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Washington Update: News From Our Nation's Capital

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Following recent catastrophic events, such as September 11th and Hurricane Katrina, and in response to threats of future national disasters, government, public and private organizations have worked to devise response plans to be implemented in the event of an emergency.

As of May 25, 2006, the Department of Homeland Security established an all-hazards approach to improve the ability of the United States to handle domestic incidents. The plan incorporates many disciplines into a unified structure and includes homeland security, emergency management, law enforcement, firefighting, public works, public health, responder and recovery worker health and safety, emergency medical services, and the private sector. Further, it establishes protocols to help protect the country from terrorist attacks and other national disasters in order to protect public health, safety, property, and the environment, save lives, and reduce post-traumatic consequences of such events.

In addition, over the past three years, Health Systems Research, Inc., in collaboration with the Health Resources and Services Administration and the Centers for Disease Control and Prevention, has assisted the Agency of Healthcare Research and Quality to share information and tools to help public health officials, health system decision makers, and providers detect and respond to acts of bioterrorism. It has designed and conducted a series of Web conferences on bioterrorism and health systems preparedness.

Finally, the National Bioterrorism Hospital Preparedness program has worked to improve state, local, and hospital preparedness and response to bioterrorism and other public health emergencies. The mission of the program is to prepare hospitals and health care systems to deliver coordinated and effective care to disaster victims.

For more information about these initiatives and trainings visit www.hsrnet.com, www.dhs.gov, and www.hrsa.gov

A recent report on the Food and Drug Administration’s review of direct-to-consumer (DTC) advertisements by pharmaceutical companies has prompted a discussion about whether increased funding is needed to allow the FDA to better regulate the industry’s marketing efforts. The report, Prescription Drugs: Improvements Needed in FDA’s Oversight of Direct-to-Consumer Advertising, was released by the Government Accountability Office (GAO) in December 2006. Among the findings was GAO’s conclusion that the FDA reviews only a “small portion” of the DTC materials it receives. The GAO also raised questions about the effectiveness of the regulatory letters the FDA sends to companies when DTC advertisements are “violative.”

Senator Herb Kohl (D-WI) met with FDA Commissioner Dr. Andrew von Eschenbach on January 10, 2007 to discuss the regulation of DTC ads. Senator Kohl is the Chairman of the Agriculture Subcommittee of the Senate Appropriations Committee panel, which has jurisdiction over the FDA budget. Senator Kohl also sent a letter to President Bush seeking additional funding in the Fiscal Year 2008 budget request to allow the FDA “to effectively review and regulate” DTC advertising of prescription drugs. Senator Kohl expressed concern that “staff and funding levels [at the FDA] have not kept up with the increase in advertisements.” According to the GAO, drug company spending on DTC advertising increased dramatically between 1997 and 2005, but the budget for the FDA’s DTC review group has increased only slightly since its inception in 2002.

Currently, the FDA has oversight of DTC ads, but there is no requirement that companies have their ads approved or screened prior to airing. If the FDA identifies a violation of laws or regulations in DTC advertising material, the agency may issue a regulatory letter asking the drug company to take specific actions. However, the GAO report also questioned the effectiveness of the regulatory letters issued by the agency. According to the report, the FDA has issued fewer letters per year since 2002, when legal review of
all draft regulatory letters was first required. The report also concludes that the agency has had only “limited” success in halting the dissemination of violative DTC materials. The 19 regulatory letters issued by the FDA in 2004 and 2005 were, on-average, issued 8 months after the materials were first disseminated. The report notes that “by the time the FDA issued these letters, companies had already discontinued use of more than half of the violative materials.” Further, the GAO says that receipt of regulatory letters from the FDA did not always prevent drug companies from later disseminating similar violative materials for the same drugs.

The GAO report recommends that the FDA document the criteria it will use for prioritizing DTC materials for review by systematically applying that criteria to the materials it receives and tracking which materials it reviews. However, the report also states that the U.S. Department of Health and Human Services “disagreed with the recommendations, stating that they would require vastly increased staff.”

Meanwhile, the pharmaceutical industry is making an effort to increase self-regulation of DTC ads. In 2005, the Pharmaceutical Research & Manufacturers of America (PhRMA) released 15 “Guiding Principles” on DTC advertising that were intended to help companies in the industry self-regulate their marketing efforts. The Guiding Principles addressed issues such as compelling pharmaceutical companies to submit their ads to the FDA for review prior to being aired, including information about other options for treatment (such as diet and lifestyle), and holding conversations with physicians prior to the launch of a new DTC campaign.

Congress Reconsiders Stem Cell Research Legislation
Research involving human embryonic stem cells has stirred much debate in the United States in the past several years. Opponents of such research liken the harvesting of stem cells to abortion because embryos are destroyed in the process, and argue that it is wrong to destroy human life. Supporters, however, emphasize the important medical breakthroughs that such research may afford, such as a cure for Alzheimer’s and Parkinson’s disease.

In 2001, President Bush announced that federal funding could be awarded for stem cell research, but only under certain conditions. First, researchers must have harvested the cells prior to August 9, 2001. Second, researchers could only harvest cells from embryos that were created, but not ultimately used, for reproductive purposes. Finally, embryo donors must provide their consent, and may not receive any financial inducements for their donation.

In 2005, Congress tried to expand the scope of President Bush’s federal policy, with the passage of H.R. 810, the Stem Cell Research Enhancement Act (the Act). The bill would have allowed for research on embryonic stem cells regardless of the date researchers harvested them. In 2006, President Bush vetoed the bill.

With the Democrats in control of Congress, and Senator Edward Kennedy’s (D-MA) appointment as Chairman of the U.S. Senate Committee on Health, Education, Labor, and Pensions, the House reintroduced the Act as H.R. 3. Although the House passed the bill, it did not achieve the necessary two-thirds margin to overturn the President’s likely veto. The Senate has placed the bill on its calendar for discussion.

Recent polls and scientific studies may shape the future of stem cell legislation. Polls indicate that most Americans support stem cell research. Furthermore, a scientific study published in January 2007 indicated that researchers may not need to destroy embryos in order to obtain viable stem cells; rather, amniotic fluid may also yield stem cells suitable for research. Opponents of the Act may use this study to argue that the harvesting of embryonic cells is now entirely unnecessary in order to conduct stem cell research. Supporters of the bill, however, note that cells harvested from amniotic fluid may not provide the same research potential as cells harvested from embryos.

At Last: Senate Approval of FDA Commissioner
On December 13, 2006, Dr. Andrew von Eschenbach was sworn in as Commissioner of the Food and Drug Administration (FDA) following the Senate’s confirmation by a vote of 80 to 11 six days earlier. Although Dr. von Eschenbach’s nomination occurred in March 2006, his confirmation had been on hold since September. Members of both parties protested the confirmation, largely because of political controversy surrounding the FDA approval of Plan B, the emergency contraception pill, for sale to adults without a prescription. As Acting Commissioner, Dr. von Eschenbach’s approval of over-the-counter Plan B sales in August quieted many Democrats’ objections to his confirmation. A vocal minority of Republicans continued to protest Dr. von Eschenbach’s confirmation over concerns surrounding drug importation and the investigation of Ketek, an FDA-approved antibiotic
which has since been linked to liver disorders and deaths.
The confirmation provides stability for the FDA as the Democrat-controlled Congress is expected to issue new regulations for the FDA. Pending legislation on drug safety, generic medicine issues, and funding for FDA drug and device centers could substantially affect the agency's regular operations.

In the last decade, no FDA commissioner has held the position for longer than two years. Of the last five years, the FDA has been without a confirmed commissioner for all but 18 months. Dr. von Eschenbach, an oncologist and surgeon, previously served as director of the National Cancer Institute and as a chief academic officer to the M. D. Anderson Cancer Center.

*Bridget Behling, Meryl Eschen Mills, Jessica Smith, and Rebecca Wolf contributed to this column.*