Top News

Researchers Call on FDA to Make Drug Safety Info More Accessible to Patients

Researchers from Dartmouth College urged in an article in the New England Journal of Medicine that the FDA provide consumers with more detailed information about drugs’ safety and effectiveness. According to the Chicago Tribune, the article advocates for the inclusion of easy-to-read fact boxes to help patients weigh the benefits and risks of medications.

CMS Reopens Competitive Bidding for Durable Medical Equipment

CMS has announced that it has relaunched the bidding process for providers of oxygen tools and other durable medical equipment, giving suppliers 60 days to file bids to become official Medicare DME providers. The competitive bidding program had been delayed for more than a year due to complaints from small suppliers that it would jeopardize their business and restrict patients’ access to quality equipment.

Merck Starts Revealing Payments to Doctor-Speakers

Merck & Co. has released data indicating that it paid doctors and nurses a total of $3.7 million this summer to give talks to colleagues about the drugmaker’s products and other health topics. Speakers were paid $1,548 on average for the talks, though dozens of doctors received more than $10,000. The disclosure comes in response to increased pressure on drug companies to release data on payments to doctors.

Congressional pressure on drug companies to release this data is also apparent in the Physician Payments Sunshine Act, part of the Senate Finance Committee’s health reform bill. The Act would require annual, public reports from drug and device makers on all payments to doctors.

Merck’s disclosure follows a similar disclosure by Eli Lilly on July 31 of this year. Pfizer Inc. and Glaxo Smith Kline PLC have announced that they will make similar disclosures, according to an article in the New York Times.
FDA Lags in Banning Researchers After Fraud

The Government Accountability Office has found that the FDA lags in completing its process to ban researchers convicted of fraud from conducting further experiments. In a review of 18 proceedings, investigators found that the FDA took between 1 and 11 years to complete the process to ban researchers, with many researchers continuing to carry on research for years after their convictions, according to an article in the *New York Times*.

Commissioner Looks to Europe in Effort to Improve 510(k)s

FDA Principal Deputy Commissioner Joshua Sharfstein has stated that CDRH may incorporate aspects of Europe's CE Marking approval rules in its 510(k) clearance process. The 501(k) process is currently undergoing an internal review and an independent evaluation to determine how it might be improved to better support the FDA’s mission.

How Drug-Industry Lobbyists Won on Health Care

An article in *TIME* discusses what is at stake for drug makers in health care reform and what’s they’re doing to protect their interests, including spending $110 million on lobbying in the first six months of 2009.

Drug Makers Are Advocacy Group’s Biggest Donors

Congressional investigators studying donations to the National Alliance on Mental Illness have discovered that about three-fourths of the alliance’s donations between 2006 and 2008, approximately $23 million, came from drug makers. The Alliance’s Executive Director has stated that the drug industry’s share of the Alliance’s financing will decrease significantly next year, according to an article in the *New York Times*.

Execs Are Seeing Stiffer Pricing Pressure on Medical Devices

Alex Gorsky, worldwide chairman at Johnson & Johnson’s medical-device unit, has said that the introduction of new devices and products will be integral to medical device firms as they seek to offset price pressure caused by the economic recession and health care reform.

FDA to Use New PREDICT System to Speed Entry of FDA-Regulated Products into US

The FDA has announced that it will be using its information technology system, PREDICT, to identify high-risk imports for possible inspection, a move which the agency expects will speed the entry of about 80 percent of FDA-regulated products into the U.S. The system will gather data on products, importers and manufacturers and use it to calculate a risk score. FDA entry reviewers will then consider data for the 20 percent of imports flagged by PREDICT as having the highest likelihood of violating FDA rules and standards. Center for Food Safety and Applied Nutrition Compliance Director Roberta Wagner has stated that PREDICT will help FDA “target our limited resources ... to make sure that we're looking at the entries that have the highest potential risk based on a number of adverse factors.”

Large, Simple Trials Can Improve Patient Care

Penny Mohr, Vice President for Programs at the Center for Medical Technology Policy, stated at a recent FDA conference that interest in large, simple trials is growing. She noted that these trials can address gaps in critical knowledge in healthcare and can help improve healthcare, reduce costs and ensure that patients are not subjected to needless tests and interventions, but that they can only be conducted in certain situations.

Flu Vaccine Requirement for Health Workers Is Lifted

The New York State Health Department has announced that it is suspending a regulation that would have required health care workers and hospital volunteers to receive the swine flu vaccine. A spokesperson from the Department stated that
the regulation’s suspension was due to a shortage of the vaccine and a desire by the state to concentrate on vaccinating pregnant women and children, according to an article in the New York Times.

Eli Lilly Loses Bid for Evista Hearing Before Canada High Court

Canada’s Supreme Court has dismissed Eli Lilly & Co.’s request for a hearing to determine whether its patent for the Evista osteoporosis treatment is valid. The company is seeking to block Apotex Inc. from selling a generic version of the drug.

Shire to Seek FDA Approval for Replagal This Year

Shire has announced that it is planning to file a BLA for its Fabry disease treatment Replagal by the end of the year to supplement the short supply of such drugs caused by a Genzyme manufacturing issue. Shire has filed a treatment protocol for Replagal (agalsidase alfa) at the request of the FDA, and it will support emergency IND requests, the company has said.

Priority Of Merck’s Integration Of Schering Is Retaining Top R&D Talent, Kim Says

Although Merck’s acquisition of Schering-Plough is not set to close until the fourth quarter of 2009, the company is already in the process of determining which research programs will continue and which will be shelved as a result of the acquisition. Merck Research Labs President Peter Kim has stated that the company has a team working with Merck and Schering scientists to develop “portfolio cards” outlining the attributes of every molecule in the pipeline, from the earliest-stage pre-clinical assets to those in post-marketing studies.

20 Charged with Medicare Fraud

The U.S. Attorney’s Office in Los Angeles has announced that it has charged 20 individuals with fraudulent Medicare billing. The charges involve seven cases and total $26 million in unneeded or undelivered medical equipment, according to an article in the Los Angeles Times.

Md. Man Profited from Drugs Meant for Needy

Joseph Egbe, the owner of e-Meditech, a charitable group with a contract with the Catholic Medical Mission Board to distribute drugs to impoverished individuals in Africa, has pleaded guilty in federal court to misbranding of pharmaceuticals, according to an article in the Washington Post. According to federal authorities, Egbe made more than $10,000 by selling some of the drugs destined for Africa to a Baltimore pharmacist, who then repackaged and resold them, federal authorities said.

Expert: Stem Cell Reprogramming Will Revolutionize Drug Development

At a speech before the Milwaukee Academy of Medicine, James Thomson, a University of Wisconsin-Madison scientist, stated that stem cell reprogramming techniques will revolutionize the process of developing new treatments over the next ten to twenty years.

CER is a “historical market opportunity,” Says Quintiles VP

John Doyle, Vice President of Quintiles Consulting, has stated that the pharmaceutical industry needs to capitalize on the opportunities that comparative effectiveness research could provide to the industry. In his recent White Paper, Doyle argues that embracing CER will create increased opportunities for the industry to “drive the establishment of a product valuation system that compensates innovation fairly.” The White Paper is available at http://www.quintiles.com/elements/media/white-papers/rewarding-innovation-and-value-what-role-comparative-effectiveness-research.pdf.
FDA Issues Notice of Safety Investigation of Certain Medical Device Power Cords

The FDA has issued an initial notification of a safety investigation into whether certain types of power cords used with medical devices may be defective. The FDA has reported that two medical device manufacturers (Hospira, Inc. and Abbott Nutrition) have sent FDA 122 reports of sparking, charring, and fires from certain power cords used with their devices. While further investigation into this matter continues, the FDA recommends that all users of medical devices, either in healthcare facilities or in the home, closely monitor the wear and tear on the electric cords used to power these devices. More information is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm187078.htm.

FDA Launches Lasik Study, Sends Warning Letters

The FDA has announced that it will be reviewing Lasik to determine whether the lasers used in Lasik surgery have affected the quality of life for patients. The review will also encompass adverse event reports related to a number of warning letters sent to Lasik providers. The study could lead to changes in the labeling for the devices used in Lasik eye surgery.

FDA Warns Sumitomo for Microbial Contamination

The FDA has posted a warning letter to Sumitomo Chemical on its website, warning the company about design flaws that are raising concerns about microbial and endotoxin levels at the company’s active pharmaceutical ingredient (API) facility. The warning letter is available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm185648.htm.

FDA Issues GMP Warning Letters to Frontier Devices, Marlen Manufacturing & Development

The FDA has issued a warning letters to Frontier Devices and Marlen Manufacturing & Development for GMP violations. Frontier was cited with regard to its orthopedic surgical instruments for failure to document the disposition of a number of distraction drivers manufactured at the plant in March 2008 that were documented as having nonconforming specifications and for failure to establish and maintain procedures for implementing CAPAs. Marlen was cited for several manufacturing violations, including failure to calibrate equipment.

Recall of Ketorolac Tromethamine Injection, USP 30 mg/mL; 1mL and 2mL Single Dose Vials

American Regent and FDA are notifying healthcare professionals of a voluntary recall of all lots of Ketorolac Tromethamine Injection, USP 30 mg/mL, including NDC# 0517-0801-25 [30 mg/mL 1mL Single Dose Vial] and NDC# 0517-0902-25 [30 mg/mL 2mL Single Dose Vial (60 mg/2mL)]. There is a potential for particulate matter in conjunction with crystallization that may be present in the product, which may result in adverse events such as obstruction of blood vessels which can induce pulmonary emboli or thrombosis, activate platelets and/or neutrophils to induce anaphylactic reactions. Other adverse effects associated with the injection of particulate matter include foreign body granulomas, and local irritation at the injection site. The MedWatch safety summary and a link to the firm press release are available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm187481.htm.

Regulatory Notices

FDA Announces Web Location of 2010 CDRH Proposed Guidance Development

The FDA has announced the Web location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances. The list of the guidance documents CDRH is considering for development in 2010 is available at
FDA Seeks Comments on Guidance on CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices


The FDA is also seeking comments on the guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable. Comments are due by December 21, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-25178.htm.

FDA Seeks Comments on Inspection by Accredited Persons Program

The FDA has announced that it is seeking comments on the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002. Under the program, the FDA accredits third parties to conduct inspections of eligible manufacturers of class II or class III devices. Comments are due by December 21, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-25395.htm.

FDA Seeks Comments on Investigational Device Exemptions Reports and Records

The FDA has announced that it is seeking comments on investigational device exemption reports and records. Comments are due by December 22, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-25539.htm.

FDA Seeks Comments on Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification

The FDA has announced that it is seeking comments on FDA Forms 3602 and FDA Form 3602A which will allow domestic and foreign applicants to certify that they qualify as a “small business” and pay certain medical device user fees at reduced rates. Comments are due by December 22, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-25538.htm.


The FDA has announced that it has published a draft guidance entitled “Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications.” The guidance provides advice to potential sponsors (e.g., generally cord blood banks, or registries, and individual physicians serving as sponsor-investigators) to assist in the submission of an IND for certain HPC-Cs, when such HPC-Cs are not licensed in accordance with certain FDA regulations, and when a suitable human leukocyte antigen (HLA) matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition and there is no satisfactory alternative treatment.

The FDA has also announced that it no longer intends to exercise enforcement discretion with respect to IND and BLA requirements for minimally manipulated, unrelated allogeneic hematopoietic stem/progenitor cell products, and that the phase in implementation period for IND and BLA requirements will end after October 20, 2011. More information is available at http://edocket.access.gpo.gov/2009/E9-25135.htm.
While the FDA will be accepting comments on the guidance at any time, to ensure that comments are reviewed before the FDA begins work on the final version of the guidance, comments should be submitted by January 19, 2010. More information is available at http://edocket.access.gpo.gov/2009/E9-25136.htm.

**FDA Announces Classification of Cardiac Allograft Gene Expression Profiling Test Systems in Class II**

The FDA has announced the classification of cardiac allograft gene expression profiling test systems into class II (special controls). FDA classified the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. The final rule is effective on November 20, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-25315.htm.

In conjunction with the final rule, the FDA has also published a special controls guidance document entitled "Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems." This guidance document describes a means by which cardiac allograft gene expression profiling test systems may comply with the requirement of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. More information is available at http://edocket.access.gpo.gov/2009/E9-25313.htm.

**FDA Publishes Guidance Documents on CADe Devices Applied to Radiology Images and Radiology Device Data**

The FDA has published two related draft guidance documents regarding computer-assisted detection devices applied to radiology images and radiology device data. The first guidance, entitled "Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data--Premarket Notification [510(k)] Submissions" provides recommendations regarding premarket notification (510(k)) submissions of certain computer-assisted detection (CADe) devices applied to radiology images and radiology device data.

The second draft guidance is entitled "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Device Data--Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions" ("CADe clinical performance assessment draft guidance"). This draft guidance provides recommendations on how to design and conduct clinical performance studies for CADe devices applied to radiology images and radiology device data. These studies may be part of a premarket submission to FDA, whether it is a 510(k) submission, an application for premarket approval PMA), an application for a humanitarian device exemption (HDE), or an application for an investigational device exemption (IDE). These draft guidances are not final nor are they in effect at this time.

Although the FDA will be accepting comments on the guidances at any time, to ensure that comments are considered before the FDA begins work on the final version of the guidances, comments must be submitted by January 19, 2010. More information is available at http://edocket.access.gpo.gov/2009/E9-25233.htm.

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**Public Meetings**

**FDA Announces Teleconference Meeting of National Vaccine Advisory Committee**

HHS has announced that the National Vaccine Advisory Committee (NVAC) will hold a meeting via teleconference on Friday, November 6, 2009, from 3:00 p.m. to 5:00 p.m. The meeting is open to the public. Pre-registration is not required, however, individuals who wish to participate in the public comment session should either e-mail nvpo@hhs.gov or call 202-690-5566 to register and RSVP. More information is available at http://edocket.access.gpo.gov/2009/E9-25366.htm.
FDA Announces Meeting of Radiological Devices Panel of the Medical Devices Advisory Committee

The FDA has announced that the Radiological Devices Panel of the Medical Devices Advisory Committee will be meeting to provide advice and recommendations to the agency on FDA's regulatory issues. The meeting will be held on November 17 and 18, 2009, from 8 a.m. to 5:30 p.m. in Gaithersburg, Maryland. More information is available at http://edocket.access.gpo.gov/2009/E9-25406.htm.

AHRQ National Advisory Council's Patient Safety and Medical Liability Reform Subcommittee to Meet October 26

The AHRQ National Advisory Council's Subcommittee on Patient Safety and Medical Liability Reform will meet Monday, October 26, from 8:30 a.m. to 4:00 p.m. at the Holiday Inn Capitol Hill, 550 C Street, S.W., Washington DC, 20024. The subcommittee will provide advice for the Department of Health and Human Services' new medical liability initiative, which is being led by AHRQ for HHS. The meeting is open to the public, and attendees will have an opportunity to comment. Individuals may also participate via the Web and by conference call. This new initiative will test models that improve patient safety and reduce preventable injuries, foster better communication between doctors and patients, ensure patients are compensated in a fair and timely manner, and reduce liability premiums. Please visit the following link for more information about the meeting or to register.

More Information

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

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