NATIONAL COALITION FOR CANCER SURVIVORSHIP

The power of survivorship. The promise of quality care.

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 (FDA-2014-N-1698-0001)

Dear Dr. Hamburg:

The National Coalition for Cancer Survivorship is a national organization that represents survivors of all forms of cancer in public policy advocacy. Our public policy program focuses on activities to improve cancer care delivery and payment, and our fundamental goal is to guarantee all cancer patients access to high quality cancer care.

We appreciate the opportunity to respond to the request for comments regarding patient participation in medical product discussions.

Consultation with Patient Advocates Early in Product Development Process

As the Food and Drug Administration (FDA) explains in the request for comments, there is a long history of designating individuals as special government employees (SGEs) to serve as patient representatives on advisory committees. The agency also provides one or more periods for public comment during advisory committee meetings. Both efforts provide some opportunity for patient engagement in and comment on FDA review of new products, but the participation comes late in the drug development and review process and may not take optimal advantage of the insights and experience of patients and patient advocates.

The agency signals that it is open to engagement with patients earlier in the product development process. This movement is advisable, as it would permit patients to offer advice about unmet medical need, the risk-benefit assessment, and clinical trial design – including incorporation of patient defined and reported outcomes PROs – into the clinical trial design process. If early consultation requires designation of individuals as special government employees, those individuals would be willing to undergo that process. However, this process may present burdens to the agency and may result in the disqualification of individuals as SGEs, as discussed below.

We note that the Office of Hematology and Oncology Products has in recent years utilized a number of different approaches to consultation with patients and patient advocates. The staff of the office has participated in workshops and meetings that have addressed a wide range of important issues related to cancer drug development, including surrogate endpoints, clinical trial design, and other pressing drug research and development issues. These meetings have informed the work of the agency and research

entities, including private cancer research foundations, pharmaceutical and biotechnology companies, and academic researchers. In addition, professionals of the hematology/oncology office accept invitations to the meetings of cancer organization that provide an important opportunity for discussion about the regulatory responsibilities and approach of the agency as well as cancer product research and development issues. The approach of the Office of Hematology and Oncology Products to interaction with patients and patient advocates is one that might be replicated by other review offices.

The Food and Drug Administration Safety and Innovation Act (FDASIA) mandated that the agency engage in a number of activities as part of a patient-focused drug development program. One of the anticipated patient-focused activities is a series of meetings that will consider drug development in specific disease areas. The agency has proposed a list of diseases that might be the subject of such meetings and is also accepting recommendations regarding additions to that list. Our recommendation does not relate to the list but instead to the manner in which the meetings are facilitated. We propose that the patient-focused meetings should be coordinated by, or at least should fully involve, the relevant review office. In the case of meetings related to cancer, we propose that the Office of Hematology and Oncology Products be responsible. Asking the review office to coordinate meetings in their area imposes another responsibility on review staffers who are already struggling to complete review activities and meet performance goals. However, the patient-focused drug development meetings will be successful and provide valuable information to review staff if those staffers are engaged in the meetings from planning through execution and follow-up.

Managing Conflicts of Interest

We note that individuals who serve as advisory committee patient representatives must be qualified as SGEs. In addition, the agency suggests that patients who might be consulted earlier in the drug development process would need to go through the process – including a conflicts of interest determination – to serve as SGEs. We endorse transparency regarding the relationships that patients and patient advocates have with product sponsors, but we are concerned that the current standards for determining conflicts of interest and eligibility to participate in FDA activities might block patient participation in FDA activities. The procedures for determining conflict of interest are burdensome for the agency, and we anticipate that there could be reluctance to undertake that process to qualify more patients as SGEs. In addition, the August 2008 conflict of interest guidance document, which implements the conflict standards of the Food and Drug Administration Amendments Act (FDAAA), provides for the grant of fewer waivers in those circumstances where there are conflicts but the need for the expertise of the individual outweighs the conflict.

We have noted at recent advisory committee meetings that relatively few committee members have been determined eligible to vote on critical questions. We assume that the number of eligible voting members has been affected by the application of conflict of interest rules. The result is that the agency is receiving advice about review questions from a relatively small number of individuals, with experts in the specific disease area disqualified from voting.

We are focusing on the process for determining conflict of interest because as currently implemented it could undermine efforts to expand patient participation in FDA activities. In addition, we are concerned

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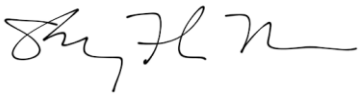
about the impact of the procedures on the advisory committee process and the quality of deliberation at those meetings. The procedures for determining conflict of interest are technically outside the scope of the request for comments, but we recommend a public discussion regarding the current application of the rules. A discussion of this sort might identify the need for legislative action to address current conflict of interest rules, but that possibility should not discourage a thorough consideration of the matter.

We appreciate the opportunity to comment on strategies for increasing patient participation in FDA review activities and to identify the problems created by current conflict of interest policies.

Sincerely,



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