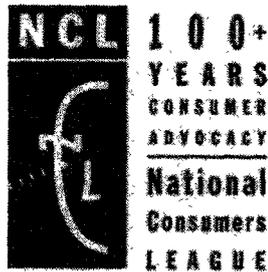


NATIONAL CONSUMERS LEAGUE

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RE-AUTHORIZATION OF THE PRESCRIPTION DRUG USER FEE ACT NATIONAL CONSUMERS LEAGUE DOCKET NO. 2005N-0410

On behalf of the National Consumers League (NCL), I would like to thank you for the invitation to share a consumer-oriented perspective of the prescription drug user fee act (PDUFA). Established in 1899, NCL is the nation's oldest nonprofit consumer education and advocacy organization. NCL provides government, businesses, and other organizations with the consumer's perspective on numerous policy issues including child labor, privacy, food safety, and medication safety and information. From the first Pure Food and Drug laws passed in 1906 to the more recent FDA Modernization Act, NCL has been working – often alongside the Agency - to ensure that the public's well being is adequately represented and protected.

It is in this context that NCL calls on the FDA to seize the upcoming PDUFA re-authorization process as an opportunity to critically examine the impact of the program to date, and consider opportunities for enhancement moving forward. Before going any further, however, I would like to pause to offer an observation on this process of comment.

There is a growing perception that the FDA has become too intimate with the companies over which it has regulatory authority. This view is only exacerbated by the fact that the public has relatively little opportunity for input into the rules governing product review and oversight. PDUFA provides a clear example of this. When PDUFA was first created, the FDA consulted with Congress and the life sciences industry, leaving health

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care consumers – arguably the Agency’s real customers – out of the loop. The process was made slightly better in the PDUFA III process, as the FDA was charged to also consult with academics and consumers. While a welcome change, consumers are still conspicuously absent from the actual negotiation process. Until consumer interests are directly represented in the final negotiations process, the FDA will not truly serve its real customers.

All of that said, I would now like to turn to the specific questions posed for this public meeting. To the first – “What is your assessment of the overall performance of the PDUFA program thus far?” – NCL has a somewhat mixed response. In the interest of time, I will just make two quick points to address this question:

1) NCL fully supports the ideal that enhanced drug approval processes benefit everyone. However, faster approval does not always mean better. Unfortunately, review time is currently the only performance goal used by the Agency to determine success. Throughput - in and of itself – is not a sufficient measure. Until there is a shift away from the current paradigm of getting drugs to market as quickly as possible, while giving little consideration to product safety in an applied or “real life” setting –Americans will continue to be exposed to unnecessary and often deadly risks.

2) NCL believes that the current structure of FDA funding – insufficient in total and with an ever-increasing percentage coming from user fees - forces the Agency into a position of robbing badly needed resources from other important program areas that are vital to preserving and protecting the public’s health. Evidence of this disturbing trend can be seen in chronic staffing deficiencies almost throughout the Agency, persistent inattention to existing programs such as MedWatch, lack of capacity to initiate much-needed adverse event monitoring and reporting programs, and reduced food safety inspections – to name just a few. As a result, the Agency is in jeopardy of losing the support and confidence of the American people, something it cannot afford to do.

While these are very real and serious issues, revealing some very real problems with the current system, reverting back to Agency funding without PDUFA does not appear to be a viable option. Given the shape of the Federal budget, our society’s increasing reliance on FDA regulated products, and the need for expanded FDA activity in the area of product safety, it would seem reasonable to actually increase the level of user fees. This would only be acceptable, however, under the conditions that a) the increase in user fees does not translate into a diminished total budget allocation from Congress, and b) the user fee funds be applied to the general FDA budget – with no conditions for its use. While Congress has, to date, allowed the regulated industries to dictate how FDA allocates its resources, there is too much at stake to allow this pattern to persist.

One potential remedy might involve introduction of a sliding user fee schedule that incents drug development in clinical areas identified by the Agency – in consultation with all relevant stakeholders, including industry, clinicians, researchers, patients, and consumers. This type of progressive fee system might do more to stimulate innovation in areas of intense clinical need.

I have already begun to answer part of the second question posed for this public meeting, which is: "What aspects of PDUFA should be retained, or what should be changed to further strengthen and improve the program?" I will focus the rest of my comments on one in particular – the introduction of a new fee for DTCA review.

NCL has long been interested in ensuring that consumers receive accurate and useful information about their healthcare, including information about the safe and effective use of prescription drugs. If DTCA is to remain an integral part of this communications process, then we would propose that product sponsors be assessed a fee as part of their submission of any DTC add – regardless of medium - to the Agency. The revenue derived from the new fee could be used to support a number of currently under funded Agency activities, including but not limited to:

1. Funding of post market safety studies, as deemed necessary on a case by case basis,
2. Expanded use of large databases to detect safety issues not identified in the pre-market clinical trial setting,
3. Expanded use of secondary data to conduct relative safety and effectiveness analyses,
4. Increased expenditure on public information sharing – about emerging safety issues as well as disease awareness, and
5. Hiring of additional staff to review - and respond to industry feedback in a timely fashion – on all DTC adds pre deployment.

In addition, FDA should be granted the authority to place a moratorium on all DTC advertising for new drugs deemed by the Agency to have inadequate safety information. Based on available safety data, the Agency could be given latitude in determining the appropriate length of the moratorium on a product by product basis. NCL also would support adding a third "provisional" status for some new drugs. Such a status would allow for limited exposure of the product to appropriate patients, thereby mitigating the likelihood of inappropriate use and over exposure while additional post-approval safety data collection is ongoing.

In closing, I would like to reiterate the point that, if FDA budgets continue to shrink at the expense of PDUFA-related programs and review goals, the Agency's ability to satisfy its mission of protecting the public health will diminish - and with it the public's remaining trust. Thank you for your consideration of these comments and recommendations.