

To: Our Clients and Friends

June 15, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

FDA: Genetic Testing Kits are Medical Devices

The FDA has sent letters to five manufacturers of genetic testing kits stating that the agency is considering the kits to be medical devices. As such, the agency has said that they need to receive approval from the agency before they can be marketed. The House Energy and Commerce Committee has announced that it too is looking into the tests.

House Committee Investigating Rapamune

The Chairman of the House Committee on Oversight and Government Reform has sent a letter to Pfizer's CEO stating that the Committee is investigating whether Wyeth, acquired by Pfizer last year, marketed its drug Rapamune for unapproved uses. The investigation follows a False Claims Act suit filed by former employees, which alleges that the company directed its sales team to market the drug for unapproved uses. The Department of Justice has indicated that it is conducting its own investigation into Wyeth's marketing of Rapamune.

House Inquiry into J&J Continues

The House Committee on Oversight and Reform has indicated that it will continue its inquiry into Johnson & Johnson, and has expressed dismay over some of the documents provided by the company. The Committee has also indicated that it was disturbed by recent documents provided by the company indicating that the company may have conducted a surreptitious recall of Motrin without notifying federal regulators. The Chairman of the Committee has stated that the company has used delay tactics and has provided misleading information to the Committee. Johnson & Johnson has denied those allegations.

Device Industry Unveils Radiation Therapy Initiative

The Advanced Medical Technology Association and the Medical Imaging and Technology Alliance have announced that they have developed a "Radiation Therapy Readiness Check Initiative." The initiative seeks to ensure that patients do not receive excessive doses of radiation and that the devices are used properly and include safeguards.

FDA Asks IOM Panel to Help Create Standards for Post-Market Safety Studies

The FDA has asked an Institute of Medicine (IOM) panel to create a threshold for the data needed before the agency should be able to require post-market drug safety studies or other regulatory action. Janet Woodcock, chief of the FDA's drug center, has stated that the agency is facing a dilemma in that it does not want to cause public concern about a medicine unnecessarily, but it also does not want the public to be placed at risk due to an unsafe medication. The IOM has stated that it plans complete a letter report by next month on the ethical and informed consent issues involved in designing randomized clinical trials to evaluate potential safety risks, and will complete a full report by next spring.

IOM Holds Public Workshop to Discuss 510(k) Process

The Institute of Medicine is holding its second public meeting to discuss potential changes to the 510(k) clearance process. The FDA has tasked the group with determining whether the process, as it currently stands, adequately protects and promotes public health. Comments at the meeting included that more resources be devoted to the process to ensure that companies are conforming to performance standards, conducting more inspections, and developing additional guidance. Industry also expressed concern that the current process may be too burdensome and may be inhibiting innovation. IOM's next public workshop is scheduled for July 28, and a report from the group on the public health effectiveness of the 510(k) program is due out next summer.

Agency News

The *Wall Street Journal* has reported that the FDA has indicated that it will seek more stringent regulations for drug companies outsourcing their manufacturing.

CMS has stated that it will announce on June 25 the single-payment amounts for the controversial durable medical equipment competitive bidding program.

The FDA and the US Pharmacopoeia have indicated that they are increasing their focus on collaboration and are launching joint initiatives aimed at ensuring drug purity, quality, and efficacy. The groups are also discussing the potential use of hand held devices by FDA inspectors to transmit information about drugs to USP.

The FDA has stated that it is working with APP Pharmaceuticals and Hospira in an effort to ensure adequate supplies of the anesthetic propofol now that Teva Parenteral Medicines no longer manufactures it.

CDRH has announced that it is working with its staff to prepare for the official debut of its Signal Escalation program by the end of the year.

In recent testimony before the House Energy and Commerce Committee's Subcommittee on Health, CDER director Janet Woodcock stated that government incentives will likely be needed to encourage continued development of antibiotics.

The FDA has indicated that it is in the process of drafting a proposed rule that would extend the disqualifications of clinical investigators to cover work on any other FDA-regulated investigational product, including biologics and drugs.

The CEO of Watson Pharmaceuticals has accused the FTC of engaging in harassment in an effort to obtain his testimony in a case regarding a pay-for-delay settlement involving Cephalon's drug Provigil.

Publications

The FDA has issued an [information sheet guidance](#) entitled "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions--Statement of Investigator (Form FDA 1572)."

The FDA has published an [updated section](#) in its Manual of Policies and Procedures entitled "Reporting Format for Nanotechnology-Related Information in CMC Review."

The FDA has published "[Modifications to the List of Recognized Standards](#), Recognition List Number: 024" (Recognition List Number: 024).

The FDA has published its online listing of [May 2010 510\(k\) Clearances](#).

The FDA has published a [guidance for industry](#) entitled “Bioequivalence Recommendations for Specific Products.”

The Association of Clinical Research (ACRO) has released findings indicating that the number of investigators participating in clinical trials declined 5 percent in the US and 6 percent in Western Europe between 2004 and 2007. The group is calling for more harmonization, the expansion of trial registries, and clarity on certain liability issues in order to address the decrease.

Approvals

Endologix Inc. has announced that the FDA has approved its stent graft products.

An FDA advisory panel has recommended approval of voted Novartis' multiple sclerosis drug fingolimod as a potential first-line treatment.

The FDA has granted fast-track status to Genzyme for its alemtuzumab drug.

The FDA has granted 510(k) clearance to AtriCure has for its AtriClip Gillinov-Cosgrove Left Atrial Appendage Exclusion System.

Recalls, Warnings, and Notifications

The FDA and Baxter BioScience are notifying healthcare professionals of a [market withdrawal](#) of GammaGard Liquid as a precautionary measure due to an increased number of adverse event reports of allergic reactions associated with two lots of the product.

Defibtech, LLC, are notifying customers of a recall of 5,418 [DBP-2800 Battery Packs](#) used in the Lifeline AED and ReviveR AED.

The FDA has stated that it is [evaluating data from two clinical trials](#) in which patients with type 2 diabetes taking Benicar had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. FDA's review is ongoing and the Agency has not concluded that Benicar increases the risk of death.

Hospira is notifying healthcare professionals of a [voluntary recall](#) of several injectable products because some of the containers may contain particulate matter, primarily made up of sub-visible inert stainless steel particles.

The FDA has issued a warning letter to Pfizer Inc. for the failure to report certain complaints about its drugs in a timely manner. The letter requires Pfizer to submit a plan to correct the problems within 15 days.

The FDA has issued a warning [letter](#) to DexCom, in which it instructs the company to prevent the unapproved use of its glucose monitoring system where it knows that the system is being used in unapproved areas of the body. The letter does not indicate that DexCom is marketing the system for an unapproved use.

International News

Reports are indicating that Chindex International plans to form a medical device joint venture with Shanghai Fosun Pharmaceutical.

Ontario's Health Minister has announced that 50% price cuts for generic prescriptions will start taking effect July 1 of this year.

Business News

Gilead Sciences, Inc. has announced that Lupin Ltd. is challenging the company's patent on the drug Ranexa.

Florida Governor Charlie Crist has signed legislation eliminating the requirement that medical device companies obtain permits from the Florida Department of Health and allow inspections at their facilities biannually.

GlaxoSmithKline PLC has announced its acquisition of Laboratorios Phoenix S.A.C.yF for \$253 million.

Blue Cross Blue Shield of Texas has indicated that it plans to file suit against Pfizer for deceptive marketing of the drugs Bextra, Geodon, and Lyrica.

Genzyme Corp. has stated that it has [settled a proxy contest](#) with investor Carl Ichan and that the company is not for sale.

Cochlear Americas has entered into a settlement with the U.S. Department of Justice, under which it will pay \$880,000 to resolve allegations that it paid kickbacks to doctors.

The *Wall Street Journal* is reporting that Medtronic has indicated that it plans to release 60 products this fiscal year, according to the company's chairman.

The *Wall Street Journal* has reported that Eli Lilly & Co. has announced that it is aiming to double its sales in emerging markets over the next five years.

A Philadelphia judge has [dismissed a lawsuit](#) against Johnson & Johnson alleging that the company hid the health risks of its drug Rispedal.

Human Genome Sciences has announced that it does not expect that its Hepatitis C drug [Zalbin](#) will receive FDA approval.

Johnson & Johnson [argued for the dismissal](#) of a lawsuit alleging that the company paid kickbacks to Omnicare to encourage prescriptions of certain drugs, saying that finding against Johnson & Johnson would result in brand allowable rebates being designated as illegal.

Merck KGaA has announced that it has resubmitted an NDA for its drug cladribine

Medtronic has announced that it will launch its Patient Care Center pilot program on Aug. 8 in Beijing. The program is designed to help educate prospective cardiovascular implant patients about the therapy.

PhRMA, EFPIA, JPMA and the IFPMA have announced their adoption of a "joint position" under which member companies are encouraged to submit summaries of all Phase III studies, as well as those having "significant medical importance" for publication in peer reviewed journals.

Regulatory Notices

FDA Seeks Comments on Labeling Requirements, Premarket Approval, Drug Co-Development

The FDA is seeking comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products. Comments are due by August 2, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-13279.htm>.

The FDA is seeking comments on requirements for premarket approval of medical devices. Comments are due by August 9, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-13763.htm>.

The FDA also seeks comments on methods to co-develop two or more distinct investigational drugs intended to be used in combination to treat a disease or condition. FDA is planning to develop guidance for industry and other affected parties on the co-development of two or more novel drugs intended to be used in combination (but not as not fixed-dose combinations) and is seeking public input to identify the affected parties' information needs concerning such co-development. Comments are due by September 7, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-13769.htm>.

FDA Submits Information Collection to OMB for Review

The FDA has announced that it has submitted for OMB clearance a proposed collection of information titled "General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and

Suspension, Postmarketing Studies Status Reports.” Comments are due July 9, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-13815.htm>.

FDA Signs MOU with IARS

The FDA has announced that it has signed a memorandum of understanding (MOU) with the International Anesthesia Research Society (IARS) to establish a framework for collaboration and to support their shared interest of promoting the safe use of anesthetics and sedatives in children. More information is available at <http://edocket.access.gpo.gov/2010/2010-13292.htm>.

FDA Announces Determination on Cysteine Hydrochloride Injection

The FDA has announced that it has determined that Cysteine Hydrochloride Injection, USP, 7.25% (Cysteine HCl), was not withdrawn from sale for reasons of safety or effectiveness. More information is available at <http://edocket.access.gpo.gov/2010/2010-13463.htm>.

FDA Requests Notifications of Intention to Participate in Meetings on PDUFA Reauthorization

The FDA has issued a notice requesting that public stakeholders notify the agency of their intent to participate in periodic consultation meetings on reauthorization of the Prescription Drug User Fee Act (PDUFA). After the statutory authority for PDUFA expires in September 2012, the FDA will consult stakeholders to develop recommendations for the next PDUFA program. Notifications of intention to participate must be submitted by June 25, 2010. The first stakeholder meeting will be held on July 1, 2010, from 9 a.m. to 11 a.m. More information is available at <http://edocket.access.gpo.gov/2010/2010-13671.htm>.

FDA Corrects Dental Device Final Rule

The FDA has issued a notice that it is correcting an error in its Final Rule on dental devices, published on August 4, 2009. More information is available at <http://edocket.access.gpo.gov/2010/2010-14083.htm>.

FDA to Create Docket for Comment on Product Labeling

The FDA has announced that CDER and CBER will create a public docket to allow interested parties to share information, research, and comments on the FDA's indexing process for product labelling. Comments are due by August 10, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14047.htm>.

Public Meetings

Anesthetic and Life Support Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee to Meet

The FDA has announced that the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will meet on July 22 and 23, 2010, from 8 a.m. to 4:30 p.m. in Adelphi, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13535.htm>.

Endocrinologic and Metabolic Drugs Advisory Committee to Meet

The FDA has announced that the Endocrinologic and Metabolic Drugs Advisory Committee will meet on July 15, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13534.htm>.

Endocrinologic and Metabolic Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee to Meet

The FDA has announced that the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committees will meet on July 13, 2010, from 8 a.m. to 6 p.m. and on July 14, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13533.htm>.

13th Annual FDA-OCRA Educational Conference

The FDA has announced that it is hosting the [13th Annual FDA-OCRA Educational Conference](#), June 16 & 17, 2010 themed "Regulatory Affairs: The Business of Regulatory Affairs."

Public Meeting on Array-Based Cytogenetic Tests

The Food and Drug Administration (FDA) is announcing a public meeting titled "Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation." The purpose of the public meeting is to seek input on challenges related to performance evaluation, determination of clinical significance, result reporting, and interpretation for array-based cytogenetic tests. The meeting will be held on June 30, 2010, from 1:30 p.m. to 5 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13768.htm>.

Public Workshops

The FDA will hold a public workshop on scientific issues in clinical development of medical products (i.e., human drugs, therapeutic biological products, and medical devices) for prophylaxis and/or treatment of acute antibody mediated rejection in kidney transplant recipients. The workshop will be held on June 28, 2010, from 8 a.m. to 6:30 p.m. and on June 29, 2010, from 8 a.m. to 4 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-13669.htm>.

The FDA has announced that it will hold a public workshop jointly sponsored by the National Institute of Allergy and Infectious Diseases and the Infectious Diseases Society of America (IDSA) regarding scientific and potential research issues in antibacterial drug resistance, rapid diagnostic device development for bacterial diseases, and antibacterial drug development. The workshop will be held on July 26, 2010, from 8 a.m. to 5:30 p.m. and on July 27, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-14048.htm>.

The FDA has announced that there has been a change in location for upcoming public workshop entitled "Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors." More information is available at <http://edocket.access.gpo.gov/2010/2010-14153.htm>.

Dental Products Panel to Meet

The FDA has announced that the Dental Products Panel of the Medical Devices Advisory Committee will meet on December 14 and 15, 2010, from 8 a.m. to 6 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-14084.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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