Proposal ties financial incentives to development of drugs for neglected diseases

Pharmaceutical firms that develop therapies for neglected diseases, like leishmaniasis, dengue fever, and Chagas’ disease, should be awarded an FDA voucher that would give the bearer priority-review status of another, potentially more profitable, drug, Duke University researchers proposed in an article published in the March/April issue of Health Affairs.

Under the plan, the authors said, a company would receive a “priority-review voucher” from FDA in exchange for paying an additional $1 million in so-called user fees and agreeing to partner with at least one generic drug maker to develop a treatment for a neglected disease.

The $1 million, the researchers estimated, would cover the personnel costs to FDA of changing a drug’s review status from standard, which generally takes 18 months, to a priority six-month review. The extra user fee, the researchers contended, would also ensure that the review process for other drugs in FDA’s queue would not be slowed.

A priority-review voucher would be worth more than $300 million to the sponsor of a potential blockbuster drug because a medication would enter the market about a year earlier, said lead author David Ridley, assistant professor at Duke’s Fuqua School of Business.

The system, he said, would give pharmaceutical companies “a prize” for creating and licensing drugs for diseases that affect people in the developing world.

Financial incentives for research and development of new therapies for neglected diseases are needed because most victims are poor and drug makers “don’t expect to be able to recoup those costs,” Ridley said.

Subsidies for malaria treatments needed now

As one of its first steps to become a more active force in global health issues, the public policy journal Health Affairs in its March/April edition published several articles focused on access to health care services and medications in poor countries, the editors announced at a March 7 briefing in Washington, D.C.

A $2.95 million, five-year grant from the Bill and Melinda Gates Foundation has allowed the journal to specifically solicit and publish articles on global health topics, said Deputy Editor Robert Cunningham.

“Given the self-evident growth and importance of global health issues in this generation,” he said, “it’s appropriate for us to try to extend the forum that we have and make it useful for these concerns.”

One of the featured papers in the March/April issue calls for an immediate global subsidy of new proven therapies to fight the emergence of multidrug-resistant malaria.

The malaria parasite has already defeated previously effective treatments, such as chloroquine and sulfadoxine—pyrimethamine, said lead author Ramanan Laxminarayan, a fellow at Resources for the Future, a nonpartisan economics and social sciences research organization.

Fortunately, he said, a class of drugs called artemisinins provides hope. But, Laxminarayan said, many health care providers in malaria-endemic countries are misusing artemisinins as monotherapy, which will likely speed up the development of resistance.

Unless subsidies from wealthy countries for the costs of artemisinin combination treatments (ACTs) for malaria are immediately made available to poor countries, he said, “we could lose these drugs to resistance very rapidly.”

A delay in the subsidy of ACTs by three or four years could “actually make things worse” and could accelerate resistance, Laxminarayan said.

“There is an urgent need for the subsidy to be enacted now,” he said.

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“So if you have a blockbuster drug, you want to get your hands on one of these vouchers in order to have priority review and get to market faster,” he said at a March 7 briefing in Washington, D.C.

“On the one hand, we have incentives for treatments for neglected diseases, and on the other hand consumers in the U.S. get access to a blockbuster drug a year sooner. We think that this is a win–win.”

To receive a voucher, Ridley noted, a company must also agree to waive all patent rights for the neglected-disease treatment. The voucher, he said, could be sold to another company or acquired as part of a buyout of its owner.

The authors argued that “priority review does not entail lower standards for safety and efficacy.”

Congress passed the Prescription Drug User Fee Act (PDUFA) in 1992, which created a system where drug companies pay fees to FDA to support its process for reviewing applications for new drugs and biologicals.

Critics have charged that PDUFA’s emphasis on faster review times has compromised drug safety.

Ridley argued that a September 2005 report by the Tufts Center for the Study of Drug Development found no correlation between review times and withdrawal of drugs from the market.

The Tufts report noted that the two cyclooxygenase-2-selective nonsteroidal antiinflammatory drugs recently withdrawn from the U.S. market each had a different review status.

Rofecoxib, or Vioxx, which was abruptly pulled off the market by Merck in September 2004, received a priority review from FDA. But valdecoxib, or Bextra, which was voluntarily withdrawn from the market by Pfizer in April 2005, received a standard review by regulators.

Jeffrey L. Moe, coauthor of the Duke report, argued at the March 7 briefing that a drug’s safety and efficacy are determined during the clinical trial process and not during FDA’s review of the data.
Therefore, he said, user fees have no effect on the review process. The authors acknowledged that a priority-review voucher might speed the approval of a product that has a high potential for sales but limited clinical benefits and that a drug given priority review might eventually be found to be unsafe. Ridley said that FDA officials have been “positive” about the priority-review voucher proposal. But, he added, the proposal would need to be enacted under legislation.

—Donna Young
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Health event aids San Antonio’s Hispanic residents

Because many Hispanics in San Antonio, Texas, cannot afford or access health care services, a free health care fair in February was the first time several of the 1000 attendees were screened for diabetes and hypertension or received counseling about their medications, said a pharmacist who helped organize the event.

“Many people in the community used this venue as one of their sole accesses to health care services,” said Cliff Littlefield, the William J. Sheffield Professor of Pharmacy at the University of Texas (UT) at Austin and director of the College of Pharmacy’s Hispanic Center of Excellence.