Senate Passes Device User Fee Bill

BY ALICIA AULT
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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, life-saving 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 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.

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The FDA is proposing to streamline its review of diagnostic imaging devices and said it would publish related draft guidance by October 2008.

The agency also is proposing to streamline its review of diagnostic imaging devices and said it would publish draft guidance on the issue by October 2008.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.

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. ■

Senate Votes to Reauthorize Prescription Drug User Fee Act

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.

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 mark-up 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.

Part D Hassles Persist Into 2 Year Program

BY MARY ELLEN SCHNEIDER
New York Bureau

SAN DIEGO — In the second year of Medicare Part D implementation, physicians continue to struggle with prior authorization requests and other hassles, Dr. Kay M. Mitchell said at the annual meeting of the American College of Physicians.

Although some of the paperwork burden remains, the prescription drug program is generally easier to manage now because patients and physicians are more familiar with the rules, said Dr. Mitchell, of the Mayo Clinic in Jacksonville, Fla.

"It's still going to cost us time and money," Dr. Mitchell said. "It doesn't matter how much we've worked at it."

For example, physicians continue to see requests for prior authorization and step therapy, said Neil M. Kirschner, Ph.D., ACP's senior associate of insurer and regulatory affairs. In addition, in 2007, several drugs were approved under both Medicare Part B and Part D, which could create denials, he said.

Officials at the Centers for Medicare and Medicaid Services are working on this issue and recommend that physicians write the diagnosis and "Part D" on the prescription, Dr. Kirschner said.

Physicians might experience some relief in terms of prior authorization and exceptions if their patients haven't changed drug plans, Dr. Mitchell said.

When you are faced with prior authorization, Dr. Mitchell suggested, save time by having the patient collect the authorization forms and bring them into the office. In her office, this saves office staff 20-35 minutes per prescription, she said.

Some physicians have decided to deal with the extra Part D paperwork by either hiring additional staff or designating staff to deal solely with Part D prior authorizations, denials, and appeals, Dr. Mitchell said

Over the course of Part D implementation, Dr. Mitchell learned that insurers may ask for documentation justifying a switch in medications. To simplify that process, she recommends, keep a sheet in the front of the chart with information on medication changes and the reasons for the switch. ■

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