

# U.S. Falling Short on Key Health Care Indicators

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Access to care has declined significantly since 2003, with 42% of all working-age adults either uninsured or underinsured in 2007, according to a national health system scorecard from the Commonwealth Fund, which found that health care system performance in the United States has worsened slightly overall since 2006.

According to the scorecard report, the United States on average continues to fall far short on key indicators of health outcomes and quality. U.S. scores are particularly low on efficiency, compared with top performers inside the country—states, regions, hospitals, health plans, or other providers—and internationally.

"These findings were very disturbing, considering the resources the U.S. spends on health care," Dr. Karen Davis, president of the Commonwealth Fund, said in a

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briefing on the report, adding that the nation spends more on health care than any other in the industrialized world.

In the report, "Why Not the Best? Results From the National Scorecard on U.S. Health

System Performance, 2008," the United States scored an average of 65 out of a possible 100—slightly below the 67 scored in 2006 in the first scorecard released—across 37 key indicators of health outcomes, quality, access, efficiency, and equity.

"We need to change direction," Dr. Davis said. "This latest scorecard demonstrates that we are in fact losing ground."

The report found that the number of uninsured and underinsured Americans continues to rise: As of 2007, 42% of all working-age adults were either uninsured or underinsured—up from 35% in 2003.

In addition, the report said that the United States failed to keep up with improvements made in other countries, and fell from 15th place to dead last among 19 industrialized nations in premature deaths that could have been prevented by timely access to effective health care.

Rates for basic preventive care, such as cancer screening, failed to improve from 2005 to 2007, the report said.

Also, "scores on efficiency are particularly low, pulled down by fragmented, poorly coordinated care," along with lack of access to care and high administrative costs, said Cathy Schoen, senior vice president of the Commonwealth Fund.

In 2007, for example, as in 2005, patients in the United States were three to four times more likely than patients in other countries to report having had duplicate tests or to report that medical records or test results were not available at the time of their appointment. And although primary care physicians in the United States

used electronic medical records (EMRs) increasingly from 2001 to 2006—17% to 28%—the United States lags far behind leading countries, where EMRs now are used by nearly all physicians (98%) to improve care, the scorecard reported.

Still, "there are some bright spots," Ms. Schoen said. The report found evidence that focusing on specific areas through targeted initiatives can yield substantial improvement.

For example, the report found that hos-

pital standardized mortality ratios, a key indicator of patient safety, improved by 19% over 5 years, following broad public and private efforts to assess and improve hospital safety. Also, chronic care and acute hospital care quality metrics that have been the focus of public reporting, pay for performance, and improvement efforts also showed significant progress.

"We find that what gets attention gets improved," Ms. Schoen said. "But to date we have focused too narrowly. Current ini-

tiatives often fail to encourage more effective or more efficient care."

Dr. Davis pointed out that, with a new president and administration coming soon, the United States has a real opportunity to refocus and rebuild its health care system.

"The most important thing is extending health insurance to all," she said. "There were 75 million American adults uninsured at some point in the year, and obviously that affects performance throughout the scorecard." ■

## 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.

**Please see brief summary of Prescribing Information on adjacent page.**

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