FDA and Drug Shortages

Congress should give the Food and Drug Administration (FDA) more power to help prevent, alleviate, and resolve drug shortages, according to the Government Accountability Office (GAO). The recommendation came in a report presented during a December 15 hearing by the Senate Committee on Health, Education, Labor, and Pensions.

In the report, the GAO indicated that even though the FDA has a drug shortage program, the agency is constrained in its ability to prevent shortages because it lacks the authority to require manufacturers to report actual or potential shortages or take actions to mitigate shortage situations (http://tinyurl.com/cc5t5ju).

The GAO report found the number of drug shortages has increased substantially since 2006, with a record number reported in 2010. On average, these shortages lasted 286 days. Anesthetic, oncology, and anti-infective drugs were among the therapeutic classes most often in short supply.

Health Care Fraud

The Department of Justice announced December 19 that it had secured more than $3 billion in settlements and judgments in civil cases involving fraud against the government in the fiscal year ending September 30, 2011. This total included $2.4 billion in recoveries for fraud committed against federal health care programs.

Enforcement actions involving the pharmaceutical industry were the source of the largest recoveries in 2011, totaling almost $2.2 billion. One of the largest recoveries reported by the Justice Department was $900 million from 8 drug makers to resolve allegations that they had engaged in unlawful pricing to increase profits. Another was $750 million paid by GlaxoSmithKline to resolve criminal and civil allegations that the company knowingly submitted, or caused to be submitted, false claims to government health programs for adulterated drugs and for drugs that failed to conform with the strength, purity, or quality specified by the Food and Drug Administration.

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Almost $2.2 billion of the more than $3 billion recovered by the Department of Justice last year to settle white-collar fraud cases came from pharmaceutical manufacturers.

Sen Chuck Grassley (R, Iowa), who authored amendments to strengthen the False Claims Act in 1986 by empowering whistleblowers to file suit on behalf of the United States against those who fraudulently claim federal funds, said in a release that since 1986 the law has helped the government recover more than $30 billion. "Year after year, the federal False Claims Act proves to be the most powerful tool in rooting out fraud against the federal treasury," Grassley said.

Clean Air Standards

It took more than 20 years, but on December 21, the Environmental Protection Agency (EPA) issued the Mercury and Air Toxics Standards, an action mandated by passage of the 1990 Clean Air Act Amendments.

The standards are designed to regulate and lower power plant emissions of mercury and toxic air pollution. The EPA estimates the new standards may prevent 4200 to 11 000 premature deaths, 4700 myocardial infarctions, 130 000 cases of childhood asthma attacks, and 6300 cases of acute pediatric bronchitis each year.

Sen Barbara Boxer (D, Calif), Chairman of the Senate's Environment and Public Works Committee, said in a release, "Power plants are not only the nation's largest source of dangerous mercury emissions, but they also pollute the air we breathe with lead, arsenic, chromium, and cyanide. These hazardous air pollutants are known to cause cancer, harm children's development, and damage the brain and nervous system of infants."

Alternative Medicaid Coverage

A demonstration project to study a new type of health insurance coverage for Medicaid enrollees has underperformed, according to a Government Accountability Office (GAO) report released December 16.

The Deficit Reduction Act of 2005 created a 5-year demonstration program allowing up to 10 states to test alternative health coverage under Medicaid. States participating in the program were required to establish savings accounts called Health Opportunity Accounts that beneficiaries could use to pay for out-of-pocket medical expenses. The states and federal government could fund the accounts with up to $2500 annually for an eligible adult and $1000 for a child, provided that they were also enrolled in a high-deductible health plan (http://tinyurl.com/77hs9pr).

The demonstration program was launched in 2007, and only South Carolina applied for it and was approved to join. Congress prohibited additional states from signing on in 2009. Meanwhile, although officials in South Carolina had anticipated that about 1000 individuals enrolled in the state's fee-for-service Medicaid program would eventually participate in the demonstration, enrollment totaled only 2 adults and 3 children.—**Mike Mitka**