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January 4, 2005

Dr. Bonny Harbinger
Office of Technology Transfer
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, Maryland 20852
Via email: harbingb@mail.nih.gov

Re: Best Practices for the Licensing of Genomic Inventions, 69 FR 67747-8

Dear Dr. Harbinger,

I am writing on behalf of the Association of American Medical Colleges (AAMC) in support of the proposed best practices on licensing genomic inventions, as published in the *Federal Register* on November 19, 2004. The AAMC is a non-profit organization representing all 142 accredited U.S. and Canadian medical schools, some 400 major teaching hospitals, and 94 academic and professional societies representing 109,000 faculty members. Our member organizations are at the forefront of research applying genomics to health care, and many of these institutions or their parent universities or systems manage extensive intellectual property portfolios in genomic research. Our comments here follow upon AAMC's remarks on an earlier draft of these best practices circulated among university technology and licensing officers.¹

The AAMC agrees with the statement in the notice that the proposed best practices are consistent with NIH policies on the sharing of research resources and on developing sponsored research agreements, and that these policies are themselves aligned with the federal objectives of the Bayh-Dole Act and other important legislation on research policy. Federal, academic, and public health interests are served by policies that foster and promote open communication and sharing of data, research tools, and other resources among PHS grantees and within the wider research community. Federal policy, through Bayh-Dole and related legislation, also recognizes the important role that intellectual property protections play in transferring new technologies to commercial application. The best practices notice provides pragmatic recommendations for balancing these objectives in genomics.

¹ AAMC letter to Dr. Mark Rohrbaugh, June 21, 2004.

We agree with NIH that, as presented, the notice clearly does not constitute additional regulation, guidelines, or conditions of award. Rather, the statement, as it pertains to both the NIH intramural program and the extramural community, reflects principled leadership by example in a critically important intersection of research and public health. The statement also appropriately underscores the necessity to preserve flexibility for grantees to determine for themselves, case by case, the most effective path by which to ensure application of new discoveries from genomic research.

Our central criticism, as noted in our earlier letter referenced above, is that the notice conveys little information to the public about the context or concerns to which these practices respond, or why the notice should focus upon genomic inventions as opposed to other technologies. AAMC has noted, for example, its concern about the impact of especially restrictive licensing practices on gene-based diagnostic testing. Such restrictive practices confine the use of a test to one or a few practitioners or laboratories and prohibit the larger population of qualified medical professionals from testing for the presence of a disease-associated or other gene after it has been described in the medical literature. To our knowledge, qualified physicians have never before been legally prohibited from performing a diagnostic test, particularly not where the necessary information is available in the published literature. Refinement of such gene-based diagnostic tests through practice on diverse populations is entirely distinct from the commercial development needed to develop a new drug, test kit, or other tangible products or technology in which, as the NIH notice precisely describes, “further significant research and development by *the private sector* is required to bring the invention to practical and commercial application” [emphasis added].

As NIH observes, the recommendations appear to be fully consistent with practices already followed by the universities and other grantees in their decision-making for pursuing intellectual property protection and technology transfer. Moreover, openly communicating and sharing genomic information is already a well-established practice within the international scientific and public health communities, and has been so for many decades. Conversely, laws and policies affecting the patenting of genomic inventions remain in flux,² and many concerns about broad claims to patentable gene sequences have been raised internationally.³ Given remaining uncertainty or ambiguity about the actual subject matter, scope, and claim of patents on some

² For example, a case currently before the Court of Appeals for the Federal Circuit is the first to challenge whether expressed sequence tags (ESTs) can meet the heightened utility standard for patentability adopted by the US Patent and Trademark Office in 2000, and whether the standard itself is correct. In that same case, an earlier decision by the PTO’s own Administrative Appeals Board would appear to permit the continued use of open-ended claim language for poorly characterized gene fragments or other nucleic acid sequences, which is contrary to our earlier interpretation of the patent office’s revised written description guidelines and applicable case law. See Brief of Amici Curiae Eli Lilly and Company et al., In re Fisher, (___ F.3d ___) (Fed. Cir. 2005) (No. 04-1465)

³ For example, a recent German patent law would limit claims to a specific, described function of a disclosed gene sequence. The Australian Law Reform Commission has proposed a narrowly focused application of gene patents with respect to human health. Public health officials in several Western European nations and Canada have mounted a campaign arguing that licensing restrictions on the diagnostic use of BRCA1 and BRCA2 are in contravention of national public health laws. Indeed, the patents on BRCA 1 and 2 have recently been rejected by the European Union.

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classes of genomic inventions, we believe that NIH's emphasis on the research and public health objectives of PHS-funded genomic research and the norms and practices of the scientific and medical communities is particularly well advised.

The AAMC also notes that since the draft best practices were first proposed, researchers have estimated that the number of genes in the human genome is even lower than earlier estimates (now approximating between 20,000-25,000 genes), relatively little more than the complement of genes in the roundworm, *C. elegans*. Thus, so many of the characteristics and traits—including susceptibility to disease or other dysfunction—that distinguish human beings from *C. elegans* must result from complex gene-gene interactions, as well as gene product interactions that we have not yet begun to understand. Elucidating these interactions will require continued systematic investigation by research teams around the world. The AAMC believes that unencumbered dissemination of and access to such genomic information, as reflected in the best practices notice, will best enable this research.

In closing, the AAMC commends the notice for recommending that NIH and its funding recipients reserve in their license agreements explicit rights for themselves and for other universities and non-profit research institutions to use the licensed technology for their own *research and educational* purposes. This recommendation becomes even more important in the aftermath of the Madey decision that for all practical purposes obliterated the “research exemption” established in US case law in 1813.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jordan J. Cohen".

Jordan J. Cohen, M.D.