Senate OKs Medical Device Act for 5 More Years

Both the House and the Senate must move quickly to avoid layoffs and interruptions at the FDA.

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The full Senate has approved a 5-year reauthorization of the Medical Device User Fee Modernization Act as part of a legislative package that included reauthorization of the Prescription Drug User Fee Act.

MDUFMA is due to expire Sept. 30. The law governs how much manufacturers are expected to pay for review of their products and also sets out review timetables that the agency must meet.

The medical device industry was largely happy with the bill as passed.

"The agreement provides additional resources to [the Food and Drug Administration] to hire additional reviewers providing patients with access to safe, lifesaving medical devices in a timely manner," AdvaMed President and CEO Stephen J. Ubl said in a statement.

"The agreement also provides manufacturers with a more predictable fee schedule with regard to user fee rates," he said.

The device user fee portion of the bill is largely the result of an agreement hammered out earlier this year by the FDA and the industry.

In a briefing with reporters unveiling the specifics of the agreement, Dr. Jeffrey Shuren, the FDA's assistant director for policy, touted its "aggressive performance goals."

Under current law, in fiscal year 2007, the FDA is required to make a decision on 90% of premarket approval applications (PMAs) within 320 days, and on 50% within 180 days.

With the new proposal, 60% of PMAs will be reviewed within 180 days, and 90% within 295 days in fiscal year 2008.

This year, 90% of priority PMAs are required to be reviewed within 300 days, and 80% of 510(k)s within 90 days. Under the new proposal, in fiscal year 2008, 90% of priority PMAs will be reviewed within 280 days, and 50% within 180 days. Ninety percent of 510(k)s will be reviewed within 90 days, and almost all—98%—within 150 days.

Dr. Jesse Goodman, director of the FDA's Center for Biologics Evaluation and Research, said that the current law had expedited the division's review of devices for blood testing and transfusion, and for cellular therapies and tissues. Before the program, it took an average of 123 days to review an application; in 2006, the average was about 55 days, Dr. Goodman told reporters.

The agency also is proposing to streamline its review of diagnostic imaging devices and said it would publish draft guidance on the issue by October 2008. The FDA would also make more use of private, outside inspectors.

Currently, manufacturers have to go through a lengthy process to use third-party reviewers.

Under the new proposal, they'd only have to give 30 days' notice, and they would be allowed to use the reviewers for a larger number of inspections.

The FDA estimated that it will require $220 million to review devices in fiscal year 2008, of which it plans to raise about $49 million from user fees. Over the 5 years of the program, it will need $1.2 billion, of which $287 million will come from industry.

In the past 5 years, the agency has had to go back to manufacturers to seek supplemental increases when there was a shortfall—which occurred when there were fewer new device applications than had been anticipated.

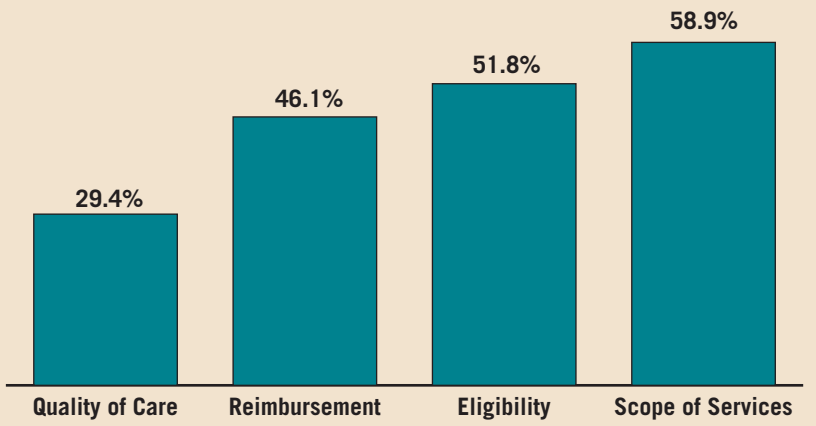
If the new legislation becomes law, fees will be fixed for each year of the program. Half the fees will come from applications—for new devices, supplements, manufacturing modifications, and classification information—and half from two new fees: one for manufacturing establishments and single-device reprocessors, and a periodic annual report fee. About 425 devices are subject to annual reporting requirements.

The House is still weighing prescription drug and medical device user fee reauthorizations.

Both the House and the Senate must move quickly to avoid layoffs and interruptions at the FDA, which has become heavily dependent on industry user fees to finance its work. ■

DATA WATCH

State Medicaid Programs Fall Short in All Categories



Note: Data calculated using the percentage of the mean score out of the total possible score.
Source: 2000-2006 data, Public Citizen Health Research Group

Senate Reauthorizes Prescription Drug User Fee Act; House Still in Early Phases

After some last-minute wrangling over drug reimportation and regulation of advertising, the Senate voted 93-1 to fund another 5 years of the Prescription Drug User Fee Act.

Among other issues, PDUFA governs how much pharmaceutical manufacturers pay to have their products reviewed by the Food and Drug Administration, and how quickly the agency must complete those reviews. The current PDUFA law expires Sept. 30.

Some have criticized the program, saying that it lets a regulated industry have too much power over its regulators. But the FDA has become increasingly dependent on user fees to fund its work.

At least one amendment to the original legislation (S. 1082) was passed that would give the agency more teeth. Senators voted 64-30 to approve Sen. Chuck Grassley's (R-Iowa) amendment to increase fines—from $10,000 to $250,000—for companies that don't comply with FDA directives on label changes, postapproval studies, and communicating new information about safety.

The penalties would double every 30 days, but would be capped at $2 million.

"These penalties need to be more than just an insignificant cost of doing business in order to affect behavior," said Sen. Grassley in a statement.

Drug safety has been a significant focus of the legislation as it has made its way through the Senate.

Sen. Edward Kennedy (D-Mass.) and Sen. Michael Enzi (R-Wy.) had been hoping to attach proposals for improved drug safety to the PDUFA reauthorization, but most of their suggestions were defeated or watered down in a committee vote in mid-April.

The centerpiece of their proposals was to require a risk evaluation and mitigation strategy (REMS) plan for all new chemical entities and biologics. Instead, the Senate Health, Education, Labor, and Pensions committee voted to give the FDA authority to determine when a new drug should have a REMS. That provision made it into the legislation that passed the full Senate. The panel also voted to require the FDA to set up a public-private partnership for routine surveillance of postmarketing drug safety, which also was part of the final bill.

PDUFA would allow the FDA to collect $393 million in drug user fees in 2008, including a $30 million increase for postapproval drug safety programs.

The bill would also require drug makers to publish a registry of all late-phase II, and all phase III and IV trials, and to make all trial results available in a public database.

Finally, PDUFA would fund another 5 years of the Best Pharmaceuticals for Children Act. Companies that conduct pediatric studies of their products are eligible for additional patent life under the law, which expires Oct. 1. The new 5-year program will extend a drug's patent life by 3 months (instead of 6 offered under the previous law) if sales of the product are more than $1 billion and by 6 months if sales are less than $1 billion.

Under the Best Pharmaceuticals for Children Act, the Government Accountability Office found that drug sponsors have initiated pediatric drug studies for most of the on-patent drugs for which the FDA has requested studies. About 87% of drugs studied had labeling changes, often because the pediatric drug studies found that children might have been exposed to ineffective drugs or dosing; overdosing; or previously unknown side effects.

The Senate vote was hailed by the brand name and generic pharmaceutical industries.

"The significant increases in user fees will provide the FDA the resources necessary to improve and modernize its already strong drug safety monitoring system," PhRMA President and CEO Billy Tauzin said in a statement.

The generic industry was happy, as it secured a promise from a group of Senators to markup legislation authorizing generic copies of biologic drugs by mid-June, with a goal of incorporating it into the final House-Senate agreement on the PDUFA law.

The Generic Pharmaceutical Association also praised a group of senators who secured passage of an amendment requiring the FDA to move forward on generic drug applications even though a brand name company has filed a citizen's petition questioning the generic. In the past, the FDA has not been able to consider approval of a generic until the petition was resolved—and, filing a petition has become a common strategy used by the brand name industry, according to the GPhA.

The PDUFA legislation still has far to go before it becomes law. The House is still in the early phases of work.