Federal Health Matters

FDA Implements New Drug Safety Measures

Recent controversies regarding the safety of FDA-approved medications—particularly the withdrawal of Vioxx (Merck & Company, Whitehouse Station, NJ) in response to reports of increased cardiovascular events—have caused some to question the FDA's current approach to drug approval and postmarketing surveillance. And though the FDA has defended the integrity, objectivity, and transparency of its policies, Acting FDA Commissioner Lester M. Crawford, MD issued a statement on November 5 outlining new measures to be carried out by the FDA's Center for Drug Evaluation and Research (CDER) to strengthen existing safety programs.

One priority is to find a recognized drug safety expert to fill the vacant position of director of the CDER's Office of Drug Safety, a job that includes overseeing the FDA's postmarketing safety program. The FDA also has contracted an Institute of Medicine study of the current safety system, with a focus on identifying ways to improve postmarketing surveillance. And to ensure that differences of scientific opinion are adequately considered during FDA review processes, Crawford announced a formalized program that provides for the creation of an ad hoc review panel consisting of FDA and outside experts who have no involvement in the disputed decision.

By the end of this month, the FDA plans to publish three guidelines—on premarketing risks; use of "risk-minimization action plans"; and postmarketing risk assessment, good pharmacovigilance practices, and pharmacoepidemiologic assessment—to help pharmaceutical companies better manage safety risks throughout a drug's life cycle. Over the course of the next year,

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the CDER expects to hold a series of workshops and meetings to "discuss complex drug safety and risk management issues." During these consultations, experts from the FDA, other federal agencies, academia, the pharmaceutical industry, and the health care community will come together to address emerging concerns about investigational and marketed products.

According to Crawford, these new measures should help to strengthen the quality of medications the FDA approves—"as well as our consumers' confidence that FDA's processes ensure the highest protection of the public health."

Congress Passes VA Health Care, Personnel, and Benefits Bills

On November 18, the House approved three bills that affect veterans' health care and benefits: the Veterans Health Programs Improvement Act of 2004 (H.R. 3936), the VA Health Care Personnel Enhancement Act of 2004 (S. 2484), and the Veterans Benefits Improvement Act of 2004 (S. 2486). All three had been approved by the Senate already and were forwarded to President Bush. At press time, H.R. 3936 had been signed into law, while the other two were awaiting signature.

Sponsored by House VA Committee Chair Chris Smith (R-NJ), H.R. 3936 establishes new VA research and education centers focused on developing treatments for complex combat injuries, permanently authorizes the VA's sexual trauma counseling program, eliminates copayments for veterans receiving hospice care furnished by the VA, mandates VA reporting on medical waste management systems, and authorizes leases for community-based outpatient clinics. It also addresses the needs of homeless veterans by increasing

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funding for the Grant and Per Diem Program and encouraging the VA to use unneeded property for homeless veterans programs. Finally, it incorporates several measures for strengthening recruitment and retention of nurses and other health care personnel.

This last topic is the main focus of S. 2484, which would reform pay systems for VA physicians and dentists, authorize alternative work schedules for VA registered nurses, and mandate special pay for nurse executives. S. 2486 contains provisions for improving the VA's job training services, strengthening legal protections for service members called to active duty, and increasing the maximum VA home loan guarantee amount and monthly benefits for some surviving spouses. ●

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