

To: Our Clients and Friends

May 25, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Supreme Court Asks for Administration's Input on Generic Labeling Case

Reports are indicating that the Supreme Court has asked the Solicitor General to submit a brief regarding whether the court should hear an appeal by generics companies involving the labeling of their drugs. Generics manufacturers are asking the Court to find that suits over the labeling of generic drugs are preempted because federal law requires that the labeling of generics be identical to the labeling of brand name drugs. The pending lawsuit involves a woman who claims that the label for the generic drug Reglan did not adequately list the risks associated with the drug.

Dorgan to Use Food Safety Bill to Push for Drug Reimportation

Sen. Byron L. Dorgan has indicated that he intends to press the Senate for another floor vote on the reimportation of prescription drugs from Canada when the food safety bill currently in the Senate moves to the floor. Dorgan has indicated that he would like the food safety bill to include a provision that would allow the reimportation of U.S.-made pharmaceuticals from Canada and other countries.

Device Companies Discuss 510(k) Process at CDRH Town Hall

At a recent town hall in Minnesota aimed at discussing CDRH's strategic priorities, stakeholders indicated that they wished for greater transparency and communication with the agency regarding its reform of the 510(k) process. Stakeholders also called for the agency to lessen the regulatory uncertainty that accompanies the device approval process in general.

GAO Investigating Device Pricing

Reports are indicating that Senate Finance Committee Chairman Max Baucus has asked the GAO to conduct an investigation into the pricing and utilization of implantable medical devices. As part of the investigation, the GAO will evaluate trends in the use of implantable devices, the pricing of those devices for hospitals, and the effect of those prices on overall Medicare spending. Some are speculating that Baucus may be considering targeting Medicare device payments as a way to reduce spending.

House Seeks Information on Genetic Tests

The House Energy and Commerce Committee and its subcommittee on oversight and investigations has sent letters to Pathway Genomics Corp., 23&Me Inc., and Navigenics Inc. [requesting information on their genetic tests](#) being sold directly to consumers. The Committee indicated that it was seeking information including how the testing is performed, and how the companies ensure accuracy and privacy. The [Committee's investigation](#) was prompted by Walgreens' announcement that it would sell Pathway's tests in its stores. Walgreens later announced that it would postpone selling the tests, after the FDA questioned whether the tests could be sold legally, as they had never received FDA approval.

FDA Offers Input on Use of Social Media

At a recent conference, FDA officials indicated that, although they realize that ensuring the accuracy of all claims made about a product on the Internet is impossible, the agency does expect companies to take certain actions with respect to the advertising of its products online. The agency stated that it will hold companies accountable for information on their websites and on linked websites, and that it will also hold companies responsible for materials posted online once the company has knowledge of the existence of those materials.

FDA Updates Procedures Manual to Formalize Use of State Data

Michael Chappell, acting FDA associate commissioner for regulatory affairs, has announced that the agency has updated its *Regulatory Procedures Manual* to formalize the use of state data in its enforcement activities. The revised procedures allow for the use of state evidence, so long as it was gathered pursuant to an agency contract inspection program or joint-inspection program with the FDA; if the inspector is trained in relevant law and the requirements related to the facility or item inspected; the inspector earned an "acceptable" rating in a qualified FDA audit; or the state inspector recorded the observations in accordance with the agency's inspection procedures. The updated procedures also allow for the use of state laboratory findings so long as the samples are collected, handled, and analyzed using FDA field science measures, or if there is a determination that a state facility meets certain criteria.

Agency News

CMS has indicated that it is changing course regarding draft policies that it released, in which it suggested that it might not be able to require drug manufacturers to provide certain discounts to individuals in the Medicare coverage gap. The agency has indicated that it will use a third-party administrator to ensure that all eligible beneficiaries in the coverage gap receive the 50 percent discount mandated by the health reform law. However, stakeholders, including AARP, are asking HHS to clarify an exemption under which an "essential" drug would not be required to participate in the program.

Unions and consumer advocates are calling on the FDA to take stronger action against the Red Cross to send a strong message to the organization that it must fully address unsafe blood-handling procedures, including through the imposition of criminal penalties and the closure of facilities where violations occur.

The FDA and NIH have introduced a [website](#) for the reporting of pre- and post-market safety data for certain types of products to the federal government.

An Institute of Medicine panel has recommended that the FDA evaluate biomarkers using the same "scientific rigor" for all products that it regulates, and has suggested that validation for food health claims should be in line with similar statements made by drug manufacturers.

Drug companies and trade associations, in their comments to the FDA on a proposed rule, indicated that they would like the agency to better distinguish between human error and intentional falsification of data. The rule would strengthen reporting guidelines and require sponsors who learn of potentially falsified trial data or analysis report the information to the FDA within 45 days.

New guidelines proposed by the FDA would allow the results of ISO inspections by auditors accredited in Canada, the European Union, Australia or Japan to be considered in the FDA's decision whether to conduct its own inspection of a facility in a given year.

Publications

The FDA has published a [report](#) entitled “FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration,” which includes [21 draft proposals](#) about expanding disclosure of information by the agency while maintaining confidentiality of trade secrets and individually identifiable patient information. Although consumer advocates have been pushing the FDA to release more information to the public, some members of the industry worry that the proposals could lead to the disclosure of proprietary data, in contravention of trade secret statutes and FDA policy. In addition, members worry that the release of certain types of data, such as the holding or withdrawal of applications, may be misinterpreted by the public.

The FDA has published [information relating to the FDA's approval](#) to market the Esteem implantable hearing system.

Medco Health Solutions Inc. has found that the use of prescription drugs by children grew faster than that for adults last year. The rise in use has been attributed to several factors, including the swine flu, type 2 diabetes, and children being prescribed certain medications normally used in adults.

NIH has published [draft guidelines](#) that would require researchers to report on a publicly accessible website payments they receive in [excess of \\$5000](#). The guidelines also contain a reporting requirement, under which universities, colleges, research institutes, businesses and other entities that employ researchers receiving NIH funding, must monitor the researcher's compliance with the guidelines.

The FDA has indicated that it received Avanir Pharmaceuticals' complete response for Zenvia and has set an October 30 user fee action date.

Approvals

The FDA has approved Watson Pharmaceuticals Inc.'s generic version of the drug Valtrex.

The FDA has [cleared](#) the Simplexa test for the 2009 H1N1 influenza virus.

The FDA has granted orphan drug designation to Repligen's RG2833 treatment for Friedreich's ataxia.

The FDA has [accepted](#) Clinical Data Inc.'s regulatory application for vilazodone.

International News

The World Health Organization criticized the European Union last week for its seizures of Indian generic drugs, destined for Latin America and Africa, for patent violations, saying that the seizures misapplied the rules against counterfeit medications.

The British General Medical Council has [banned Dr. Andrew Wakefield](#), the doctor who first suggested an association between the MMR vaccine and autism, from practicing medicine in Britain. The Council found that Wakefield engaged in unethical conduct, including conducting unnecessary procedures on children and accepting research funding from parents seeking to sue vaccine manufacturers.

Health Canada has indicated that it may update its Therapeutic Products Directorate's list of recognized standards for medical devices to reflect recent international standards. The agency released a proposal last month calling for the addition of 22 standards, an update to 92 standards, and the deletion of 31 standards. Comments on the proposed changes are being accepted until June 18.

The Regulatory Affairs Professional Society has indicated that it will be working with a Chinese university to develop educational materials focusing on device regulation, as part of a partnership aimed at government inspectors, industry-based regulatory professionals, and scientists and engineers involved in device R&D.

Devicemakers who wish to market their products in Saudi Arabia must begin applying for marketing authorization beginning on September 1 of this year. After February 28, 2011, only devices receiving marketing authorization will be permitted to enter the country.

Business News

The *Financial Times* has reported that the pharmaceutical industry expects to lose about \$2 billion this year as a result of the U.S. health reform law. Although European drug companies have indicated that they expect to absorb the impact more quickly than U.S. companies, most companies are predicting a loss of between 1 and 3 percent this year, and as much as double that level in 2011.

Hospira, Inc. has indicated that it is extending its \$145 million offer to acquire Javelin Pharmaceuticals Inc.

A German court has held that a patent on GlaxoSmithKline's asthma drug, Advair is invalid, a decision that could pave the way for generic competition. The ruling only applies to the drug in Germany.

Medicis Pharmaceutical Corp. has [filed suit against](#) Nycomed GmbH in an effort to prevent it from selling a generic form of its Vanos ointment.

A federal judge in Massachusetts has ordered a Johnson & Johnson subsidiary to pay a little more than [\\$81 million](#) for the [illegal promotion](#) of the drug Topamax.

Abbott Laboratories has announced that it will [purchase Piramal Healthcare Ltd.'s generics unit](#) in India for \$3.72 billion.

Aspen Pharmacare Holdings Ltd. has [offered to purchase](#) Sigma Pharmaceuticals Ltd. for approximately \$1.24 billion, in an effort to expand in Australia.

Genzyme Corp. has signed an [agreement](#) with U.S. regulators under which it will pay [\\$175 million](#) for manufacturing violations at its plant in Boston. The consent decree also requires that Genzyme submit to oversight and submit annual reports prepared by an independent consultant for five years.

Retractable Technologies Inc. announced that it was successful in its \$5 million patent infringement case against Becton, Dickinson and Co.

Actor Dennis Quaid has filed suit against Baxter Healthcare Corp., the maker of heparin, alleging that the packaging of the drug led to the hospital giving overdoses of the blood thinner to his newborn twins three years ago.

Consumer advocacy groups, 34 states, AARP and other stakeholders are encouraging a federal court to consider whether pay-for-delay settlements violate antitrust law following an opinion by a three judge panel that urged the plaintiffs to seek an en banc hearing.

Teva Women's Health has filed suit against Watson Pharmaceuticals over Watson's application to make a generic version of the drug Cenestin.

Novo Nordisk has filed a lawsuit against Lupin to block Lupin from producing the generic version of PrandiMet.

Apotex has announced that it has launched its version of Pfizer's drug Lipitor. Pfizer has rejected Apotex's assertion that the drug is a bioequivalent of Lipitor.

A federal judge in Michigan has dismissed a whistle-blower lawsuit against Stryker, on the grounds of a lack of evidence.

The U.S. District Court for the Eastern District of Pennsylvania has unsealed a complaint against Pfizer in a whistleblower lawsuit alleging that the company marketed its drug Rapamune for off-label uses, calculated bonuses to sales representatives based on sales of the drug for unapproved uses, and offered incentives to encourage health care providers to prescribe the drug for unapproved uses.

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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