CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 4, 2014

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Comments on FDA Activities for Patient Participation in Medical Product Discussions

Dear Dr. Hamburg:

The undersigned organizations of the Cancer Leadership Council (CLC) represent cancer patients, researchers, and health care professionals. We appreciate the opportunity to respond to the request for comments regarding patient participation in medical product reviews.

Current Engagement of Patients in Advisory Committees

Patient advocates affiliated with our organizations have been qualified as special government employees (SGEs) in order to serve as patient representatives on Food and Drug Administration (FDA) advisory committees. Many others have participated during public comment periods at advisory committee meetings. These opportunities permit patient voices to be heard at the end of the cancer product review process. Although there is value to engagement late in medical product review, these opportunities do not take full advantage of the experience and expertise of patients and patient advocates. For example, patients have a valuable perspective on unmet medical need for those with their disease, insights about risk-benefit assessment and quality of life assessments, and advice about clinical trial design and the willingness of patients to enroll in trials of certain design.

FDA and cancer research and development entities would benefit from patient advice on these topics during early conversations about product development plans. Patient insights may influence trial design determinations and may inform other clinical development decisions.

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Consultation during Early Medical Product Discussions

We are pleased that the agency has identified the potential for increased patient participation early in medical product development and has clarified that such participation would require a patient to be qualified as an SGE. Patients are willing to undergo this process in order to be engaged with the agency and medical product sponsors early in the regulatory process.

The Office of Hematology and Oncology Products has been a pioneer in the various ways that it engages with patients on issues related to research and development and regulatory review of new cancer therapies. The office has collaborated with patient organizations, medical professional societies, and research foundations in meetings to consider a wide range of topics that are related to cancer product development and regulation. These cooperative meetings have considered surrogate endpoints, clinical trial design, quality of life measurement, risk-benefit analysis, and other research and development issues.

For patient advocates, these meetings provide an opportunity to share advice and experience with the agency and drug developers early in the development process. In addition, the staffers of the office routinely attend patient meetings to explain and update the patient community regarding the FDA regulatory mission and the specific activities of the office. The philosophy of open and productive communication between FDA and patients that is embraced by the Office of Hematology and Oncology Products is one that should be adopted by other review offices at FDA. Moreover, as FDA considers additional options for patient participation in medical product discussions, it should protect the efforts that are already working well.

We also recommend that planning and coordination of the patient-focused drug development meetings be the responsibility of review offices. We appreciate that these meetings could represent a burden for review staffers who have significant review responsibilities and must meet performance goals, and that burden should be carefully considered. However, these meetings could be structured to provide relevant patient advice to review staffers if those reviewers were engaged in the design and implementation of the meetings.

Determination of Conflict of Interest

We observe that the determination of conflicts of interest, a process defined in a 2008 guidance document that implements the Food and Drug Administration Amendments Act, seems to be resulting in the disqualification of a significant portion of advisory committee members from voting. This raises questions about the application of the conflict rules to patients and patient advocates; are the current rules so rigorous and the limits on the granting of waivers so severe that patients will be disqualified from medical product discussions?

We urge a discussion about the current standards for determining conflicts of interest and granting waivers. If the current process is depriving the agency of valuable expertise, the rules may need to be revisited.

Collaboration with Patient Groups to Announce New Product Approvals

Cancer patients carefully monitor the regulatory review process and the consideration of new drug applications, and the organizations that serve those patients attempt to communicate product approvals at the earliest possible time. Patients increasingly want detailed information about newly approved drugs, including the information that is included in product labeling. The organizations of the CLC see important opportunities for cooperation with FDA to promptly distribute information about product approvals. Although such collaboration is outside the scope of the medical product discussions generally defined in the request for comments, we believe these efforts are a logical outgrowth and complement to patient engagement in medical product discussions.

We appreciate the opportunity to offer advice about strategies for patient participation in FDA activities. We look forward to continuing the discussion with FDA on these issues, including the matter of management of conflicts of interest.

Sincerely,

CANCER LEADERSHIP COUNCIL

Cancer*Care*
Cancer Support Community
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVE**STRONG** Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen
Us TOO International Prostate Cancer Education and Support Network

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