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May 22, 2007

The Honorable Xavier Becerra
United States House of Representatives
1119 Longworth House Office Building
Washington, DC 20515-0915

Re: Genomic Research and Accessibility Act

Dear Representative Becerra:

I am writing in reference to your recently introduced bill, the Genomic Research and Accessibility Act. The American College of Medical Genetics (ACMG) appreciates that you have acknowledged our position with regard to the patenting of gene sequences in your bill. The ACMG is the professional organization that represents the board certified Medical Genetics laboratory and clinical service providers in the US. The ACMG believes firmly that gene sequences are naturally occurring substances for which patents should not be awarded. In addition, however, we have significant concerns about the many gene and gene mutation sequence patents that already exist and which are being enforced against those using the information for research, clinical investigation, and for the delivery of diagnostic tests. We acknowledge the importance of intellectual property protections with regard to the development of therapeutics but have seen little IP-related incentive to clinical research or to the development of diagnostic testing devices and products. Rather, the impact of current IP policies has been decidedly negative.

At this point in time, a significant proportion of the human genome sequence has been patented and numerous unreasonable licensing practices have triggered the public's negative view of patenting human genes. An exemption for diagnostic testing would address this important problem. It is also useful to appreciate that at least 95% of the nearly 1,000 genetic tests currently offered are for rare diseases. Inherent in rare diseases is the fact that the small number of patients available limits the statistical power that is critical for documenting their validity and utility to the same degree as is possible with tests for more common diseases. In the absence of orphan disease considerations that are designed to ensure access to such tests and well-recognized under FDA practices, these tests can remain in a clinical investigation stage for many years. It would not be useful if these tests were not open to the clinical community for continuous improvement. Hence, a research exemption that ensures that a broad range of investigators are able to access genomic sequences and, thereby, participate in the ongoing development and improvement of genetic tests would be beneficial.

We appreciate your willingness to seek ways of ensuring that the fruits of the human genome project remain accessible to the public. If we can be of additional assistance as you move forward with your legislation, please feel free to contact me.

Sincerely,

A handwritten signature in black ink that reads "Michael S. Watson". The signature is written in a cursive style with a clear, legible font.

Michael S. Watson, PhD, FACMG
Executive Director, ACMG
Director, National Coordinating Center for Regional
Genetics and Newborn Screening Collaboratives
Adjunct Professor of Pediatrics, Washington University