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Tel: (212) 477-9600. Fax: (212) 505-1364

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THE FIRST WORD/

USABLE USERS' FEES

Talk of "user fees" usually sends chills up our spine; a big-brotherly boot usually follows close behind. For a while there, U.S. administrations found "user fee" a convenient way to circumvent their promise of "no new taxes." Thus, there was to be no tax on bank accounts in the wake of the nation's wave of savings and loan failures—but there would be a user's fee on the balances. Boats would not be taxed—heaven forbid—but boat-owners would have to pay a user's fee to cover navigational aids and Coast Guard services. The trouble was, most of the time these user fees were to be paid into the general fund, with none of the money earmarked to provide the services for which the taxpa...um, user...was supposedly paying.

But now industry and the U.S. congress seem finally to be reaching an agreement to apply drug-maker users' fees to expanding the horrendously overburdened U.S. Food and Drug Administration. If it holds, the accord could unclog the Rockville Bottleneck and halve administrative delay in product approvals.

The plan is still evolving. The last we heard, the agency was to fulfill a pledge made by FDA commissioner David Kessler last winter, adding 600 reviewers and cutting review times from nearly two years to about twelve months. In return, drug makers would pay registration of $150,000 for each new drug application and annual membership fees of $50,000 per company plus $5,000 for each approved drug in production.

The solution makes sense. For industry, the amounts are reasonable and the returns are tremendous—for a $100-million-a-year product, the one-year return on the application fee is over 600 percent.

There are some...well, if not dangers, then call them concerns.

Once ponderous governmental beast gets used to sipping on users' fees, its appetite might grow. Legislatures and bureaucracies are famous for their covetousness. Once the mechanism is in place, it becomes relatively easy to override FDA's claims on the income, escalate the charges, escalate them again, and use the windfall on programs that have nothing to do with pharmaceuticals or the FDA.

There must be a mechanism for preventing that sort of diversion of funds. Fortunately, it looks as though there will be one: At very least, the user-fee arrangement should face reauthorization after five years to allow by industry and the regulators to review how well the collaboration is working.

There is another, though perhaps far-fetched, concern. The current system—under which the federal government foots the entire bill for drug regulation—grew out of the conviction that those who stood to benefit—the people—should pay.

In agreeing to underwrite part of the costs, the drug-makers are at least tacitly acknowledging that they, too, benefit from well-run regulation.

Drug regulators the world over—but especially in the U.S.—are eternally under fire for being too cozy with the industry they regulate. Even if industry does start to pay some of the regulatory bills, it must stifle any I-paid-for-it-and-I-want-results posturing. Public safety must remain FDA's sole concern (always remembering that one way to protect public health is to get safe, efficacious products to the people who need them as soon as possible).

Obviously, industry can safeguard its long-term future best by ensuring that the regulators can carry out this mandate. It should go without saying that all industry should expect from a user-fee deal is speedier justice. But, sadly, there will be those, ever vigilant for a sign that the regulated have captured the regulators, who will be quick to say otherwise.

—**Douglas McCormick**