

To: Our Clients and Friends

May 13, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Lawmakers Announce Review of FDA Inspection, Oversight Procedures

Members of the House of Representatives have indicated that they plan to review the FDA's inspection procedures as part of a review of McNeil Consumer Healthcare's voluntary recall of more than 40 children's over-the-counter medicines. Last week, the House Oversight and Government Reform Committee announced that it was commencing an investigation on whether further regulatory action was needed. Senator Charles Grassley has also announced that he plans to introduce legislation that would increase the FDA's oversight of unapproved drugs.

Industry Encourages FDA to Use Quasi-Enforcement Actions Sparingly

Industry representatives are calling on the FDA to carefully evaluate its use of quasi-enforcement actions. Industry has warned that the agency has begun to use quasi-enforcement actions with more regularity, and that, because there is no set legal standard governing the use of such actions, they may lead to the release of confusing or misleading information to consumers.

FDA Launches "Bad Ad Program"

The FDA has announced that it has launched [a new program](#) designed to encourage health care providers to play a role in recognizing and reporting misleading drug advertising and promotion. Part of an outreach effort by the FDA's Division of Drug Marketing, Advertising, and Communications, the Program is set to be rolled out in three parts. Phase one will consist of interaction with health care providers at industry events and other educational efforts, with Phases 2 and 3 expanding this collaboration.

Industry Concerned that New Health Law Will Increase Whistleblower Suits

A provision in the new health law that allows whistleblowers to file claims based on information previously disclosed by a company, so long as the whistleblower has knowledge "materially" adding to the publicly disclosed allegations, has some in the industry concerned that the recent uptick in whistleblower suits could continue to grow.

FDA to Put Quality Management System in Place

CDER director Janet Woodcock has stated that the FDA is working to improve NDA and ANDA submissions and is also putting into place a quality management system. Woodcock stated that the current system, whereby generic drugmakers race to be the first to file applications, has led to lower quality submissions being made to the agency.

Danish Researchers Unveil Data on Country's Antibiotic Ban

Research unveiled at a briefing on Capitol Hill last week regarding Denmark's ban on the use of antibiotics in animals is spurring debate on the actual effects of such a ban on food safety and antibiotic resistance. While some are saying that data surrounding the ban demonstrates that the ban on antibiotics has lowered concerns about antibiotic resistance and made food safer, some say that no substantive conclusions can be drawn from the data. The issue has recently become a central concern of the international community, who fear that the increased use of antibiotics in animals is resulting in more drug-resistant bacteria.

Regulators, Industry Discuss Approaches to REMS

Regulators and members of industry from both sides of the Atlantic discussed the difficulties inherent in measuring the effectiveness of risk management programs for pharmaceuticals at a recent summit. Commenters indicated that regulators need better methodologies to evaluate the effectiveness of risk minimization plans, and that both regulators and industry need tools to determine whether the risk management programs themselves have had adverse consequences.

Publications

The Center for Digital Democracy has issued a letter to FDA Commissioner Margaret Hamburg encouraging the agency to act carefully as it develops rules governing the advertising of drugs and devices through social and online media.

A US Pharmacopeial Convention advisory panel committee has issued recommendations that prescription drug labels be standardized so that consumers can read and understand them more effectively. Among the recommendations include that critical information be printed in at least 12 point font, and that text be written and punctuated in concise, standard English.

The Tufts Center for the Study of Drug Development has published a report finding that the increase in complexity of clinical trials is leading to more difficulty for biopharmaceutical companies to realize time and cost savings and retain patients.

The International Federation of Pharmaceutical Manufacturers and Associations published 10 principles on which it would like the industry to focus as it combats counterfeit drugs. In its comments about the 10 principles, the group emphasized the need for a patient-centric focus, the recent increase in adverse events caused by counterfeit drugs, and the risks that counterfeits pose to the developing world.

Approvals

The FDA has approved upgrades made by Boston Scientific to its patient management system, which would allow doctors to remotely track patients who have heart devices.

The FDA has granted conditional approval for Japanese device maker Terumo to begin enrollment for a clinical trial in the U.S. of its Misago superficial femoral artery stent. The trial is part of a pilot program between the U.S. and Japan, in which the countries will work in tandem to review a Class III device.

Recalls, Warnings, and Notifications

The FDA has announced that it is [investigating new over-the-counter genetic tests](#) that [Pathway Genomics](#) plans to sell in drugstores. The FDA has said that the test is not approved by federal regulators, and that it is [worried that consumers](#) may misuse the results.

The FDA has issued a warning letter April 23 to St. Jude Medical, Inc. for unapproved claims made in the promotion of the company's Epicor line of surgical ablation devices.

A recent Form 483 indicates that Nycomed U.S. failed to conduct an adequate investigation of consumer complaints regarding storage of its products.

The FDA has issued a warning letter to Medibo for medical device reporting deficiencies, including failure to conduct complete adverse event investigations.

Agency News

The FDA has announced that its new supercomputer is set to come online this summer. The agency noted that the computer could shorten device approval times, prevent recalls, and reduce data requirements for certain devices.

The FDA has announced that the 513(g) user fee will increase this October to \$3,191 for large companies and \$1,595 for small businesses. In addition, the FDA has announced that it will not be issuing refunds. Comments on the user fees and on a draft [guidance](#) on submitting 513(g) requests are due July 28.

Office of New Drugs Director John Jenkins has announced that the FDA is developing a matrix to assist drug reviewers in determining whether a drug's benefits outweigh its risks. The matrix highlights the various factors that the agency will consider, with the severity of the condition being considered the most important.

Vaccine makers should prepare for increases in both cost and delays, as they will need to check their products for unwanted "adventitious" viruses and viral DNA using new technologies, according to statements at a recent FDA advisory panel meeting to discuss the discovery of DNA from porcine circovirus 1 in GlaxoSmithKline's vaccine Rotarix.

International News

Chinese heparin supplier Shenzhen Hepalink Pharmaceutical [rose 18.3 percent](#) in its first day of trading on the Shanghai stock exchange, according to an article in the *New York Times*.

Business News

Boston Scientific Corp. has stated that it received a civil investigative demand from the Justice Department, seeking information on advice the company gave regarding reimbursement for its implantable defibrillators.

Abbott Laboratories has announced that it will license [a minimum of 24 products](#) in emerging markets, in an effort to boost foreign sales.

Scancell Holdings PLC has indicated that it will sign a global licensing agreement with NIH for the use of melanoma antigens gp100 and TRP-2.

Canadian physician David Juurlick is joining with Public Citizen's Director in [calling for a halt](#) to a international trial of the drug Avandia against other drugs in the same class.

Boston Scientific barred the press from its annual shareholders' meeting.

Two [whistleblowers have settled claims](#) with AstraZeneca relating to the company's marketing of its schizophrenia drug Seroquel and will split the \$45 million settlement.

Merck & Co. has announced that it plans to seek approval from U.S. regulators for [five new medicines in 2010](#), which will include treatments for hepatitis C and diabetes.

Evotec AG has announced that it has entered into a drug discovery agreement with Roche Holding AG's Genentech.

Watson Pharmaceuticals Inc. has announced that it has settled a patent dispute with [Teva Pharmaceutical Industries Ltd.](#) over birth control drug Seasonale.

Teva Pharmaceutical Industries Ltd. and Baxter International Inc. have indicated that they [plan to appeal awards](#) against the companies totaling approximately \$500 million over the labeling of the drug propofol.

Pfizer has announced that it plans to [lay off approximately 1400](#) of its New York employees.

Merck & Co. has announced that it has [reached a settlement](#) with Glenmark Pharmaceuticals over cholesterol drug Zetia.

Reports are indicating that GlaxoSmithKline Plc has agreed to pay [approximately \\$60 million](#) to settle several lawsuits over its drug Avandia.

MAP Pharmaceuticals has announced that it plans to file for FDA approval of its migraine treatment Levadex in the first half of 2011.

Steris and the FDA have filed a consent decree in Ohio, under which the company could pay up to \$100 million in rebates to assist purchasers of the company's Steris System 1 in switching to legally marketed sterilizers. The decree must be approved by the court.

Penwest Pharmaceuticals and Endo Pharmaceuticals announced that they have settled a dispute over Barr Laboratories' ANDA for a generic form of Opana extended-release tablets.

C.R. Bard Inc. has announced that it will acquire SenoRx for \$200 million.

Baxter has indicated that it expects that the U.S. recall of its Colleague infusion pumps will result in an initial cost to the company of up to \$600 million.

Regulatory Notices

FDA Amends Animal Drug Regulations

The FDA has announced that it is amending the animal drug regulations to reflect approval of an abbreviated new animal drug applications filed by [Sparhawk Laboratories, Inc.](#), by [First Priority, Inc.](#) and by [Intervet, Inc.](#)

Public Meetings

FDA to Hold Public Meeting with NIH

The FDA is announcing a public meeting, in conjunction with the National Institutes of Health, to solicit comments from interested persons on how the agencies can more effectively collaborate to advance the translation of biomedical research discoveries into approved diagnostics and therapies as well as promote science to enhance the evaluation tools used for regulatory review. The meeting will be held on June 2, 2010, from 8:30 a.m. to 12:30 p.m. in Silver Spring, Maryland. Persons interested in attending must register by May 26, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-11008.htm>.

Dermatologic and Ophthalmic Drugs Advisory Committee to Meet

The FDA has announced that the Dermatologic and Ophthalmic Drugs Advisory Committee will meet on June 28, 2010, from 8 a.m. to 5 p.m. in Beltsville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-11039.htm>.

Pediatric Advisory Committee to Meet

The FDA has announced that the Pediatric Advisory Committee will meet on June 21, 2010, from 9 a.m. to 5 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-11038.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](#).

If you have any questions regarding any of these issues, please contact:

Mark Mansour	Partner	mark.mansour@bryancave.com	1 202 508 6019	Washington
Megan A. Gajewski	Associate	megan.gajewski@bryancave.com	1 202 508 6302	Washington
Patrice M. Hayden	Associate	pmhayden@bryancave.com	1 202 508 6147	Washington
Emily K. Strunk	Associate	emily.strunk@bryancave.com	1 202 508 6360	Washington

This bulletin is published for the clients and friends of Bryan Cave LLP. To stop this bulletin, please reply to this email. To stop this bulletin and all future commercial e-mail from Bryan Cave LLP, please reply to: opt-out@bryancave.com and leave the message blank. Information contained herein is not to be considered as legal advice. Under the ethics rules of certain bar associations, this bulletin may be construed as an advertisement or solicitation.