Patients Against Lymphoma

Non-Profit | Independent | Evidence-based

Founded in 2002

October 15, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA 2009-N-02047 Food and Drug Administration Transparency Task Force

Dear Sir or Madam:

We have observed through our involvement with the lymphoma patient community that significant misunderstandings exist regarding the criteria for the approval of new therapies for medical conditions, which are apparently sustained in part by current rules and policy that restrict the agency from disclosing its reasons for denying a new drug application.

So we welcome the initiative to increase transparency and recommend that when FDA issues letters of rejection to drug sponsors that the rationale be disclosed to the public in non-technical language.

We think this can be done in a way that does not compromise trade secrets – as rarely, if ever, are such decisions based on the putative mechanism of action, or on proprietary production methods.

- Rather, as you know, it's the outcome of patients that matters: the impact of the drug on the clinical course of the disease (response rates and duration of response), if any, or the relief of symptoms, weighed against adverse events including the impact on patients who did not respond – judged in the context of what is already available as therapy.

We anticipate that such disclosures, along with a summary of conflict of interest rules, will foster greater (and deserved) trust in our regulatory system, and will promote a better understanding of the rationale for evidence-based standards, which is to promote the public health and safety.

- Presently, the public has access only to the interpretations of the sponsors regarding the merits of FDA decision. And some patient groups, lacking access to the data, can form and distribute opinions, which foster mistrust and sometimes misdirected advocacy initiatives. Finally, the mistrust that arises from a lack of transparency appears to aid and abet

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unproven alternative medicine practices, which can sometimes directly harm patients with serious medical conditions.

Sincerely,

Karl Schwartz

President, Patients Against Lymphoma
Patient Consultant to the FDA/Oncologic Drug Advisory Committee

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