BRYAN CAVE
A Broader Perspective

Bulletin

**To: Our Clients and Friends** **November 24, 2009**

# Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin

## *Top News*

### Democrats Look to Unify as Senate Health Debate Looms

On November 21, 2009, the Senate voted 60-39 to begin formal debate on the Senate health bill, but Democrats who united last week still need to settle disagreements, including over the public option, in their own ranks to pass President Barack Obama's top domestic initiative. Not a single Republican backed the motion to proceed with the bill. Sen. George V. Voinovich (R-Ohio) missed the vote.

Meanwhile, conservatives are seizing on the controversial recommendation issued by the U.S. Preventive Services Task Force that women should have fewer mammograms as an example of the rationing will happen under the Senate's health plan.

The bill matches the $2 billion device industry tax in the House bill, gives biologics innovators 12 years of exclusivity, and requires a 50 percent discount on negotiated prices for brand drugs in Medicare formularies when beneficiaries fall into a coverage gap. Unlike the House bill, it would charge brand-drug makers $2.3 billion in annual fees.

The device tax imposed under the bill would be assessed annually on companies based on the ratio of a firm's prior-year qualifying device revenues to the total industry qualifying device revenues. Sales of all Class I devices and of Class II devices that sell at retail for $100 or less would be exempt; annual revenues below $5 million would not count towards the total, and revenues between $5 million and $25 million would count at half their value. Collection would begin in 2010.

### Department of Justice Recovers $867 Million in Settlements with Pharmaceutical and Device Companies in 2009

U.S. Assistant Attorney General Tony West, head of the U.S. Department of Justice's civil division, has stated that the department currently has 985 pending healthcare fraud cases, and that the department recovered $867 million in settlements with pharmaceutical and medical-device companies during the government's 2009 fiscal year, according to a November 20 article in the Wall Street Journal.

## FDA Issues 22 Warning Letters to Web Site Operators

The FDA has issued 22 warning letters to the operators of 136 websites that appeared to be engaged in the illegal sale of unapproved or misbranded drugs to U.S. consumers, as part of its International Internet Week of Action. None of the Web sites were for pharmacies in the United States or Canada.

## Anti-Counterfeiting Effort Seizes 167,000 Pills

The five-day international anti-counterfeiting operation Pangea II, involving regulators, police, and customs officials from 24 countries, took place last week and resulted in the identification of 751 websites engaged in illegal activity and the seizure of 167,000 counterfeit pills.

## Pharma Industry Watchdog Brill Nominated For FTC Commissioner

President Obama has nominated Julie Brill to be one of the five commissioners of the Federal Trade Commission. Brill, who has had a long-standing interest in pharmaceutical industry pricing and marketing practices, would serve a seven year term and replace Commissioner Pamela Harbour. Obama also nominated Los Angeles-based commercial litigator Edith Ramirez to fill a commissioner vacancy.

## Device Firms Want Two Years To Comply With Electronic MDR Rule

Covidien, AdvaMed and the Medical Imaging and Technology Alliance are asking the FDA to give device manufacturers two years to comply with an upcoming rule requiring adverse event reports to be submitted to the agency electronically. The FDA's proposed rule would give manufacturers one year to comply.

## Clarity Sought on Lab-Developed Tests, Disagreement Persists On Details

Stakeholders are calling for greater clarity on the FDA's pending approach to personalized medicine, and particularly laboratory-developed tests, with some fearing that the FDA will use stifling guidelines and others hoping for a risk-based overall strategy.

## New Respiratory Infection Tests Pose Challenges To FDA, Industry

Diagnostics that quickly identify respiratory viral infections could help curb antibiotic abuse, but getting new tests to market likely will require a closer meeting of the minds between the FDA and industry.

## Social Media Promotion Guidance Requested, But Won't Be Out Soon

Although medical products companies are asking for more guidance from the FDA on best practices for Internet marketing and promotion using social media tools, such guidance is not likely to be issued soon, according to director of the Division of Drug Marketing, Advertising and Communications at the Center for Drug Evaluation and Research Thomas Abrams.

## Co-Packaging Enters Gray Area as Option For OTC/Supplement Combos

Disagreement exists among experts on whether creatively co-packaging OTC drugs and dietary supplements is a legitimate alternative to problematic combination products or simply another regulatory quagmire. A former FDA chief counsel, Sheldon Bradshaw, has stated that marketing OTCs and supplements in tandem may represent enough of a gray area for firms to take a stand on, though the agency could still come down against such dual stock-keeping units.

## Clinical Data Needed for Some Digital Mammography 510(k)s, Panel Says

The Radiological Devices Panel has recommended that the FDA require some clinical data in 510(k) or de novo 510(k) submissions for new full-field digital mammography devices that substantially change or improve the perception of breast

cancer images when compared with prior models. The panel stated that new digital mammography systems with essentially the same features as products on the market should require only laboratory bench tests.

## More Bang for The Buck Needed in Pediatric Cardiac Device Development

Physicians are emphasizing that, despite recent attention from Congress, further incentives are needed to induce development of pediatric devices, particularly in the pediatric cardiology arena, where profit motive remains minimal.

## Reporting Adverse Events Found Online Complicated by Internet's Anonymity

Pharmaceutical Research and Manufacturers of America Assistant General Counsel Jeffrey Francer, called for the FDA to only require manufacturers to report AE incidents discovered online where the online reporters are privately contactable. One industry recommendation was for companies to place a MedWatch widget on their websites to allow patients to contact the FDA directly.

## Firms Advised to Focus on Comparative Effectiveness Study Methodology

Speakers at a recent reimbursement conference hosted by the Medical Device Manufacturers Association in Washington, D.C. emphasized that the device industry has a critical role to play as the federal government fine-tunes the methodology it uses for comparative effectiveness research.

## Some Internet Postings Should Be Exempt From DDMAC Clearance – Sanofi

Sanofi-Aventis is calling for the FDA to distinguish between drug company postings on static portions of the Internet and those that are part of a conversation when applying requirements on submission of promotional materials prior to their use.

## Conflicts of Interest By Academics Should Be Better Policed by NIH, OIG Says

The HHS Office of Inspector General has released a report calling for NIH to play a greater role in eliminating financial conflicts of interest among academic researchers. The report recommends that NIH collect details on the nature of all reported conflicts and how they are managed, reduced, or eliminated and require grantee institutions to obtain information on all significant financial interests held by researchers.

## Antibiotic Firms Push Ahead with cSSSI Trials, Despite Lack of FDA Guidance

Antibiotic developers with unpartnered compounds are forging ahead with late-stage trials for complicated skin and skin structure infections, or cSSSI, even though they still lack formal guidance from the FDA on drug development in this area.

## Pfizer Must Pay $6.3 Million in Damages Over Prempro

A Philadelphia jury has found that two of Pfizer Inc. units' hormone- replacement therapy drugs, Wyeth's Prempro and Pharmacia & Upjohn's Provera, caused an Illinois woman's breast cancer, and that they are liable for at least $6.3 million in damages.

## AstraZeneca's Seroquel Study Found No Diabetes Link

An expert witness at a pre-trial hearing on lawsuits over AstraZeneca Plc drug Seroquel stated that a company found "no significant" link between the drug and the onset of diabetes. The company is currently facing more than 14,000 lawsuits alleging that company officials hid Seroquel's diabetes risk.

## Jury Sides with Novartis in Generic Famvir Patent Case

A jury in the U.S. District Court for the District of New Jersey decided that Novartis' patent on Famvir was not invalid based on obviousness and that the drugmaker did not withhold or misrepresent information to the PTO, a finding which could make Teva Pharmaceutical Industries liable for damages due to its 2007 launch of a generic version of the drug.

## OraSure Settles with Inverness Medical for $3M

OraSure Technologies Inc., a maker of diagnostic kits to detect HIV and drug use, has agreed to pay Inverness Medical $3 million to settle a patent dispute over HIV tests.

## Oxytrol Bladder Drug Patent Suit Settled by Watson, Barr

Watson Laboratories has stated that it has settled a patent infringement lawsuit with Barr Laboratories over the overactive bladder drug Oxytrol under which Watson has granted Barr a royalty-bearing license to the U.S. patents covering Oxytrol and under which Barr may start marketing its product April 26, 2015, or earlier under certain circumstances.

## U. of Nebraska Defeats Tighter Limits on Stem Cell Research

The University of Nebraska Board of Regents defeated an effort to limit human embryonic stem cell research at the university on Friday, according to an article in the New York Times.

## Preventing Cross-Contamination in Endoscope Processing

The FDA, CDC, and the VA have issued a communication cautioning healthcare facilities, including hospitals, ambulatory care facilities and private practices, about the risks to patients if flexible endoscopes and their accessories are not processed properly, and recommending steps to reduce these risks. The communication also reminds manufacturers of endoscopes and endoscope processing equipment of their responsibilities in helping assure proper endoscope processing in healthcare facilities.

## Device Approval Review Includes Payments to Clinical Trial Sites

Mark Melkerson, director of the Division of Surgical, Orthopedic and Restorative Devices at CDRH, has stated that sponsor payments to clinical trial sites may soon become part of the public record in FDA reviews of applications for device premarket approval.

## Experimental Flu Vaccine Fails Safety Vote

Members of an FDA advisory panel voted 6 to 5 that Protein Sciences Corp. failed to prove that its experimental flu vaccine is safe enough to be approved and that more study is needed.

## Cardiac Science Corporation: Initial Communication

Cardiac Science Corporation has received multiple complaints related to defective components in certain AEDs that indicate the affected devices may not deliver electric shocks and that the devices' self-test may not detect the defect in advance of their use. Because the AED display screen and/or audible indicators may not accurately indicate whether the device is functioning properly or will function properly at time of use, FDA encourages users of the affected AEDs to follow the additional precautions provided in this communication.

## Meridia: Early Communication About Ongoing Safety Review

The FDA has notified healthcare professionals and patients that it is reviewing preliminary data from a recent study suggesting that patients using sibutramine have a higher number of cardiovascular events than patients using a placebo.

Sibutramine is marketed as Meridia, a prescription drug approved by FDA in 1997 for the management of obesity, including weight loss and maintenance of weight loss, in conjunction with a reduced calorie diet.

## FDA Approves Abilify as Treatment for Autism-Related Irritability

Bristol-Myers Squibb Co. has announced that the FDA has approved Abilify as a treatment for autism-related irritability in children from the ages of 6 to 17.

## Provenge Gets FDA Review Date

Biotechnology company Dendreon Corp. announced Friday the FDA will make a regulatory decision on its potential prostate cancer vaccine Provenge by May 1.

## FDA Delays Exalgo Review

Covidien PLC has announced that the FDA is delaying its decision on the company's potential opioid pain drug Exalgo to February 22.

## FDA Panel Backs Safety, Benefits of Spiriva

An FDA panel of lung specialists voted 11-1 in favor of new labeling about the benefits of Boehringer Ingelheim's Spiriva Handihaler, brushing of safety questions about the drug, and suggesting that the drug carry bolder benefit claims.

## Boston Scientific's Esophageal Stent Gains FDA Approval

The FDA and European regulators have approved Boston Scientific's WallFlex esophageal stent, which is used to treat blockages in patients with certain types of esophageal cancer.

## Novartis Pediatric Post-Market Plans For Xolair Fall Short Of FDA Request

A post-market program designed by Novartis to control Xolair (omalizumab) in the 6-11 pediatric population was not adequate to convince FDA or its Pulmonary-Allergy Drugs Advisory Committee to extend the indication for use in moderate to severe allergy/asthma patients below 12 years of age.

## FDA Warns Cornerstone about Distributing Unapproved Products

The FDA has issued a warning letter to Cornerstone Therapeutics accusing it of selling unapproved chewable tablets of Deconsal CT and Deconsal DM.

## Pfizer May Join Japanese Generics Market in 2011

Pfizer has floated the idea of entering Japan's $5.8bn (€3.9bn)-a-year generic drugs market in 2011 in an effort to further diversify its revenue streams.

## $150M Biologics Plant to be Built in Abu Dhabi

The Khaleej Times is reporting that a $150m biologics manufacturing plant is being setup in Abu Dhabi to produce therapeutics for the Middle East and North Africa.

### Pharma Must Change How it Sells Products

A recent report by Deloitte Consulting suggests that drug companies need to incorporate commercial considerations earlier in the development process, build superior data management capabilities and develop a more target approach to sales to boost ROI.

### Thoratec's HeartMate II Implant Boosts Stroke-Free Survival Four-Fold – Study

A recent study has found that Thoratec's next-generation HeartMate II continuous-flow left ventricular assist device enables a more than four-fold increase in two-year survival rate free from stroke and reoperation compared with the firm's HeartMate XVE pulsatile-flow LVAD.

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## *Regulatory Notices*

### FDA Issues Two Debarment Orders

The FDA has issued orders permanently debarring Anthony W. Albanese and Niaja Kane from providing services in any capacity to a person that has an approved or pending drug product application. More information is available at http://edocket.access.gpo.gov/2009/E9-28084.htm and http://edocket.access.gpo.gov/2009/E9-28083.htm.

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## *More Information*

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


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