and Notice Decisions for April 2010.

The FDA has [updated](#) its online listing of information for healthcare professionals and the public about the safe use of approved pancreatic enzyme products.

An article in *USA Today* reported that the FDA has issued at least 43 [warnings to drug manufacturers](#) in recent months for failure to correct manufacturing practices.

The American Society of Nuclear Cardiology has issued recommendations on measures to help reduce patients' exposure to radiation from myocardial perfusion imaging procedures, including verifying that the tests are appropriate and necessary prior to conducting them.

Scientia Advisors has published a report predicting that as much as 30 per cent of biologics production will be outsourced by 2013.

CMS has published a revised final guidance requiring drug manufacturers to sign gap discount agreements by next year, rather than by 2012, as stated in a previous guidance.

Approvals

The FDA has [approved](#) Lumizyme for patients ages 8 years and older with late-onset Pompe disease.

The FDA has [approved](#) Prolia for [the prevention](#) of fractures in [postmenopausal women](#). The drug has also received approval from the European Commission.

The FDA's Endocrinologic and Metabolic Drugs Advisory Committee recommended the approval of Theratechnologies Inc.'s tesamorelin to treat HIV-associated lipodystrophy.

The FDA has granted priority-review designation to Eisai's breast cancer treatment eribulin.

The FDA has granted clearance for CoaguSense's in-home monitoring device.

Recalls, Warnings, and Notifications

The FDA is notifying healthcare professionals and patients about [revised labeling](#) for Xenical that includes new safety information about cases of severe liver injury that have been reported in association with the use of the medication.

The FDA is notifying consumers and health care professionals about a [possible increased risk of fractures](#) of the hip, wrist, and spine with high doses or long-term use of proton pump inhibitors. The agency has indicated that the product labeling for these medications will be revised to describe this potential increased risk.

Baxter International Inc. has announced that it is [voluntarily recalling](#) all manufactured lots of Hylenex recombinant as a precaution due to instances of particulate matter observed in a limited number of vials during routine stability testing.

The FDA and Ortho-McNeil-Janssen are notifying healthcare professionals of [changes to the Warnings section](#) of the prescribing information for tramadol. The strengthened Warnings information emphasizes the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warns of the risk of overdose.

Blacksmith Brands and FDA are [notifying healthcare professionals](#) and patients about a [nationwide recall](#) of all lots of four PediaCare children's products.

The FDA has [notified healthcare professionals not to use](#) the intravenous medications, metronidazole, ciprofloxacin and ondansetron manufactured by Claris Lifesciences due to contamination.

The FDA issued a warning letter to Advanced Sterilization Products, a part of J&J's Ethicon, Inc. unit, citing the company's failure to correct and upgrade procedures.

The FDA has indicated that it is questioning the safety of AstraZeneca's lung drug for infants, which the agency says causes more skin reactions than a drug already approved.

The FDA has issued a warning letter to DexCom, a maker of glucose-monitoring devices, concerning the company's failure to report fractures in its monitoring wires.

The FDA has issued a warning [letter](#) to St. Jude Medical for off-label promotion of its Epicor LP cardiac ablation system and the Epicor UltraCinch LP ablation device.

International News

The *Financial Times* is reporting that European countries are indicating that they may impose additional price reductions on certain drugs, following cuts recently imposed by Greece. Thus far, Spain and Italy have agreed to such reductions, and there are indications that Germany, Italy, and France may impose similar controls.

The European Medicines Agency has published a [reflection paper](#) on the ethical and practical aspects of conducting third country clinical trials, including the need for communication and cooperation among regulators.

The European Commission has issued an updated guidance on radiation safety, which is broader in scope than the FDA's recent initiative on the subject. In addition to the technologies covered by the FDA's initiative, the EC's guidance encompasses general radiography, mammography, dental radiography and dual-energy x-ray absorptiometry equipment. Comments on the guidance are due June 30.

The European Commission has mandated the use of the device databank Eudamed.

Business News

Beehive Botanicals, Inc. has entered into a [Consent Decree](#) of condemnation and injunction, and has agreed to forfeit certain bee-derived products and components to the United States.

Teva has announced that it will [cease producing its sedative propofol](#), saying that the drug is difficult to manufacture and brings limited, if any, profits to the company.

The National Vaccine Information Center is urging the FDA to strengthen its vaccine safety testing and labeling requirements and implement regulations on adventitious agent contamination. The group also urged the agency to recommend that health care professionals suspend the use of RotaTeq until the vaccine's manufacturer can guarantee it is free of porcine circovirus types 1 and 2.

Genzyme Corp. is filing suit against Watson Pharmaceuticals Inc. over its plans to manufacture a generic version of Genzyme's drug Renvela.

Senators Tom Coburn of Oklahoma and Richard M. Burr of North Carolina have introduced legislation providing \$126 million to the AIDS Drug Assistance Program (ADAP) to give low-income individuals greater access to AIDS treatments.

A [report in Time](#) magazine questions whether imposing fines on companies for violations associated with the marketing of their drugs discourages those companies from engaging in similar conduct in the future. Some view the fines as being a cost of doing business to the drug companies, which then roll those costs into the prices that consumers pay for the drugs.

Pfizer has reported that it has sold its H1N1 vaccine business to a subsidiary of Harbin Pharmaceutical Group Co.

AstraZeneca stated that it received [response letters](#) from the FDA regarding its new drug Axanum and for its proposed expanded use for its drug Nexium.

Bayer has indicated that it will file a lawsuit against Teva Pharmaceutical Industries Ltd. for patent infringement related to Teva's launch of a generic version of Bayer's drug Yaz.

Applications for the final phase of a grant program to educate physicians on drug marketing are due June 3. The program, which was formed as part of the Neurontin settlement, is designed to educate young physicians on how the drug industry promotes its products, and particularly on issues like comparative effectiveness, with the hopes that it will result in increased evidence-based prescribing.

Cornell University and Life Technologies Corp. has indicated that they are [filing suit](#) against Illumina Inc. for patent infringement of DNA research products.

Covidien has announced that it plans to acquire ev3 for approximately \$2.6 billion in an effort to expand its vascular device offerings.

A federal court in Pennsylvania has found that federal law does not preempt generic-drug makers from modifying their labels and that Impax Laboratories and Teva Pharmaceuticals could be held responsible for injuries patients suffered after taking generic versions of the drug Wellbutrin XL.

A federal appeals court has upheld the validity Daiichi Sankyo and Ortho-McNeil Pharmaceutical's patent on antibiotic Levaquin.

Roche and Biogen Idec has announced that they are ceasing development of the potential rheumatoid arthritis treatment ocrelizumab following deaths in clinical trials and a disappointing risk-benefit assessment.

The FDA sent a complete response letter to Forest Laboratories for its NDA for Daxas.

Regulatory Notices

FDA Announces MOU with Drugs.Com

The FDA has announced that it has entered into a memorandum of understanding (MOU) with Drugs.Com. The purpose of the MOU is to extend the reach of FDA Consumer Health Information and to provide consumers with better information and timely content concerning public health and safety topics, including alerts of emerging safety issues and product recalls. More information is available at <http://edocket.access.gpo.gov/2010/2010-12638.htm>.

HRSA Seeks Nominations for Members of National Vaccine Advisory Committee

The Health Resources and Services Administration (HRSA) has announced that it is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV advises the Secretary of Health and Human Services on issues related to implementation of the National Vaccine Injury Compensation Program. Nominations are due by July 2, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-13150.htm>.

Public Meetings

FDA to Hold 13th Annual Educational Conference

The FDA is announcing the 13th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and District Offices, as well as other industry experts. The conference will be held on June 16 and 17, 2010, from 7:30 a.m. to 5 p.m. in Irvine, California. More information is available at <http://edocket.access.gpo.gov/2010/2010-12615.htm>.

FDA to Host Public Workshop on Unmet Health Needs, Innovation

The FDA will host a public workshop entitled "Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development." The purpose of the workshop is to obtain public input on the most important unmet public health needs and the barriers to the development of medical devices that can cure, significantly improve, or prevent these illnesses and injuries. The workshop will be held on June 24, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. Registration is required by June 10, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-12588.htm>.

Oncologic Drugs Advisory Committee to Meet

The FDA has announced that the Oncologic Drugs Advisory Committee will meet on July 20, 2010, from 8 a.m. to 3 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-12870.htm>.

Cardiovascular and Renal Drugs Advisory Committee to Meet

The FDA has announced that the Cardiovascular and Renal Drugs Advisory Committee will meet on July 28, 2010, from 8 a.m. to 5 p.m. in Adelphi, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13141.htm>.

More Information

Archived issues of the Bryan Cave Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin and other FDA news bulletins are available at www.bryancave.com on the [FDA Practice Bulletins web page](#).

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