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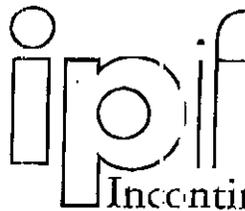
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Incontinentia Pigmenti International Foundation

March 5, 2007

HFA-305
 Food and Drug Administration
 5630 Fishers Lane
 Room 1061
 Rockville, MD 20852

Re: Docket #2006D-0336 and Docket #2006D-0347

To Whom It May Concern:

The Incontinentia Pigmenti International Foundation (IPIF) writes to express our concern with FDA's ASR and IVDMIA Draft Guidance.

IPIF organizes patients, physicians, educators, parents, relatives, and volunteers to combat incontinentia pigmenti, a genetic disease of the skin, hair, teeth and central nervous system. Our mission promotes research and development is dedicated to the improvement of treatment for IP. We believe that the FDA draft guidance on ASR and IVDMIA could stifle innovation and restrict vital research on IP and many other diseases.

The ASR draft guidance may not only reduce the effectiveness of genetic testing on IP, but it may also reduce the number of genetic tests legally available in the marketplace. This step could potentially decrease health benefits for the American public by prohibiting the research that could expedite genetic test results and may significantly advance treatment of IP and other diseases.

Similarly, the IVDMIA draft guidance may hinder much of the promising research gained through laboratory testing. Researchers and physicians may be banned from interpreting test results that improve their diagnostic capabilities for IP and other diseases. Furthermore, researchers have now identified the gene responsible for IP. As a result, diagnosis may be supplemented with molecular testing. But under the FDA's draft guidance, molecular testing for many diseases like IP may no longer be possible.

IPIF believes that we must keep the potential for innovation open and allow new medical technologies to emerge. While we agree that oversight over medical testing is important and necessary, we respectfully recommend that the FDA refrain from implementing the ASR and IVDMIA draft guidance.

We are eager to work together to ensure an environment in which genetic testing may generate the innovative treatments and cures of the 21st century.

Sincerely,

Susanne Bross Emmerich
 Executive Director