OPINIONS

Is a new industry watchdog necessary?

In the January/February 2002 issue, PharmaVOICE asked readers if the Food and Drug Administration should collect special user fees from pharmaceutical manufacturers to analyze and disseminate data on new drugs and biologics after they are released into the general population. We wanted to know if post-market surveillance should continue to be a function of the FDA, or should the industry become its own watchdog?

The Time Has Come

The idea of setting up a separate agency to oversee post-marketing surveillance has been proposed over the past two to three decades — perhaps now its time has come.

I would endorse using a new source of user funds to establish a quasi-autonomous agency separate from FDA and industry whose charge would be to act as a focus for drug safety issues. It should use various methods, ranging from having access to the numerous electronic claims and pharmacy databases available to designing specialized registries to assess drug use.

It will only be successful if there is a large volume of input and the opportunity for follow up with individual reporters. Using today's technology, communications and recording of information must be easy, confidential, and without risk of liability to the reporter. This is a tall order but now more possible with a combination of adequate funding and contemporary communications methods.

John J. Schrogie, M.D.
VP, Peri-Approval Research Services
Omnicare Clinical Research

A Complicated Issue

This is an immense and complicated issue. Generally, user fees paid by the industry are a good practical solution to delays in processing drug approvals. Faster approvals mean drugs get to market faster, saving lives and improving the quality of life. In the meantime, they might even lower the cost of branded drugs because they give the company a longer patent protected period to sell the drug. This gives them more time to recoup the cost of development and marketing, thus improves the chances of plowing more money into drug development.

In the perfect world, if the government would do this efficiently, never make a mistake, the costs of approval and regulatory compliance would be lower.

Post-market issues are a very different issue. Sure, we all want good, timely data on the experience of drugs in the population. But, the FDA is just one source of these data. Clinician experience and university research are great sources. If serious unanticipated side effects emerge, all parties should work together as quickly as possible to get to the bottom of it; industry, clinicians, researchers, and government. And if possible, lawyers and courts should be the last resort.

John Kamp
Of Counsel
Wiley Rein & Fielding LLP

The Yeahs Have It

Yes, we support fees and a system where much of the generation and evaluation of safety data are done post-launch. This would reduce the need (and the cost) of large Phase III trials, whose increasing size are driven by the desire to detect rare adverse events prelaunch.

We believe in the ability of pharma companies to be self policing. The benefits of this approach are many: patients will get faster access to life-saving medications, and the costs of achieving our current level of safety will fall.

Gerald R. Marschke
Director
The Webster Consulting Group Inc.

Fair and Reasonable

Yes, I think fair user fees are reasonable. Many other industries are expected to support the government agencies that oversee them — USDA and meat manufacturers, airlines and the FAA, etc.

No, I don't think user fees should be levied to create a new role for the FDA in after-approval activities of any kind.

Tracey Meyer
Cardiovascular, district sales manager
AstraZeneca

On Equal Funding

Although the FDA can certainly be overly bureaucratic and reactionary, I believe they play a critical, closer-to-impartial role in the post-marketing surveillance of new drugs and biologics.

How this activity is funded is a more complex public policy quandary, but on the surface it would seem that funding should come from federally budgeted, tax-based resources, not incremental industry user fees.

Matt Giegerich
President and CEO
CommonHealth

Who Pays?

Post-marketing surveillance is very important and beneficial. The questions are: who is going to do it and who is going to pay for it? To be done right, it needs to be funded at sufficient levels to provide continuity. So should it be funded privately, but conducted by the FDA? In today's world there are so many drugs on the market that it would completely stretch the FDA's resources.

The last thing we need is another regulatory agency. I would vote to continue letting the industry self regulate.

Rita Sweeney
President and chief operating officer
Dorland Sweeney Jones

The Nays Have It

"Nay" I say! The FDA should concentrate on speeding up drug approvals. The industry will be its own watchdog. Fear of litigation will keep it honest.

Sandy Buck
Group Copy Supervisor, VP
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