Federal Health Matters

VA Researchers Under Fire for Response to Warnings About Smoking Cessation Drug

The VA was criticized heavily by media, members of Congress, and veterans' organizations in June for allegedly failing to inform study participants properly about the possible adverse effects of the smoking cessation drug varenicline (Chantix, Pfizer Inc., New York, NY).

These criticisms followed a joint investigation and June 17 reports by *The Washington Times* and ABC News about a VA study involving the drug. The study, which was ongoing at the time of the reports, aimed to learn whether smoking cessation therapy and therapy for posttraumatic stress disorder (PTSD) are more effective when combined or when administered separately. Of the study's 945 participants, 143 took varenicline, a FDA-approved drug for which over six million U.S. prescriptions were written in 2007. Other participants used such smoking cessation treatments as nicotine replacement patches or gum. The VA has emphasized that all treatments used in the study were recommended by the patients' physicians and that the patients were monitored clinically by mental health professionals.

This study was underway when safety concerns about varenicline began to arise in November 2007. On November 20, the FDA issued an alert describing reports of suicidal thoughts and aggressive and erratic behavior in patients who had taken varenicline, although the drug's role in those cases was not clear. The agency issued a revised alert on February 1 stating that patients taking the drug had experienced behavioral changes, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. In May, Pfizer updated varenicline's prescribing information to include warnings about the possibility of severe mood and behavioral changes. More recent data from the FDA have linked the drug to over 40 suicides and over 400 cases of suicidal behavior. To date, however, the drug has not been withdrawn from the market.

At issue is whether the VA acted appropriately to provide study participants with information about these safety concerns. The VA says that it immediately provided practitioners at all of its medical centers with the information in the FDA's initial alert, that it distributed the revised alert to VA pharmacists on the day it was issued, and that it informed VA researchers of the revised alert four days later. The VA researchers conducting the study did not mail a letter about varenicline's potential adverse effects to the study participants, however, until February 29—over three months after the FDA's initial alert. And while this letter listed anxiety, nervousness, tension, depression, and untoward changes in behavior as potential adverse effects of varenicline, it did not mention suicidal thoughts. In contrast, a secondary research consent form enclosed with the letter said varenicline might be linked to thoughts of suicide, as well as to attempted and completed suicide.

During the study, the VA has since revealed, 25 of the 143 patients taking varenicline reported a total of 26 serious adverse events, 11 of which were psychiatric in nature. There were three reports each of suicidal thoughts, depression, and nightmares and one report each of anxiety and auditory hallucination. The incidence of suicidal thoughts was actually greater, however, among the 802 study participants who did not take varenicline (4%) than it was among those who took the drug (2%).

In the aftermath of the media reports, the VA came under fire from at least eight members of Congress. Sen. John Cornyn (R-TX) and Rep. Steve Buyer (R-IN) requested that the VA investigate its handling of the study, while Rep. Bob Filner (D-CA), chairman of the House VA Committee, said he will hold hearings on the matter in early July. Representatives of three veterans service organizations—the Veterans of Foreign Wars, Iraq and Afghanistan Veterans of America, and Veterans for Common Sense—also criticized the VA's actions.

The VA appears to have shifted from an initial posture of defending the researchers' actions to a somewhat more conciliatory stance. In the initial *Times* report, Miles McFall, director of the VA's PSTD programs, explained the three-month gap as resulting from VA's need to approve the letters through an institutional review board. He said that the letters did not mention suicidal thoughts because they were meant to be brief and to direct participants to the enclosed consent forms; many veterans, he added, are elderly and have problems reading. And, in response to the media reports, the VA emphasized the steps that it took to inform its providers about varenicline's potential adverse effects after the FDA alerts. On June 19, however, VA Secretary James B. Peak announced that he would send letters to approximately 33,000 veterans taking varenicline to warn them about its potential adverse effects, including suicidal thoughts. The same day, he told the *Times* that he didn't understand McFall's explanation as to why the initial letter failed to mention suicidal thoughts and that he thought the letter "could have been stronger."

Continued on next page

Continued from previous page

TRICARE Launches Web-Based Formulary Access for Civilian Providers

TRICARE announced on June 3 that it will allow nonmilitary health care providers to access the DoD's uniform formulary through a web-based network. As a result, it said, these providers will receive more information about the DoD pharmacy benefit, fewer patients will present nonformulary prescriptions to pharmacies, and the overall quality of care will be improved. The formulary will be made available to civilian providers through RxHub (Saint Paul, MN), a private provider of web-based prescription eligibility, benefit, formulary, and medication history information. TRICARE described the move as a significant step toward the DoD's goal of working in partnership with the electronic prescribing industry, as well as toward the "ultimate goal" of transmitting prescriptions electronically. If the latter goal is achieved, all TRICARE providers and managed care support contractors will be able to send prescriptions electronically to all dispensing points—including military treatment facilities, mail order pharmacies, and retail pharmacies.

House VA Subcommittee Reviews New Vet Bills

On June 23, the House VA Economic Opportunity Subcommittee, chaired by Rep. Stephanie Herseth Sandlin (D-SD), conducted a legislative review hearing on eight bills that would affect VA benefits—including two that involve health care benefits.

H.R. 2721, introduced by Rep. Dennis Cardoza (D-CA), would require the VA to develop a CD containing the following: explanations of the health, education, and other benefits to which veterans are entitled; a "comprehensive explanation" of how veterans may apply for these benefits; and a listing, with contact information, of all VA facilities. The DoD would be responsible for distributing the disk to all members of the armed forces upon their discharge or release from active duty, and the disk would be available to veterans' family members upon request. The bill also would require both the VA and the DoD to make the disk's information available over the web.

H.R. 4255, introduced by Rep. Robert Filner (D-CA), would allow the VA to grant $10 million each year, through fiscal year 2012, to the United States Olympic Committee (USOC) for the committee's Paralympic Program. Since 2005, this program has been providing special training and rehabilitation to disabled veterans and members of the armed forces; it introduces them to adaptive sports techniques and paralympic sports programs in their hometowns. The VA under secretary for health would oversee USOC's use of the grants, which would include program planning, development, management, and implementation. Rep. Filner said that the bill is intended to "enhance the rehabilitation and quality of life of current severely injured service members and veterans and to reduce the chance of secondary medical conditions." ●