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FDA Public Meeting on PDUFA reauthorization

Background

-The UAW is a member of both the Patient & Consumer Coalition and RxHealthValue

-The UAW testified at the September 15, 2000 FDA hearing on PDUFA, emphasizing drug safety issues created by PDUFA

-Together with other members of the P&C Coalition, the UAW has identified several concerns associated with the user fee system:
1. The dependence on user fees represents a conflict of interest that could compromise safety. On this issue, the numbers of withdrawls is not the proper focus. The question is whether pressure to meet performance goals has rushed any drug to approval that shouldn't have been.
2.PDUFA drains resources away from other crucial FDA functions
3.The performance goals are more than just aspirations and, according to the FDA, they've lead to excessive perspiration. They are determined inappropriately [leaving out the patient/consumer voice], implemented inflexibly and are open to manipulation by the industry [by foot-dragging and withholding of information until late in the timeline; see Testimony by National Women's Health Network and Public Citizen regarding Tamoxifen 9/15/00]

-This hearing would be more appropriately held before Congress. It needs to hear how critical funds are lacking for post-market surveillance [PMS], drug and food inspections, medical devices, direct-to-consumer advertising oversight, health fraud investigations, inspections of IRBs, OTC division work and other critical areas. Congress should know, for example, that:
**The FDA diverted $34 million of appropriated funds to drug review to meet the user fee trigger
**That workforce and real resources for most programs other than prescription drug review has contracted each year since 1994
**That support for PDUFA-related research from fee revenues is being phased out, so the FDA will be increasingly dependent on appropriated funds to sustain its knowledge base in areas like gene and cell therapy

-For the past two years, the UAW joined other consumer and patient organizations in lobbying for increased FDA appropriations, especially in the areas of PMS, protection of human subjects in clinical trials, product and facility inspections and DTC

-While we welcome the increases announced in the 2002 budget, more must be done. We are at a critical point. The FDA has been clearly and publicly saying for some time that it is not able to provide critical safety functions because of a lack of funds. We need to get on top of this now, given projections about the expected output levels of both new drugs and NMEs in the coming years, as well as the risks associated with the increased use of drugs by an older population and the swift dissemination of new drugs because of DTC.

-As a matter of public policy the UAW believes all funding for the FDA should come through the appropriations process and be funded through general revenues that are collected via a progressive tax system. The drug industry benefits from the work of the FDA and it is fair that it shoulder an appropriate part of the "burden". Instead of looking for ways to bolster the user fee system, perhaps we should be looking at ways to revise our corporate tax code and its numerous tax credits and deductions to provide more general revenue funds for appropriations. For example,

a 1999 CRS analysis of federal taxation of the drug industry found that the net income of the drug industry was taxed "relatively lightly" between 1990 and 1996, despite high earnings.

-If user fees are to continue, there must be a revamping of the system. The UAW suggests that a utility-type model be adopted, wherein an assessment fee is based on revenues and the money is in a pool and its use is subject to the sole discretion of the FDA. There should be no trigger formula that requires the FDA to make artificial decisions about spending merely to get to the user fees. Instead, perhaps, if the FDA does not receive a budget increase, than PDUFA drug approval goals should decline accordingly. Fees should be imposed from the time that FDA activities with the drug companies begin.

-The performance goals must be totally renegotiated with all concerned stakeholders. The following changes to the performance goals should be considered:
1. Lengthening deadlines/loosening percentages for standard and priority review decision-making deadlines
2. Allow differentiation of drugs within priority review category or strictly limit priority review to those drugs that are truly life saving or breakthrough therapies
3. Include performance goals regarding public health criteria like review time for DTC ads, response time for adverse event reports, etc

-In principle, the UAW is opposed to further expansion of the user fees. However if this is our fate, these fees must be used for safety initiatives and must be subject to the sole discretion of the FDA, without the requirement of "collaboration" or "consultation" with industry or any others. Cynically, the threat of further user fees may get industry to push harder on the appropriations front. At the 9/15/00 hearing PhRMA, BIO and the AMA mentioned the need for adequate FDA funding. We look forward to working with them on a better appropriation for the FDA. Participants at meetings like this one should be as passionate in lobbying the Congress for increased appropriations as they are about defending the merits of user fees.

QUESTIONS POSED TO PANEL 3

How can FDA ensure that PDUFA goals are met if there continues to be a funding shortfall?
-In 2.5 words: "it can't". The FDA has said that it expects the goals to slip because of the resource problem. Further, it is unacceptable that safety issues suffer because of resource constraints. Clearly, adjustments must be made.

If the funding shortfall persists, should the FDA, in order to best protect and promote the public health, set review priorities?
-This question is rhetorical. Of course the FDA should set priorities, reviewing first those drugs that are for serious or life-threatening conditions or rare diseases and for which there is no reasonable substitute; life-style and me-too drugs should receive low priority.

Should there be flexibility in setting the user fees to cover the increased cost of the program?
-Yes. If there is to be a user fee program, it shouldn't be tied to artificial appropriations triggers; fees should kick in earlier; the protocol for fee-waiving should be reviewed and perhaps tightened; new sources of revenue could include assessment on pediatric exclusivity and fast-track functions of FDAMA, which the FDA has indicated have resulted in FDA resource needs.