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Overburdened FDA accused of biting off more than it can chew

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The FDA received an earful this week.

A month after the Food and Drug Administration had to reveal the deaths of dozens of patients who had been medicated with tainted versions of the blood thinner heparin, FDA Commissioner Andrew C. von Eschenbach faced the music in hearings before the House Energy and Commerce Committee.

This bad news was only one more in a long list of grievances (Vioxx, contaminated food imports) that the overseers in Congress have with the agency.

The bi-partisan headhunters were not shy in expressing their exasperation. In doing so, they are in line with the public's sentiments: A Wall Street Journal/Harris Poll survey this month revealed that only 35 percent of the respondents thought the FDA was doing a good job.

According to two articles in the latest edition of the New England Journal of Medicine, the FDA is clearly overwhelmed with the prospect of not only being tasked to regulate "\$1 trillion worth of consumer products," but also having to do so while the share of imported products is rising.

A report by the non-partisan Government Accountability Office, which featured prominently in the hearings before Congress, estimates that regular inspections of overseas producers would cost approximately \$70 million per year, which is seven times the amount currently budgeted for this task.

In the face of such reports, the Senate has just proposed to increase the agency's total appropriations by hundreds of millions of dollars (or 20 percent), a move that is opposed by the administration, which favors a 3 percent increase.

Given the amount of money involved as well as the serious public health issues, one would expect that the workings of the FDA have been studied extensively.

However, as an article in the newest volume of the Journal of Economic Perspectives points out, "If a product application was supplied to the FDA with the scant amount of analysis that currently exists on the efficiency and performance of the policies of the agency itself, such an application would clearly be rejected on the basis of insufficient evidence."

The study's authors, University of Chicago professor Thomas J. Philipson and RAND Fellow Eric Sun, lament the dearth of explicit research asking how wisely the budget of the FDA is utilized. Given this lack of information, pouring more money into the agency may not necessarily be the optimal approach.

On the other hand, Philipson and Sun suggest an increase in the FDA's responsibilities that would justify an even bigger budget.

They state that there "may be a case for a product liability exemption for manufacturers of new drugs and medical products" if the FDA has approved those.

This would be in line with a recent Supreme Court decision, which now explicitly prevents plaintiffs from suing manufacturers of medical devices for damages in state courts in case of injuries or death, if the FDA has approved those devices.

Their argument relies on the fact that having regulatory oversight while also permitting product liability suits to go forward can be characterized as a duplication of safety intervention.

Assigning responsibility for ensuring product and drug safety solely to the FDA, though, would directly increase the agency's workload and expenses. Given that the FDA seems already to have bitten off (or been assigned) more than it can chew, that added responsibility would clearly be a mouthful.

Michael Reksulak teaches economics and public finance in Georgia Southern University's College of Business Administration. He may be reached by e-mail at [mreksula@ georgiasouthern.edu](mailto:mreksula@georgiasouthern.edu) [1].

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