

To: Our Clients and Friends

March 2, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

FDA May Ask for Rescission Authority for 510(k) Clearances

CDRH Director Jeffrey Shuren has stated that, as the agency considers proposed changes to the 510(k) process, it may request additional authority from lawmakers, including 510(k) rescission authority. The agency has said that it is challenged by a lack of robust ability to rescind device clearances. Industry officials argue that any new powers should be limited and restrained, while patient advocates praise rescission authority as an important step towards strengthening the safety of devices cleared through the 510(k) process.

After Summit, Focus Still on Health Reform

Although last week's health care summit made clear that the divide between Republicans and Democrats on health reform continues to exist, Democrats and the Administration have made clear their intention to continue to work to pass a health reform bill this year. Some have estimated that passage may occur by the end of March. The President is expected to announce a way forward on the bill this week; it has been reported that the President is expected on Wednesday to call for Congress to pass healthcare reform bill through the Senate's reconciliation process. However, reports are also indicating that it remains unclear whether House Democrats can muster the votes needed. The proposed reform package put forth by the President includes a provisions that would require device manufacturers to pay a point-of-sale excise tax designed to net \$20 billion for the government by 2019. The tax would start in 2013. The proposal does not specify a tax rate.

Stakeholders Call For More Authority for Post-Market Surveillance

The recent report by the Senate Finance Committee on safety issues associated with the drug Avandia is refueling the call by lawmakers and consumer advocates for greater authority and more independence for officials in the agency's Office of Surveillance and Epidemiology. Sen. Charles Grassley, the ranking Republican on the Finance Committee, has stated that he supports greater independence and authority for post-market surveillance, and he has hinted at possible plans to renew his push for legislation to overhaul the agency's post-market surveillance process.

Devicemakers Worried About Bayh's Retirement

Devicemakers with facilities in Indiana, including Boston Scientific, DePuy Orthopaedics, Medtronic and Zimmer, have expressed concern about losing support in the Senate following Sen. Evan Bayh's retirement at the end of this year. In announcing his decision to step down, Bayh touted his advocacy for device companies as a major accomplishment; the industry employs more than 45,000 in the state.

FDA, European Medicines Agency Announce New Process for Single Orphan Drug Designation Report

The FDA and the European Medicines Agency have announced that they have agreed to [a more streamlined process](#) to help regulators better identify and share information throughout the development process of orphan drug and biologic products. Both agencies have agreed to accept the submission of a single annual report from sponsors of orphan drug and biologic products designated by both the United States and the European Union.

Panel Calls for More Oversight on Radiation

A panel of witnesses, including representatives of professional groups in medical radiation, told a House subcommittee during a hearing Friday that more needs to be done to make sure that radiation helps but does not harm patients. The panel called for more comprehensive [oversight](#) of both diagnostic and therapeutic radiation. CT manufacturers, including GE Healthcare, Siemens, Philips, Toshiba and Hitachi, have announced that, over the course of the next year, they will include automated alerts and warnings into newly released CT machines and as part of software updates released for already installed products.

Patent Reform Bill May Reduce 'Inequitable Conduct' Litigation

Senate Judiciary Committee Chairman Patrick Leahy announced on Feb. 25 that he and Ranking Minority Member Jeff Sessions have reached a tentative agreement on a patent reform bill. Under the proposed bill, patent holders could request a "supplemental examination" of a patent if new information arises after the initial examination. The patent office would have three months to determine if the information is relevant. The director would order a reexamination if a substantial new question of patentability is raised by one or more items of information. Another party would then not be able to use this information in subsequent litigation to allege misconduct by the patent holder.

FTC Loses "Pay-for-Delay" Case

A federal judge in Georgia dismissed the FTC's challenge to a settlement over generic AdroGel, citing a higher court's ruling that payments to a would-be generic competitor do not necessarily violate antitrust law, and finding that the settlement was no more anti-competitive than the patent itself.

Pharmacies Calling for Restrictions on Vaccines to be Lifted

Drugstores, including Walgreen Co. and CVS/Caremark Corp. are lobbying for the permanent removal of state restrictions on who may administer vaccine shots, including the seasonal flu shot.

Criminal information Filed Against Guidant for Defibrillators

The US Department of Justice has stated that medical device manufacturer Guidant LLC, a wholly-owned subsidiary of Boston Scientific Corporation, has been [charged with criminal violations](#) of the Federal Food, Drug, and Cosmetic Act related to safety problems with some of its implantable defibrillators. The Justice Department filed the criminal information in connection with an agreement with Guidant to resolve the charges. A formal guilty plea agreement is expected to be filed with the court at a later date. Boston Scientific previously announced in a November 2009 press release that the company would pay \$296 million on behalf of Guidant in connection with these charges.

FDA Announces New Position

The FDA has announced that it has created a [new position](#) of Associate Director for Rare Diseases in the Agency's Center for Drug Evaluation and Research's Office of New Drugs. Dr. Anne Pariser has been selected as the new Acting Associate Director for Rare Diseases. The agency has stated that it will move quickly to fill the position permanently.

FDA Appoints Two to Tobacco Panel

Reports are stating that the FDA has selected Jack Henningfield, VP for research and health policy at Pinney Associates, which works on behalf of GlaxoSmithKline, and Neal L. Benowitz, a UC San Francisco professor who has consulted for GlaxoSmithKline and Pfizer, to a panel responsible for regulating the tobacco industry.

Office of Device Evaluation Director to Step Down

Office of Device Evaluation Director Donna-Bea Tillman has announced that she will step down March 26 to become the director of Regulations and Policy for Microsoft's Health Solutions Group.

China Health Reform Spending Benefits Device Manufacturers

The \$125 billion in [spending by the Chinese government](#) to start a national health insurance system is benefiting manufacturers of medical devices, including makers of imaging and diagnostic equipment. \$41 billion of this amount is being spent to build 31,000 hospitals and equip them with diagnostic and imaging equipment.

EDQM Announces Updates to CEP Process

The European Directorate for Quality of Medicines & HealthCare has announced that drugmakers seeking to amend or renew a Certification of suitability of European Pharmacopoeia monographs (CEPs) soon will be able to group amendments to multiple CEPs into a single application, a part of several changes that the directorate is adopting.

Publications

The FDA has published a [draft guidance](#) entitled "Non-Inferiority Clinical Trials."

The FDA has published a [draft guidance](#) entitled "Adaptive Design Clinical Trials for Drugs and Biologics."

The FDA has published a [guidance](#) entitled "Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes."

The FDA has [added recommendations](#) to its listing of "Individual Product Bioequivalence Recommendations."

GAO has released a report finding that specialty pharmaceuticals drive up both Medicare and out-of-pocket costs for senior citizens, and that specialty drugs account for most of seniors' out-of-pocket drug costs.

The Association for the Treatment of Tobacco Use and Dependence and the Society for Research on Nicotine and Tobacco have filed a joint petition asking the FDA to take a more flexible regulatory approach to nicotine replacement therapy products by expanding indications, availability, and access.

Hong Kong's Medical Device Control Office has published a guidance stating that devicemakers seeking approval for a product in Hong Kong should justify placing it into a particular risk class.

A recent analysis report found that statins taken to lower cholesterol may increase patients' risk of developing diabetes by 9 percent. The findings may lead the FDA to informally request manufacturers of such products to undertake additional studies on the potential diabetes risk.

Drug firms with a major stake in neurologic and psychiatric drug development are monitoring the psychiatric profession as it revamps its Diagnostic and Statistical Manual of Mental Disorders for changes that could present new opportunities for

the industry. Any changes would not affect new psychiatric drug applications and expanded use applications sent to the FDA until at least 2013.

Approvals

The FDA has [approved](#) velaglucerase alfa for injection (VPRIV) to treat children and adults with a form of the rare genetic disorder Gaucher disease.

An FDA panel has recommended approval [belatacept](#) for kidney-transplant patients.

Ariad Pharmaceuticals, Inc. has announced that US and European regulators have given 'orphan drug' status for its candidate drug intended to treat certain forms of leukemia.

European regulators have granted CE Mark approval to NovoStent for its stent delivery device used for treating peripheral artery disease.

Lupin Pharmaceuticals has stated that it has received an official communication from the FDA acknowledging that the company has resolved an earlier warning letter to its Mandideep, India, facility. The UK Medicines and Healthcare products Regulatory Agency and the Australian Therapeutic Goods Administration also conducted a recent joint inspection of the Mandideep facility and found it acceptable, according to the company.

Recalls, Warnings, and Notifications

The FDA is notifying healthcare professionals of a [Class I recall](#) of the StatSpin Express 4 Centrifuges, Model #510, Serial Numbers 00100 through 001679, manufactured and distributed from November, 2007 through January, 2010.

LifeScan and the FDA are notifying healthcare professionals of a [voluntary recall](#) of eight lots of OneTouch SureStep Test Strips, used by people with diabetes to measure their blood glucose levels at home. The test strips are being recalled because they may provide falsely low glucose results when the glucose level is higher than 400 mg/dL.

The FDA has issued a [warning letter](#) to Eli Lilly citing significant deviation from cGMP at its API production facility in Puerto Rico.

The FDA has issued a Form 483 to OMT for GMP violations, including failure to conduct internal audits.

Business News

Cell Therapeutics has announced that the FDA's meeting to review the company's cancer drug has been rescheduled for March 22.

Bidel Inc. has stated that the FDA will review its diabetes drug candidate VIAject, and that the company expects that the agency will make a decision on the drug on Oct. 30.

A county in northern California has filed suit against GlaxoSmithKline accusing the pharmaceutical company of suppressing evidence that its diabetes drug Avandia causes increased risk of heart attacks.

The American Civil Liberties Union is leading a [lawsuit](#) against Myriad Genetics, in which it alleging that the company's patents on isolated BRCA sequences impede research.

Merck of Germany has announced that it has agreed to buy Millipore, an American provider of purifiers and filters for biotechnology laboratories, for about \$7.2 billion.

Generic drug maker Actavis has indicated that it will ask the U.S. Supreme Court to hear an appeal on decisions by the 5th and 8th U.S. Circuit Courts of Appeals that federal preemption does not apply to generic drug makers and they, like brand-name manufacturers, are responsible for their labels.

The Department of Justice has announced that nursing home chains Mariner Health Care Inc. and SavaSeniorCare Administrative Services LLC have agreed to pay [\\$14 million](#) to settle allegations kickbacks from a supplier of drugs to nursing home patients.

Stratophase has announced that it is leading a £1.2m (\$1.8m) consortium, which also includes GlaxoSmithKline, Green Biologics, and The Centre for Process Innovation, focused on meeting the Quality by Design needs of manufacturers of active pharmaceutical ingredients. The consortium is developing Stratophase's SpectroSens technology.

CDRH has indicated that it will consider novel drug-eluting stent trial designs that maximize the strengths of U.S. and Japanese approaches.

Regulatory Notices

FDA Seeks Comments on Proposed Information Collections

The FDA is seeking public comment on the information collection requirements relating to FDA regulations for human tissue intended for transplantation. In addition, the FDA is seeking comments on pretesting of tobacco communications. Comments are due by April 30, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-4066.htm>.

FDA Publishes Notice of Determination

The FDA has determined the regulatory review period for FIRMAGON and is publishing a notice of that determination. The FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product. Anyone with knowledge that any of the dates as published in the determination are incorrect may submit to the Division of Dockets Management written or electronic comments and ask for a redetermination by April 30, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 30, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-4159.htm>.

FDA Publishes Draft Guidance on Non-Inferiority Clinical Trials

The FDA is announcing the availability of a draft guidance for industry entitled "Non-Inferiority Clinical Trials." This draft guidance provides sponsors and review staff in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) with the agency's interpretation of the underlying principles involved in the use of non-inferiority (NI) study designs to provide evidence of the effectiveness of a drug or therapeutic biologic product. Although the FDA will accept written comments on the guidance at any time, comments must be submitted by June 1, 2010, to ensure their consideration before the agency begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2010/2010-4109.htm>.

FDA Announces Revision to Advisory Committee Information Hotline

The FDA is announcing that it has revised the Advisory Committee Information Hotline. The hotline can be accessed by dialing 1-800-741-8138 or 301-443-0572. The advisory committee meeting information and information updates can also be accessed via FDA's Advisory Committee Internet site at <http://www.fda.gov/AdvisoryCommittees/default.htm>. More information is available at <http://edocket.access.gpo.gov/2010/2010-4258.htm>.

Public Meetings

FDA Announces Meeting of Oncologic Drugs Advisory Committee

The FDA has announced that the Oncologic Drugs Advisory Committee will meet on March 22, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. The committee is scheduled to review pixantrone at the meeting. More information is available at <http://edocket.access.gpo.gov/2010/2010-4261.htm>.

FDA Announces Meeting of Orthopaedic and Rehabilitation Devices Panel

The FDA is announcing that the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee will meet on March 23, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-4260.htm>.

FDA Announces Meeting of Pulmonary-Allergy Drugs Advisory Committee

The FDA is announcing that the Pulmonary-Allergy Drugs Advisory Committee will meet on April 7, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-4262.htm>.

FDA Announces Meeting of Tobacco Products Scientific Advisory Committee

The FDA is announcing that the Tobacco Products Scientific Advisory Committee will meet on March 30 and 31, 2010, from 8:30 a.m. to 5 p.m. in Washington, D.C. More information is available at <http://edocket.access.gpo.gov/2010/2010-4195.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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