NATIONAL COALITION FOR CANCER SURVIVORSHIP

*The power of survivorship. The promise of quality care.*

August 11, 2010

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

RE: Docket No. FDA-2010-N-0274

Submitted electronically at http://www.regulations.gov

Dear Dr. Hamburg:

The National Coalition for Cancer Survivorship (NCCS) strongly supports the recent initiative by the Food and Drug Administration (FDA) to assert regulatory authority over laboratory-developed tests (LDTs). The question of FDA's responsibility was earlier raised by a Citizen Petition urging FDA to regulate LDTs (FDA-2008-P-0638-0001 CP). NCCS is on record endorsing the result sought by that Citizen Petition, and we are pleased to see that FDA is moving forward with a risk-based approach to the regulation of LDTs.

Our interest in this issue stems from concerns about the lack of reliable oversight of LDTs, which are increasingly important in identifying genetic or other anomalies that are the targets of new pharmaceutical or immunological interventions. While regulation under the Clinical Laboratory Improvement Amendments (CLIA) may assure accuracy of a given test, CLIA offers nothing to establish its clinical utility. Cancer patients have a reasonable expectation that genetic or other LDTs will not only provide an accurate measurement, but that such measurement will be useful in determining the appropriate course of treatment.

The public forum conducted by FDA on July 19-20 represented a good start in the process of establishing a new regulatory environment that will help assure patients of the reliability and utility of LDTs. However, the public comments offered at that forum were necessarily general and diffuse because they were not responding to any specific proposal by FDA.

The next step in the process should be the initiation by FDA of rulemaking under the Administrative Procedure Act, 5 U.S.C. 553. We appreciate that the agency has more often than not utilized the less structured "guidance" process to provide regulatory oversight, but we are not convinced that such an approach is appropriate in this circumstance.

It is important to note that FDA has, for many years, declined to exercise its regulatory authority over LDTs. While we welcome the agency's change in policy, we think public acceptance demands an explanation of the reasons and justification for the shift, based on public health imperatives as articulated by FDA. In addition, it is appropriate that the interested public be informed of the substance of proposed new regulations, and, following public comment, the agency's response and its underlying rationale.

We understand that compliance with APA notice-and-comment rulemaking requirements carries a burden of additional agency resources, as well as a certain amount of delay. FDA assertion of regulatory authority in this area comes after years of declining such authority. Such a significant change in agency policy calls for a well-articulated and justified public statement, and modest delay in such circumstances may well be warranted.

Companies that market LDTs have expressed concern that FDA oversight will contribute to expense and delay in development of new tests and ultimately discourage progress in this vital area. We doubt that such a result will flow from FDA's involvement. Instead, we anticipate that a well-defined regulatory pathway for these products will encourage development by providing more certainty and predictability, not only with respect to marketing approval but also in the related sphere of reimbursement. The stamp of approval by FDA will be the most helpful spur to ready coverage of LDTs by Medicare and other third-party payers.

NCCS greatly appreciates the willingness of FDA to engage with patient advocates and other interested parties on this very important issue, and we look forward to working with you and your staff to achieve an improved regulatory environment for these tests that are so crucial to people with, or at risk for, cancer and other life-threatening diseases.

Sincerely,

Thomas P. Sellers, MPA
President and CEO
*11-year Cancer Survivor*

TPS/vb

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