INTERNATIONAL PATIENT
ADVOCACY ASSOCIATION
La Jolla, California • Bellevue, Washington

September 15, 1998 '98 SEP 18 P2:08

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0339
Public Meeting on Section 406(b)
of the Food and Drug Administration
Modernization Act of 1997
(September 14, 1998)

Dear Sir/Madam:

The International Patient Advocacy Association (IPAA) is a not-for-profit organization that provides legal resources to support individuals with chronic illnesses and rare genetic disorders.

On behalf of IPAA, I offer the following comments in response to the call for a public meeting on September 14, 1998 on how the FDA can best meet its statutory obligations under the Federal Food Drug an Cosmetic Act.

- IPAA commends the FDA for initiating this public dialogue. I believe that openness can lead to improvement in public health and it is in this spirit that I offer my comments.

In Response to Question #7:

- IPAA's primary concern is one of emphasis. The FDA's consumer protection functions should not be viewed as equal. As a patient with genetic disease myself, and as an advocate for patients both here and abroad, I believe that the FDA's mission to "promote" health should have precedence. Promoting access to new treatments and information about new and existing treatments is critical to saving lives, improving patients' quality of life and preventing the deterioration that comes with so many diseases. While I agree that protection of public health is also extremely important, the imbalance that arises between the "promote" and "protect" missions has, in my opinion, a greater ability to harm patients who have already received a disease diagnosis than it does to harm healthy consumers. Today, I have two stainless steel hips because there was no drug available for many years to treat my

98N-0339 C15

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Gaucher disease. Most people with a disease diagnosis are getting worse while research continues on their disease. This deterioration often cannot be reversed. So it is critical to move the clinical trial and drug approval process forward as quickly as is safely possible.

In Response to Objective 2:

- IPAA contends that the objective to "maximize the availability and clarity of information for consumers and patients concerning new products" is critical. However, I caution FDA to not view "clarity" so narrowly as to restrict the availability of information. With the rapid growth of the internet, there is so much bad information available today that to restrict access to information that FDA may deem unclear or unbalanced is wrong. Patients are becoming more activist about gathering and analyzing information on their health or disease. They must do this in order to advocate for themselves and ensure they get the best, most appropriate care. But if some information is restricted, patients are prevented from determining what is best for them or their family members. I believe this would be a serious error for FDA to make.

I thank you for the opportunity to submit these comments and look forward to working with the FDA to ensure successful implementation of the Food and Drug Administration Modernization Act of 1997. Please feel free to call me at 425-462-4037 should you have any questions.

Sincerely,

Lenny Van Pelt
Founder & Attorney
International Patient Advocacy Association

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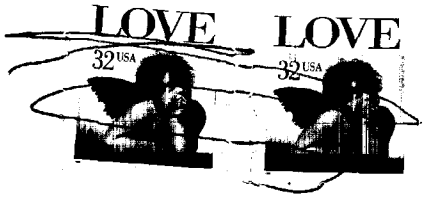

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