AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Thom Tillis
United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Chris Coons
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

Dear Senators Tillis and Coons:

On behalf of our physician and medical student members, the American Medical Association (AMA) is writing to thank you for the opportunity to participate in the November 20 stakeholder call led by your staffs on patent reform legislation to be introduced in the 117th Congress. Our members include pathologists and medical geneticists among other specialties who have a critical role to play in providing diagnostic tests to patients and a vested interest in ensuring that patent reform does not restrict the ability of physicians to provide quality diagnostic services to the patients they serve.

The AMA is supportive of thoughtful patent reform but does not believe it should include changes that would allow for patents on naturally occurring human genes or disease associations. Gene patents would be a major step backward by adding barriers that constrain patient access to genomic tests that are lifesaving and critical to the practice of medicine. Consequently, the AMA strongly believes that patent reform must preserve the rulings in the *Mayo*, *Myriad*, and *Alice* Supreme Court decisions as the Senate Judiciary Committee explores modifications to Section 101 of the U.S. Patent Act ("Section 101").

Prior to the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, Myriad was the sole laboratory with licensed patents covering *BRCA1* and *BRCA2*, the genes most frequently associated with hereditary breast and ovarian cancer. Myriad's aggressively enforced testing monopoly left women without another laboratory test option to assess their risk of breast cancer based on a patient's own gene sequences. Preventing laboratory competition was predictably associated with higher costs and therefore more limited patient access. By suppressing tests offered by other laboratories, Myriad also denied patients access to confirmatory testing that could help ensure accuracy of their results, as well as limited patient access to more comprehensive test offerings that may help prevent false negatives.

After the *Myriad* decision, the cost of testing has fallen by more than 10-fold, powered not only by technological advances such as genetic sequencing but also through broader competition among laboratories. Researchers can more freely share the results of their findings without fear of infringing upon patent claims. Laboratories can offer more diverse and comprehensive testing options, such as including the *BRCA1* and *BRCA2* genes in large sequencing panels that assess the risk of hereditary cancers, in addition to broader population screening and confirmatory tests.

The AMA believes that patients need access to their own pathology tests results including second opinions on genetic or clinical test interpretations. Unlike more conventional clinical diagnostic testing, it would be very difficult for a patient to get this kind of second opinion for a genetic or genomic test covered by a gene patent. Organs and cell types in the human body are not considered patentable, and the

same principle should also apply to human genes. Otherwise, gene patents may jeopardize medical training and practice when exclusive license agreements, fees, and conditions constrain reasonable access to clinically relevant information.

We are also writing to follow up with some concerns around the process for designing legislation intended to modify Section 101 that you outlined at the end of the call on November 20. Breaking the stakeholders into two groups, one pro-reform and the other anti-reform, is an overly simplistic and inaccurate characterization of the groups on the November 20 call. While some groups oppose patent reform legislation, there are others who are open to clarifications around patent eligibility that do not overturn U.S. Supreme Court precedent. We appreciate your consideration of these nuances between groups and support the creation of as many groups as are needed with their own representatives at the table to accurately reflect the range of interests. We also have concerns with the limited number of participants designated to speak on behalf of the two groups and support adding additional subgroups and representatives to ensure that all stakeholders are adequately represented.

The process and timeline laid out is also incredibly ambitious and not feasible given the constraints that many organizations are facing with the ongoing COVID-19 pandemic. We appreciate that your staff have shown a willingness to be flexible on both the representation of stakeholders and the timeline for negotiators and we look forward to continued work with them to ensure this is an equitable, inclusive, and thoughtful negotiation process.

Last, we understand the importance of broad stakeholder engagement in these negotiations. Given the gravity of the reform under consideration we believe it is important to participate. That said, we cannot commit to endorsing a proposal emerging from these negotiations that narrows the scope of *Myriad* and other recent Supreme Court decisions or otherwise imperils patient access to innovative tests, treatments and therapies.

Thank you for your consideration of our comments about the proposed process for developing patent reform policy. We would be happy to speak with you further about these concerns and look forward to working with you to protect the interests of patients, providers, researchers, and innovators.

Sincerely,

James L. Madara, MD