ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

ASHG
American Society of Human Genetics
discover. educate. advocate.

July 29, 2019

Senator Chris Coons
218 Russell Senate Office Building
Washington D.C., 20510

Senator Thom Tillis
113 Dirksen Senate Office Building
Washington D.C., 20510

Representative Doug Collins
1504 Longworth House Office Building
Washington D.C., 20515

Representative Hank Johnson
2240 Rayburn House Office Building
Washington D.C., 20515

Representative Steve Stivers
2234 Rayburn House Office Building
Washington D.C., 20515

Dear Senators Coons and Tillis, and Reps. Collins, Johnson, and Stivers:

As leaders of the American College of Medical Genetics and Genomics (ACMG) and the American Society of Human Genetics (ASHG), we write to express our deep concern about draft legislation that would amend the Patent Act, section 101. As written, the legislation would:

1) Increase costs of genetic testing;
2) Reduce access to genetic testing; and
3) Stymie genetics and genomics research and novel medical applications.

Congress should affirm and protect existing policies that encourage sharing of emerging fundamental genetic knowledge. Current policies and sustained investment in research and clinical innovation have benefited patients in this era of novel research and discovery. Medical advances in genetics and genomics are improving the health of millions facing a wide variety of diseases such as developmental disorders, cancer, and blindness. The research enterprise responsible for these health care advances strengthens our nation's cities and states medically and economically.

ACMG is the only nationally recognized professional membership organization dedicated to improving health through the practice of medical genetics and genomics. The College's membership includes over 2,000 genetics professionals, nearly 80% of whom are board-certified clinical and laboratory geneticists and genetic counselors. ASHG is the primary professional membership organization for human genetics specialists worldwide. The Society's nearly 8,000 members include researchers, academicians, physicians, genetic counselors, laboratory practice professionals, nurses, and others who have a special interest in human genetics.

Together, we know first-hand that it is essential to have open sharing, free of patent restrictions, not only of human genomic information, but also of emerging associations between genomic information and human health. Over the past decade, our communities have helped create a revolution in medical research, novel genetic tools, and patient diagnostics and care. Many breakthroughs and advances have been possible in part because of landmark rulings by the Supreme Court of the United States, including the 2013 *AMP v Myriad* decision, that concluded human genomic sequences are naturally occurring and cannot be patented. Following this ruling, access to genetic testing

has increased and, as a result of competitive market forces, the cost of diagnostic testing has dropped. This ruling has resulted in an opportunity for more families to learn about their genetic and genomic predispositions, take preventive measures when applicable, and enhance their life span and quality.

Yet there is so much more we can learn and apply to improve care. Because of *AMP v Myriad* and other decisions, research can be done quickly and at relatively low cost and brought more rapidly to clinical trial and application. Allowing patents on naturally occurring genomic information would be inconsistent with the realities of basic biology and nature. Importantly, the phrase, "naturally occurring genomic information" must include (as it does now) DNA or RNA that has been isolated, amplified, or sequenced. It would thwart this rapid progress by introducing exponential and prohibitive patent costs and unwieldy administrative burden as we further investigate the approximately 21,000 genes in the human genome and an incalculable amount of other actionable genetic information found in its roughly 3 billion base pairs. It would also impose barriers for the development and use of new clinical genetic tools, slowing down a booming — and highly competitive — genetic testing and diagnostics community that is improving physician insights, enhancing patient health, and driving down payer costs. Competition has made genetic testing more affordable and thus available to more people. Many insurance carriers, including state Medicaid programs, changed their coverage policies.

The ability to perform research and diagnostic testing, and thus bring new knowledge to patients without undue legal risk and repercussion, has helped make the U.S. a world leader in research and medicine. We request that any legislation revising patent law protect and enable future genomic advances by continuing to prohibit the patenting of human genomic information and its association with disease. Both ACMG and ASHG would be pleased to work with you as health care professionals and scientific research experts to ensure that patent law reform protects and extends this exciting era of scientific discovery, medical innovation, and ever-better patient care — goals we are confident that all Americans share.

Sincerely,

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ACMG President

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