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Before the
Senate Labor and Human Resources Committee Hearing
On FDA Performance, Efficiency and Use of Resources
April 11, 1997

Senator Jeffords and members of the Committee, thank you for the invitation to present our views on the Food and Drug Administration.

If it ain't broke, don't fix it. Similarly, if there is a problem, the legislative solution is not the only one. This hearing wisely precedes the introduction of any legislation, and the task you have therefore set out for witnesses is to look more broadly at the FDA to see if it can be strengthened in a variety of ways including, but not limited to, new legislation.

For more than 25 years, the Public Citizen's Health Research Group has spent a large proportion of our time being critical of the FDA in the form of research-based petitions and–with Public Citizen's Litigation Group–lawsuits against the agency. However, we learned long ago that our ability to get the FDA to change—to get a dangerous drug, device or food additive off the market or to force warning labels on such products—is highly dependent on the FDA having strong regulatory authority to collect information about such products and to be able to decide, if the evidence merits, to take an enforcement action. During this time, we have also learned that, if anything, the FDA needs more, not less regulatory authority in order to do a better job to fulfill its Public Health Service mandate (see answers to question 4, below). To the extent that a most important aspect of FDA's duty is to police regulated industries, strengthening rather than disabling its authority must be a goal of any constructive criticism.

There is no legitimate dispute that the FDA is a vastly different and–to use the language of the day–more modernized organization and functions in very different ways than it did 25 years ago. However, with the exception of the 1976 Medical Device amendments, subsequent legislative changes to that law, and the 1992 Prescription Drug User Fee Amendment (PDUFA) there has been little significant change in FDA's statutory authority concerning the authority, standards or processes for new drugs or devices approved during this time. Thus, the enormous and largely positive changes which have occurred have been in the form of new regulations, new policies and new priorities under existing statutory authority. There is also little doubt that the important role of the United States Senate and House of Representatives in getting the FDA to change has been confined to a large number of non-legislative oversight hearings on specific drugs, devices, food additives or classes of these products and a much smaller number of legislative hearings which did not (except for the instances cited above) result in new legislation but which focussed the FDA on what it could do within existing laws. These pressures have been present whether the

Congress was controlled by Democrats or Republicans. The FDA understandably feels besieged no matter from which side of the aisle the assaults are launched.

I will now briefly answer the four questions which you have asked the FDA and the other witnesses to respond to :

I. Administrative changes to improve agency performance: steps agency is or should be taking to improve its performance concerning timely and consistent review of new products.

As I will be referring to this in the next two questions as well, it is important to define "timely and consistent review of new products."

Although the almost exclusive focus of those FDA activities which are funded by the Prescription Drug User Fee Amendments (PDUFA) has been the approval process which precedes the marketing of the drug and, from an advertising perspective, the initial launch campaign for the drug, it is for at least the first three or four years following approval if not longer that there is still heightened concern about new adverse effects of the drug not detected during pre-marketing studies which could be cause for taking the drug off the market or, more commonly, for a new warning on the labeling for the drug. In other words, the safety net which underlies our use of FDA-approved drugs has dangerous holes in it if there is not much more emphasis on what happens in the first several years after approval. Similarly, after the initial advertising launch for the drug, especially with the large proportion of new drug approvals for products which are yet another me-too addition to an already crowded therapeutic category, there is a massive amount of advertising in the first few years attempting to convince doctors–now patients as well–that the drug is better than others even if it isn't. This invitation to false and misleading advertising, by getting doctors to prescribe drugs based on understatement of risk and overstatement of benefits can be quite dangerous to patients.

Even before PDUFA, we have always been concerned that inadequate resources and priorities were being devoted to this extended but safer definition of "timely review". Now, with the vastly increased workload in FDA's Center for Drug Evaluation and Research consequent to PDUFA, the resources for addressing these postmarketing problems are stretched ever more thinly since no PDUFA funds, as the law is now written, can be used for these purposes (see answer to question 3, below). Thus, these areas of postmarketing surveillance for drugs, including their advertising, need to be given more attention and, as suggested in question 4 below, under an amended PDUFA, authorization for additional funding to cover these currently PDUFA-unfunded responsibilities.

2. Possible changes in FDA priorities/resources

As mentioned above, even before PDUFA we do not believe that the FDA had a well-coordinated plan to do postmarketing surveillance once drugs got on the market. Many plans to reorganize drug epidemiology and surveillance have been considered but no effective plan has been implemented. This is a matter of great concern to us.

3. PDUFA

As alluded to above, the reauthorization of PDUFA should include an amendment in the legislation to provide funds for postmarketing monitoring for new evidence of dangers and postmarketing advertising surveillance. The following information, obtained from the FDA, documents that since PDUFA went into effect, there has been a marked increase in resources of the Division of Drug Marketing Advertising and Communication (DDMAC) devoted to launches of new drugs and a concomitant decrease in regulatory actions such as warning letters and notices of violation, both of which categories constitute violation of FDA laws or regulations concerning advertising.

Year	# launch campaigns	# warning letters	# notice of violation letters	FTE Staff (by calendar year)
FY 1993	118	4	247	NA
FY 1994	185	2	210	26
FY 1995	306	0	163	30
FY 1996	>300	2	137	29

What can be seen is that there was a doubling--almost a tripling--in the number of very labor-intensive drug advertising launch campaigns that DDMAC had to monitor from 1993 to 1996. With only a slight increase in personnel (FTE's) in that Division, it is not surprising that resources were not sufficient to keep up with the important enforcement activities, most of which have to do with drugs which had been on the market for at least a year. The most common kind of regulatory action, a notice of violation letter (NOV) from the FDA to a drug company, always cites a violation of FDA advertising laws and/or regulations and asks the company to cease such activity. In the same interval of 1993 to 1996, there was almost a 50% decrease in the number of such letters.

4. Legislative changes

We are strongly in favor of FDA enforcement legislation, similar to that introduced by Congressman Waxman in the early 1990s as a way of strengthening FDA's ability to regulate the industries it is mandated to regulate. Among the items of enhanced enforcement authority we favor are: civil monetary penalties for any drug-related violation of the Food Drug and Cosmetic Act; broadening FDA inspection authority to include over-the-counter drugs; giving the FDA authority to require mandatory recalls and to be promptly notified of voluntary ones and to inspect drug-testing laboratories; and subpoena power for drug and other regulated industry records. There are others which there is not time to discuss here. We are strongly opposed to the kinds of legislative changes proposed in last year's Senate and House legislation including privatizing important FDA drug, device and food additive review functions and legalizing the promotion of off-label uses of prescription drugs.