

To: Our Clients and Friends

April 2, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

FDA Faces Allegations of Retaliation

The FDA is finding itself under fire regarding allegations of retaliation and misconduct by FDA device center managers toward agency scientists and physicians who expressed concerns about a product. The issue was raised at a recent meeting, at which Julian Nichols, who formerly worked in the FDA's Reproductive, Abdominal and Radiological Devices review branch from October 2006 through October 2009, stated that he and some of his colleagues expressed concerns about patients receiving radiation from CT devices, which the agency later suppressed.

The Inspector General of HHS has issued a report stating that federal investigators have discovered no evidence of criminal wrongdoing against those scientists. Still, current and former device center scientists have earned support from individuals, including Rep. Chris Van Hollen (D-MD), who has written a series of letters to FDA demanding that the agency promptly resolve cases involving intimidation and marginalization.

Stakeholders Watching Issues that Could Affect Biosimilars

Although implementing a new approvals pathway for biosimilars will mostly fall to the FDA, stakeholders are also keeping tabs on several issues outside the agency's purview, including reimbursement policies, that could have a significant impact on the strength of the pathway and the market for biosimilars.

Stakeholders are also keeping tabs on whether, and the extent to which, the availability of biosimilars will put pressure on biologic drug manufacturers, which have not had to grapple with the same limited marketing exclusivity periods and patent cliffs for biologics that small molecule drugs have been subject to for two decades. The provisions in the health reform law granted 12 years of marketing exclusivity for innovator products. While the future impact of biosimilars on the industry is unknown, there is consensus among the industry in general that biosimilars will be a distant relation to their generic small molecule cousins, as the complexity of manufacturing and questions about requirements to demonstrate equivalent effectiveness and safety will likely to limit the number of players in the space and limit price erosion of brand drugs.

Administration Official Confirms Berwick Pick

An administration official has confirmed that the White House has picked Harvard professor and pediatrician Donald Berwick to serve as CMS Administrator.

Health Care Reform Law Requires Drugmaker Disclosure

Under the new healthcare reform law, drugmakers will be required to disclose any payment or other transfer of value made to a physician after Dec. 31, 2011. The law requires drugmakers to file an annual report to HHS by March 31, 2013, disclosing any payment or other transfer of value made to physicians during the previous calendar year.

Some Stakeholders Continue to Push for National Device Registry

Although a provision mandating the creation of a national medical device registry was not included in final health care reform legislation, some stakeholders are continuing to press for the creation of such a registry. Sources indicate that lawmakers will not likely take up the issue of such a registry in the near future.

Amphastar Documents Reveal Hiring of Investigator

Corporate documents of drug company Amphastar indicate that the company hired Kroll, a New York-based private investigative firm, to [uncover information](#) about director of the FDA's Center for Drug Evaluation and Research Janet Woodcock, and paid the firm more than \$100,000 for the investigation. In addition, the company investigated and created a file on Moheb Nasr, director of the FDA's Office of New Drug Quality Assessment. While the company has stated that all of its actions were legal, Senator Max Baucus has made clear his dismay over the company's actions.

In Aftermath of Gene Patent Ruling, Companies Assess Future

Executives and other stakeholders in the biotechnology companies are worrying about the long-term impact of a recent [ruling](#) by a US district judge in Manhattan that parts of patents held by Myriad Genetics covering BRCA1 and BRCA2 were invalid. Although the immediate impact of the ruling will be limited to the gene patents considered, and Myriad Genetics has stated that it plans to appeal the decision, the decision potentially could have [a far-reaching impact](#) on diagnostics companies that offer tests based on genes.

Publications

The FDA has published an [update](#) regarding its Transparency Initiative.

IMS Health has reported that [U.S. drug sales increased](#) 5.1 percent to \$300.3 billion in 2009, and that generics sales made up 75% of all prescriptions filled in 2009, compared to 57% in 2004. The report also found that the increase was led by growth in demand for antidepressants and cancer medicines.

The WHO has published a [guideline](#) for the production and control of specified starting materials.

The FDA has published a [draft guidance](#) on adaptive design in clinical trials.

The Bioanalytical Quality Standard Initiative is encouraging the FDA to adopt its guidance on quality system requirements (QSR) for bioequivalence and bioavailability testing during drug clinical trials.

iRAP has published research finding that the market for "nano-enabled" pharmaceutical packaging is growing 16.5 per cent a year and will be worth \$8.1bn by 2014.

Approvals

The FDA has [approved](#) Asclera injection for the treatment of varicose veins.

GlaxoSmithKline PLC has announced that it has received European approval for Duodart.

An FDA advisory panel has recommended approval with conditions for Medtronic's Revo MRI SureScan Pacing System.

Recalls, Warnings, and Notifications

The U.S. Food and Drug Administration (FDA) is [evaluating clinical trial data](#) that may suggest that patients taking Stalevo, a Parkinson's disease medication, may be at an [increased risk](#) for developing prostate cancer.

Business News

Medical device maker CryoLife Inc. has stated that it filed an emergency motion for a preliminary injunction to stop Medafor Inc. from ending their partnership.

The Wall Street Journal has reported that private-equity firm GTCR Golder Rauner LLC has announced that it is seeking to buy Johnson & Johnson's Ethicon Endo-Surgery Inc. division.

AstraZeneca PLC and Abbott Laboratories have announced that that the FDA has asked for more information about their Certriad cholesterol drug prior to approving it for sale.

Vivus Inc. has announced that it has ended its development and commercialization partnership with Acrux for a testosterone treatment for women.

Reports are indicating that Horizon Therapeutics Inc., a US developer of pain medications, [is close to an agreement](#) to buy Switzerland's Nitec Pharma AG.

Pfizer, as part of its agreement to settle a government probe into whether the company marketed certain drugs off-label, has [disclosed that it paid](#) about \$20 million to 4,500 doctors and other medical professionals for consulting and speaking on its behalf in the last six months of 2009, and that it also paid \$15.3 million to 250 academic medical centers and other research groups for clinical trials in the same period.

Pfizer Inc. has filed suit against Teva Pharmaceuticals Industries Ltd. in an effort to block the company from selling a generic copy of its Viagra drug in the US until 2019.

Allergan Inc. has announced that it will pay \$43 million to Serenity Pharmaceuticals Inc. for development and commercialization rights to a potential urological disorder treatment.

Sanofi-Aventis has announced that it has settled three patent infringement lawsuits in the US related to generic versions of its drug Eloxatin.

Drugmaker Eli Lilly and Co. has stated that a federal judge has upheld one of the patents protecting its cancer treatment Gemzar. The drug still faces another challenge in a separate court.

Teva Pharmaceutical Industries has announced that a Nevada district judge has found that its [patent](#) on the contraceptive Seasonique was valid.

Reports are indicating that Pfizer Inc. has agreed to pay about [\\$400,000](#) to settle a lawsuit alleging that its drug Neurontin helped cause a Massachusetts man's suicide.

The FDA has asked Protalix BioTherapeutics for additional product validation data for its Gaucher's disease drug taliglucerase alfa NDA.

A CDC official has stated that it will take time to determine how many doses of the H1N1 vaccine must be discarded if they expire before being administered.

Abbott Diagnostics has announced that it has filed an application with the FDA seeking clearance for a urine-based test that can spot neutrophil gelatinase-associated lipocalin, a biomarker for acute kidney injury.

In comments to the FDA's proposed [rule](#) on GMPs for combination products, Johnson & Johnson stated that it needs more guidance and the rule should better address legacy products.

A judge in the U.S. District Court for the Southern District of Ohio has ruled that three drugmakers accused of delaying the entry of a generic version of the blood-thinner Plavix did not violate antitrust laws.

The FDA has predicted that the I-SPY 2 clinical trial will save sponsors millions in development costs and usher in a wave of personalized medicine. The first phase of the trial will use genetic markers from patients' tumors to identify which of five cancer treatments they should receive.

Stryker has stated that it has resolved quality system issues at one of its reconstructive implant manufacturing facilities, settling the second of four warning letters issued to the company by the FDA in recent years.

Some are worried that new proposed changes to federal sentencing guidelines that would require companies to self-report engagement in criminal activity to the government and pay restitution to victims could lead to unintended consequences for FDA-regulated companies, and particularly small companies.

Mylan has settled two patent infringement lawsuits with Takeda Pharmaceuticals over diabetes drugs Actos and Actoplus Met.

Regulatory Notices

FDA Seeks Comments on Information Collection Requirements

The FDA is seeking comments on information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA-regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act (the act) as amended. Comments are due by June 1, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7111.htm>.

FDA Amends Regulations on Premarket Approval of Medical Devices

The FDA is amending the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. Comments on the information collection requirements are due June 1. The rule will take effect on August 16, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7193.htm>.

The FDA is also proposing to amend the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. Comments on the proposed rule are due June 15, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7192.htm>.

FDA Removes Portions of Animal Drug Regulations

The FDA is removing portions of a regulation that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofurans, and sulfonamide drugs administered in animal feed as they have been determined to be obsolete or redundant. More information is available at <http://edocket.access.gpo.gov/2010/2010-7108.htm>.

FDA Amends Animal Drug Regulations

The FDA is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of a suspension containing orbifloxacin, mometasone furoate monohydrate, and posaconazole for the treatment of otitis externa in dogs. More information is available at <http://edocket.access.gpo.gov/2010/2010-7163.htm>.

FDA Amends Medical Device Regulations

The FDA is amending certain medical device regulations to correct statutory and regulatory references to ensure accuracy, consistency, and clarity in the agency's regulations. More information is available at <http://edocket.access.gpo.gov/2010/2010-7288.htm>.

FDA Issues Final Rule on Organizational Change in Agency, Amends Admin Regs

The FDA is issuing a final rule to amend the regulations to reflect organization change in the agency and to make other conforming changes. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations. More information is available at <http://edocket.access.gpo.gov/2010/2010-7282.htm>. The agency is also amending its administrative regulations. More information is available at <http://edocket.access.gpo.gov/2010/2010-7286.htm>.

HHS Renews Declaration of Emergency

The Secretary of HHS has announced that the declaration of an emergency justifying the authorization of emergency use of certain in vitro diagnostic products is being renewed effective March 26, 2010. The declaration of an emergency justifying the authorization of certain antiviral products is renewed effective March 26, 2010. The declaration of an emergency justifying the authorization of emergency use of certain respiratory protection products is renewed effective March 26, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-7529.htm>.

DEA Issues Interim Final Rule on E-Prescribed Controlled Substances

The Drug Enforcement Agency has issued an [interim final rule](#) on e-prescribed controlled substances that requires that security systems must authenticate based on two of the following three devices: (1) biometrics (e.g., thumbprint); (2) hard token, or (3) password. The rule also allows pharmacies to substitute generic versions of controlled substances when the prescription is submitted electronically. The rule will become effective on June 1, 2010.

Public Meetings

Anti-Infective Drugs Advisory Committee

The Anti-Infective Drugs Advisory Committee will meet April 29, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-7113.htm>.

Antiviral Drugs Advisory Committee

The Antiviral Drugs Advisory Committee will meet June 2, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-7114.htm>.

FDA to Host Public Workshop

The FDA is announcing a public workshop entitled "2010 PDA/FDA Pharmaceutical Supply Chain Workshop--Enough Talk: Let's Find and Implement Solutions." The workshop, cosponsored with the Parenteral Drug Association (PDA), will focus on solutions to reduce the risk to product quality in the pharmaceutical supply chain. The workshop will be held on Monday, April 26, 2010, from 8 a.m. to 6 p.m.; Tuesday, April 27, 2010, from 7:15 a.m. to 5:45 p.m.; and Wednesday, April 28, 2010, from 7:15 a.m. to 1:15 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-7151.htm>.

FDA to Host Public Meeting

The FDA is announcing a public meeting entitled "2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System." The topic to be discussed is the results from the National Antimicrobial Resistance Monitoring System (NARMS) and related antimicrobial resistance monitoring and research, including activities in other national programs. The meeting will be held on July 15 and 16, 2010, from 8 a.m. to 5 p.m. in Atlanta, Georgia. More information is available at <http://edocket.access.gpo.gov/2010/2010-7496.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:

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