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Transparency, strength at the FDA

By Susan F. Wood and David Michaels | August 1, 2007

CONGRESS IS pressuring the Food and Drug Administration to improve controls and inspections over products imported from China. News reports about parasites growing in contact lens solution and stents that do more harm than good have reminded us that medical devices can also be dangerous. Fear about avian flu has added to concerns about vaccines. And, in the wake of the drug safety debacles involving the pain medication Vioxx, the antibiotic Ketek, and the diabetes drug Avandia, changes are finally coming to the FDA.

But will the changes really make enough of a difference?

As Congress finalizes the first major FDA legislation in years, there is momentum for real change, and resistance from powerful forces that like the system the way it is.

Vioxx, drug-eluting stents, and other dangerous medical products were approved, in part, because the current system has worked exactly as designed: to get the products approved quickly and, only later and half-heartedly, to attempt to collect data on side effects.

New drugs and medical products are reviewed by the FDA based on relatively small, short-term clinical trials conducted by the firms that make the products. These studies are not designed to identify rare, adverse effects or even common long-term risks that occur after months of use. Once their products are on the market, manufacturers have little incentive to discover adverse effects, and the FDA has limited authority and even more limited resources to require manufacturers to conduct the long-term, postapproval studies that would fill in the blanks.

The FDA's ability to identify the adverse risks of approved drugs is further limited by the Prescription Drug User-Fee Act, which became law in 1992. The law directs the agency to collect user fees from drug manufacturers for the purpose of speeding up the review process, and it limits how the agency can spend the funds. As it has turned out in practice, this system has also drawn funding away from other critical FDA functions, including inspections, oversight of advertising, and the scientific infrastructure of FDA. A similar law created user fees for medical devices. This also focuses on quick approvals rather than inspections, long-term safety studies or other safeguards.

User fees appear to save the taxpayer money, but the cost to the public is unacceptable. More medical products are approved more quickly, but with less information about their dangers. But the efficient review of applications for new drugs, vaccines, and devices does not have to conflict with improved safety analysis and monitoring. With adequate support, we can develop a system that maximizes both.

Today, FDA scientists are urged to be "team players," and to ignore any concerns they have about potential risks. The culture that disparages such disagreement at the FDA is dangerous and contributes to the agency's inability to recognize the early signals and safety concerns, and to its waning scientific credibility. That's why the FDA's medical and scientific reviews should be made electronically available to the scientific community after those reviews are completed.

The heart attack risk associated with Avandia was identified several months ago by a non-FDA scientist, Dr. Steven Nissen, analyzing publicly available data, many months after the data were available to the FDA. The agency confirmed that analysis only a few days ago. Making that kind of data promptly available to the public for every medical product would help safeguard the health of all Americans.

At the same time, the FDA must put an end to outside advisers with financial ties to the drugs and other medical products they are recommending. It is unacceptable for the FDA to allow doctors and scientists with stock in a company or consulting relationships with that firm to advise FDA to approve that company's new product. The FDA regulates one-fourth of the American economy. The agency should be accountable to the American people, not to the companies it is supposed to regulate.

Congress has already decided to continue FDA user fees, but it can improve the focus on safety for drugs, vaccines, and medical devices, insist on advisers without financial conflicts of interest, carefully monitor long-term safety studies for previously approved products, and make research findings public. Senator Edward Kennedy, Representative Edward Markey, and other lawmakers have a key role to play in making our medical products safer, or not. What they

decide before their August recess has the power to save lives and to strengthen the FDA through a new focus on safety, scientific transparency, and adequate funding -- or to allow the unacceptable status quo to continue.

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