

HHS Committee Calls for Medical Home Funding

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Support for the concept of the patient-centered medical home continues to grow, with the latest nod coming from the federal Advisory Committee on Training in Primary Care Medicine and Dentistry.

The committee, which provides policy advice to Congress and the Health and Human Services secretary, is finalizing a report that recommends that policy makers invest in training physicians on how to operate within the medical home model and evaluate the health outcomes associated with this model of care.

A failure to invest in the medical home model now will impair efforts to improve quality and control costs, the committee wrote. The United States "faces a watershed moment when it can restructure health care to focus on prevention and coordinated, comprehensive care through the adoption of this promising new model of care," the committee wrote in the draft report.

The report, which is expected to be released in its final form in late 2008, calls for changes to Title VII, Section 747 of the Public Health Service Act. For example, the committee is recommending that the

HHS secretary expand the authority of that law to include directing continuing medical education programs to train currently practicing physicians in aspects of the medical home, including interdisciplinary team-based care, care of disadvantaged and vulnerable populations, and the use of information technology.

It also calls on the HHS secretary to promote dissemination of the best practices related to providing a medical home that have been identified by researchers.

Other draft recommendations from the committee include the following:

- ▶ Funding pilot programs that contribute to the development and evaluation of the medical home, with priority given to those programs that address the needs of underserved populations.
- ▶ Developing measures to evaluate the medical home in terms of accessibility and patient satisfaction, health status, quality of care, health disparities, and cost.
- ▶ Implementing key components of the

medical home model in academic medical centers, in an effort to prepare faculty educators.

The committee's next report, due out in May 2009, will explore how primary care training would need to be redesigned to further the concept of the medical home. It will also address the difficulties in hand-offs between pediatric and adult medicine specialists when patients with chronic illnesses reach adulthood, as well as on workforce issues and medical school debt. ■

IMPORTANT CORRECTION OF DRUG INFORMATION ABOUT EFFEXOR XR® (VENLAFAXINE HCl) EXTENDED-RELEASE CAPSULES

An advertisement in professional journal publications for EFFEXOR XR® (venlafaxine HCl) Extended-Release Capsules for the treatment of major depressive disorder was the subject of a Warning Letter issued by the U.S. Food and Drug Administration (FDA) in December 2007. The FDA stated that the journal ad was misleading because it overstated the efficacy of EFFEXOR XR, made unsubstantiated superiority claims, and contained other unsubstantiated claims regarding EFFEXOR XR.

Wyeth would like to take this opportunity to clarify the content of the advertisement.

Claims that Reference the Baldomero et al Study and Other Related Claims

The FDA objected to the claim, "In an open-label study of patients who failed previous antidepressant treatment, nearly 60% achieved remission when changed to EFFEXOR XR." The FDA determined that the Baldomero study (the cited reference for this claim) could not be relied upon as substantial evidence to support the claim due to the following reasons: (1) the study was an open-label study, which is not an appropriate study design to measure subjective end points because it fails to minimize potential bias; (2) the study did not include a placebo group, so there was no way to determine the actual effect size of the drug; and (3) the study did not provide information about whether EFFEXOR XR was superior to failed therapy because study subjects were not randomized to their previously failed therapy. Therefore, the FDA stated that the study failed to support the 60% remission rate claim as well as any conclusion that EFFEXOR XR is superior to other antidepressant treatments. In addition to the above claim, the FDA stated that other claims added to the misleading impression that patients who have failed previous antidepressant therapy can expect improvement when switching to EFFEXOR XR.

Claims from the PREVENT Study

The FDA objected to the claim, "In the PREVENT study, the probability of preventing a new episode of depression was 92% with EFFEXOR XR in maintenance year 2 vs. 55% with placebo." The FDA stated that the cited claim overstated the efficacy of EFFEXOR XR by implying that the general patient population suffering from major depressive disorder can expect a 92% probability of preventing a recurrent depressive episode after two years of treatment when this is not supported by substantial evidence.

The cited study for this claim was a randomized, multicenter, double-blind study (n=1096) comparing EFFEXOR XR with placebo. The study was designed to provide efficacy data regarding recurrence prevention with EFFEXOR XR after two years of maintenance

treatment. It followed patients through 4 different time periods: a 10-week acute period, a 6-month continuation period, an initial 12-month maintenance period (maintenance year 1), and a second 12-month maintenance period (maintenance year 2). At the end of each period, patients were only considered eligible for inclusion in the next period if they were still responding to the drug. Patients dropped out of the study during each of the periods for different reasons (eg, lack of efficacy, adverse events). At the start of each maintenance period, the remaining patients who still showed a response to EFFEXOR XR were re-randomized to EFFEXOR XR or placebo. Because a high percentage of EFFEXOR XR patients were either re-randomized to placebo or were discontinued from the study before entering maintenance year 2 and because only patients who responded to EFFEXOR XR were selected to continue to the next phase of treatment, the FDA determined that the results of the study could not be extrapolated to the general patient population suffering from major depressive disorder.

Claim Regarding Clinical Experience and Number of Patients

The FDA objected to the claim, "More than 12 years of clinical experience and over 20 million patients treated with EFFEXOR/EFFEXOR XR." The claim of 20 million EFFEXOR/EFFEXOR XR patients was estimated from the number of U.S. prescriptions, average daily consumption, and average length of therapy. The FDA determined that this claim was misleading based on the referenced data because the calculations used did not reflect the number of "unique" patients. Because there are no unique patient-level data available for the entire 14-year period during which EFFEXOR/EFFEXOR XR has been on the U.S. market, the claim is no longer used in EFFEXOR XR promotional materials.

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published 5 years after the drug in question was approved. Among all the trials, those with statistically significant results were nearly twice as likely to have been published as those without statistically significant results, and pivotal trials were three times more likely to have been published as nonpivotal trials. But the study revealed "selective reporting" of results, the authors said. "A pivotal trial in which the new drug does no better than an old drug is less likely to be published than one where the new drug is more effective, a publication bias that could establish an inappropriately favorable record for the new drug in the medical literature," the authors wrote.

Florida Files Vioxx Suit

Florida Attorney General Bill McCollum has sued Merck & Co. on behalf of state agencies he said were damaged by "the company's allegedly deceptive marketing and promotion" of Vioxx. The lawsuit follows a 3-year investigation of Merck's promotional practices of Vioxx (rofecoxib) and alleges that, due to the company's marketing practices, numerous Florida agencies approved the inclusion of Vioxx as a covered or approved drug. Vioxx purchases by the Florida Medicaid program exceeded \$80 million between 1999 and 2004, according to Mr. McCollum, who argued that, if the facts about Vioxx had been known earlier, physicians and their Medicaid patients would have chosen other, less expensive prescriptions. Eight other states have filed similar lawsuits, according to Merck spokesman Ronald Rogers, who said in an interview that Merck acted responsibly on Vioxx and will defend against the suits.

—Jane Anderson

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