

To: Our Clients and Friends

May 4, 2010

## Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



### *Top News*

#### **Court Says Patent Settlements May Violate Antitrust Laws**

A federal appeals court in New York indicated that [patent settlements](#) reached by drug companies may violate antitrust laws when they include payments to rivals to delay the introduction of generic products. The Justice Department has previously asserted that those types of payments may be illegal and the FTC has called on courts to consider the merits of the patents at issue when determining whether such settlements should be valid. FTC Chairman Jonathan Leibowitz has stated that these settlements cost consumers \$3.5 billion per year through higher drug prices.

#### **FDA Chief Counsel Overhauls Role within Agency**

FDA Chief Counsel Ralph Tyler has indicated that he intends to serve a different role than his predecessors and has stated that he intends to assist the agency in finding creative legal avenues and interpretations of the law to implement new policies that support the agency's overall mission. Tyler has indicated that, under this new interpretation of his role, the Commissioner will drive policy-making, and he will provide the required legal support in advance of identified policies. Some are worried that this new approach could result in a significant expansion of the FDA's legal authority.

#### **House Committee: FDA Didn't Pursue Leads on Heparin Contamination**

Members of the House Energy and Commerce Committee have stated that they have concluded an investigation into the FDA's handling of the contaminated heparin crisis and found that the FDA failed to pursue certain leads which could have uncovered those responsible.

#### **Members of Congress Call For FDA Reviewer Independence**

Members of Congress are advocating for the FDA to give its drug safety evaluators more independence to express their views about the safety of a drug, without fearing reprisal by the agency.

## Director of CMS Office of Research Being Transferred to White House

Reports are indicating that Timothy Love, current director of the CMS Office of Research, Development and Information (ORDI), is being transferred to the White House Office of Health Reform.

## Speakers at Conference Advise Companies Not to Wait for FDA Guidance to Use Social Media

Speakers at a recent FDLI annual conference encouraged companies not to wait until after the FDA issues guidance on the use of the internet and social media to use those mediums. They did recommend that companies use caution when using social media or developing certain websites, including not promoting specific products and monitoring the sites and postings regularly.

## Case Could Allow Drug Companies to Hold Consultants Liable for Bad Advice

Some are pegging the case of *Cell Therapeutics v. Lash Group* as one to watch, as it could allow drug manufacturers to hold consultants liable for the advice they provide. The case involves advice that Lash provided to Cell Therapeutics (CTI) regarding Medicare reimbursement for off-label uses of its drug Trisenox. After the government began investigating CTI and Lash, which concluded with CTI settling with the government, CTI filed suit against Lash for damages it suffered as a result of the investigation and the settlement, as well as breach of contract. The appeals court recently overturned the circuit court's ruling that CTI could not seek damages from Lash.

## President of GPhA Will Not Resign Following Teva Departure

President and CEO of the Generic Pharmaceutical Association Kathleen Jaeger has indicated that she will not be leaving her post after the departure of Teva last week.

## Some Concerned About Part D Discounts

Reports are indicating that some are concerned that a draft CMS guidance reveals that the agency may not be able to mandate that drugmakers offer 50 percent discounts to eligible seniors in the Part D coverage gap by 2011, as formularies for the Part D plan sponsors have already been submitted and CMS has not yet issued a notice of model manufacturer agreement. Nonetheless, it is being reported that manufacturers likely will provide the discount rather than face potential backlash.

## Publications

The Center for Responsive Politics has issued a report finding that the health industry spent [\\$137.9 million](#) on lobbying in the first quarter of 2010.

The Office of the United States Trade Representative (USTR) has issued a [Special 301 report](#), in which it calls for stronger action to counter the manufacture, sale, and distribution of counterfeit drugs and substandard medicines in countries including Brazil, China, India, Indonesia and Russia.

The FDA's 2008 performance report on user fee goals prepared for the president and Congress indicates that the agency did not meet some of its sponsor-related goals in fiscal year 2008, including scheduling meetings with sponsors to review NDAs and BLAs and responding to clinical holds and special protocol assessment requests.

## Approvals

The FDA has [approved](#) Abbott Prism Chagas Antigen as the second test for screening blood, tissue and organ donors for the parasite, *Trypanosoma cruzi* (T. cruzi) that causes Chagas disease.

The FDA has [approved](#) Pozen Inc. and AstraZeneca Plc's arthritis drug Vimovo.

The FDA has granted clearance to Immucor for its automated blood testing device Neo.

## Recalls, Warnings, and Notifications

McNeil Consumer Healthcare and the FDA are [notifying healthcare professionals](#) of a [voluntary recall](#) of certain over-the-counter (OTC) [Children's and Infants' liquid products](#) manufactured in the United States, including [Tylenol](#), Motrin, Zyrtec, and [Benadryl products](#) because some of these products [may not meet required quality standards](#).

The FDA has announced that it is [conducting a safety review](#) of Gonadotropin-Releasing Hormone (GnRH) agonists, a class of medications primarily used to treat men with prostate cancer. The FDA has advised that patients should not stop treatment with a GnRH unless so instructed by a health professional, but health professionals should be aware of and monitor for the potential risks associated with these medicines.

## Business News

Reports are indicating that the FDA has denied Philip Morris' request to remove four individuals from the agency's tobacco-products advisory panel. Philip Morris argued that they should be removed due to conflicts of interest. Spokespersons on behalf of the agency stated that the agency continues to monitor potential committee members for conflicts of interest, but acknowledged that some experts on a particular subject matter may have such conflicts.

Reports are indicating that Shire PLC experienced a decline in its first-quarter profits of 22% due to the loss of patent protection over its drug Adderall.

Medtronic Inc. has announced that it will acquire ATS Medical Inc. for \$350 million.

Bristol-Myers Squibb Co., AstraZeneca LP and Sanofi-Aventis have each indicated that they had strong first quarter sales and profits, though reports are warning that the outlook for the next three quarters may not be so rosy.

Reports are indicating that Pfizer Inc. is talking with Brazilian generic drug manufacturer Teuto about a potential acquisition.

Edwards Lifesciences Corp. has announced that it won its patent infringement case against Cook Inc. before the Federal Patent Court in Munich, Germany. The case found that Cook's transcatheter heart valve patent was invalid.

Orchid Chemicals & Pharmaceuticals Ltd. announced that it has reached a [settlement](#) in its patent litigation against Forest Laboratories Inc., under which it will begin selling a generic version of Forest's Namenda drug in January 2015.

The FDA held a hearing last Friday regarding the possible establishment of a compassionate use program that would give some hepatitis C patients access to the investigational drug Rebetol.

Siemens AG has announced that it is revamping its healthcare unit and will focus on clinical products in high demand in developing markets, including [x-ray and ultrasound equipment](#).

Reports are indicating that the FDA has requested additional data from Bristol-Myers Squibb Co.'s Phase III studies of belatacept so that it can better evaluate the long-term effect of the drug.

A court has ordered HemCon Medical Technologies to pay \$29.4 million to Marine Polymer Technologies in connection with a patent-infringement case over chitosan. HemCon has said that it plans to appeal the decision.

Pozen and Teva Pharmaceuticals USA have stated that they have reached an agreement to settle patent litigation over Teva's ANDA for a generic version of migraine drug Treximet.

CDRH has indicated that its corrective fix program is part of Signal Escalation, a postmarket transformation program CDRH quietly launched in 2008.

Ortho-McNeil-Janssen Pharmaceuticals (OMJ), a subsidiary of Johnson & Johnson, has entered into a settlement agreement under which it will pay \$81.5 million plus interest and enter into a five-year corporate integrity agreement to resolve allegations that it illegally promoted its epilepsy drug Topamax.

A federal court has ruled that claims on a patent for Schering-Plough's cholesterol treatment Zetia are invalid.

Integra LifeSciences has announced that sales of its orthopedic devices rose 9% to \$70.2 million in the first quarter.

The FDA has indicated that it is seeking to include flexibility in its drug/diagnostic co-development guidance, so that it can better address the manner in which therapeutics and diagnostics are developed.

Representative Rosa DeLauro has indicated that she does not support user fees to finance reviews of generic drug applications.

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## **Regulatory Notices**

### **FDA Seeks Comments on Proposed Collections of Information**

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of information on administrative procedures for the Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization. Comments on the collection of information are due July 6, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-10358.htm>.

The FDA is also seeking comments on for research entitled "Experimental Study of Patient Information Prototypes." This study is designed to determine, based on different prototype testing, whether consumers are able to comprehend serious warnings, directions for use, drug indications and uses, contraindications, and side effects in the material that is presented. Comments are due July 6, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-10359.htm>.

The FDA has also announced that it has submitted a proposed collection of information regarding requirements for submission of labeling for human prescription drugs and biologics in electronic format to the Office of Management and Budget (OMB) for review and clearance. Comments on the collection of information are due June 3, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-10361.htm>.

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## **Public Meetings**

### **Drug Safety and Risk Management Advisory Committee to Meet**

The FDA has announced that the Drug Safety and Risk Management Advisory Committee will meet on September 14, 2010, from 8 a.m. to 5 p.m. in Adelphi, MD. More information is available at <http://edocket.access.gpo.gov/2010/2010-10384.htm>.

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## **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](http://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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