

To: Our Clients and Friends

January 26, 2010

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



### ***Top News***

#### **On Eve of State of the Union, Democrats Pause on Health Reform**

Democrats in the House and Senate have announced that they plan to take a break from the health reform bill to focus on other issues, such as job growth. While White House Senior Adviser David Axelrod has indicated that the White House intends to continue to pursue comprehensive reform, Republican leadership has called for Congress to scrap the current bills and begin again.

The pharmaceutical industry has indicated that it likely will seek to renegotiate its financial contributions under the bill if the bill's scope were to be scaled back. While the fate of the tax on the device industry remains unclear, so does the potential for the increased growth potential due to coverage of an additional 30 million individuals, particularly for diagnostics.

#### **FDA Schedules Meeting on Premarket Clearance Process**

The FDA has announced that it will hold a public meeting to discuss key challenges related to the premarket notification, or 510(k) process. The meeting will take place from 8 a.m. to 5:30 p.m. on February 18, 2010, in Gaithersburg, Maryland. At the meeting, the FDA plans to review four categories of challenges, including predicate devices, new technologies and scientific evidence, FDA practices in response to the high volume of submissions, and post-market surveillance and new information about marketed devices.

Those interested in attending or participating in the meeting must register by 5 p.m. on Feb. 12, 2010. The agency is accepting written or electronic comments by March 5, 2010.

#### **FDA to Publish Cross-Contamination Guidance**

Brian Hasselbalch and Steven Wolfgang of CDER's Office of Compliance have stated that the FDA will release a general draft guidance for manufacturers on cross-contamination this year, as well as final guidances on process validation and mechanical calibration of dissolution apparatuses.

## **Nanotechnology Bill Introduced in Senate**

US Senators Mark Pryor and Benjamin Cardin have introduced the Nanotechnology Safety Act of 2010, designed to establish a nanotechnology program at FDA to address potential health and safety risks posed by the technology. The program would receive \$25 million a year from 2011 to 2015, and would assess the health and safety implications of the technology and develop best practices for using the technology.

## **FDA Official: Some Device Manufacturers Mistaking Corrective and Preventive Actions**

An FDA official has stated that some device manufacturers are not applying corrective actions and preventive actions correctly due to a lack of understanding between those activities. The official emphasized that corrections are fixes for a particular product or issue, and corrective actions are responses to those issues that are intended to prevent a problem from recurring. Preventive actions, on the other hand, are put into place before any issues arise.

## **MTPPI Argues Against Bundled ESA Reimbursement Rate**

The Medical Technology and Practice Patterns Institute is pushing for Congress to stop basing the bundled rate of erythropoiesis stimulating agents on historical usage of the drug, saying that the government can encourage doctors to prescribe lower doses without inflating ESA reimbursement. CMS' Medicare Evidence Development and Coverage Advisory Committee is scheduled to meet on March 24 to discuss ESA in the cancer setting, and a final rule establishing bundled payment for ESAs is set to be released this spring.

## **Federal Judge Rules that Electronic Cigarettes Not Drug-Device Combos**

A federal judge has ruled that the FDA cannot regulate "electronic cigarettes" as drug-device combinations, and the agency must lift import alerts on the products. The decision stated that the FDA cannot treat products as drug-device combinations solely because they are intended to be used the same way as traditional products but with less risk.

## **Genetics Policy Institute Calls for Law Easing Stem Cell Research Restrictions**

Bernard Siegel, executive director of the Genetics Policy Institute, is calling for President Obama's executive order that eased restrictions on embryonic stem cell research to become law in order to prevent a potential future reversal.

## **NOTA Re-emerges to Protest FDA Drug Test Regulation**

National On-Site Testing Associates (NOTA) was revived this month to advocate against the FDA's regulation of drug screening tests used in the workplace and other non-medical settings.

## **Publications**

The FDA has updated its listing of [Current Drug Shortages](#).

The FDA has updated its medical, statistical, and clinical pharmacology [reviews of pediatric studies](#) conducted in response to a Written Request issued under the BPCA and pediatric assessments conducted under PREA.

The FDA has published a [guidance](#) entitled "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals."

The FDA has published a study on the effects of RFID on pacemakers and implanted cardioverter-defibrillators. Study author Seth Siedman has stated that industry needs to design implantable cardiac devices to mitigate possible interference from RFID readers because advances in technology may cause more exposure in the future.

European device trade association Eucomed has posted comments stating that the device industry can help the European Union achieve the goals of a proposed economic strategy by creating jobs and improving the health of EU citizens.

HHS' Office for Human Research Protections has issued a determination [letter](#) stating that concerns about institutional review board (IRB) oversight of research at Northern Arizona University (NAU) have been resolved.

HHS' Office of Inspector General has published a report finding that with an average manufacturer price-based federal upper limit, pharmacies could be reimbursed more than they paid for the drugs overall, even as a number of drugs are under-reimbursed.

## Approvals

The FDA has approved [Ampyra](#) (dalfampridine) extended release tablets to [improve walking](#) in patients with [multiple sclerosis](#).

## Recalls, Warnings, and Notifications

Nipro Medical Corporation and the FDA are notifying healthcare professionals of a [voluntary nationwide recall](#) of all GlucoPro Insulin Syringes. These syringes may have needles that detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection.

The FDA has issued an updated warning about a [counterfeit version](#) of Alli 60 mg capsules (120 count refill pack) being sold over the internet, particularly at online auction sites. The FDA is advising people who believe that they have a counterfeit product not to use the drug and dispose of it immediately.

Biogen Idec Inc. has agreed that it will communicate with doctors once a month on the occurrence of new cases of progressive multifocal leukoencephalopathy in patients using Tysabri (natalizumab), according to a report in the Wall Street Journal.

The FDA's Clinical Division of Drug Marketing, Advertising, and Communications has cited an investigator for promotional statements made to the media during a trial of the anti-wrinkling compound Dysport.

The FDA has issued a warning letter to McNeil Consumer Healthcare for being too slow to alert the FDA and consumers to trace amounts of a wood-treating chemical in some of its products.

The FDA has issued a warning [letter](#) to Daniel Potter, an investigator at Huntington Reproductive Center Medical Group, for problems with informed consent as part of a clinical trial.

The FDA has issued an untitled [letter](#) to Cephalon, stating that the pocket dosing card for its cancer drug Treanda omits important risk information.

Abbott has stated that it is withdrawing its anti-obesity drug sibutramine from the European Union markets at the urging of the European Medicines Agency.

Dow Jones has reported that the FDA has stated that a website for GE Healthcare's drug Visipaque is misleading and omits certain risk information.

## Business News

The Court of Appeals for the Federal Circuit has ruled that Teva Pharmaceutical Industries Ltd. [did not infringe](#) Takeda Pharmaceutical Co.'s patent for its Prevacid SoluTab heartburn drug.

A Pennsylvania state court has ruled that plaintiff's attorneys [are allowed to post a video](#) relating to Pfizer's Prempro drug, but that the title of the video must be changed, and the video must indicate that it is a plaintiff's presentation.

The recent decision by the Fifth Circuit in *Demahy v. Actavis* indicates that generic drug makers are facing increasing difficulty arguing that lawsuits against them are pre-empted by federal regulations.

Antigenics has announced that it will not seek FDA approval for its kidney cancer drug Oncophage.

As GlaxoSmithKline and Merck & Co. launch Web sites reporting their payments to doctors, New York Gov. David Paterson is calling for stricter regulations on marketing practices of the pharmaceutical industry to prevent conflicts of interest among physicians. Senator Chuck Grassley (R-Iowa) is asking the director of the National Institutes of Mental Health (NIMH) to hand over communications as part of an investigation into researchers' financial ties with drugmakers.

Medtronic has announced that it will acquire Italian firm Invatec for an initial payment of \$350 million and up to another \$150 million in milestone payments.

Thoratec has announced that it will be expanding its sales force in order to increase physician referrals for destination therapy, now that its HeartMate II ventricular assist device has received FDA approval.

EvaluatePharma is reporting that although \$12 billion in brand sales are expected to face generic competition this year, this figure is lower than the \$18.9 billion in brand drugs that were replaced by generics in 2009, and the \$25.9 billion expected for 2011.

Watson Pharmaceuticals has stated that it has filed an ANDA to market a generic version of Teva Pharmaceutical Industries' LoSeasonique.

Spectranetics has reached an agreement with the Justice Department under which it will pay \$5 million to resolve claims involving clinical trials and imported unapproved devices.

When the makers of combination products, as well as other industry representatives, met with the FDA to discuss its proposed new approach to combination product manufacturing, they expressed concerns about issues such as which elements are actual components of a combo product and when the new system would kick in. The FDA and industry agreed that final guidance before implementation of the rule will be critical.

The FDA's Vaccines and Related Biological Products Advisory Committee will meet in February to determine whether the H1N1 pandemic flu virus will be among the three strains of flu that make up the 2010-11 seasonal influenza vaccine.

The Juvenile Diabetes Research Foundation has announced that it has begun partnering with device companies to speed the commercialization of artificial pancreas technology, including giving \$8 million to a partnership with Johnson & Johnson's Animas division to develop a first-generation automated system for managing Type 1 diabetes.

Members of the device industry in Minnesota have formed a group, called the Minnesota Medical Device Alliance, to lobby the FDA and Congress on potential 510(k) reforms.

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## ***Regulatory Notices***

### **FDA Announces Proposed Information Collections**

The FDA has announced that it is seeking public comment on reporting requirements for firms that intend to export certain unapproved medical devices. The FDA is also seeking comments on its collection of information relating to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Forms FDA 356h and 2567. Comments are due by March 29, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-1438.htm> and <http://edocket.access.gpo.gov/2010/2010-1439.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](#).

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