U.S. Senate Committee on the Judiciary
"*From Genes to Machines: the Patent Eligibility Debate*"
Chairman Charles E. Grassley
Questions for the Record: Dr. Debra G.B. Leonard, M.D., Ph.D.

1. The unanimous 2013 U.S. Supreme Court opinion *Association for Molecular Pathology v. Myriad Genetics* ruled that naturally occurring DNA segments could not be patented even though it took human effort to isolate the gene. This opinion radically changed public accessibility to genetic testing by lowering the cost from thousands of dollars to hundreds of dollars, particularly in breast cancer gene testing.

    a. Would PERA, S. 1546, change whether genes are patent eligible? Why or why not?

Yes, PERA would allow genes, as well as all biomarkers, to be patent eligible because it abrogates the *Myriad* decision and, further, the exclusion included in the legislation does not sufficiently codify the decision into law.

The currently introduced version of PERA (S.1546) includes an exclusion in subsection (b) applicable to a genetic sequence, which reads as follows:

(D) An unmodified human gene, as that gene exists in the human body.

A human gene is comprised of DNA which is simply a sequence of nucleotides or base pairs, which are noted as A, C, T, and G. That sequence of nucleotides is the exact same if the DNA is in a cell within a human body or is being read off of a next generation sequencing platform or other diagnostic technology. Thus, while this "exclusion" appears to codify the *Myriad* decision, there is no meaningful difference between the sequence of a gene *inside* or *outside* of the human body, i.e. it is the exact same genetic information.

Further, it doesn't provide any protection to shorter DNA sequences, noncoding regions of the genome, etc. that do not constitute a gene, which are clinically meaningful in genetic testing. It isn't always the whole gene that is evaluated. Also, even if this exclusion were adequate, it only applies to human genes and would still mean that patents on non-human DNA, RNA, and other biological biomarkers would be allowed, including pathogenic sequences from viruses or bacteria. The *Myriad* decision, in effect, applies to more than "human genes."

    b. Would this bill change whether genes isolated using human effort are patent eligible? Why or why not?

Yes, PERA would render genes separated from other biological material using human effort as patent eligible because of the limitations of the exclusion in subsection (b). This is for the same reason as discussed in the answer to the previous question, and because of the conditions pertaining to that exclusion:

A human gene/natural material shall not be considered unmodified if that human gene/natural material is -

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'(i) purified, enriched, or otherwise altered by human activity; or
''(ii) otherwise employed in a useful invention or discovery;

Removing the multiple negatives, the conditions essentially read:

"A human gene shall be considered modified if that human gene is purified, enriched, or otherwise altered by human activity;"

The steps in performing any genetic test include isolating or purifying the DNA from a patient sample to remove all other cellular material, and enriching (or amplifying) the DNA usually by PCR, and then doing further testing steps such as next generation sequencing (NGS) to determine the sequence of nucleotides. If the act of isolating, purifying, or enriching DNA means the human gene has been modified, then any genetic sequence would be patent eligible under PERA. I recognize that since the last Congress, the bill text no longer includes the word "isolated" in that condition; however, from a scientific standpoint, isolated and purified are essentially the same process in that one is removing the DNA from its environment. As the *Myriad* decision states, "...separating that gene from its surrounding genetic material is not an act of invention." PERA as a whole does not codify the *Myriad* decision, and therefore, PERA, if enacted, would establish that human genetic sequences and other important natural biomarkers relevant to human health are patent eligible.

c. Would enactment of this bill help or hurt the development of gene therapies and other medical treatments? Please explain.

Under *Myriad,* naturally occurring DNA sequences are not patentable, allowing researchers to freely study disease-causing genes and develop competing gene therapies. Patents on naturally occurring DNA sequences could significantly impede the development of gene therapies by increasing the cost, complexity, and legal risk of researching and developing treatments for genetic diseases. Gene therapies work by delivering into a patient a functional copy of a naturally occurring gene, repairing a defective gene, or editing a patient's DNA to restore normal function. If the underlying human gene sequence itself were subject to patent protection, developers could be required to obtain licenses simply to use that naturally occurring genetic sequence as the therapeutic target or therapy. This could result in royalty payments, protracted licensing negotiations, and the possibility of litigation, particularly when multiple patented genes or genetic variants are implicated. These additional costs and uncertainties would be especially burdensome for startups and academic researchers developing treatments for rare diseases, where patient populations are small and development costs are already high.

Companies can still obtain patents on genuine inventions including engineered vectors, gene-editing systems, novel DNA constructs, manufacturing methods, and delivery technologies, which ensures strong incentives for innovation without granting exclusive rights over the genes

that exist in nature. This balance lowers barriers to therapeutic development while preserving robust intellectual property protection for the technologies that make gene therapy possible.

Beyond gene therapy, precision oncology treatments that target mutations and variants within a tumor's genome not only improve overall survival but reduce adverse events from non-targeted therapies. Reflecting on how genotyping a tumor has become standard of care, the Centers for Medicare and Medicaid Services finalized National Coverage Decision 90.2: Next Generation Sequencing to provide Medicare beneficiaries with access to these innovative diagnostic tests. These tests not only determine the appropriateness of initiating a specific therapy, but also are utilized to monitor for response, disease recurrence, and more. If enacted, PERA would also lock up the genome of tumor cell DNA and RNA, and make the development of these biomarker-driven therapies even more costly as well as increasing the cost of the tests themselves. We have seen some of the greatest advances in precision oncology in the past decade, indicating that the current patent system is actively enabling innovation in this area.

d. How would enactment of this bill impact patient access to diagnostic tests? Please give examples of the cost of tests and Medicaid and Medicare coverage if you are able to do so.

My written testimony refers to numerous examples of how costs of tests were higher because of the patent on the gene. For example, over 7 million Americans are living with Alzheimer disease, and the *APOE* gene has been central to understanding Alzheimer disease risk and genetic susceptibility. Athena Diagnostics previously exclusively licensed a patent on the *APOE* gene and enforced its patents to such an extent that it didn't even offer licensing options, establishing itself as the sole provider of the test. The company charged $195 per test, but my laboratory at the University of Pennsylvania charged $100.50 per test. The patent on the *APOE* gene meant that patients, insurance companies, etc., would incur unnecessary costs to obtain this important risk information. As of July 2026, the Genetic Test Registry shows 38 tests across 17 laboratories in the United States currently offering this testing. The patent on the *APOE* gene served only to establish a monopoly and increase the cost of care, rather than to foster innovation.

Additionally, in 2002, my laboratory entered into an agreement with Invivoscribe to license a test to diagnose leukemia and lymphoma and monitor for residual disease after treatment. The agreement was incredibly unreasonable and costly, requiring payment of tens of thousands of dollars at the outset to license the test and a continuing royalty of up to $60 per test. In the end, it cost our institution approximately $300 per test. For comparison, in 2002, Medicare only reimbursed this test at $55.39. If PERA were enacted and allowed for patents on naturally occurring genetic sequences, these financial burdens would be devastating to clinical

laboratories, which are already experiencing significant annual cuts in Medicare payments. Especially in the private payer setting where patients often have out-of-pocket payment obligations for laboratory testing, PERA would increase the cost of tests and thus, further shift the cost of testing to the patient.

The two genes at the focus of the *Myriad* decision, *BRCA1* and *BRCA2,* offer another example. Prior to 2013, Myriad Genetics was the sole provider of the test to sequence those two genes and billed approximately $4000 per test. On the day of the Supreme Court decision, five laboratories announced they would begin offering tests to sequence those two genes. Today, in the United States, there are 263 clinical tests involving the analysis of *BRCA1*, and 284 clinical tests involving the analysis of *BRCA2*.[1] Because of advancements in the field, these tests often involve sequencing many genes all at the same time, and Medicare reimburses this kind of panel testing at $1303.95 (CPT code 81432). Moreover, in the 2024 Subcommittee hearing on PERA, Invitae testified that patients have access to multigene hereditary cancer panels with dozens of genes for as low as a "couple hundred dollars."[2] If PERA were to be enacted, monopolies would drive the cost of diagnostic testing back up. This would directly increase Medicare payment as well because the Protecting Access to Medicare Act (Public Law No: 113-93) established that Medicare payment for laboratory tests would be based on private payers' rates that laboratories report to the Centers for Medicare and Medicaid Services.

Further, it is also important to consider past experiences that impacted Medicaid beneficiaries. Due to pre-2013 *BRCA1* and *BRCA2*monopolies, if a state's Medicaid program did not contract with the test's patent holder, those beneficiaries had to either pay out of pocket for the test or were unable to have tests that, if positive, could lead to lifesaving health care.

2. Please share examples of processes similar in effort and knowledge to the process of isolating a gene that are used in scientific research and medical treatment. Do they also risk being patent eligible if PERA is enacted? If PERA is to be considered, we need to understand the full breadth of its impact on medicine and scientific research.

All naturally occurring biomarkers would be patent-eligible if PERA were enacted, and this would have a devastating impact on healthcare. Drawing on language from the *Myriad* decision, as "basic tools of scientific and technological work", they should be "free to all men and

[1] Data accessed on July 7, 2026 from Genetic Testing Registry; httpsit ://www.ncbi.nlm.nih.gov/gtr/
[2] https://www.judiciary.senate.gov/imo/media/doc/2024-01-23_,,who have-_testimony_-_blaylock.pdf

reserved exclusively to none" for the benefit of humankind. Consider the following healthcare examples not involving human genes:

Cyclospora cayetanensis is a microscopic parasite that causes cyclosporiasis, an intestinal illness that has impacted thousands of patients this year across Illinois, Indiana, Kansas, Kentucky, Michigan, Ohio, Oklahoma, Pennsylvania, and West Virginia. The US Government recommends Cyclospora laboratory testing on stool specimens because routine ova and parasite examinations might not reliably detect the parasite, and moreover, it is specified that molecular, PCR-based, diagnostic testing be considered by healthcare providers because it can improve detection (https://www.cdc.gov/han/php/notices/han00531.html). PCR testing is a highly sensitive molecular method that detects the parasite's DNA in a stool sample. While it does not involve testing on a "human gene", the human impact of the disease is painfully obvious and significant for both the individual patients that have contracted the pathogen and more broadly for public health. This is a recent example of the importance of pathogen detection but it is also relevant in many other conditions, including COVID-19. Rather than involving DNA, SARS-CoV-2 is made up of ribonucleic acid (RNA, a similar material to DNA) that contains all the genes the virus needs to function within a human cell. During the pandemic, current patent eligibility jurisprudence allowed pathologists to develop diagnostics and meet the testing needs of this nation, without patent incentives.

The Committee should also consider the impacts on patents on non-coding regions of the genomic. For decades, the roughly 99% of the human genome that doesn't code for proteins was dismissively called "junk DNA." We now understand that assumption was false. Non-coding regions include promoters, enhancers, and silencers – sequences that control when, where, and how much a gene is expressed. A gene's protein-coding sequence can be perfectly normal, but if the regulatory DNA controlling it is mutated, the gene might be turned on in the wrong tissue, at the wrong time, or at the wrong level. Some non-coding DNA is transcribed into functional RNA molecules that never become protein but still do work in the cell, such as microRNAs. In fact, the discovery of microRNAs has been so pivotal that Victor Ambros and Gary Ruvkun were awarded a Nobel Prize in 2024 for their discovery. We understand today that abnormal microRNA activity has been implicated in cancer development, and mutations in microRNA-coding sequences have been identified in humans as a cause of conditions including congenital hearing loss and eye and skeletal disorders. As an example, problems with microRNA production can result in a condition known as *DICER1* syndrome, a rare but severe inherited syndrome that significantly increases the risk of developing cancerous tumors in the lungs, thyroid, and ovaries. As another example, non-coding variants near the *BCL11A* gene influence fetal hemoglobin persistence, affecting disease severity.

U.S. Senate Committee on the Judiciary
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Questions for the Record: Dr. Debra G.B. Leonard, M.D., Ph.D.

Non-DNA biomarkers are also relevant in cancer care. Tumors shed small DNA fragments into the bloodstream as cells die. Tests are now available that look for tumor-specific mutations, copy number changes, or methylation patterns in the circulating DNA from cancers. It's powerful for detecting mutations, tracking treatment resistance, and spotting recurrence, but "circulating tumor" DNA detection is often not used alone. For instance, DNA methylation patterns are chemical modifications attached to DNA that indicate whether DNA came from a tumor cell or a normal cell, independent of whether a specific mutation is present, which enhance detection sensitivity beyond standard genomic alteration detection methods alone.

Other important molecular tests look for naturally occurring proteins in the body. A relevant example is new FDA-approved Alzheimer's protein blood tests that check plasma for specific neurological biomarkers. The right biomarker type depends on what kind of disease process being detected. PERA, as drafted, would lead to a world where all of these biomarkers relevant to disease are patent eligible, which would be detrimental to the molecular field and patients by increasing costs or even limiting research on patented biomarkers. These biomarkers are products of nature and their relationship to diseases are laws of nature, neither of which should be patent eligible.

3. On a more general note, where is the science around genetics headed? What are the next great, yet realistic discoveries and uses? Would enacting PERA affect this development and use? Would it impact financial investment in scientific research?

The field of genetics is entering a new era. The Human Genome Project provided the foundational map of the human genome, but the next generation of discoveries will focus less on identifying new genes and more on understanding how genes interact with one another, with the environment, and with other biological systems to influence health and disease. Rather than simply reading the genetic code, scientists are increasingly able to interpret, predict, and even modify biological processes, opening the door to more precise and personalized approaches to medicine. One of the most significant advances will be the ability to predict disease before symptoms appear. While genetic testing today can identify many inherited disorders and estimate risk for common diseases, future approaches will integrate genomic information with gene expression, biomarkers, electronic health records, wearable device data, and environmental factors. Artificial intelligence will play a critical role in analyzing these complex datasets, allowing physicians to provide individualized risk assessments and recommend targeted interventions that prevent disease rather than simply treating disease after it develops.

Precision medicine will also continue to transform healthcare by tailoring diagnosis and treatment to the molecular drivers of disease. This approach has already revolutionized cancer care, where therapies are increasingly selected based on the genetic mutations present in a

patient's tumor rather than the organ in which the cancer originated. Similar strategies are expanding into cardiovascular disease, neurological disorders, autoimmune conditions, and rare genetic diseases, enabling more effective therapies with fewer unnecessary treatments.

At the same time, advances in gene editing are moving from the laboratory into clinical practice. Technologies such as CRISPR, base editing, and prime editing are making it possible to correct disease-causing mutations with unprecedented precision. Early successes in treating inherited disorders such as sickle cell disease demonstrate the promise of these approaches, and ongoing research is expected to extend these therapies to conditions including cystic fibrosis, muscular dystrophy, inherited blindness, hemophilia, and numerous other rare diseases. Complementing these advances, RNA-based medicines—including personalized cancer vaccines and therapies that temporarily modify gene expression without permanently altering DNA—are likely to become an increasingly important part of modern medicine.

Another major frontier is understanding the vast portion of the human genome that does not directly code for proteins. As noted above, once dismissed as "junk DNA," these regions are now known to play essential roles in regulating when, where, and how genes are expressed. Artificial intelligence and large-scale genomic datasets are beginning to reveal how variations within these regulatory regions contribute to disease, potentially leading to entirely new classes of diagnostic tests and therapeutic targets. The future of genetics will also be shaped by the integration of multiple layers of biological information, often referred to as multi-omics. By combining genomic, transcriptomic, proteomic, metabolomic, and epigenomic data, researchers can develop a far more complete understanding of human biology than DNA sequencing alone can provide. Together with advances in single-cell technologies, which allow scientists to study individual cells rather than averaging signals across entire tissues, these approaches are revealing previously hidden mechanisms of disease and identifying opportunities for more precise interventions.

Ultimately, the greatest advances in genetics are likely to come not from discovering additional genes, but from learning how to interpret and apply the enormous amount of genomic information that is already available. As artificial intelligence, computational biology, and functional genomics continue to mature, genetics will become an increasingly powerful tool for predicting disease, selecting the right therapies, developing curative treatments, and preventing illness before it begins. The future of genetics is therefore not simply about understanding our DNA, but about translating that understanding into better health outcomes through more personalized, predictive, and effective medicine.

Enacting PERA and once again allowing patents on naturally occurring DNA sequences and other naturally occurring biomarkers, as well as their association to human health, would likely impede many of the advances that are expected to define the future of genetics. While patents

have an important role in incentivizing the development of new technologies, therapies, and engineered inventions, granting exclusive rights over fundamental biological information—the building blocks of human biology—would create barriers to research, clinical testing, and innovation across the entire precision medicine ecosystem.

Many of the most promising developments in genetics depend on the ability of researchers, clinical laboratories, biotechnology companies, and physicians to freely study and analyze naturally occurring genes and biomarkers. Disease prediction, for example, requires scientists to identify and validate thousands of genetic variants and biomarkers across large populations. If individual DNA sequences or biomarkers were subject to exclusive patent rights, researchers would need to negotiate licenses or avoid studying certain genes altogether, increasing costs, delaying research, and discouraging the large-scale data sharing that is essential for developing accurate predictive models.

Similarly, precision medicine depends on the ability of laboratories to develop diagnostic tests that analyze combinations of biomarkers rather than a single genetic mutation. Modern genomic testing often evaluates hundreds or even thousands of genes simultaneously to diagnose disease or identify the most appropriate therapy. If patents covered individual DNA sequences or naturally occurring biomarkers, laboratories could face a patchwork of licensing requirements from numerous patent holders before offering comprehensive testing. Such "patent thickets" would reduce the number of clinical laboratories doing testing, increase costs, limit testing innovations, and reduce patient access to timely and affordable molecular diagnostics.

4. Has there been a decrease in investment into medical research since *Myriad*?

No, in fact, investment has soared since the *Myriad* decision. Mr. Richard Blaylock, in his testimony to the Subcommittee on Intellectual Property on January 23, 2024[3] reported that venture capital investments in companies prior to their initial public offering more than tripled three years later to a peak in 2015 at $419 million. A similar trend was found for private companies as well.

[3] https://www.judiciary.senate.gov/imo/media/doc/2024-01-23_-_testimony_-_blaylock.pdf

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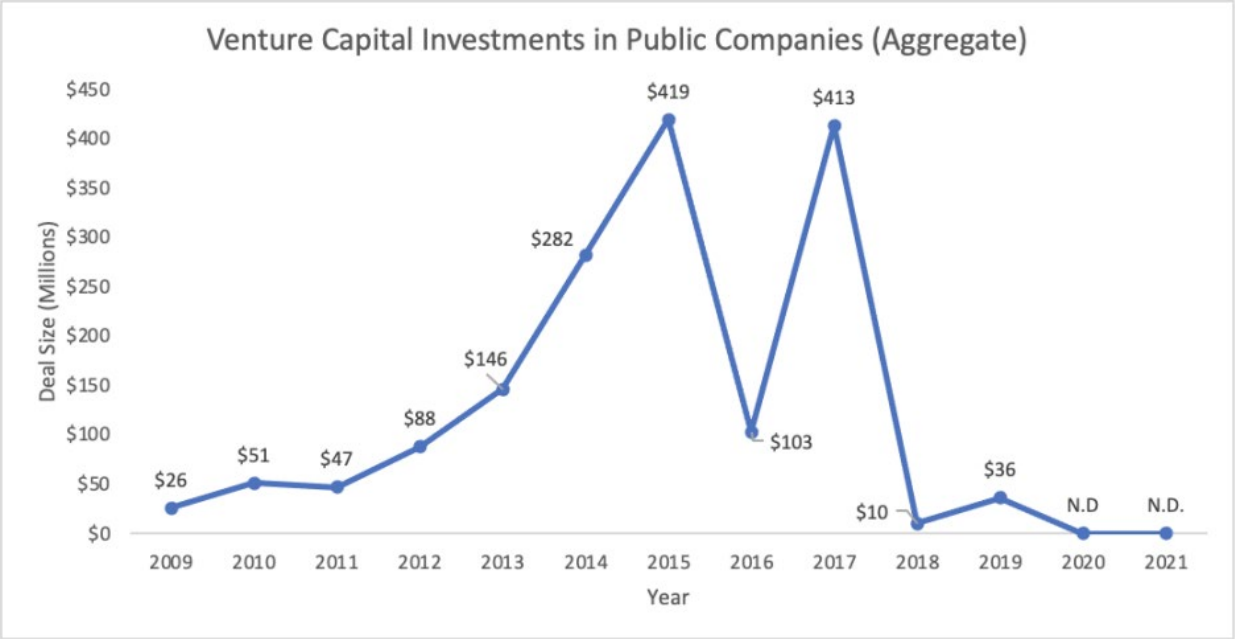

Above: Data from Adaptive Biotechnologies Corporation (2020-2021), CareDx, Inc. (2015-2021), Castle Biosciences, Inc. (2020-2021), Exact Sciences Corporation (2009-2021), Exagen, Inc. (2020-2021), Guardant Health, Inc. (2019-2021), Hologic, Inc. (2012-2020), Invitae Corporation (2015-2021), Myriad Genetics, Inc. (2009-2020), Natera, Inc. (2016-2021), NeoGenomicsLaboratories, Inc. (2009-2021), Veracyte, Inc. (2014-2021). (Note: parentheticals indicate years for which data is provided for each company; "N.D." means no data from any company for that year).

As shown below, aggregate data for BioTheranostics, Inc., Caris Life Sciences, Cernostics, Freenome, and Inivata, Inc. experienced almost a 300-fold increase.

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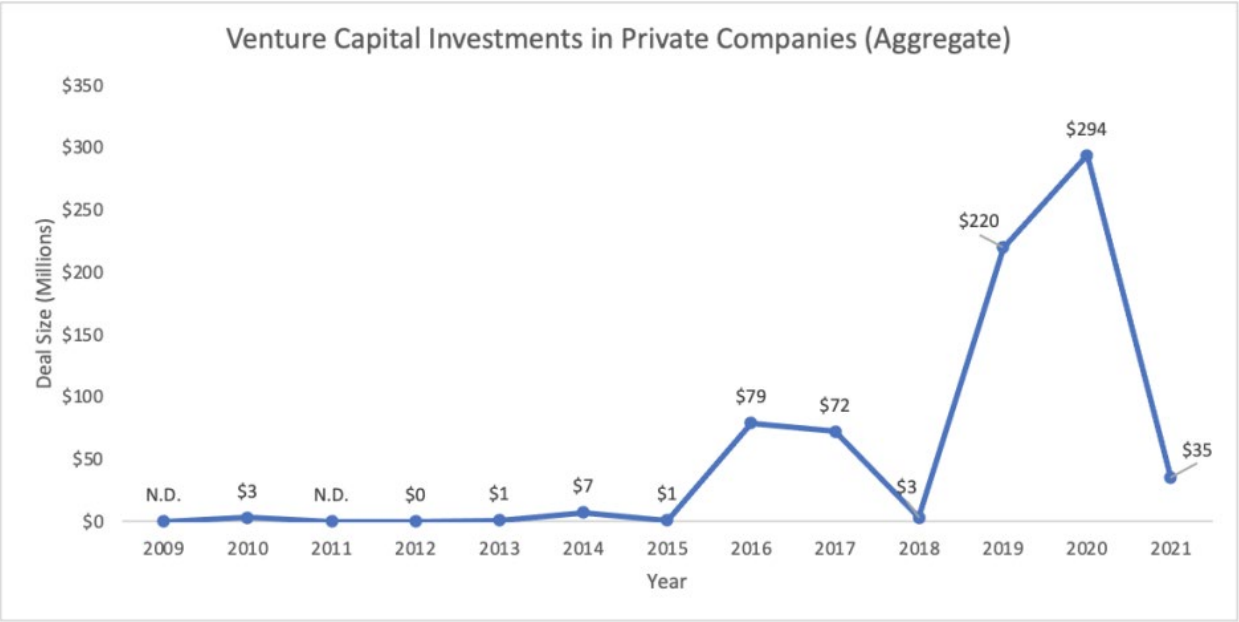

Moreover, Mr. Blaylock found that market capitalization has increased since the Myriad and Mayo decisions, indicating that they did not have a negative impact on growth in this sector.

Moreover, according to public reports from Concert Genetics, in 2022, there were over 175,000 genetic tests in the US market[4] -- an over 180 percent increase compared to the number of genetic tests in 2016.[5] It has been estimated that 14 genetic tests are entering the market every day.[6] Additionally, genetic tests are becoming more complex and moving beyond single gene tests. For instance, during the 12 months ending March 1, 2018, a net total of 801 new genetic testing panels entered the market.[7] This growth is also having a tremendous positive impact on the economy. According to a 2019 report issued by the American Society of Human Genetics (ASHG), human genetics and genomics contributed $265 billion to the US economy in that year alone, and for every federal dollar invested in human genetics and genomics research in 2019, it yielded a $4.75 return.[8]

5. Would the development of the COVID-19 vaccine have been different if the Supreme Court had not previously ruled that genes, including the COVID-19 genome, are not patent eligible? If so, how would it have been different? Also, what would the impact have been on the cost of and access to the vaccine?

Yes, had patents been allowed on the SARS-CoV-2 genetic sequence including new mutations, it would have greatly hampered the United States' response efforts. If one patent holder owned the RNA sequence of the virus, that holder could have opted to have a monopoly on testing, research, and therapeutic development in the United States.

At the height of the pandemic, FDA had nearly 400 individual emergency use authorizations for in vitro diagnostics molecular tests for COVID-19 listed on its website. Reflecting the end of that

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[4] Concert Genetics, "Genetic Test Price Transparency Report." 2023. http://www.concertgenetics.com/wp-content/uploads/2023/11/Concert-Genetics-2023-Genetic-Test-Price-Transparency-Report-07Nov2023.pdf Accessed January 18, 2024.

[5] Concert Genetics, "The Current Landscape of Genetic Testing – Market size, market growth and the practical challenges of the clinical workflow." 2016. http://concertgx.wpengine.com/wp-content/uploads/2017/02/ConcertGenetics_TheCurrentLandscapeOfGeneticTesting_March2016.pdf Accessed August 31, 2021.

[6] Concert Genetics, "The Current Landscape of Genetic Testing: Market Growth, Reimbursement Trends, Challenges and Opportunities – 2018 Edition." 2018. http://www.concertgenetics.com/wp-content/uploads/2018/04/12_ConcertGenetics_CurrentLandscapeOfGeneticTesting2018.pdf Accessed August 19, 2021.

[7] Concert Genetics, "The Current Landscape of Genetic Testing: Market Growth, Reimbursement Trends, Challenges and Opportunities – 2018 Edition." 2018. http://www.concertgenetics.com/wp-content/uploads/2018/04/12_ConcertGenetics_CurrentLandscapeOfGeneticTesting2018.pdf Accessed August 19, 2021.

[8] American Society of Human Genetics, "The Economic Impact and Functional Applications of Human Genetics and Genomics." May 2021 https://www.ashg.org/wp-content/uploads/2021/05/ASHG-TEConomy-Impact-Report-Final.pdf. Accessed August 19, 2021

public health emergency (PHE), the number of tests listed on the FDA's website as of July 23rd includes 247 individual tests. The lack of a patent led to rapid, incredible innovation in diagnostics for an emerging novel pathogen. The necessity for molecular professionals to operate, innovate, and develop testing for patients during a PHE relies on full, unrestricted access to genomic sequences.[9]

The Association for Molecular Pathology surveyed its membership multiple times over the course of 2020, and respondents reported that supply chain interruptions were having a significant impact on their work. To overcome testing supply shortages and maintain their testing capacity, molecular professionals deployed multiple testing methodologies, i.e. they built redundancy in testing methods within their laboratories and testing diversity played an important role in the PHE to meet the clinical need for an accurate diagnosis of a SARS-CoV-2 infection. If laboratories and manufacturers had been required to navigate multiple patent and licensing arrangements related to SARS-CoV-2 genetic sequence with each test introduction or adjustment, the observed testing response would not have been possible.

Contrasted with the response to a PHE before the *Myriad* decision, during the 2003 outbreak of severe acute respiratory syndrome (SARS), biotechnology and pharmaceutical companies raced to patent everything from the genetic sequences within the virus' genome to the virus itself. In competition with these companies was the Centers for Disease Control and Prevention (CDC), which sought to defensively patent the virus and its entire genetic content "to make sure access to the virus remains available to anyone" as stated by then CDC Director Julie Gerberding.[10]

Not only would a patent have greatly limited the rapid deployment of diagnostics, but it would have dramatically increased the cost of research and development of therapeutic countermeasures such as vaccines which leverage inert segments of the virus' genomic sequence to trigger an immune response. If the SARS-CoV-2 viral genome had been protected by an enforceable patent, the rapid development of COVID-19 vaccines could have become substantially more expensive and legally complex. Vaccine developers would likely have needed to negotiate licenses to use the viral genetic sequence as the basis for designing vaccines, thereby introducing transaction costs, legal uncertainty, and the potential for royalty payments. Companies unable to secure timely licenses could have faced delays or litigation, slowing research and increasing development costs at a time when speed was critical. The unprecedented pace of COVID-19 vaccine development—multiple vaccines reaching authorization within a year of the virus's emergence—was made possible in part because researchers worldwide had immediate access to the published SARS-CoV-2 genome without needing to navigate proprietary rights over the naturally occurring viral sequence. While patents remained available for genuinely inventive technologies, such as novel mRNA platforms, lipid nanoparticle delivery systems, manufacturing processes, and vaccine formulations, the absence of patent restrictions on the viral genome itself reduced barriers to innovation, enabled parallel efforts by multiple developers, and helped accelerate the delivery of lifesaving vaccines.

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[9] https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2

[10] https://www.wsj.com/articles/SB105226807345954200

U.S. Senate Committee on the Judiciary
"*From Genes to Machines: the Patent Eligibility Debate*"
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Questions for the Record: Dr. Debra G.B. Leonard, M.D., Ph.D.

6. Iowa, and similar states with long drives and rural areas, have challenges with patient access to medical care and treatment, particularly treatment by specialists and advanced treatments. Small, local and regional hospitals and clinics provide much of the services for my rural residents. How would PERA, if enacted, impact these people?

PERA would disproportionately harm rural patients precisely because the small, local, and regional hospitals and clinics that serve them have the least ability to absorb the cost increases, licensing burdens, and reduced testing options that would result from allowing patents on naturally occurring genes and biomarkers.

There are many advantages to supporting testing capabilities across the country. When a hospital or health system in a rural area, such as in Iowa, has its own molecular pathology or clinical laboratory capable of performing a given test, results come back in days rather than the weeks it can take when a specimen is shipped to an outside reference laboratory and placed into that laboratory's testing queue. For a patient waiting to learn whether they have a hereditary cancer mutation, whether a tumor carries a targetable variant, or whether an infection requires a particular treatment, that difference in turnaround time can directly affect how quickly treatment begins. Local testing also allows the pathologist interpreting the result and the physician treating the patient to be colleagues within the same health system – able to walk down the hall or pick up the phone to discuss an ambiguous or borderline result, flag a finding that warrants urgent follow-up, or tailor the interpretation to what the treating provider already knows about the patient. That kind of direct, informal consultation is much harder, and often unavailable, once testing is handled by a distant, unaffiliated commercial laboratory that has no access to the medical record of the patient and no ongoing relationship with the ordering provider.

PERA would likely force smaller laboratories to shoulder the burden of licensing and royalty fees, or worse, stop offering testing options altogether. As a result, sole-source patent monopolies would concentrate testing in a small number of large commercial or out-of-state laboratories, which would push rural health systems further away from being able to keep this kind of testing and collaborative care local.

Even when a rural or community hospital does not have the volume, capital, or specialized personnel to run advanced molecular and genetic testing in-house, they benefit from the competitive landscape that the *Myriad* decision made possible. As described above, when Myriad Genetics held exclusive patent rights to the *BRCA1* and *BRCA2* genes, it was the only laboratory in the country permitted to test them, and it charged approximately $4,000 per test. The day the Supreme Court invalidated that patent, five additional laboratories began offering the test, and today there are 263 clinical tests for *BRCA1* and 284 for *BRCA2*, with patients able

to access multigene hereditary cancer panels for a few hundred dollars. That kind of competition leading to price reductions is what currently allows a rural clinic to order advanced genetic testing for a patient. If PERA restores gene patentability, a single company could again become the sole source for a clinically important test, and small hospitals, with no negotiating leverage and thin operating margins, would have no alternative but to pay whatever that company charges, delay testing, or forgo it altogether.

This also compounds the risks I noted for Medicaid beneficiaries. Before Myriad, if a state's Medicaid program had not separately contracted with a test's patent holder, beneficiaries either paid out of pocket or went without testing that could inform lifesaving care. Rural states often have Medicaid programs with less purchasing leverage, so their beneficiaries would be especially exposed to this dynamic if PERA reintroduces single-source patent monopolies on diagnostic testing.

Finally, precision oncology and other biomarker-driven therapies depend on broad, affordable access to genomic testing to determine whether a rural cancer patient is even eligible for a targeted therapy or clinical trial. If PERA increases the cost and legal complexity of offering these tests, as described throughout my testimony, rural patients who already face long drives to see a specialist would face the additional burden of reduced local access to the diagnostic testing that determines their treatment path in the first place. In short, PERA would not just raise costs generally, it would fall hardest on exactly the small, local, and regional institutions that rural patients rely on, widening the access gap between rural and urban patients rather than closing it.

Questions from Senator Tillis
for Dr. Debra Leonard
Witness for the Senate Committee on the Judiciary Hearing
"From Genes to Machines: The Patent Eligibility Debate"

1. Do you agree that the courts, specifically the Supreme Court, have turned Section 101 from a historically coarse filter into a fine filter?

No.

2. Do you agree that just because an invention is eligible under Section 101, it does not mean that the invention is automatically patentable?

Yes; however, products of nature and natural phenomena should not be patent eligible and current patent eligibility policy related to products of nature and natural phenomena should remain intact. Allowing naturally occurring genetic sequences and their association with health conditions to be patent eligible would be detrimental to patient care and innovation.

3. Do you agree that there is a need for patent eligibility from?

No.

4. The latest version of PERA incorporated several changes based on stakeholder feedback.

   Do you believe that these were good changes to the bill? Why or why not?

The Association for Molecular Pathology greatly appreciates your willingness to modify PERA to codify the *Myriad* decision and the opportunity to work with your staff on drafting language to modify PERA so that patient access to clinical care and medical practice are not restricted and innovation is not discouraged. However, the changes have not sufficiently mitigated my and AMP's concerns for the following reasons.

The currently introduced version of PERA (S.1546) includes an exclusion in subsection (b) applicable to a genetic sequence, which reads as follows:

(D) An unmodified human gene, as that gene exists in the human body.

A human gene is comprised of DNA which is simply a sequence of nucleotides or base pairs, which are noted as A, C, T, and G. That sequence of nucleotides is the exact same if the DNA is in a cell within a human body or is being read off of a next generation sequencing platform or other diagnostic technology. Thus, while this "exclusion" appears to codify the *Myriad* decision, there is no meaningful difference between the sequence of a gene *inside* or *outside* of the human body, i.e. it is the exact same genetic information.

Further, it does not provide any protection to shorter DNA sequences, noncoding regions of the genome, etc. that do not constitute a gene, which are clinically meaningful in genetic testing. It is not always the whole gene that is evaluated. Also, even if this exclusion were adequate, it only applies to human genes and would still mean that patents on non-human DNA, RNA, and other biological biomarkers would be allowed, including pathogenic sequences from viruses or bacteria. The *Myriad* decision, in effect, applies to more than "human genes."

PERA further includes conditions pertaining to that exclusion:

A human gene/natural material shall not be considered unmodified if that human gene/natural material is -
'(i) purified, enriched, or otherwise altered by human activity; or
''(ii) otherwise employed in a useful invention or discovery;

Removing the multiple negatives, the conditions essentially read:

"A human gene shall be considered modified if that human gene is purified, enriched, or otherwise altered by human activity;"

The steps in performing any genetic test include isolating or purifying the DNA from a patient sample to remove all other cellular material, and enriching (or amplifying) the DNA usually by PCR, and then doing further testing steps such as next generation sequencing (NGS) to determine the sequence of nucleotides. If the act of isolating, purifying, or enriching DNA means the human gene has been modified, then any genetic sequence would be patent eligible under PERA. I recognize that since the last Congress, the bill text no longer includes the word "isolated" in that condition; however, from a scientific standpoint, isolated and purified are essentially the same process in that one is removing the DNA from its environment. As the *Myriad* decision states, "...separating that gene from its surrounding genetic material is not an act of invention." PERA as a whole does not codify the *Myriad* decision, and therefore, PERA, if enacted, would establish that human genetic sequences and other important natural biomarkers relevant to human health are patent eligible.

Senate Committee on the Judiciary
Hearing: From Genes to Machines: The Patent Eligibility Debate
July 14, 2026

Questions for the Record for Debra G.B. Leonard, M.D., Ph.D. from Senator Coons

The language in the Patent Eligibility Restoration Act (PERA) pertaining to human genomics—specifically the ineligibility of unmodified and isolated human genes—was developed following years of debate and input from stakeholders. The intent of this language is to codify the *Myriad* decision.

- You testified that you do not believe the current language is sufficient to codify *Myriad*. Why?

The currently introduced version of PERA (S.1546) includes an exclusion in subsection (b) applicable to a genetic sequence, which reads as follows:

(D) An unmodified human gene, as that gene exists in the human body.

A human gene is comprised of DNA which is simply a sequence of nucleotides or base pairs, which are noted as A, C, T, and G. That sequence of nucleotides is the exact same if the DNA is in a cell within a human body or is being read off of a next generation sequencing platform or other diagnostic technology. Thus, while this "exclusion" appears to codify the *Myriad* decision, there is no meaningful difference between the sequence of a gene *inside* or *outside* of the human body, i.e. it is the exact same genetic information.

Further, it doesn't provide any protection to shorter DNA sequences, noncoding regions of the genome, etc. that do not constitute a gene, which are clinically meaningful in genetic testing. It isn't always the whole gene that is evaluated. Also, even if this exclusion were adequate, it only applies to human genes and would still mean that patents on non-human DNA, RNA, and other biological biomarkers would be allowed, including pathogenic sequences from viruses or bacteria. The *Myriad* decision, in effect, applies to more than "human genes."

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- What revisions to Section 3 of PERA would you suggest to address your concerns about excluding human genes from patent eligibility and codifying *Myriad*, while preserving incentives to innovate in diagnostics? Please provide a red line indicating your proposed changes.

The Association for Molecular Pathology (AMP) and I greatly appreciate your willingness to modify PERA to codify the *Myriad* decision and the opportunity to work with your staff on drafting language to modify PERA so that patient access to clinical care and medical practice are not restricted and innovation is not discouraged. AMP plans to consult with other genomics experts and patent law professionals to develop redline edits and will reach out to your committee staff with recommendations soon.

Additionally, and in the meantime, the best way and most critical need to preserve incentives for diagnostic development is to ensure consistent and predictable coverage and reimbursement for laboratory services. Your colleague, Sen. Tillis is the lead sponsor of S. 2761, the *Reforming and Enhancing Sustainable Updates to Laboratory Services (RESULTS) Act*. This bipartisan, bicameral legislation reforms Medicare's Clinical Laboratory Fee Schedule to establish appropriate market-based payment for these lifesaving tests and reform provisions within the Protecting Access to Medicare Act (Public Law No. 113-93) which lead to drastic payment cuts which threaten the sustainability of and investment in diagnostics. I encourage you to consider joining as a cosponsor and advocating for its swift passage in the Senate.