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June 9, 2011

Margaret A. Hamburg, M.D.

Commissioner

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

**Re: Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 - 2017**

Dear Commissioner Hamburg:

The National Patient Advocate Foundation (NPAF) thanks you for the opportunity to submit comments to the Food and Drug Administration (FDA) regarding updates on the Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 – 2017. The notice addresses the development of a user fee program for biosimilar and interchangeable biological product (351(k)) applications submitted under the Public Health Service Act.

NPAF is a non-profit organization dedicated to improving patient access to healthcare services through both federal and state policy reform. Its mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. While other commenters may find responding to a patient-centric rule to represent a new paradigm, NPAF has a fifteen year history of serving as the trusted patient voice. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from our companion organization, Patient Advocate Foundation (PAF). In 2010, PAF resolved 82,963 cases nationally and provided information to almost 4 million online contacts.

Assessing the potential patient impact of proposed rules is of significant importance to NPAF. The aforementioned rule is a crucial one as it represents a first step in the creation of an abbreviated approval pathway for biological products shown to be highly similar (biosimilar) to, or interchangeable with, an FDA-licensed reference biological product. Currently, the fee for a biologics license application is the same whether the application is submitted under the new 351(k) approval pathway or the preexisting 351(a) approval pathway. While the identified principles for the development of a 351(k) user fee program, a proposed structure for the program based on these principles and proposed performance goals may appear to be merely procedural in nature, they will certainly have significant precedential value which will indirectly impact patient access to biosimilars in the future.

NPAF is keenly aware of the critical public health benefit biosimilars and interchangeable biologics represent as well as the resultant benefit of potentially offering life-saving or life-altering benefits at

reduced costs to the patient. NPAF is sensitive to the balancing of priorities that FDA must conduct to assure sufficient review capacity to prevent unnecessary delay in biosimilar and interchangeable biologic review with its priority to assure the user fee program provides adequate resources for FDA to determine reference product compatibility in terms of safety, purity, and potency. In other words, the user fee amount must be adequate for FDA to determine the product is “highly similar” to the reference product and “exhibit no clinically meaningful differences” relative to the reference product. NPAF is pleased to see that FDA has proposed that the initial 5-year authorization of the 351(k) user fees should remain comparable to the 351(a) user fees.

NPAF commends FDA’s decision to subtract the sum of all of the previously paid annual Biosimilar Product Development fees associated with the biosimilar product that is the subject of the 351(k) application from the marketing application fee. To further ward against a potential chilling effect in simultaneous biosimilar and interchangeable biologic development by industry, NPAF advises FDA to consider providing a total or partial refund of biosimilar product development fees should the product not progress to the marketing application stage. As noted in the background section of the notice, the FDA “review to determine biosimilarity or interchangeability of proposed product in a 351(k) application is expected to be comparably complex, technically demanding, and resource intensive as review of a proposed 351(a) application.” The full or partial refund may help mitigate the challenge some smaller companies may experience in accessing the capital necessary to research and develop additional biosimilar and interchangeable biologic products, thereby delaying patient benefit. A total or partial refund would also further the FDA desire to develop an effective 351(k) user fee program that would “fund critical activities that support submission of a marketing application.” Because of the tremendous promise that affordable biosimilar and interchangeable biologic products hold for the patient population, NPAF encourages FDA to work closely with industry to facilitate safe biosimilar and interchangeable biologic product development.

NPAF questions why FDA departs from its desire to make the 351(a) and 351(k) process similar by instituting an annual 351(k) Biosimilar Product Development Fee when there is no corresponding fee for 351(a) products. This is particularly confusing as the notice is replete with language stating the complexity and level of effort required for FDA oversight of manufacturing and postmarket safety issues for products licensed under 351(k) is expected to be comparable to that required for products under 351(a). The indication that the 351(k) user fee structure would shift payment for FDA review to the earlier stage of development where FDA activities currently are in greatest demand and increased review activity is needed does not appear to justify the annual development fee. NPAF encourages FDA to further explain the need for such a fee in light of the aforementioned balancing between assuring FDA review capacity without challenging industry submission of a new product marketing applications.

NPAF thanks you for the opportunity to comment on this rule. As noted above, safe and affordable biosimilar and interchangeable biologic products hold great promise for the patient population. NPAF would like to see this promise realized.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Nancy Davenport-Ennis", written in black ink on a white background.

Nancy Davenport-Ennis  
Chief Executive Officer and President