



3017 Princeton Dr.
Plano, TX 75075
(214) 893-6960
www.hemoinfo.org

August 31, 2011

Margaret A. Hamburg, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
Docket No. FDA-2011-D-0305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-D-0305, Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions; (Vol. 76, No.105), June 1, 2011.

Dear Dr. Hamburg:

I am writing to you on behalf of our more than 800 individual members to express concerns over the draft guidance related to the FDA's regulatory requirements applicable to manufacturers of in vitro diagnostic products intended for Research Use Only (RUO) or Investigative Use Only (IUO).

We believe that this draft guidance may have a negative impact on the ability of hospitals and clinical laboratories that use these products for clinical diagnosis of hemochromatosis. We know that early detection of hemochromatosis and subsequent treatment is extremely important to preventing the devastating effects of iron overload. It is my understanding that there is an HLA allele association with hemochromatosis which is identified with RUO sequenced based DNA typing reagents. This test is usually performed by hospitals and laboratories for clinical diagnosis of hemochromatosis. In addition, I understand that some post organ transplant testing is done with RUO reagents. This could negatively impact hemochromatosis patients who may need liver or other organ transplants.

Of course, we appreciate all of the FDA's efforts to ensure the safe and appropriate use of laboratory products and tests. However, we are concerned that the FDA's draft guidance could have a negative impact on patients. We have reviewed the recommendations put forth by the American Hospital Association in their letter to you dated August 30, 2011 and we are in agreement with their recommendations. We hope that you will consider the recommendations before the guidance document is finalized.

Thank you the opportunity to provide comment on this important issue. If you have any questions, please do not hesitate to contact me at (214) 893-6960 or jpedwards@hemoinfo.org.

Sincerely,

Jason Edwards
President