

CBER/FDA Stakeholder's Meeting

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Good morning. My name is Lee Klosinski and I am the Director of Education at AIDS Project Los Angeles (APLA), a community-based organization which provides free services to over 7,300 women, men and children with symptomatic HIV disease. I am grateful for the opportunity to make these public comments in response to the Food and Drug Administration's open invitation.

Out of urgency and desperation in the mid-1980's, the HIV community initiated a series of interactions with the FDA to expedite the delivery of promising anti-HIV drugs to people with AIDS. Undoubtedly, many of you recall this history and some of us were part of it. Whether it was gaining access to ribavirin from Mexico, the 1987 march on FDA headquarters or the development of the process of accelerated approval of anti-HIV drugs, the HIV community has played an essential role in the modernization of the FDA for over 10 years. That role, at times confrontational and fraught with drama, more recently constructive and collaborative, always has been motivated by two core values: the needs of the FDA to be timely in response to emerging needs and to protect the public's safety.

I am proud to argue that the FDA is different today because the HIV community acted up and fought back. The FDA can be different tomorrow if it learns lessons from its interaction with the HIV community.

AIDS Project Los Angeles feels that intense working relationships between stakeholders and the FDA patterned after those initiated by the HIV community in the 1980s and continuing today is a viable model for the agency to use to meet many of its statutory regulations.

Many stakeholder groups already exist, having formed themselves after seeing the success of the HIV community in advocating for its needs and becoming a dialogue partner at the table with both the FDA and industry. A strategic and aggressive use of these stakeholder groups initiated by the FDA itself could reap tremendous benefits.

AIDS Project Los Angeles and the HIV community, along with other groups of people challenged with life-threatening illness, believes in a strong, responsive FDA with

regulatory authority throughout the product pre- and post-approval process. The HIV community's experience with the FDA is that a combination of political pressure, reasoned discussion and recognition of common goals can lead to institutional, bureaucratic and regulatory change. Given this history, the HIV community was not supportive of "a legislative fix" which could lower the agency's standards and authority.

We are especially concerned that the Section 406 timelines do not drain valuable staff time away from other urgent statutory obligations, thereby tipping the balance toward industry and away from consumers.

To fulfill its mission, the FDA needs strong leadership. The agency has been severely challenged by the absence of a permanent director. This executive and congressional inertia has been a serious impediment to the agency's ability to reform itself. We hope that Dr. Henney's appointment is approved expeditiously and without political intrigue. We strongly urge Dr. Henney to make her first task the development of a realistic working budget for the agency. This budget must include funding of additional staff and equipment to meet the agency's needs as well as an eye toward the future and the increasing demands that scientific advances will place on the agency. Part of budget development must be a concrete plan to advocate for its funding on Capitol Hill. Section 406 can only be operationalized with a realistic budget. It is urgently needed.

AIDS Project Los Angeles is extremely concerned about the FDA maintaining its role as a sentry of product safety. Please think for a moment about the development and approval of the HIV protease inhibitor class of drugs. This was the first group of similar anti-HIV drugs to be approved under the expedited process. Now after two years of use it is clear that some consumers of them are experiencing a lipodystrophy syndrome which many believe is associated with their use. It is essential to the health and safety of our clients that Phase IV trials be completed on these drugs and health concerns associated with their ongoing use be documented as clearly as the dramatic effect they have had on restoring health and productivity.

Some of our colleagues testifying in similar meetings in Washington two weeks ago have advocated for the creation of an Office of Drug Safety. AIDS Project Los Angeles enthusiastically supports this proposal.

In fact, nothing about the implementation of the Modernization Act's objectives must compromise consumer safety.

It is appropriate that a Center for Biologics Evaluation and Research (CBER)-sponsored hearing receive comment from a representative of the HIV community. Many of the most promising developments in HIV disease -- vaccines, monoclonal antibodies, gene therapy and xenotransplantation -- are emerging areas of immense potentially preventative and therapeutic value and are part of CBER's regulatory responsibilities. They are also new frontiers in science and therefore suggest complicated ethical and practical questions.

AIDS Project Los Angeles reminds the FDA that the safety of participants in clinical trials, especially in clinical trials in these newer areas, is part of our concern for the comprehensive safety of consumers. It must be monitored closely. This happens at the local level through strong Institutional Review Boards (IRBs). We applaud the effort to review the work of these IRBs and urge its institutionalization.

Now let me summarize my remarks.

- 1) The HIV community has been one of the most powerful and effective forces in the modernization of the FDA. The model between stakeholders and the FDA initiated by the HIV community deserves replication and is a practical, cost-effective means of sharing information about products and monitoring their safety at every stage of the pre- and post-approval process.
- 2) To successfully operationalize its mission, the FDA needs a strong leader who can grow its staff, research capacity and budget and advocate strongly for its needs to the executive and legislative branches of government.
- 3) Safeguarding consumer safety must remain the agency's core value.

AIDS Project Los Angeles and the HIV community recognize the importance of this consultative process. Rarely have so few civil servants been asked to do so much to protect the health of so many different generations with so little money. And rarely have we been so committed to be not only stakeholders but also partners in this reform. After all, for many of us, our lives depend on it.