

# Comment Report

HF 2157

A bill for an act relating to insurance coverage for biomarker testing.(See HF 2492, HF 2668.)

Subcommittee Members: Lohse-CH, Srinivas, Young

Date: 02/06/2024

Time: 08:15 AM

Location: House Lounge

**Name:** Margaret Uhler

**Comment:** Attached are comments from Iowa clinicians in support of biomarker testing. Thank you for the opportunity to comment on this important conversation.



**Alliance for  
Patient Access**

February 6, 2024

The Honorable Brian Lohse  
Chair, House Commerce Subcommittee  
Iowa State Capitol  
1007 E. Grand Ave  
Des Moines, IA 50319

The Honorable David Young  
Vice Chair, House Commerce Subcommittee  
Iowa State Capitol  
1007 E. Grand Ave  
Des Moines, IA 50319

The Honorable Megan Srinivas  
Ranking Member House Commerce Subcommittee  
Iowa State Capitol  
1007 E. Grand Ave  
Des Moines, IA 50319

**RE: SUPPORT FOR HF 2157 - Biomarker Testing**

Dear Subcommittee Members:

On behalf of the Alliance for Patient Access (AfPA), I am writing to urge your support, with amendment, for HF 2157, which would expand and simplify health insurance coverage for biomarker testing. This bill requires coverage for biomarker testing for the purposes of diagnosis, treatment, prognosis, management and ongoing monitoring of a patient's disease. However, this bill should be amended to include disease agnostic language that will cover testing for patients across disease states.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making, promote personalized care and protect the provider-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials. AfPA also convenes an Iowa State Chapter, a group of Iowa health care providers that advocate for policies prioritizing patient-centered care.

Health care is rapidly moving towards an advanced, precision-based approach. For example, with the advancements of precision medicine in oncology care, doctors can offer cancer patients targeted treatments based on the molecular understanding of their disease, allowing for more personalized, patient-centered care. This can lead to more effective treatment, with fewer side effects – and has been proven to improve patient outcomes for some types of cancer.<sup>1</sup>

This type of individualized treatment is possible by knowing the specific genomic alterations in the patient, which can only be detected through biomarker testing. Advances in precision medicine are also being seen in a number of disease states including rheumatology, neurology and mental health. For example, a recent study highlighted that a simple blood biomarker test was found to be up to 96% accurate in identifying the most important biomarker in Alzheimer's disease pathology.<sup>2</sup> Similarly in rheumatology, biomarkers reveal whether specific medications such as TNF inhibitors would be ineffective for patients who have been diagnosed with rheumatoid arthritis.<sup>3</sup>

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<sup>1</sup> <https://ascopubs.org/doi/full/10.1200/jop.2016.011486?cookieSet=1>

Biomarker testing can reduce the number of time-consuming and costly tests used to determine a patient's diagnosis, as a biomarker analysis will provide insight as to whether a targeted or specific treatment might work for a specific patient. This could be lifesaving for countless patients. However, **without insurance coverage of biomarker testing, patients would face delays in identifying the best treatment options and risk experiencing significantly worse disease outcomes.**

Unfortunately, patients in Iowa face coverage barriers for both biomarker testing and individualized treatments from insurance companies. This can cause delays in care that can be devastating for patients with diseases like advanced cancer but also other diseases. HF 2157, will ensure that patients will have equal access, regardless of their disease stage, to biomarker testing by requiring appropriate coverage. Promoting early detection and faster diagnosis, when possible, can lead to life-saving precision treatment.

HF 2157, supports the clinician-patient relationship by allowing clinicians to access appropriate medical tools for their patients and helping ensure patients can access testing to help drive accurate diagnosis and effective treatment decisions. We are pleased that the state legislature has prioritized this crucial issue. On behalf of the Alliance for Patient Access, I urge your support of HF 2157, to ensure patients across disease states can access the tests and treatments they need. Should you have any questions, please reach out to Casey McPherson at [cmcpherson@allianceforpatientaccess.org](mailto:cmcpherson@allianceforpatientaccess.org).

Sincerely,

Sakeer Hussain, MD  
Heartland Oncology and Hematology  
Council Bluffs, IA

Spas Kotev, MD  
Mercy Iowa City  
Iowa City, IA

Lynn Rankin, MD  
UnityPoint Health  
Des Moines, IA

Michael Brooks, MD  
Cedar Rapids, IA

Jason Kruse, DO  
Broadlawns Medical Center  
Des Moines, IA

**Name:** Margaret Uhler

**Comment:** Attached are comments from Iowa clinicians in support of biomarker testing. Thank you for the opportunity to comment on this important conversation.

**Name:** Zach Hardy

**Comment:** Letter of support for HF 2157, a bill pertaining to insurance coverage for biomarker testing. Thank you for your time and consideration.



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***Re: Support for HF 2157, AN ACT Relating to Insurance Coverage for Biomarker Testing***

Dear Subcommittee Members:

On behalf of The Michael J. Fox Foundation for Parkinson's Research (MJFF), I write in support of **HF 2157**, which will require health care plans, including Medicaid, to provide coverage for biomarker testing.

Founded in 2000, MJFF has been singularly dedicated to finding a cure for Parkinson's disease through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson's today. To date, MJFF has funded nearly \$2 billion in global Parkinson's research.

Biomarker testing is a crucial step for accessing precision medicine, including targeted therapies that can lead to improved survivorship and better quality of life for patients. While most current applications of biomarker testing are in oncology and autoimmune diseases, there is research underway to benefit patients in other areas, including neurological conditions such as Parkinson's disease.

This past April, MJFF announced that through the ongoing work of our landmark clinical study, Parkinson's Progression Markers Initiative (PPMI), a new biomarker had been identified for Parkinson's disease. This breakthrough was published in the scientific journal *The Lancet Neurology* and opens a new chapter for research, with the promise of a future where every person living with Parkinson's can expect improved care and treatments — and newly diagnosed individuals may never advance to full-blown symptoms.<sup>1</sup>

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<sup>1</sup> "Breaking News: Parkinson's Disease Biomarker Found." The Michael J. Fox Foundation for Parkinson's Research | Parkinson's Disease, 13 Apr. 2023, <https://www.michaeljfox.org/news/breaking-news-parkinsons-disease-biomarker-found>.

There are an estimated more than one million Americans currently living with Parkinson's disease, with about 90,000 more diagnosed each year.<sup>2</sup> According to the Centers for Disease Control and Prevention, Parkinson's disease is the second most common and the fastest-growing neurological disorder worldwide.

MJFF recognizes the potential that biomarking testing possesses to revolutionize the way that people living with Parkinson's disease are diagnosed and treated. There is additional work to be done to make this newly discovered biomarker available to the public and ensure that it is covered by health care plans. It is critical to ensure that people living with Parkinson's will be able to access a biomarker test as an important tool in their health care as they become more widely available.

**To ensure that this legislation covers all proven and necessary testing, I urge this subcommittee to utilize the language in SF 2159.** This is the opportunity to guarantee that the most patients possible can benefit from this advanced, critical healthcare tool.

For these reasons, MJFF strongly supports **HF 2157**. I urge this subcommittee to support this important piece of legislation and look forward to seeing it move forward. If you have any questions, you may contact me at [zhardy@michaeljfox.org](mailto:zhardy@michaeljfox.org) or 202-638-4101, ext. 225.

Sincerely,

A handwritten signature in black ink, appearing to read 'Z Hardy', with a stylized flourish at the end.

Zach Hardy  
State Government Relations Officer

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<sup>2</sup> "New Study Shows the Incidence of Parkinson's in the U.S. Is Nearly 50 Percent Higher than Previous Estimates." The Michael J. Fox Foundation for Parkinson's Research | Parkinson's Disease, 15 Dec. 2022, <https://www.michaeljfox.org/news/new-study-shows-incidence-parkinsons-us-nearly-50-percent-higher-previous-estimates>.



**Name:** Kate Feuling Porter

**Comment:** Attached is written testimony regarding HF 2157. Thank you.



February 5, 2024

Chair Lohse, Vice Chair Young, and Ranking Member Srinivas:

On behalf of the patients, family members, donors, volunteers, and staff at NMDP thank you for the opportunity to submit written testimony in support of H.F. 2157, which would help more Iowans access biomarker testing so that they can get the right treatment at the right time.

As a global nonprofit leader in cell therapy, NMDP<sup>SM</sup> creates essential connections between researchers and supporters to inspire action and accelerate innovation to find life-saving cures for blood cancers and disorders. Entrusted by Congress to operate the national registry of the world's most diverse donors and with an extensive network of transplant partners, physicians, and caregivers, NMDP is expanding access to treatment so that every patient can receive their life-saving cell therapy. Biomarker testing is one tool physicians can use to determine the best treatment for their patients.

Biomarker testing is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker which helps doctors certify that they are getting patients the most effective treatment for their diagnosis—but not everyone is benefiting from the latest advancements in cancer treatment, due in part to lack of insurance coverage. H.F. 2157 helps ensure that all Iowans have access to the benefits of biomarker testing.

While most cell therapies NMDP facilitates are to treat cancer, transplant is also a treatment for non-malignant chronic diseases such as Sickle Cell Disease (SCD). Some SCD patients must receive biomarker testing to determine suitability and eligibility for clinical trials. If a patient's insurance does not cover biomarker testing, the cost may preclude them from accessing their needed therapies.

Biomarker testing is also used to identify the best treatment for Graft versus Host Disease (GvHD), a potential side effect of any bone marrow transplant that is also considered a chronic disease. This condition occurs when the donor immune cells attack the patient's healthy cells and tissue. Biomarker tests can be used to determine the extent and severity of GvHD, which allows physicians to choose a treatment that balances effectiveness and side effects, resulting in the best outcomes for the patients.

H.F. 2157 aligns coverage of biomarker testing with the latest science, providing a gateway to targeted therapies that can lead to better health outcomes and improved quality of life. Greater access to biomarker testing can allow Iowans to bypass costly and ineffective treatments by connecting patients with therapies that will be most effective for their individual cancer right away. Please support H.F. 2157 to increase access to biomarker testing for all Iowans facing cancers and consider expanding this bill to cover non-cancerous conditions like SCD and graft-vs-host disease. Thank you for your consideration.

Kate Feuling Porter  
Regional Grassroots Manager  
NMDP

**Name:** Ashira Vantrees

**Comment:** Please see attached PDF comment.



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The Honorable Megan Srinivas  
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House Commerce Subcommittee  
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Re: Letter of Support for Biomarker Testing Bill (HF2157)

Dear Health Care & Wellness Committee:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to express our support for House Bill 2157 relating to insurance coverage for biomarker testing. This legislation, if amended to incorporate a disease-agnostic approach, holds promise in advancing medical diagnostics and tailoring treatment options for individuals facing diverse health challenges.

Biomarker testing plays a pivotal role in gathering personalized information essential for the disease prevention, diagnosis, and treatment.<sup>1</sup> By analyzing biological specimens such as tissue and blood, practitioners can identify key biomarkers, including genetic and molecular indicators that can help inform treatment decisions and patient outcomes.<sup>2</sup> The expansion of insurance coverage for biomarker testing is a critical step towards improving accessibility to this invaluable diagnostic tool. Identifying specific biomarkers allows health care practitioners to personalize treatments for individual patients, reducing unnecessary interventions and maximizing therapeutic benefits.<sup>3</sup>

While biomarker testing has made substantial progress in fields like oncology, its applications extend beyond cancer diagnosis and treatment. There is a growing body of evidence underscoring its clinical benefits across a diverse range of diseases and chronic illnesses, such as

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<sup>1</sup> Ali Bodaghi et al., *Biomarkers: Promising and valuable tools towards diagnosis, prognosis and treatment of Covid-19 and other diseases*, 9 Helyion e13323 (2023).

<sup>2</sup> Biomarker Testing, *Oncology Nursing Society*, <https://www.ons.org/genomics-taxonomy/biomarker-testing>.

<sup>3</sup> Biomarker Tests and Cancer Treatment, *American Cancer Society*, <https://www.cancer.org/cancer/diagnosis-staging/tests/biomarker-tests.html>.



preeclampsia,<sup>4</sup> cardiovascular diseases,<sup>5</sup> diabetes,<sup>6</sup> neurodegenerative disorders,<sup>7</sup> and autoimmune diseases.<sup>8</sup> For example, the FDA recently approved a biomarker test for preeclampsia, facilitating the identification of pregnant individuals at the highest risk and leading to improved management and outcomes for both mothers and their newborns.<sup>9</sup>

The innovative use of biomarker testing has the potential to improve patient outcomes, reduce healthcare costs, and enhance overall quality of life.<sup>10</sup> The broad scope of medical conditions addressed by biomarker testing, as highlighted in the disease-agnostic language of SF2159, promotes innovation and progress across various conditions. We urge you to adopt the language used in SF 2159 to ensure equal and equitable access for all consumers eligible to benefit from this testing and information.

In conclusion, we respectfully request you to recognize the substantial benefits of biomarker testing in enhancing a diverse range of health outcomes and to amend this legislation to use disease agnostic language. We sincerely appreciate your time and consideration of this important issue.

Sincerely,

Ashira Vantrees  
Counsel

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<sup>4</sup> Thermo Fisher, *Scientific Announces FDA Clearance of Breakthrough Immunoassays to Aid in the Risk Assessment of Preeclampsia*, Businesswire (2023), <https://www.businesswire.com/news/home/20230519005071/en/Thermo-Fisher-Scientific-Announces-FDA-Clearance-of-Breakthrough-Immunoassays-to-Aid-in-the-Risk-Assessment-of-Preeclampsia>.

<sup>5</sup> Crystal Ghantous et al., *Advances in Cardiovascular Biomarker Discovery*, 8 *Biomedicines* 552 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7759775/>

<sup>6</sup> Brenda Dorcelly et al., *Novel biomarkers for prediabetes, diabetes, and associated complications*, *Diabetes, Metabolic Syndrome and Obesity* 345–61 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565252/>

<sup>7</sup> *Blood Biomarkers in Neurodegenerative Diseases: Implications for the Clinical Neurologist*, 101 *Neurology* (2023), <https://n.neurology.org/content/101/4/172#:~:text=The%20most%20rigorously%20studied%20blood,detect%20AD%20in%20older%20adults>.

<sup>8</sup> Fenghe Zhang et al., *Biomarkers in autoimmune diseases of the central nervous system*, 114 *Frontiers in Immunology* (2023), <https://www.frontiersin.org/articles/10.3389/fimmu.2023.1111719/full#:~:text=They%20are%20easy%20to%20quantify,of%20disability%20in%20clinical%20practice>.

<sup>9</sup> Thermo Fisher, *Scientific Announces FDA Clearance of Breakthrough Immunoassays to Aid in the Risk Assessment of Preeclampsia*, Businesswire.

<sup>10</sup> Biomarker Testing and Cost Savings, American Cancer Society Cancer Action Network (Jan. 25, 2023), <https://www.fightcancer.org/news/biomarker-testing-and-cost-savings-1#:~:text=Timely%20access%20to%20guideline%2Dindicated,biomarkers%20based%20on%20clinical%20guidelines>.

**Name:** Lindsey Viscarra

**Comment:** Attached please find comments from the National Organization for Rare Disorders.



Alone we are rare. Together we are strong.®

February 5, 2024

The Honorable Brian K. Lohse  
Iowa House of Representatives  
Iowa State Capitol  
1007 East Grand Avenue  
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Iowa House of Representatives  
Iowa State Capitol  
1007 East Grand Avenue  
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The Honorable Megan L. Srinivas  
Iowa House of Representatives  
Iowa State Capitol  
1007 East Grand Avenue  
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Re: Keep **House File 2157** Relevant for all People with Rare Conditions

Dear Representatives Lohse, Srinivas, and Young;

The National Organization for Rare Disorders (NORD) is the leading independent advocacy organization representing the more than 30 million Americans living with a rare disease. At NORD, we believe that all patients should have access to quality, accessible, innovative, and affordable health coverage that is best suited to their medical needs. On behalf of the estimated one in ten Iowans with a rare disorder, NORD has been proud to support HF2157, legislation that would expand access to biomarker testing. However, it is vital that HF2157 is not limited to one disease area in order for the legislation to fully benefit our community. We encourage you to utilize the language from SF2159 to ensure the bill covers proven and necessary testing.

Biomarkers are characteristics, such as radiographic abnormalities or biological molecules found in blood, tissue, or other bodily fluid that can be objectively measured to determine the sign of a condition or disease. The result of a biomarker test can be used to assess how well a patient responds to a treatment for a disease or condition, as well as determine the best course of action for a patient.<sup>i</sup> This can significantly improve patient outcomes; for instance, in rare cancers, including pediatric cancers, this can mean that treatments can be targeted specifically for the genetic or molecular makeup of the tumor.<sup>ii</sup> Biomarker testing allows for targeted care and precision medicine, thus decreasing the treatment time and increasing the likelihood of survivorship for patients.<sup>iii</sup> While currently biomarker testing is often used in oncology,

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biomarker testing can benefit patients in many disease groups, including autoimmune diseases, and research is underway that may unlock benefits in other rare conditions. **That is why it is essential that HF2157 remain disease agnostic.**

Limiting the scope of HF2157 to cover only biomarker testing in oncology will dramatically lessen the impact of this legislation now and in the future and means that many patients will not be able to benefit from future innovation in biomarker testing. This change would be detrimental to the rare disease community and would force NORD to reconsider our support for this legislation. We urge you to adopt the language in SF2159 to ensure all relevant patients can benefit from this quickly evolving aspect of precision medicine, and to swiftly advance the legislation out of your subcommittee.

Thank you for your attention to this matter. For any questions, please contact me at [lviscarra@rarediseases.org](mailto:lviscarra@rarediseases.org).

Sincerely,



Lindsey Viscarra  
State Policy Manager, Western Region  
National Organization for Rare Disorders

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<sup>i</sup> Biomarkers. ONS. (n.d.). Retrieved December 7, 2022, from <https://www.ons.org/genomics-taxonomy/biomarkers>

<sup>ii</sup> Biomarker testing for cancer treatment. National Cancer Institute. (n.d.). Retrieved December 7, 2022, from <https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment#:~:text=Biomarker%20testing%20is%20a%20way,how%20certain%20cancer%20treatments%20work>.

<sup>iii</sup> Biomarker testing for cancer treatment. National Cancer Institute. (n.d.). Retrieved December 7, 2022, from <https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment#:~:text=Biomarker%20testing%20is%20a%20way,how%20certain%20cancer%20treatments%20work>.