

DRUGS AND DEVICES

Physician and Industry Relationships

The topic of industry-physician relationships continues to get a lot of attention – both in the media and by policymakers. The following highlights some recent activity. Although this topic was not legislated last year, we expect that Congress will pass a law requiring drug and device companies to disclose financial relationship that they have with physicians. So far most of the efforts seem to be focused on just this element and do not go beyond to regulate/prohibit industry support of CME, although that is something that we will be closely monitoring. In addition to federal activities, the states are now getting into the business of regulating in this area. Six other states and the District of Columbia have laws or regulations with regard to the conduct of pharmaceutical or medical-device manufacturers.

MedPAC

The Medicare Payment Advisory Commission (MedPAC) included recommendations for regulating physicians-industry relationships in their March 2009 report. Aspects of their recommendations include:

- Manufactures should report payments in total annual value of payments to a recipient exceeds \$100
- Should report: gifts, food, entertainment, travel honoraria, research, funding for education and conferences, consulting fees, investment interests and royalties
- Companies should report
 - Value, type, date of each payment;
 - Name, specialty, Medicare billing number (if applicable);
 - Name of related drug/device
 - Medicare billing
- Federal law should preempt state laws that collect data on same types of payments and recipients
- HHS Secretary should have authority to assess civil penalties on manufacturers

For more information go to: http://www.medpac.gov/documents/Mar09_EntireReport.pdf

ACCME

The Accreditation Council for Continuing Medical Education (ACCME) is also evaluating its policy and standards for regulating industry support of CME. Last year they called for comments on:

- Limiting Interactions between Accredited Providers and Commercial Interests over Commercial Support with Industry
- Elimination of Commercial Support of Continuing Medical Education Activities
- Additional Features of Independence in Accredited Continuing Medical Education

AANS and CNS will need to monitor this activity closely. The ACCME has also proposed significant increases in its budget to, among other things, step-up its oversight of commercial support of CME.

Sunshine Act Reintroduced

Members of Congress, including Senator Charles Grassley (R-IA), ranking member of the Senate Committee on Finance, continue their investigations conflicts of interest with device companies. On January 22, 2009, Senators Grassley (R-IA) and Herb Kohl (D-WI) reintroduced the Physicians Payment Sunshine Act, S. 301. The bill would require all manufacturers and marketers of drugs, devices, biologicals, or medical supplies to disclose payments to physicians on a website maintained by HHS

beginning on March 31, 2011. The bill is available on the web at:
<http://www.grassley.senate.gov/private/upload/12209.pdf>.

Grassley Letter Regarding FDA Orthopaedics Panel Members Selection

On March 6, 2009, Senator Grassley sent letters to acting FDA Commissioner Frank Torti and to Gerald Bisbee Jr., chairman and chief executive officer of ReGen Biologics, Sen. Grassley said that it appeared to him that FDA was going out of its way to accommodate the company and that the company had inappropriate influence in the selection of participants for the November 14, 2008 FDA Orthopaedics Panel meeting convened to consider the ReGen Biologics product "Collagen Scaffold" for knee surgery. In the letter, he asked that the FDA and the company provide copies of "all internal and external communications and other materials, including emails, memoranda, personal notes, and telephone notes, relating either directly or indirectly to ReGen and the FDA, the make-up of the Orthopaedic and Rehabilitation Devices Advisory Committee, and the development of the panel questions." Sen. Grassley's letters are available on his website at:
http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=19632

Revised AdvaMed Code of Ethics

In response to recent scrutiny by policymakers, the Advanced Medical Technology Association (AdvaMed), has issued a draft revised "Code of Ethics on Interactions with Health Care Professionals" that they plan to make final on July 1, 2009. Activities prohibited by the new code include the provision of any entertainment or recreational activities (e.g., theater, sporting events, golf, etc.) for physicians or their staff, even if business or education is conducted as part of the event. This includes circumstances in which the physician serves as a consultant. Companies can no longer provide branded notepads, mugs, pens or other so-called "logo" items. Companies may provide modest meals in connection with scientific, educational or business information programs but only for those who have a bona fide professional interest in the information. Meals for spouses, guests, and those not attending the program are not permitted.

The code permits medical device manufacturers to continue to provide training and education on products, including out-of-town travel when necessary; support research, educational and charitable grants; and engage health care professionals as consultants, if appropriate and subject to restrictions. A copy of the new code is available at <http://www.advamed.org/MemberPortal/About/code>.

HHS OIG Report on Clinical Investigators' Conflicts

On January 12, 2009, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued a report entitled The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information. The HHS OIG concluded that the Food and Drug Administration (FDA) does not adequately determine whether sponsors applications for drug and device approval have provided complete and accurate financial information for clinical investigators. The OIG recommended that FDA develop a process for improving oversight of their practices in this area. The report is available at: <http://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf>

HHS OIG Plans to Prosecute Surgeons for Industry Conflicts

On March 4, 2009, the New York Times published an article stating that soon Federal prosecutors plan to file civil and criminal charges against a number of surgeons who the officials say demanded "profitable consulting agreements from device makers in exchange for using their products." The article quotes Lewis Morris, chief counsel to the inspector general of the Department of Health and Human Services as saying, "What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it." The full text of the article is available at:
<http://query.nytimes.com/gst/fullpage.html?res=9507E1DC163BF937A35750C0A96F9C8B63>

JAMA Article on Conflict of Interest

In the March 30, 2009 issue of the Journal of the American Medical Association, a group of physicians and researchers led by David J. Rothman, PhD, a professor at the College of Physicians and Surgeons at Columbia University in New York, called on medical associations to sharply limit the funding they receive from drug and device companies in order to limit industry's influence on how medicine is practiced. The new proposals call for medical specialty societies to refuse general budget support from industry. The recommendations, which aren't binding, would allow the groups to continue to accept industry advertising in medical journals and payments for industry-sponsored booths at doctors' conferences. A Wall Street Journal article on the issue is available at:

<http://online.wsj.com/article/SB123854648226076095.html>

New England Journal Support of Sen. Pallone Bill on Preemption

Controversy surrounding the issue of federal law preemption of state law governing FDA approved devices continues, with device manufacturers favoring preemption and consumer groups such as Public Citizen opposing preemption. On March 19, 2009, the New England Journal of Medicine published an article by Gregory D. Curfman, MD, Stephen Morrissey, PhD, and Jeffrey M. Drazen, MD supporting legislation introduced in the house by Rep. Henry Waxman (D-CA), chair of the House Committee on Energy and Commerce, and Frank Pallone (D-NJ), chair of the Health Subcommittee entitled Medical Device Safety Act of 2009. The bill, along with a companion bill introduced by Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT), would nullify the Supreme Court's ruling issued in February 2008 in the case of Riegel v. Medtronic, Inc, which barred lawsuits in state courts involving the safety and effectiveness of certain medical devices that are FDA approved. The Court ruled that these devices are subject to Federal law which preempts state law. However, on March 4, 2009, in the case of Wyeth vs. Levine the court ruled that FDA-approved drug labeling does not preempt state tort claims, creating a seemingly disparate situation between devices and drugs in this regard.

A copy of the decision is available at <http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf> The legislation introduced by Senator Pallone would add language to the Medical Device Amendments to explicitly prevent federal law from preempting state lawsuits against device companies, and thereby to place medical devices and drugs on a level playing field with respect to patient lawsuits.

Food and Drug Administration Activities

FDA Scientists Claim Improprieties with PMA Process

On January 26, 2009, nine FDA scientists sent a letter to President Obama alleging improprieties in the device approval process at FDA. Specifically, the scientists stated that they had been forced to approve high-risk medical devices without proper vetting of their safety and efficacy. The same nine scientists had complained in May 2009 to FDA Commissioner Andrew C. von Eschenbach, and the agency began an internal review at that time. Dissatisfied with the pace and results of that review, the scientists wrote a letter to Congress in October 2008 asking for an investigation, and the House Committee on Energy and Commerce began considering the allegations. The New York Times article is available at http://www.nytimes.com/2009/01/28/us/28fda.html?_r=1&ref=health

Acting FDA Commissioner Issues Confidentiality Memo

On March 13, 2009, acting FDA Commissioner Frank Torti issued a memo reminding FDA staff of the importance of confidentiality in dealing with trade secrets; confidential commercial info; personal privacy data; law enforcement records and privileged intra-agency and inter-agency documents, such as emails, memos and letters between FDA employees. He also reminded the staff that

consequences of a breach of confidentiality could include disciplinary sanctions, criminal liability, and potential lawsuits against the FDA for damages. The memo came in response to recent accusations of improprieties on the part of certain FDA employees. A copy of the memo is available at http://www.windhover.com/pdf/3-13-09_pm_3-52_Torti_Agency-WIde_Email_about_Confidential_Information.pdf

GAO High-Risk Series Questions FDA Competency

Since 1990, the General Accountability Office (GAO) has published a biennial report on high-risk areas for mismanagement in federal government agencies. The high-risk identification is intended to “help resolve serious weaknesses in areas that involve substantial resources and provide critical services to the public.” In its January 2009 report on this issue, GAO implicated FDA as an agency at risk. Regarding FDA oversight of medical products, GAO includes a section entitled “Protecting Public Health through Enhanced Oversight of Medical Products.” Specifically, GAO states that “new laws, the complexity of items submitted to FDA for approval, and the globalization of the medical products industry are challenging FDA’s ability to guarantee the safety and effectiveness of drugs, biologics, and medical devices. As a result, the American consumer may not be adequately protected from unsafe and ineffective medical products. FDA needs to improve the data it uses to manage the foreign drug inspection program, do more inspections of foreign establishments that manufacture drugs or medical devices, more systemically review the claims made in drug advertising and promotional material, and ensure that drug sponsors accurately report clinical trial results.” The report, *High-Risk Series: An Update*, is available on the web at: <http://www.gao.gov/cgi-bin/getrpt?GAO-09-271> and Highlights are available at: <http://www.gao.gov/highlights/d09271high.pdf>

FDA Off Label Guidance Issued

On January 13, 2009, the FDA issued a new off-label guidance notice for companies that wish to distribute published studies to promote their drugs and medical devices for indications that are not FDA approved, or “off-label use.” The legal provision which previously allowed distribution of journal articles on off-label use expired in 2006. The Federal Register Notice on the new guidance is available on the web at: <http://edocket.access.gpo.gov/2009/E9-452.htm> and an FDA Good Guidance Practices Document is available at: <http://www.fda.gov/oc/op/goodreprint.html>

Numerous medical devices that are routinely used by neurosurgeons are considered “off-label” despite having been used safely for many years and the confusion between “off-label” and “investigational” among the general public is a concern. The Washington Committee has asked the AANS/CNS Drugs and Devices Committee to write a *Position Statement on Off-label Use of Drugs, Devices, and Biologics* and the Committee is in the process of drafting the document for further review.

FDA Leadership

On March 14, 2009, President Obama officially nominated Margaret Hamburg, MD, as incoming FDA Commissioner and Joshua Sharfstein, MD, as Deputy Commissioner. Dr. Hamburg is a former New York City health commissioner and currently senior scientist at the Nuclear Threat Initiative, a non-profit organization dedicated to reducing the threat to public safety of nuclear, biological, and chemical weapons. Dr. Sharfstein is currently Health Commissioner for the City of Baltimore. Initial press reports have speculated that Ms. Hamburg will focus on food safety--and tobacco regulation should Congress transfer that issue to FDA, as some have recommended—and that Dr. Sharfstein will focus on drug and device regulation. However, subsequently Administration officials have denied that they plan a “split leadership” for the FDA.

Pediatric Drugs and Devices Meeting

On February 26, 2009, the National Institutes of Health National Institute of Child Health and Human Development hosted a meeting entitled *Consortium Meeting on Development of Pediatric Drugs and Devices: Expectations and Specifications*. The meeting was a follow up to the July 2008 interagency meeting at NIH in July 2008, at which NIH, FDA, physician specialty societies, and drug and device industry representatives made presentations regarding barriers and difficulties in the development of pediatric devices. Washington Office Staff attended the meeting. A third meeting is tentatively scheduled for May. More details from the meeting are available at http://www.ctsaweb.org/index.cfm?fuseaction=meeting.viewMeeting&year=2009&com_ID=282#mtg_ID_908

FDA Workshop on Biomaterials for Neurological Devices

The AANS/CNS Washington Office has been asked by FDA staff to assist with a workshop on Neurotoxicity in Biomaterials for neurological devices to be held on May 19, 2009 in Vancouver, Canada. Richard Fessler, MD, and Stephen Haines, MD, have agreed to speak at the meeting on behalf of AANS and CNS. The meeting is being held in conjunction with a meeting of the American Society for Testing and Materials (ASTM).

Unique Device Identification System Regulation

On February 27, 2009, AANS and CNS joined other specialty societies in signing a letter to the FDA in response to a January 15, 2009 *Federal Register* notice requesting comments on the Unique Device Identification (UDI) System for medical devices that the FDA has been working on for several years. Specifically, the letter, which was coordinated by the Advancing Patient Safety Coalition, suggested that the UDI be considered for all devices, be included on the individual package provided to the patient or facility using the device, coordinated with existing international standards, and be both encrypted and clearly readable to the end user.

Biosimilar Legislation

AANS and CNS joined 9 other specialty societies in sending a letter from the Alliance of Specialty Medicine to Reps. Anna Eshoo (D-CA), Jay Inslee (D-WA), and Joe Barton (R-TX) on behalf of their follow-on biologics/biosimilars bill introduced on Tuesday, March 17, 2009, that would help the development new biologics in a process somewhat analogous to the generic drug approval process. In the letter, also dated March 17, 2009, the groups urged the bill's sponsors to be vigilant in including patient protection safeguards in any legislation that goes forward to allow for a follow-on biologic or biosimilar product approval pathway in order to create great options for patients without undue risk. Specifically, the Alliance letter provided details on the unique nature of biologics and the difficulty of determining if a follow-on product is appropriate. The letter emphasizes "We have stated in the past our belief that legislation should not allow substitution or interchangeability of biosimilars for innovator products, because biosimilars can only be similar to, and are never identical to, an innovator product. They are not like generics, which are exact copies of innovator drugs. Interchanging biosimilar medications with original versions creates a complex risk-benefit assessment that can only be made appropriately by the patient's physician"