

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Stakeholders Meet to Discuss 510(k) Clearance

At the meeting convened by the FDA on February 9 for stakeholders from across the medical device industry, industry representatives and consumer groups called for transparency and notification regarding adverse events associated with legacy devices. The FDA has stated that it will be modifying the 510(k) clearance process, and has indicated that it is considering whether the FDA should refrain from approving certain medical devices after new, safer, and more effective technologies emerge. Some are questioning whether it is appropriate for the FDA to compare the effectiveness of new devices to the status quo as part of its pre-market reviews. The FDA has indicated that it plans to issue draft recommendations for public comment in May and begin instituting the new policies by September, but CDRH Post Market Operations Associate Director Jonathan Sackner-Bernstein has indicated that he prefers not to wait for formal guidance on the issue before implementing changes to device approval and clearance processes when incorporating new science. Senator Grassley sent a letter to the FDA asking for an immediate update on plans for guidelines for new medical devices.

White House to Hold Health Care Summit Next Week

The White House is scheduled to hold a health care summit for Democrat and Republican leaders next week. The summit is scheduled to begin at 10 AM on February 25 and will be televised live. Minnesota Governor Tim Pawlenty is urging the President to allow governors to participate in the summit. White House Chief of Staff Rahm Emanuel has stated that the White House will post online the text of a proposed health-insurance reform package prior to the summit. HHS Secretary Kathleen Sebelius has stated that the President plans to use the already-passed House and Senate bills as a starting point.

However, some worry that the recent resignation of PhRMA head Billy Tauzin may present an additional complication for Democrats as they work to pass health reform. In addition, a recent Zogby International Poll has found that 57 percent of Americans support scrapping the current health care bills and starting the process again.

Court of Appeals Agrees to Delay E-Cigarette Decision

A federal court of appeals has agreed to stay the decision of the U.S. District Court for the District of Columbia that lifted FDA restrictions on e-cigarettes. The court ruled last month that the FDA misused its authority when it classified e-cigarettes as a drug-device combination and placed the products under an import alert.

FDA Radiation Initiative May Require Legislation, Discussion with CMS

Sources are saying that the FDA's new initiative to reduce unnecessary radiation exposure from three types of medical imaging procedures could require legislation and involve discussions with CMS and that the move to cut radiation exposure may fuel CMS' ongoing interest in reducing imaging use. The FDA's new initiative, revealed in a recent white paper, consists of three prongs: promoting safe use, informing clinical decisions and increasing patient awareness.

Office of Pediatrics Outlines Future Projects

The FDA's Office of Pediatric Therapeutics has stated that it plans to develop by 2012 a manual to guide agency staff on the use of extrapolation when assessing pediatric products and their development programs. Other projects planned include a pilot program to collect post-market data on the safety of drugs used in children, an examination of the pharmacological and therapeutic use of midazolam to treat seizures associated with nerve gas exposure and development of a strategy for the drug's use in pediatric patients, and analyses of failed clinical trials for treating migraines in adolescents and for pediatric trials for conditions including diabetes.

Tavener Appointed

Marilyn Tavener has been appointed to the position of principal deputy administrator of CMS.

Budget Request for AHRQ Indicates Increased CER Emphasis

Some are pointing to the Agency for Healthcare Research and Quality's \$286.3 million budget request for comparative effectiveness research as a signal that the Administration is targeting the Agency as the leader for such research, particularly in the absence of a health care bill with CER provisions. The AHRQ budget request for 2011 includes additional funds for AHRQ identification of new and emerging issues for patient-centered health research, evidence synthesis, evidence gap identification, evidence generation, translation and dissemination, training and career development, and a citizen's forum.

Drug Companies May Have to Wait Longer for REMS Final Guidance

It is being reported that the final guidance on risk evaluation and mitigation strategies (REMS) may be delayed, as the CDER staff developing the recommendations must also review all proposed REMS from drugmakers.

Companies Comment on Proposed Combination Products Rule

Manufacturers of combination products, including Johnson & Johnson, have submitted comments on the FDA's proposed rule on good manufacturing practices (GMPs) for combination products, saying that the rule needs more guidance and should better address legacy products.

Stakeholders Want Clarity on Assay Development Guidance

Stakeholders in the biotech industry are calling for increased clarity and defined limits from the FDA regarding its recent draft guidance on assay development for immunogenicity testing of therapeutic proteins. However, firms are also calling for strict testing requirements for follow-on biologics.

Device Issues in EU Transferred to Directorate-General for Health and Consumers

As part of a recent reorganization of the European Commission, EU device issues have been transferred to the Directorate-General for Health and Consumers and will be overseen by John Dalli, the newly approved commissioner for Health and Consumer Policy.

Publications

The FDA has published a guidance embracing the Bayesian statistical method to bolster use of available data in device clinical trials. The method allows manufacturers to shorten clinical trials by factoring prior information into clinical trial assessments.

The FDA has republished the [reorganization of the Office of the Commissioner](#) due to several errors in the originally published version.

The FDA has published a listing of drugs under safety investigation by the FDA, which includes Novartis' cancer drug Gleevec, Roche Holding's flu drug Tamiflu, and Biogen Idec and Elan's multiple sclerosis drug Tysabri.

The "Cracking Counterfeit Europe" study sponsored by Pfizer has found that Germans and Italians are the largest consumers of counterfeit drugs in Europe, where approximately \$10.5 billion of counterfeit drugs are sold annually.

The European Fine Chemicals Group has stated that it welcomes the addition of excipient GMP requirements to the draft amendments to the EU falsified medicines directive, but it warned that deeper analysis may be needed to establish which products warrant further regulation.

Device trade group AdvaMed has presented to the FDA a list containing 30 lower-risk diagnostic tests that it argues should be exempt from pre-market review. The group also presented an additional 25 tests that could potentially be exempt with adequate laboratory practices.

The European Commission has published a report finding that one of the greatest challenges facing the European device industry is the length of time needed for marketing approval. The report suggests that the Commission improve the harmonization of best practices and guidelines between EU member states.

The European Medicines Agency has released a simplified version of its guideline on bioequivalence focusing on quality issues.

The FDA has published a final rule, which took effect this year, that requires drug manufacturers having authorized generic drugs to submit certain information on them in their annual reports to the FDA.

Approvals

The FDA has approved a [risk management program](#) to inform healthcare providers and their patients about the risks of a class of drugs called [Erythropoiesis-Stimulating Agents](#) (ESAs).

The FDA and Anthera Pharmaceuticals have agreed on a special protocol assessment (SPA) for a Phase III trial of the company's acute coronary syndrome candidate varespladib.

CMS has approved the American College of Radiologists, the Intersocietal Accreditation Commission, and the Joint Commission as accrediting bodies for facilities that operate advanced imaging equipment. The choice surprised some at the American College of Radiologists and the Intersocietal Accreditation Commission, who stated that the Joint Commission lacks the background necessary to serve as an accrediting facility.

U.K.'s health-cost agency is [recommending](#) that Novo Nordisk A/S's diabetes drug Victoza be given to British patients in combination with two other medications.

Recalls, Warnings, and Notifications

Health Canada has issued a warning to consumers regarding “rare but potentially deadly skin reactions” that have been reported related to the use of Accutane.

United States Attorney Karen P. Hewitt announced that James Folsom was sentenced to serve 51 months in custody and a \$250,000 fine following his conviction on twenty-six felony counts relating to the sale of [unapproved medical devices](#) and the commission of offenses while on pretrial release.

The FDA has issued a warning letter to Cardiac Science following an inspection finding that the company did not meet requirements on correcting and preventing problems with its automated external defibrillators.

The FDA has issued a warning letter to Cayman Chemical for sponsoring and investigating a clinical trial of an eyelash-growth enhancement drug without filing an investigational new drug (IND) application or getting institutional review board approval, as well as for informed consent failures.

U.K.'s health cost agency has rejected the use by the National Health Service of Bristol-Myers Squibb's Sprycel and Novartis' Tasigna in chronic myeloid leukemia patients who are intolerant to Glivec.

Business News

The UK Telegraph is reporting that the Royal Pharmaceutical Society (RPSBG) is calling for urgent action in response to wholesalers exporting drugs abroad for higher profits, a move that is making it more difficult for pharmacies to acquire certain drugs.

A UK appeals court has revoked a Human Genome Sciences (HGS) patent for a gene because it was not accompanied by an industrial application.

The Arkansas Attorney General has announced that Eli Lilly & Co. has agreed to an \$18.5 million settlement in a lawsuit against the company over the off-label marketing of its drug Zyprexa.

Sanofi-Aventis has announced that it formed a research partnership with France's National Alliance for Life Sciences and Healthcare to boost research in areas including as aging, infectious diseases, and regenerative medicine.

Roche has announced that it is collaborating with Merck & Co. to develop a potential cancer test that could be used to more accurately target therapies.

Coviden has announced that it has reached an [agreement](#) with Poland's Institute of Atomic Energy that will allow the company to continue to obtain the isotope used in many diagnostic procedures.

The US Patent and Trademark Office [partially rejected](#) Pfizer Inc.'s patent on its drug Viagra.

A jury in New Jersey has found Roche Holding AG liable to pay [\\$25.16 million in damages](#), after a former user of the drug Accutane claimed that it caused inflammatory bowel disease.

The New York Times is reporting that certain brand-name pharmaceutical companies are looking to offer generic medications in emerging markets like Eastern Europe, Asia and Latin America, where individuals cannot afford brand name drugs but are willing to pay a premium for [branded generic drugs](#) to ensure that they are not counterfeit.

The FDA has decided to [deny approval](#) of XenoPort's treatment for restless leg syndrome.

A Nevada judge has dismissed a lawsuit filed by the state's attorney general against major drug companies alleging that hormone treatments damaged the health of Nevada women.

Merck & Co has stated that it will cut manufacturing and R&D jobs by 15% in 2012, as the company aims to save \$3 billion.

Panelists at the Informex summit stated that Asian companies are becoming more established as ingredient suppliers and manufacturers, but the region still suffers from promises of unrealistic timelines and a poor supply chain.

Eleven Therapeutics has announced that it has completed a \$35 million Series A financing.

United for Medical Research, an advocacy group consisting of academic and industry groups, is calling for a long-range effort to end the boom or bust funding cycles experienced by the National Institutes of Health, and stating that maintaining a stable level of funding will create jobs and ensure NIH's continued buying power.

Research collaboration underway between the FDA and Northeastern University could help agency officials understand the mechanisms of action of follow-on biologics. Among the goals of the collaboration are to stimulate research and information exchange in biological product characterization and regulation and to develop training programs for the FDA.

ViroPharma, in its continued battles with the FDA over approval standards for generic oral vancomycin, has charged in a petition supplement that the Office of Generic Drugs' decision to change bioequivalence methods for the antibiotic included many irregularities and is seeking records relating to the FDA's decision to change its interpretation of regulations on bioequivalence for generics.

Regulatory Notices

FDA Seeks Comments on Proposed Information Collections

The FDA has announced an opportunity for public comment on several proposed collections of information. The agency is seeking comment on information collection requirements relating to [shipment of nonsterile devices](#) that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking. The agency is also seeking comments on a new exception from the [general requirements for informed consent](#) to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency also seeks comments on its [Guidance for Industry](#) on How to Submit a Protocol Without Data in Electronic Format to the Center for Veterinary Medicine. Comments are due by April 19, 2010.

In addition, the agency is seeking comments on [Antimicrobial Animal Drug Distribution Reports](#) and on its [Guidance](#) for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers. Comments are due by March 22, 2010.

FDA Seeks Comments on Proposed Data Falsification Rule

The FDA is proposing to amend its regulations to require sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor. Comments on the proposed rule are due by May 20, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-3123.htm>.

Public Meetings

FDA Announces Meeting of Circulatory System Devices Panel

The FDA has announced that the Circulatory System Devices Panel of the Medical Devices Advisory Committee will meet on March 18 and 19, 2010, from 8 a.m. to 6 p.m. in College Park, Maryland. The panel is scheduled to vote on FDA approval of expanded labeling for Boston Scientific's line of cardiac resynchronization therapy defibrillators (CRT-Ds) and on whether to allow Medtronic to market a pacemaker that can be safely used with magnetic resonance imaging machines. More information is available at <http://edocket.access.gpo.gov/2010/2010-3032.htm>.

FDA Announces Meeting of Pediatric Advisory Committee

The FDA has announced that the Pediatric Advisory Committee will meet on Monday, March 22, 2010, from 8 a.m. to 6 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-3024.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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