

To: Our Clients and Friends

January 29, 2010

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



### *Top News*

#### **State of Union Address Calls for Reform, but No Timeline Set**

President Obama called for Congress to pass a health reform package that includes insurance reforms and protections for Americans during his [State of the Union](#) address on Wednesday, but Congressional leaders have not set a firm [timeline](#) for reform. Speaker of the House Nancy Pelosi has called for the use of ["budget reconciliation"](#) to make the changes some lawmakers in the House are demanding for the bill passed by the Senate. Senate health committee Chair Tom Harkin has stated that the Senate has enough votes for reconciliation.

Pelosi has also floated the idea of [two tiered reform](#), with incremental changes occurring now and more comprehensive changes to occur at a later date. Devicemakers have indicated that they are hoping that, if Congress chooses incremental reform or chooses to start over, they can avoid paying the \$2 billion annual device tax included in both the House and Senate healthcare bills.

#### **HHS Spokesperson: Steele Won't Be Nominated for CMS Administrator**

A spokesperson from HHS has stated that rumors that President Obama intended to nominate Geisinger Health Systems CEO Glenn Steele to be the new CMS administrator are untrue.

#### **FDA May Look for Increased Veterinary Involvement in Animal Drug Oversight**

Industry sources are reporting that the FDA is seeking additional involvement of veterinarians in the oversight of antibiotics in animal feed, although it has yet to fully formulate its regulatory approach or decide whether to revoke the over-the-counter status of certain animal antimicrobials.

#### **Consumer Groups Call for FDA Mandatory Recall Authority over Drugs**

Consumer groups, in the wake of an expanded recall of Tylenol products, are calling for the FDA to gain mandatory recall authority over drugs.

## HHS Signals Policy Change on IRBs

The HHS' Office for Human Research Protections (OHRP) has archived two institutional review board (IRB) guidances, officially signaling that it has changed its policy and now views external IRBs as equally capable of handling local issues.

## CDRH to More Aggressively Recruit Advisory Panel Members

CDRH has announced that it will begin to more aggressively recruit members for its device advisory panel after it received limited response to its request for nominations last fall.

## Publications

The FDA has published its online posting of [December 2009 PMA approvals](#).

The FDA has published an updated a list of [drug products](#) for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification.

The Swedish government's Medical Products Agency has published a report in which it calls for the expansion of Good Manufacturing Practices requirements to include environmental certification of drug production facilities.

GBI has published a report estimating that the vaccine market will reach \$52 billion by 2016.

The European Commission has published a report on the future of the medical device industry in Europe. The report highlights two areas needing attention: the need for a more standardized technology assessment system and the need for more funding and other incentives for innovation, particularly at the small medical enterprises, or small medical device business level.

The European Medicines Agency has published a guideline recommending that sponsors testing gastroesophageal reflux disease (GERD) treatments for reflux esophagitis in Phase III trials use a primary endpoint of complete healing of mucosal breaks. Comments on the guidance are due by June 30.

The Therapeutic Goods Administration has posted a [presentation](#) on its website states that devicemakers manufacturing therapeutic products in Australia should implement a quality risk management system that is fully documented and monitored for effectiveness by July.

## Approvals

The FDA has [approved](#) the [Medtronic Melody Transcatheter Pulmonary Valve and Ensemble Delivery System](#).

The FDA has [approved](#) Victoza (liraglutide) to treat [type 2 diabetes](#) in [some adults](#).

The FDA has [approved](#) Morphine Sulfate Oral Solution for the relief of moderate to severe, acute and chronic pain in opioid-tolerant patients.

The FDA has granted orphan drug designation to Erytech Pharma's acute-lymphoblastic leukemia treatment Graspa.

The FDA has granted drug orphan drug designation EpiCept Corp.'s NP-1 pain drug.

## Recalls, Warnings, and Notifications

The FDA has issued a [warning letter](#) to GE Healthcare for its website for its drug product, Visipaque, saying that the website is misleading.

The FDA has issued a [warning letter](#) to Bracco Diagnostics Inc. for false and unsubstantiated claims related to Isovue on the product's website.

The FDA has [notified](#) healthcare professionals of a [Class I recall](#) of Exel/Exelint Huber needles, Exel/Exelint Huber Infusion Sets and Exel/Exelint "Securetouch+" Safety Huber Infusion Sets, manufactured by [Nipro Medical Corporation](#) for Exelint International Corporation.

Takeda Oncology and FDA are notifying healthcare professionals about [revisions to the Prescribing Information](#) for Velcade, section 2.5, pertaining to patients with hepatic impairment at the start of Velcade therapy. The changes also include new safety information on dose adjustment for patients with moderate to severe hepatic impairment.

The FDA has announced that diagnostic procedures dependent on technetium 99m (Tc-99m) will be unavailable worldwide March 21 through 25.

Abbott Laboratories has agreed that it change the label for its drug Meridia to indicate that it is contraindicated for patients with cardiovascular disease, and that it will submit a full study report on the drug to the FDA in March.

## Business News

The US Department of Energy has awarded GE's Hitachi Nuclear Energy unit \$4.5 million to develop radioisotopes using technology that does not require highly enriched uranium. The National Nuclear Security Administration awarded \$9 million to Babcock & Wilcox Technical Services Group for development of reactor technology for the production of isotopes.

Lawmakers in Minnesota are contemplating various controls on the drug industry including preventing drug companies from accessing physician prescribing data for marketing purposes, creating a drug-vetting program and removing that responsibility from industry representatives, and enacting lower limits on gifts from drug companies to physicians.

Spectrum Pharmaceuticals Inc. has stated that the FDA has asked for additional information on its drug Fusilev but will not require additional human testing of the drug. Spectrum Pharmaceuticals also announced that it will stop developing its drug ozarelix because of disappointing study results.

Novartis head Daniel Vasella has stated that those countries who had been reliable partners for the flu vaccine industry would be treated favorably in the future, while those who now seek to cancel contracts might not see as quick a response in the next pandemic.

Novartis has agreed to pay \$185 million as part of a plea agreement with federal investigators over the promotion of its epilepsy drug Trileptal.

A US District court judge in Delaware has ruled that Merck's patent on Temodar is unenforceable, and that Teva can sell its generic version of the chemotherapy drug.

The UK National Institute for Health and Clinical Excellence has stated that it "has blocked" dronedarone, due to issues with its cost effectiveness.

Generic drug prices in Alberta, Canada will be reduced from 75 percent to 45 percent of the brand-name drug price as of April 1, 2010, an action which some worry will mean the end to small pharmacies.

Pfizer has announced that it will discontinue testing of approximately 100 experimental drugs from its own and Wyeth's research operations to focus more resources on its priority areas.

EpiCept Corp. has announced said Wednesday the Food and Drug Administration granted the company's pain drug orphan drug designation.

The family of a young girl who received injections of Botox to treat muscle spasms associated with cerebral palsy has filed a [lawsuit against Allergan](#) alleging that her death was attributable to the drug.

Drug ads are becoming increasingly serious as ads are being [more closely scrutinized](#). Some in the industry are predicting that, if the trend continues, it may become counterproductive to advertise to consumers.

AstraZeneca has announced that it plans to cut 8,000 jobs by 2014, primarily in its R&D and supply chain operations.

The FDA has rejected Warner Chilcott's application for a low-dose contraceptive due to third-party manufacturing issues.

Two committees of the Mississippi state legislature have approved bills to classify cold medicines containing pseudoephedrine as prescription drugs.

Abbott Laboratories has reached a settlement agreement with 23 states and the District of Columbia under which it will pay \$22.5 million to settle claims that the company conspired to block generic competition for its cholesterol drug TriCor.

Biotronik has commented that the FDA's proposed rule on good manufacturing practices (GMPs) for combination products underestimates the burden of applying certain cGMP requirements to device-drug combinations.

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## ***Regulatory Notices***

### **FDA Published Draft Guidance on Abuse Potential of Drugs**

The FDA is announcing the availability of a draft guidance for industry entitled "Assessment of Abuse Potential of Drugs." This draft guidance is intended to assist sponsors who are developing drug and other medical products with the potential for abuse that may need to be scheduled under the Controlled Substances Act. Comments should be submitted by March 29, 2010, to ensure that they are considered before the agency begins work on the final draft of the guidance. More information is available at <http://edocket.access.gpo.gov/2010/2010-1516.htm>.

### **FDA Publishes Guidance on Mechanical Calibration of Dissolution Apparatus**

The FDA is announcing the availability of a guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2--Current Good Manufacturing Practice (CGMP)." This guidance recommends an alternative method for manufacturers to comply with FDA's CGMP regulations that require laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications. More information is available at <http://edocket.access.gpo.gov/2010/2010-1517.htm>.

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## ***Public Meetings***

### **Neurological Devices Panel to Meet**

The FDA has announced that the Neurological Devices Panel of the Medical Devices Advisory Committee will meet on March 12, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-1519.htm>.

### **FDA Science Board to Meet**

The FDA has announced that the Science Board Science Board will meet on Monday, February 22, 2010, from 8 a.m. to 3 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-1520.htm>.

### **FDA to Hold Meeting on 510(k) Review Process**

The FDA is announcing a public meeting entitled "Strengthening the Center for Devices and Radiological Health's 510(k) Review Process." The purpose of the public meeting is to identify actions that the Center for Devices and Radiological Health (CDRH) can consider taking to strengthen the premarket notification process for review of medical devices, also known as the 510(k) process. The meeting will be held on February 18, 2010, from 8 a.m. to 5:30 p.m. in Gaithersburg, Maryland. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on February 12, 2010. Submit electronic or written comments by March 5, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-1620.htm>.

## USTR to Hold Meeting on 2010 Special 301 Report

The United States Trade Representative (USTR) has announced that it will hold a public meeting and will permit foreign governments and other individuals to testify before it issues its 2010 Special 301 report on countries it deems do not provide adequate protection of intellectual property rights. The hearing will take place on March 3 at the USTR's headquarters in Washington, DC.

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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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