



Consumer Federation of America

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CDER STAKEHOLDERS MEETING
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According to the Senate Labor and Human Resource Committee report issued following its referral of then-Senate bill 830, the Federal Food, Drug and Cosmetic Act "provides no form of public accountability by the FDA for its performance of its statutory obligations." The legislation required the FDA to develop a plan and submit an annual report which would, according to the Committee, improve agency accountability and provide for better resource allocation by setting priorities.

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The Irony of This Plan

Well, let me say first that section 406 was neither sought nor endorsed by consumer or patient groups. Prior to its passage, we, the industry and Congress all sought through various methods to hold the FDA accountable. As consumers, we believe that the FDA knows what to do—it just doesn't have adequate staff to do it, let alone worry about timeliness.

The irony is, then, that this provision will further divert the time and energy of the FDA away from its other statutory obligations. And while some of the objectives of the plan should work to the benefit of patients and consumers, on balance, we think that the plan favors industry issues regarding review of applications. Once the time periods for review of applications and elimination of backlogs have been charted, is there any doubt that there will be relentless pressure on the FDA to meet those periods at the expense of other tasks?

Minimization of Deaths and Injuries Must Be Explicitly in the Plan

You have asked what other objectives related to the agency's statutory duties or public expectations should be included in the FDA plan. We note that under the version of FDAMA passed by the Senate committee the plan included an objective to "minimize deaths and injuries suffered by persons who may use products regulated by the FDA." We think that objective should be specifically built back in. Now it might be argued that under current objectives (B) and (C)—regarding clarity of information and postmarket monitoring—deaths and injuries should be lessened. And that is probably correct—but it is only part, and maybe only a small part, of what it will take to minimize deaths and injuries.

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"Collaboration" with Industry Must Not Become Defacto Deregulation

As you know, CFA bitterly opposed FDAMA. Despite the claims of its supporters, we think it represented nothing less than a roll back of FDA authority. We cannot reopen the legislative language at this time, but we can advocate that this plan not make the dynamic worse. The FDA is to regulate various industries to protect the public health and safety. FDAMA speaks of "collaboration", but it must not be allowed to become a sugar-coated version of deregulation.

Let's face it, the trend in this country for almost the last 20 years has been to deregulate one industry after another: airlines, telephones, cable and now electricity--none of which has been to the overall benefit of consumers. The call has been to let the market prevail. To our knowledge, no one has openly called for the deregulation of the food, drug, device or cosmetic industries. This is for good reason--the public would, we believe, have a visceral reaction to such a suggestion. However, if the new pressure to "collaborate" has the effect of moving or blurring the lines which define the FDA's role of regulator, the market will, in fact, rule.

We know that the FDA is under pressure to bring drugs and devices to market faster. As consumers and patients, we benefit, too. But these drugs and devices must be safe and they must work. So we should, for the purposes of the FDA plan, measure success not only by the number of drugs and devices approved, but also by a reduction in the number of deaths, adverse reactions and recalls reported.

Threats to Plan Implementation: Commissioner Status & Inadequate Resources

While we will offer comments today and in the future about various provisions of FDAMA, we continue to express our on-going concern about the impact caused by the lack of a Commissioner. It has now been almost two years since Dr. Kessler departed. The lack of attention to filling this position--by both the Administration and Congress-- is appalling and demonstrates a lack of commitment to the mission of the agency.

Now as has been reported, we expect a confirmation hearing for Dr. Henney on September 1. But it is extremely distressing to read about the number and nature of questions submitted to Dr. Henney by Labor and Human Resources Committee Chair Jim Jeffords. As reported, the hearing may not go forward if Dr. Henney fails to respond sufficiently.

This is an unprecedented effort to tie the hands of the Commissioner in advance of proper study of the issues. According to reports, Dr Henney received

questions from industry that were in some case verbatim to the ones received from Sen. Jeffords and the process has been described as an effort by industry to work through senators to pin down the agency and Dr. Henney.

It is hard to read this effort other than as an attempt to compromise the independence of Dr. Henney and, by extension, the agency.

However, there is one question that needs to be asked and answered before the public—even though it is best directed back at Congress: “What will you do to ensure that new initiatives, like food safety and tobacco, do not draw resources away from other FDA priorities?”

We wonder why that question wasn’t discussed fully last year when FDAMA was being considered, in light of the new responsibilities it placed on the agency. Consumer and patient groups unsuccessfully raised the issue and it was also noted in the media.

The agency in “A Message to FDA Stakeholders” has admitted that it “finds itself severely challenged to meet all of its statutory obligations”. The nation’s chief health officer, Surgeon General David Satcher, has also noted the FDA’s underfunded status.

We wonder about the time and energy spent developing this plan if the agency simply lacks the resources to adequately execute it.

This problem must be addressed now by all stakeholders. CFA has certainly had disagreements with PhRMA and they will no doubt continue, but we call on PhRMA to work with us to secure adequate funding to implement FDAMA—which industry pushed—in a way that will not compromise the safety of the public.

In general, CFA supports user fees for product application reviews. One point of agreement during last year’s debate was that PDUFA has been, to quote industry, “a smashing success”. Congress should give serious consideration to expanding the user fee program.

Safety Under Rigorous Challenge

As we’ve said, safety goals need to be included in the plan. We join with the Patients Coalition in calling for the creation of an Office of Drug Safety. My colleague Scott Saunders will describe this in more detail later.

A particular challenge has been raised as the result of the new efficacy standard in FDAMA which will allow drugs to be approved on the basis of one clinical trial. We have no doubt that the agency will be under heavy pressure to make this the rule rather than the exception. Indeed, there is a question to Dr. Henney asking her views on the necessity of two clinical trials.

CFA unsuccessfully fought this provision last year. We were especially dismayed by the lack of attention paid by Congress to reports about clinical trial fraud and irregularities which surfaced while FDAMA was pending.

In one case, two researchers relied upon by many drug companies were indicted on 172 charges involving drug-testing operations. According to a lengthy article in the Wall Street Journal, prosecutors and medical college officials were incredulous that none of the drug companies appeared to notice that anything was wrong and they overlooked obvious signs that proper procedures weren't being followed.

Earlier work by one of the researchers had been reviewed and criticized by the agency. But that did not impede future contracts with major drug companies. The recent allegations involve charges of unqualified personnel, inadequate supervision and ineligible patients who were misled. One former employee of the researchers described the drug-testing inspection system as a "joke" and said that drug companies treat researchers like kings because they supply the study data.

In this particular case, according to the Journal, the FDA found serious violations but had sufficient evidence from other test sites to uphold its approvals of drugs the researchers tested.

In addition, last fall the president and two employees of a research firm plead guilty to falsifying clinical data in trials of several drugs conducted for major pharmaceutical companies. In this case, data were falsified in experimental drugs for a range of conditions including asthma and heart disease.

The FDA later approved some of the drugs and noted that the agency "always require[d] two controlled multi-center trials." Perhaps true at the time, but not into the future.

Both the FDA and industry must ensure the integrity of the clinical trial process--an appropriate subject for collaboration.