

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

House to Conduct Hearing on J&J Recall, CEO Asked to Testify

The House Committee on Oversight and Government Reform has asked Johnson & Johnson CEO William Weldon to testify at its May 27 hearing on the recall of certain of its children's medicines, including Motrin, Tylenol, Zyrtec, and Benadryl. In addition, the FDA has expanded its investigation into the recall that is the subject of the hearing, and is looking into the manufacturing at J&J's McNeil Consumer Healthcare.

In addition, Rep. Rosa DeLauro has asked the FDA whether giving it authority to mandate a drug recall would improve the agency's ability to pull a drug from the market. Industry spokespeople have stated that such enhanced authority is unnecessary because the agency can easily persuade companies to issue recalls voluntarily.

FDA Serious About Warning Letters

FDA Commissioner Margaret Hamburg has made clear that, when she said the agency would step up its enforcement efforts, she meant it. Sources are indicating that the FDA issued more than 570 warning letters in 2009, compared with 436 in 2008 and 381 in 2007, and has sent 186 so far this year. In addition, the FDA's launch of its new "Bad Ad" program serves as an additional tool in the agency's enforcement arsenal.

FDA to Release Proposals on Public Disclosure Policies

The FDA has announced that it [will release 21 draft proposals](#) for public comment on [public disclosure policies](#) aimed at helping consumers, stakeholders, and others understand how the agency operates and makes decisions on May 21. The proposals are part of the second phase of the FDA's Transparency Initiative, launched last summer by FDA Commissioner Margaret Hamburg.

Industry Discusses Effect of Increased Regulations

A recent article in the *New York Times* discussed industry's impression of the [growing number of regulations](#) put into effect by the Obama administration. With new regulations involving the environment, product and food safety, and other health regulations, many in the industry are concerned at the costs that come with the regulations, as well as with the general lack of individuals from industry in the agencies drafting the regulations. Although the Administration has defended many of the regulations as producing cost-savings over the long-term, some in the industry say that the regulations will only hinder industry growth and development.

FDA Uses Informal Briefings to Help Train Reviewers

Center for Drug Evaluation and Research Deputy Director Douglas Throckmorton stated at a recent conference that the FDA has begun to sue two-hour informal meetings as informal training sessions for the agency's reviewers. Reports are indicating that the informal briefings, held on Fridays, allow reviewers to discuss issues pertaining to more challenging products prior to the agency making a formal decision. Throckmorton also stated that the meetings have no regulatory standing, but stated that if a significant issue were to arise during a meeting, it would be communicated to the sponsor.

Senate Republicans Say Berwick Favors Rationing Health Care

Senate Republicans are asserting that Obama's nominee to head CMS, Dr. Donald Berwick, [favors rationing health care](#) as a means of saving money. Spokespeople from the Administration have responded that rationing runs rampant in the health care system as it currently exists in the U.S., and that Berwick has devoted his career to ensuring that coverage decisions are transparent and work better for patients.

NIH to Build Diagnostics Database

An official from the National Institutes of Health has indicated that the entity intends to build a database including information on genetic diagnostics, including laboratory-developed tests that have not received FDA approval and information provided by product manufacturers. NIH has indicated that it is seeking input from the FDA on the database, and that participation will be voluntary.

Senate Committee Forms Fraud Unit

The Senate Health, Education, Labor and Pensions Committee has announced that it has formed a new unit to investigate consumer protection and fraud issues, which will be led by Beth Stein as chief investigative counsel.

Biotechs Anxiously Await Release of Regulations for Qualifying Therapeutic Discovery Project Tax Credit

Reports are indicating that the biotech industry, and small biotech companies in particular, are anxiously awaiting the release of IRS regulations pertaining to the Qualifying Therapeutic Discovery Project Tax Credit, due out on May 21, 2010. However, many in the industry have stated that they anticipate they will apply for a Treasury grant under the program. Strong competition for programs funds is expected.

Agency News

The FDA has stated that available scientific evidence, including findings released by the [World Health Organization \(WHO\) findings](#) do not demonstrate increased health risk from electromagnetic radiation emitted by cell phones. The FDA also cited findings from a National Cancer Institute program that [did not find increases in brain cancer risk](#) during the time period in which cell phone use dramatically increased.

Reports are indicating that industry is concerned that the FDA may be increasing its focus on superiority claims related to a drug's delivery system, as evidenced by DDMAC's recent sending of "untitled letters" to Shire for its drugs Lialda and Pentasa. In both of the letters, the agency stated that the claim that a drug's delivery system gave it an advantage was unsupported.

The FDA may use a pilot program at five Massachusetts hospitals as a way to explore the potential of a future effort to broaden its Sentinel post-market safety system to include devices, according to speakers at a recent roundtable held by the Brookings Institution. The deputy director of the Office of Surveillance and Biometrics at FDA's device center has stated that the agency hopes to learn from the pilot program and use it to assess how best to approach safety surveillance. The pilot is focused on interventional cardiovascular devices.

CMS has proposed to loosen its restrictions on the number of covered PET scans as part of the initial treatment of solid tumors and myeloma.

Publications

The FDA has published its online listing of April 2010 [drug safety labelling changes](#).

The FDA has published [revised recommendations for rotavirus vaccines](#) for the prevention of the disease in infants, finding that it is [appropriate](#) for [clinicians and health care professionals](#) to [resume the use of Rotarix](#) and to continue the use of RotaTeq.

A study published in the May 13, 2010, issue of the *New England Journal of Medicine* found that, although whistleblowers in health fraud cases can receive millions in rewards, they also face personal and professional hardship in the process. The authors of the article warn that these hardships may discourage some from coming forward, and encourage the government to decrease the length of investigations and provide temporary benefits to whistleblowers who lose their jobs.

The FDA has published an updated [Enforcement Report](#) for May 2010.

AARP has reported that the manufacturer prices for brand-name drugs widely used by Medicare enrollees rose nearly 10 percent from April 2009 to March 2010, the largest increase recorded by the association since it began compiling the data in 2002.

The FDA has published a [draft guidance](#) entitled "[Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program](#)." The draft guidance is not final nor is it in effect at this time. To ensure that comments on the guidance are considered prior to the agency commencing work on the final version of the guidance, comments should be submitted by August 18, 2010.

The Global Harmonization Task Force has issued a [guidance](#) urging sponsors design device trials to generate new data and answer specific safety or performance questions.

Approvals

Hansen Medical Inc. has received conditional approval from the FDA for a trial of its Sensei robotic catheter system and Artisan Control catheter.

The FDA has approved mid-stage tests on Aeterna Zentaris Inc.'s compound AEZS-108 for the potential treatment of bladder cancer.

The FDA approved a new delivery method for an injectable form of the antibiotic cefepime.

Boston Scientific Corp. has announced that it received approval from the EU to market its Taxus Element drug-coated stent.

The FDA has approved Roxro Pharma's Sprix nasal spray.

The FDA has granted orphan drug status to Allos Therapeutics' pralatrexate treatment for advanced or metastatic transitional cell carcinoma of the bladder.

The FDA has granted approval for Strides Arcolab Ltd. to sell vecuronium bromide injections in the US.

Recalls, Warnings, and Notifications

Sagent Pharmaceuticals, Inc. has announced that it is [voluntarily recalling](#) nationwide all lots of metronidazole injection, USP 500mg / 100mL manufactured by Claris Lifesciences and distributed by Sagent due to the discovery of non-sterility in two lots of metronidazole injection.

The FDA has posted information about the [Class I recall](#) of certain Shiley inflatable cuff tracheostomy tubes.

GE and FDA are notifying healthcare professionals of a [Class I Recall](#) of specific lots of the Aisys and Avance Anesthesia Systems.

GlaxoSmithKline and FDA are notifying healthcare professionals of a [new safety finding in patients with thrombocytopenia](#) due to chronic liver disease treated with eltrombopag, a thrombopoietin receptor agonist approved for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenic purpura. The ELEVATE study was terminated following the identification of an imbalance of thrombosis of the portal venous system in the patients treated with eltrombopag versus matching placebo.

Johnson & Johnson and FDA notified consumers and healthcare professionals of changes to the graphics and information displayed on the front of the product container to [reduce the risk of serious side effects](#) from swallowing the topical Benadryl Extra Strength Itch Stopping Gel intended "For Skin Use Only."

Baxter International Inc. has recalled all of lots of its Hylenex recombinant due to glass particles found in vials of the product.

The FDA has issued a warning letter to St. Jude Medical for its Epicor LP cardiac ablation system, alleging off-label promotion of the device. In response, the company has removed marketing materials for the device from its website.

International News

India and Brazil have registered [complaints with the World Trade Organization](#) regarding European Union customs rules, stating that the EU has confiscated generic Indian medicines and unfairly targeted their generics industries.

Turkey's 2D barcode system, intended to help track drugs and reduce the sale of counterfeits, crashed in its second day after 24,000 pharmacies tried to access the system.

Datamonitor Group has predicted that the cancer drug market in India will grow at about [16 percent per year](#) over the next five years.

Australia's pharmaceutical industry announced that it signed a memorandum of understanding with the government that combines new drug price reductions and a promise of a stable economic environment for R&D. The agreement guarantees drug companies that there will be no further price cuts before June 30, 2014. It has been estimated that the move will save taxpayers \$1.9 billion over five years.

Business News

Takeda Pharmaceutical Co. and Astellas Pharma Inc. have released forecasts indicating that the companies predict a [decline in profit](#) this year due to generic competition for their top-selling drugs. Takeda has also announced that it is [cutting almost 1600 jobs in the US](#) in response to slowing revenues.

Pfizer Inc. has announced its acquisition of the rights to the experimental pulmonary arterial hypertension drug terguride.

The FDA's Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee declined to endorse the approval of anti-inflammatory drug naproxcinod.

Walgreens has announced that it will [not sell genetic testing kits](#) manufactured by Pathway Genomics. The drugstore chain was [set to begin selling](#) the tests in its stores on Friday, but [reversed course](#) after the FDA wrote a letter to the manufacturer indicating that the test [may need to receive regulatory approval](#) prior to sale.

Pfizer has announced that it will be closing eight of the company's manufacturing sites, will reduce operations at an additional six by the end of 2015, and will shed around 6000 jobs as part of a reorganization following the company's acquisition of Wyeth.

Teva Pharmaceutical Industries and AstraZeneca have reached a settlement under which Teva will delay its generic version of AstraZeneca's Crohn's disease drug Entocort until February 2012.

Ev3 announced that it is seeking premarket approval from the FDA for its Pipeline Embolization Device.

Breathe Technologies announced that it has received 510(k) clearance from the FDA for a ventilator mask, and has obtained \$23 million in a round of venture financing.

The FDA again rejected a citizen's petition filed by Teva Pharmaceutical Industry Ltd., in which the company was seeking for the FDA to deny approval of generic versions of Copaxone.

The FTC has approved the sale of Thoratec's diagnostic unit, International Technidyne, to Danaher for \$110 million.

Astellas Pharma Inc., Japan's second-biggest pharmaceutical maker, has announced that it [intends to purchase](#) NY-based OSI Pharmaceuticals, Inc., for [\\$4 billion](#) in cash.

Pfizer, Inc. has [settled a second claim](#) that the company failed to warn doctors and patients of the suicide risks resulting from its drug Neurontin.

Avanir Pharmaceuticals Inc. stated that the FDA plans to decide on its drug candidate Zenvia by October 30.

A federal jury in New York has found that a pharmaceutical unit of Novartis AG [discriminated against its female employees](#) and must pay \$3.4 million, in addition to a not-yet-determined sum for punitive damages.

GlaxoSmithKline announced that it has stopped a trial of its treatment Promacta after six patients in the study suffered blood clots.

A federal appeals court ruled that a pay-for-delay deal between Bayer and Barr Laboratories over the antibiotic Cipro does not violate federal antitrust law, but encouraged the plaintiffs to file an appeal for review by the full court.

Novartis and other drugmakers have indicated that they are developing their own alternatives for online drug advertising that they hope will strike a balance between the FDA's requirements for presenting balanced risk-benefit information and the specific challenges and constraints posed by social media.

Steris has announced that it plans to expand its Ohio facility for an estimated cost of \$11 million, a move that would create 300 new jobs.

Reports are indicating that GlaxoSmithKline has agreed to pay around \$60 million to settle more than 700 lawsuits concerning its drug Avandia in advance of an upcoming FDA advisory committee meeting about the drug. The judge overseeing the federal cases has delayed hearings in the cases until after the advisory committee meets.

Regulatory Notices

FDA Seeks Comments on Proposed Information Collections

The FDA has announced that it has submitted to the Office of Management and Budget a "Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference in Electronic Format to the Center for Veterinary Medicine." Comments are due by June 14, 2010. Additional information is available at <http://edocket.access.gpo.gov/2010/2010-11453.htm>.

The FDA has announced that it has submitted to the Office of Management and Budget an extension to "Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products." Comments are due by June 14, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-11396.htm>.

The FDA has announced that it has submitted to the Office of Management and Budget an extension to "Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Form FDA 3486 and Addendum 3486A." Comments are due by June 14, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-11541.htm>.

The FDA has announced that it has submitted to the Office of Management and Budget a "Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission

Gateway.” Comments are due by June 17, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-11808.htm>.

The FDA has announced that it is seeking public comment on a pilot program for manufacturers and distributors to voluntarily submit final product labeling and information electronically for all devices cleared by the FDA for home use. Comments are due by July 19, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-11810.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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