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**Testimony of the Department of Commerce and Consumer Affairs**

**Before the**  
**House Committee on Health and Homelessness**  
**Wednesday, January 31, 2024**  
**8:30 a.m.**

**State Capitol, Conference Room 329 and via Video Conferencing**

**On the following measure:**  
**H.B. 2223, RELATING TO INSURANCE**

Chair Belatti and Members of the Committee:

My name is Gordon Ito, and I am the Insurance Commissioner for the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

The purpose of this bill is to, beginning January 1, 2025, require health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing.

We note that it is unclear whether the amendments in sections 1 through 3 of this bill, which require health plans to provide benefits for biomarker testing, would be construed as "in addition to the essential health benefits" within the meaning of 45 Code of Federal Regulations (CFR) § 155.170(a), or subject to defrayment provisions under 45 CFR § 155.170(b) which apply to benefits "in addition to the essential health benefits."

For the Committee's information, Hawaii Revised Statutes section 23-51 provides, in part, that "[b]efore any legislative measure that mandates health insurance coverage for specific health services, specific diseases, or certain providers of health care services as part of individual or group health insurance policies, [sic] can be considered, there shall be concurrent resolutions passed requesting the auditor to prepare and submit to the legislature a report[.]"

The Department notes that section 1, page 2, lines 9 to 13, and section 2, page 6, lines 4 to 9, contain a provision that states, "When coverage under this section is restricted for use by a policy, the patient and prescribing health care provider shall have access to clear, readily accessible, and convenient processes to request an exception." The use of the term "policy" as used in this section is not defined and is unclear as to which policy would restrict coverage. Additionally, the Department is unclear how the process to request an exception would operate with section 432E-5, Hawaii Revised Statutes, which requires that a health carrier shall establish and maintain a procedure to provide for the resolution of an enrollee's complaints and internal appeals.

Thank you for the opportunity to testify on this bill.



# UNIVERSITY OF HAWAII SYSTEM

## ‘ŌNAEHANA KULANUI O HAWAII

### Legislative Testimony

### Hō'ike Mana'o I Mua O Ka 'Aha'ōlelo

Testimony Presented Before the  
House Committee on Health & Homelessness  
Wednesday, January 31, 2024 at 8:30 a.m.

By

Teruo Yamauchi, MD

And

Naoto T. Ueno MD, PhD, Director  
University of Hawai'i Cancer Center

And

Michael Bruno, PhD, Provost  
University of Hawai'i at Mānoa

#### HB 2223 – RELATING TO INSURANCE

Chair Belatti, Vice Chair Takenouchi, and members of the Committee:

The University of Hawai'i Cancer Center (UH Cancer Center), thank you for the opportunity to provide testimony in **strong support** for House Bill 2223. This measure addresses the critical matter of ensuring insurance coverage for biomarker testing which is crucial in advancing the standard of care for individuals facing various diseases and conditions, particularly in the field of oncology where biomarker testing plays a pivotal role in personalized medicine.

The UH Cancer Center is at the forefront of cancer research and patient care, and we firmly believe that the inclusion of biomarker testing coverage in health insurance policies is a significant step towards improving patient outcomes and promoting evidence-based healthcare practices.

Biomarker testing is an invaluable tool in the diagnosis, treatment, appropriate management, and ongoing monitoring of diseases or conditions. This testing allows for a more precise and personalized approach to medical care by identifying specific genetic, molecular, or biochemical markers associated with an individual's disease. It enables healthcare providers to tailor treatments based on the unique characteristics of a patient's condition, leading to more effective and targeted interventions. In addition, it is imperative to utilize biomarker testing to circumvent unwanted physical and financial ramifications that may arise as a result of cancer drug therapy. Healthcare providers can not only minimize the risk of treatment-related side-effects, but also reduce the financial burden associated with ineffective therapies. Therefore, the integration of biomarker testing into clinical practice is pivotal in ensuring optimal patient outcomes and fostering a more sustainable healthcare system.

House Bill 2223 is comprehensive in its approach, mandating coverage for biomarker testing when supported by medical and scientific evidence. The criteria outlined in the bill, including FDA-approved or FDA-cleared tests, indications for FDA-approved drugs, warnings and precautions on FDA-approved drug labels, CMS national coverage determinations, and adherence to nationally recognized clinical practice guidelines, ensure that coverage is grounded in rigorous scientific standards.

By requiring insurance coverage for biomarker testing, HB 2223 aligns with the advancements in medical research and the evolving landscape of precision medicine. This not only benefits patients by providing access to cutting-edge diagnostics and treatments but also contributes to the overall improvement of healthcare outcomes in our community.

In conclusion, the UH Cancer Center wholeheartedly supports HB 2223, recognizing its potential to enhance the quality of healthcare delivery in our state. We urge you to consider the positive impact this legislation can have on patient care and to pass this bill for the benefit of all residents of Hawai'i.

Mahalo for your attention to this matter.



January 30, 2024

***Re: Support for H.B. 2223, Requiring health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing.***

Dear Chairwoman Belatti,

On behalf of The Michael J. Fox Foundation for Parkinson's Research (MJFF), I write in support of **H.B. 2223**, 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>

There are estimated to be more than 1 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 biomarker 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.

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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>.

<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>.

For these reasons, MJFF strongly supports **H.B. 2223**. I urge this committee 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).

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

CC:  
The Honorable Jenna Takenouchi, Vice Chair  
Members of the House Committee on Health & Homelessness

January 30, 2024



The Honorable Chair Della Au Belatti  
House Committee on Health and Homelessness  
Hawai'i State Capitol, Room 420  
415 S Beretania St.  
Honolulu, HI 96813

**Re: HB 2223 () biomarker testing – SUPPORT**

Dear Chairwoman Belatti:

On behalf of the ALS Association, I am writing to express our strong **support for HB 2223**. If enacted into law, this legislation would expand patient access to biomarker testing to save lives and improve quality of life for many Hawaiians battling cancer and other chronic conditions and diseases, including those living with ALS.

Amyotrophic lateral sclerosis (ALS), commonly referred to as Lou Gehrig's Disease, is a rare, progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. The mean survival time with ALS is two to five years from the time of diagnosis, however the disease progression, including the range and order in which symptoms present, varies from one patient to another. Unfortunately, there is no cure for ALS yet.

Established in 1985, The ALS Association is the only national nonprofit organization fighting ALS on every front in California and beyond. By leading the way in global research, providing assistance for people with ALS and their families through a nationwide network of staff and resources, coordinating multidisciplinary care through certified clinical care centers, fostering government partnerships and advocating for better public policies for people living with ALS, the Association builds hope and enhances quality of life for those impacted by ALS while urgently searching for new treatments and a cure. The Association is committed to advancing critical policies that help to find new treatments and a cure, optimize current treatments and care, and prevent or delay the harms associated with ALS.

Biomarker testing is the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker, a type of precision medicine that looks for genes, proteins and other substances that can provide information about a patient's chronic condition. The results can help doctors choose the most effective targeted therapies and lifesaving treatment for an individual patient. Biomarker testing is increasingly important to cancer care and for the treatment for autoimmune conditions and rare diseases. Biomarker testing research is also happening in many other areas including cardiology, neurological conditions and infectious disease.

Despite the fact that biomarker testing is essential to high-quality, personalized care to treat serious illness and enhance patients' quality of life, patients cannot easily access it. Insurance coverage has not kept pace with the speed of medical innovation, creating significant barriers to care for our most vulnerable patients.

Thankfully, HB 2223 seeks to increase access to this critical diagnostic tool by ensuring that state-regulated health insurance plans, mutual benefit societies and health maintenance organizations cover biomarker testing. HB 2223 aligns coverage of biomarker testing with the latest science, providing a gateway to targeted therapies that can and lead to better health outcomes and improved quality of life for chronically ill patients, avoiding costly and ineffective treatments.

Expanding access to biomarker testing will help physicians ensure that Hawaiians get the right treatment at the right time, which will ultimately save lives, help lower long-term healthcare costs and reduce health disparities. Several other states have already passed laws to increase access to comprehensive biomarker testing – and it's time for Hawaii to do the same.

It is for these reasons that we respectfully request your Committee **support HB 2223**. Should you have any questions, please don't hesitate to reach me at [Kelly.Goss@als.org](mailto:Kelly.Goss@als.org).

Sincerely,

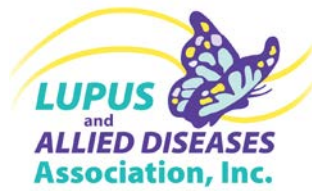
A handwritten signature in black ink, appearing to read "Kelly Goss".

Kelly Goss, J.D., LL.M  
Managing Director, Advocacy

cc: Members, House Committee on Health and Homelessness

Consultants, House Committee on Health and Homelessness





## MEMORANDUM IN SUPPORT

HB 2223

January 29, 2024

On behalf of the Lupus and Allied Diseases Association and the millions of Hawaiians both directly and indirectly affected by autoimmune conditions, cancer and other diseases of unmet need, we passionately urge you to please support HB 2223 An Act to amend the insurance law and the social services law, in relation to requiring health insurers, mutual benefit societies, and health maintenance organizations to cover biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a covered person's disease or condition when the test is supported by medical and scientific evidence to ensure that Hawaiians have improved access to innovative therapies by facilitating insurance coverage of biomarker testing.

As patient stakeholders who represent individuals dealing with serious medical conditions on a daily basis and their loved ones who strongly support establishing essential patient protections that improve access to vital therapies, we strongly urge your support and passage of **HB 2223** to ensure that Hawaiians have coverage for biomarker testing when medically appropriate. Access to appropriate medication can dramatically improve disease outcome and quality of life and effective treatment can reduce the severity and frequency of disease activity and decelerate its progression, enabling individuals to remain productive.

Due to the heterogeneity of autoimmune diseases like lupus, no two patients are alike and treatment is highly individualized. We have been eagerly awaiting more efficacious and safer groundbreaking treatments that target the offending molecule or cell that disrupts our immune system and in a perfect world, people like us would take one pill a day for treatment instead of forty-eight. We desperately need safer, more innovative treatments that address the pathogenesis of diseases, while impacting what matters most to patients—reducing symptoms and improving daily functioning and quality of life. Biomarker testing will provide the path forward to targeted therapies and precision medicine.

Hawaii has a longstanding record of providing access to affordable healthcare as well as some of the strongest patient protections in the country. By improving coverage and access to biomarker testing, **HB 2223** has the potential to reduce health disparities and inequities for communities of color, individuals with lower socioeconomic status, rural communities, disabled populations, and those receiving care in non-academic medical centers who are all currently less likely to receive testing for biomarkers.

The Lupus and Allied Diseases Association was founded in 1978 and is a national non-profit organization led by people with lupus and allied diseases and their loved ones who are dedicated to ensuring that the patient perspective is included and recognized as an equal stakeholder in the healthcare, regulatory and public policy arenas and across the research continuum. It is our goal to improve access to care and quality of life by fostering collaboration among stakeholders and by

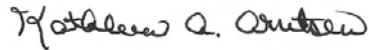
wielding the patient voice as a catalyst to advance innovative advocacy, education, awareness and biomedical research initiatives that will identify causes, advance better diagnostics, and discover superior treatments, and cures.

We urge the House Health Committee and state legislature to support **HB 2223** and stand with patients and their loved ones by helping to advance biomarker testing and ultimately, precision medicine. There are millions of people who could benefit from innovative drugs now, and many more in the future who are yet to be diagnosed. Patients with rare and chronic diseases of unmet need with only limited or no therapies need access to an array of novel, promising treatments and biomarker testing is the key to unlocking the right treatments for the right patients. Public policy must keep pace with innovation.

Please contact me at 315-264-9101 or [kathleen@ladainc.org](mailto:kathleen@ladainc.org) if you have any questions.

We thank you for considering our unique patient viewpoint.

Respectfully Submitted-



Kathleen A. Arntsen  
President & CEO

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January 30, 2024

The Honorable Della Au Belatti  
Chair  
House Committee on Health and Homelessness  
Room 420  
Hawai'i State Capitol  
415 South Beretania Street  
Honolulu, HI 96813

### **Re: Support for HB 2223, Health Insurance; Biomarker Testing; Mandatory Coverage**

Dear Chair Belatti and Members of the Committee,

We are writing in strong support of HB 2223 to require health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing. HB 2223 will ensure that those Hawaiians covered by these plans will be covered for biomarker testing when medically appropriate.

Founded in 1996, ICAN, International Cancer Advocacy Network, is a Phoenix-based non-profit that has helped over 18,000 Stage IV metastatic cancer patients in Hawai'i, throughout the United States, and in 72 countries. We work every day to secure the most effective drugs and treatments for our patients.

Our goal is to find the right drugs at the right time for each individual patient. Nothing is more critical in achieving that goal than testing for the ever-increasing number of actionable biomarkers identified in cancer. This testing allows the choice of the targeted drug most likely to reduce or eliminate that individual patient's specific cancer. Biomarker testing replaces educated guesswork with scientific evidence and makes truly personalized, precision medicine possible.

Stage IV metastatic cancer patients simply do not have the time to try any but the most optimal treatment options. Without the correct tests, delays in finding the right drugs at the right time lead to adverse consequences for the patient in terms of the cancer progressing to a more serious stage. This puts the patient in a weakened condition when and if the right drugs are finally found—thus making that therapy less effective.

The negative result for the healthcare system—a very avoidable negative result—is that the patient’s care actually costs more overall: the costs of the wrong drugs initially, and then the higher costs for all the conditions that the patient suffers as a result of the inadequately treated and worsening disease.

For patients dealing with cancer, or other lethal or chronic diseases, finding “the right drug” for relief, treatment, or cure, can be a long struggle. The last thing that should happen is to make the patient (or an often overworked and overmatched oncology practice) fight with an insurance company to get the right test to know which drugs are most likely to work.

To delay the optimal treatment for any patient is wrong. To delay the optimal treatment for a Stage IV metastatic cancer patient is simply cruel beyond belief.

HB 2223 ensures that the most vulnerable patients can quickly receive the treatments that biomarker tests indicate are most likely to be effective.

Codifying these critical patient protections into Hawaiian law is the right thing to do. Please let Stage IV metastatic cancer patients and their physicians fight cancer, not insurance companies.

Expanding coverage for biomarker testing will also help achieve other critical objectives of our health care system: reducing health disparities for the poor, for underserved ethnic or racial groups, and for residents of rural areas who lack access to comprehensive cancer centers.

On behalf of all the patients we serve in Hawaii who will be helped by HB 2223, we thank you for your consideration of this very worthy legislation, and we look forward to seeing it successfully go through the legislative process and be signed into law.

That will be a day that all Hawaiians can celebrate.

Please do not hesitate to contact me at [marcia@askican.org](mailto:marcia@askican.org) or (602) 513-9217 if you need any additional information. Thank you for your consideration.

Respectfully submitted,

*Marcia K. Horn*

Marcia K. Horn, JD  
President and CEO  
ICAN, International Cancer Advocacy Network  
27 West Morten Avenue  
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Alone we are rare. Together we are strong.®

January 30, 2024

The Honorable Della Au Belatti, Chair  
House Committee on Health & Homelessness  
Hawai'i State Capitol, Room 420  
415 South Beretania St.  
Honolulu, HI 96813

The Honorable Jenna Takenouchi, Vice Chair  
House Committee on Health & Homelessness  
Hawai'i State Capitol, Room 420  
415 South Beretania St.  
Honolulu, HI 96813

Re: Support for House Bill 2223 – Coverage for Biomarker Testing

Dear Chair Au Belatti and Vice Chair Takenouchi;

On behalf of the more than 30 million Americans living with one of the over 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) writes to share our support for House Bill 2223 (HB 2223), legislation that would expand access to biomarker testing.

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people living with rare diseases. NORD was founded 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. NORD's mission has always been, and continues to be, to improve the health and well-being of people with rare diseases by driving advances in care, research, and policy. We believe that all patients should have access to quality, accessible, innovative, and affordable health coverage that is best suited to their medical needs.

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, biomarker testing can benefit patients in many disease groups, including autoimmune diseases, and research is underway that may unlock benefits in other rare conditions.

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*NORD® and its icon are registered trademarks of the National Organization for Rare Disorders. NORD is a registered 501(c)(3) charity organization.*



Unfortunately, patient access to biomarker testing is often delayed or denied by health insurance plans. HB 2223 would require coverage for biomarker testing if the use of the test is supported by medical and scientific evidence. Furthermore, it would establish clear parameters and processes for utilization review, including prior authorization, to ensure limited disruptions in care for patients.

We urge you to support this legislation to ensure all patients can benefit from this quickly evolving aspect of precision medicine by swiftly passing HB 2223 out of the House Committee on Health & Homelessness Committee. 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  
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>.



House Committee on Health and Homelessness  
Representative Della Au Belatti, Chair  
Representative Jenna Takenouchi, Vice Chair

Hearing Date: Wednesday, January 31, 2024

**ACS CAN SUPPORTS with Amendments HB 2223 – RELATING TO HEALTH.**

Cynthia Au, Government Relations Director – Hawaii Guam  
American Cancer Society Cancer Action Network

Thank you for the opportunity to SUPPORT and offer Amendments on HB 2223 – RELATING TO HEALTH. This bill requires health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing. On behalf of our constituents, many of whom have been personally affected by cancer, we urge your support of this important bill and for the committee to consider amendments to include Medicaid coverage of biomarker testing.

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, non-partisan advocacy affiliate of the American Cancer Society advocates for public policies to reduce the cancer burden for everyone.

This critical legislation will improve patient access to care. Timely access to guideline-indicated comprehensive biomarker testing will enable more patients to access the most effective treatments for their disease and can help achieve the triple aim of health care: better health outcomes, improved quality of life and reduced costs.

Biomarker testing is the analysis of a patient’s tissue, blood, or other biospecimen for the presence of a biomarker that may impact treatment decisions. To qualify for coverage under this bill, there must be robust medical and scientific evidence to demonstrate the effectiveness of the testing. The bill clearly sets parameters for both the circumstances when testing may be appropriate and the evidence that must be met, thus requiring coverage by all state regulated insurance plans, only for tests that will benefit patients when medically appropriate.

In Hawaii, both private insurers and Medicaid are already covering much of this testing. To keep up with the science so that patients get the testing they need for the right treatment, at the right

time, ACS CAN requests the committee to decrease health inequities and increase access to care and include Medicaid coverage of biomarker testing.

We request the following amendment by adding two sections to a House Draft 1:

*"Section \_\_\_\_ . The department of human services shall apply to the United States Department of Health and Human Services for any amendment to the state Medicaid plan or for any Medicaid waiver necessary to implement section 2 of this Act. The department shall submit the Medicaid state plan amendment no later than \_\_\_\_\_"*

AND

*"Section \_\_\_\_ . This Act shall take effect on January 1, 2025; provided that section 2 of this Act shall take effect upon approval of the Hawaii medicaid state plan by the Centers for Medicare and Medicaid Services."*

Currently, of the Hawaii policies that were reviewed in a recent peer reviewed study, 64% were classified as "more restrictive" than National Comprehensive Cancer Network guidelines for biomarker testing for advanced breast, non-small cell lung cancer, melanoma and/or prostate cancer – common cancers for which there are many effective targeted treatments available.

As precision medicine becomes the standard of care in treatment for diseases like cancer, mental health, and autoimmune diseases, biomarker testing has risen in importance as the gateway to many of these therapies. Attached to this testimony is a fact sheet showing the support of many patient and provider organizations. This bill will impact more than cancer patients. Patients with lupus, ALS, preeclampsia, or arthritis benefit from biomarker testing. There is groundbreaking research in biomarker testing for Alzheimer's and heart disease. This legislation is about making sure current patients and future patients can access the testing needed to find treatment best suited for them.

According to a Milliman analysis conducted on biomarker testing coverage, the average allowed unit cost to insurers, per biomarker test, ranges from only \$78 to \$224. However, when biomarker testing is not covered by insurance, patients can be on the hook for hundreds or even thousands of dollars in out-of-pocket costs.

Similar legislation aligning coverage of biomarker testing across private and public insurance plans - including Medicaid - has recently been enacted in 13 states and is currently being heard in 12 others. We urge the committee to amend the bill to include Medicaid coverage in an HD1 and make it possible for Hawaii patients to get the right treatment, at the right time.

Thank you again for the opportunity to provide testimony in SUPPORT on this important matter. We urge that you pass out of committee this important bill. Should you have any questions, please do not hesitate to contact Government Relations Director Cynthia Au at 808.460.6109, or [Cynthia.Au@Cancer.org](mailto:Cynthia.Au@Cancer.org).



# EXPAND ACCESS TO BIOMARKER TESTING IN HAWAII

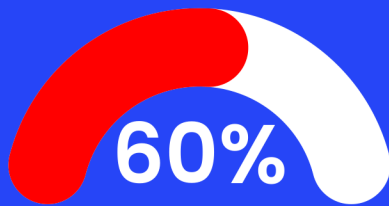
THE RIGHT TREATMENT AT THE RIGHT TIME

## WHAT IS BIOMARKER TESTING?

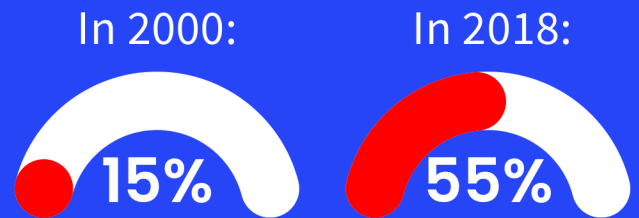
**Biomarker testing is often used to help determine the best treatment for a patient.**

- It is the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker.
- Biomarker testing is an important step for accessing precision medicine, including targeted therapies that can lead to improved survivorship and better quality of life for cancer patients.
- While most current applications of biomarker testing are in oncology, autoimmune disease, and rare disease, there is research underway to benefit patients with other conditions including heart disease, Alzheimer's disease, and other neurological conditions, rare disease, infectious disease and respiratory illness.

## THE IMPORTANCE OF BIOMARKER TESTING



Of oncology drugs launched in the past five years require or recommend biomarker testing prior to use <sup>1</sup>



Of cancer clinical trials involved biomarkers <sup>2</sup>

## BIOMARKER TESTING & HEALTH EQUITY

- **Not all communities in Hawaii are benefitting from the latest advancements in biomarker testing and precision medicine.**
  - Patients who are older, Black, uninsured or Medicaid-insured, are less likely to be tested for certain guideline-indicated biomarkers.
  - There are lower rates of testing in community settings versus academic medical centers.

## THE BOTTOM LINE

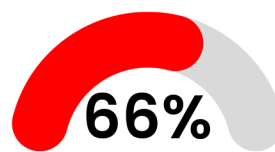
**Access to appropriate biomarker testing can help to achieve:**

- better health outcomes
- improved quality of life
- reduced costs

**Insurance coverage for biomarker testing is failing to keep pace with innovation and advancement in treatment:**

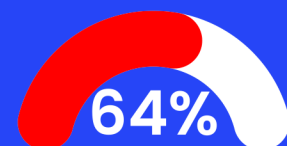
- Without action, this could increase existing disparities in health outcomes by race, ethnicity, income and geography.

**Fourteen states have recently passed legislation to expand coverage of comprehensive biomarker testing.**



Of oncology providers reported that insurance coverage is a **significant or moderate barrier** to appropriate biomarker testing for their patients <sup>3</sup>

**In Hawaii:**



Of fully insured covered lives enrolled in a plan with coverage that is more restrictive than National Comprehensive Cancer Network guidelines <sup>4</sup>

# SUPPORTERS OF HAWAII BIOMARKER TESTING LEGISLATION HB 2223



<sup>1</sup>Global Oncology Trends 2021. IQVIA Institute; June 2021.

<sup>2</sup>The Evolution of Biomarker Use in Clinical Trials for Cancer Treatments: Key Findings and Implications. Personalized Medicine Coalition, 2019.

<sup>3</sup>ACS CAN. "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021.

<sup>4</sup>Wong WB, Anina D, Lin CW, and Adams D. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. Per Med 2022; 10.2217/pme-2021-0174.

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## Biomarker Testing: Beyond Oncology

Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.<sup>i</sup> As patients are living longer, and some cancers become more of a chronic condition, cancer patients and survivors are often living with one or more comorbidities (additional diseases or medical conditions) due to shared risk factors and side effects of cancer treatment.

- A recent study found that nearly 2 in 3 patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.<sup>ii</sup>
- According to the National Cancer Institute, the top four most commonly diagnosed cancers—lung, colorectal, breast, and prostate—have rates of comorbidity at 52.9%, 40.7%, 32.2%, and 30.5%, respectively for patients over age 66.<sup>iii</sup>
- **The most common comorbidities cancer patients and survivors face include diabetes, COPD, cardiovascular diseases (e.g., congestive heart failure, cerebrovascular disease, peripheral vascular disease), renal failure, and rheumatological conditions (e.g., osteoarthritis and rheumatoid arthritis).<sup>iv</sup>**
  - Anxiety is also more common in cancer patients, and patients with cancer are five times more likely to suffer from depression compared to the general population.<sup>v</sup>

While most current applications are in cancer, biomarker testing is becoming increasingly important to the treatment of other disease areas including rheumatoid arthritis, other autoimmune conditions, organ and tissue transplant, rare diseases, preeclampsia. Pharmacogenomic biomarker testing also guides treatment across a wide range of conditions. There is biomarker research happening in many other areas including Alzheimers, other neurological conditions, cardiology and more. Current non-oncology biomarker testing applications could be used to address common comorbidities in cancer patients and survivors and as personalized medicine continues to evolve, non-oncology biomarker testing applications will likely have an increasing role in guiding treatment for patients with and without a cancer diagnosis.

## Biomarker Testing and Autoimmune and Autoinflammatory Arthritis Diseases

One in 10 people are living with autoimmune and autoinflammatory arthritis diseases.<sup>vi</sup> The average age of onset in adults is 20 – 40.<sup>vii,viii,ix,x</sup> Age of juvenile onset disease varies, but can happen in early childhood.<sup>xi</sup> While it is recommended to initiate treatment within six months of disease onset to increase the probability of remission<sup>xii</sup>, it takes several years to get an accurate diagnosis for a majority of patients.<sup>xiii</sup> Due to several factors, including clinical trials that do not represent real world populations, comorbidities, and disease heterogeneity, only 40-60% respond well to existing treatments.<sup>xiv,xv, xvi, xvii</sup> It is estimated that as many as 70% of patients develop comorbidities (including dual diagnosis and conditions such as heart disease or Alzheimers).<sup>xviii,xix</sup> The standard arthritis treatment approach of trial-and-error further complicates therapy response. Biomarker testing can be an important tool to pinpoint diagnosis, understand prognosis, and develop treatment plans that improve quality of life and increase chances for remission.

Biomarkers are not new in the autoimmune and autoinflammatory arthritis disease space. For example, doctors often refer to elevated rheumatoid factor, anti-CCP, and antineutrophil cytoplasmic antibodies (ANCA) to assist in diagnosis and to predict worse outcomes in rheumatoid arthritis (RA).<sup>xx</sup> Some tests, like multi-biomarker disease activity (MBDA) blood tests, test for several biomarkers at one time to monitor disease activity and predict joint damage. While there are current applications, recent research continues to advance the use of biomarkers in rheumatology, which can aid in detection, diagnosis, and determining treatment response.

### **Current applications of biomarker testing for arthritis patients include:**

#### Anti-CCP Antibody Testing for Rheumatoid Arthritis (RA)

Molecular signature response classifier (MSRC) tests monitor levels of specific antibodies and gene expressions which can help indicate a patient's likelihood to respond to tumor necrosis factor inhibitors (TNFi), a specific class of medications used to treat inflammatory conditions. A low score means the patient will be less likely to respond to these types of therapies. Ninety percent of RA patients are prescribed TNFi biologics as first line therapies, and better access to predictive biomarker testing could potentially improve health outcomes and lead to cost avoidance for millions of patients.<sup>xxi</sup>

#### Polyglutamate Testing

This testing measures the effectiveness of one of the most commonly prescribed drugs for RA. This test allows a provider to determine if the dose needs to be adjusted, or if the patient needs to be prescribed a different medication.

## Biomarker Testing for Organ and Bone Marrow Transplants

Biomarker testing is used in bone marrow transplants to match patients and donors. A close match between a donor's and a patient's tissue markers is essential for a successful transplant outcome.<sup>xxii</sup> Biomarker testing is also critical in organ transplant to assess risks and monitor for rejection, with research happening on methods to utilize non-invasive biomarker testing to monitor for rejection and ultimately improve outcomes. While bone marrow transplants are best known for their use in the treatment of blood

cancers, biomarker testing is also essential for other disorders. For example, bone marrow transplants are used in the treatment of non-malignant chronic diseases such as Sickle Cell Disease.

### Organ Rejection Status Testing

This type of testing analyzes donor derived cell-free DNA (dd-cfDNA) present in the bloodstream of a patient to determine if rejection of the transplanted organ is occurring. It is used to monitor a transplant patient for signs of rejection, allowing for modification of immunosuppressive therapy to maximize longevity. The cost for managing a failed transplant may be up to 500% more than a patient with a functioning transplant.<sup>xxiii</sup>

### Sickle Cell Disease

Sickle cell disease is a chronic disorder which causes the body to make unhealthy red blood cells, causing organ damage, and need for a bone marrow transplant as a life-saving treatment. Beyond the implications of biomarker testing for bone marrow transplants to treat the disease, there is ongoing research in using biomarker testing to predict the risk of a patient with sickle cell disease experience vaso-occlusive crisis, which can result in severe pain and organ damage.<sup>xxiv</sup>

### Biomarker Testing and Rare Diseases

A rare disease is defined in the United States as a disease or condition that impacts fewer than 200,000 people. There are more than 7,000 known rare diseases, affecting about 1 in 10 people in the United States.<sup>xxv</sup> Of the newly FDA approved personalized treatments in 2022, 35% were for the treatment of rare diseases<sup>xxvi</sup>. Personalized treatments often require biomarker testing prior to use to determine patient eligibility. Often, patients with rare diseases suffer while going undiagnosed or misdiagnosed for years. Biomarker testing often plays a critical role in rare diseases to establish or confirm a diagnosis and monitor disease progression and treatment effectiveness.

### Biomarker Testing and Preeclampsia

The United States is the only developed country in the world where maternal morbidity and death rates are increasing.<sup>xxvii</sup> Hypertensive disorders of pregnancy, like preeclampsia, are a leading cause of these preventable deaths. Preeclampsia manifests with heightened maternal blood pressure and organ dysfunction, leading to severe complications like kidney and liver failure and cerebral edema. If left untreated (and in rare cases without preeclampsia symptoms), it can escalate to eclampsia, a condition categorized by seizures or a variant called HELLP Syndrome which can cause liver rupture, bleeding/clotting issues, and other morbidities.<sup>xxviii</sup> There is a disparate impact when it comes to maternal morbidity, with black women three times more likely to die from pregnancy-related complications compared to white women.<sup>xxix</sup>

Preeclampsia can vary in severity. Patients with a diagnosis should be monitored closely, but those at high risk of severe preeclampsia will likely remain in the hospital until delivery.

### Prognostic sFlt1 and PIGF testing

This test measures two proteins in the blood to identify those at highest risk of developing severe preeclampsia.<sup>xxx</sup> The test helps providers to develop the appropriate treatment plan. Low-risk patients can

be monitored from home, alleviating financial and emotional burdens and reducing healthcare costs. Those at higher risk receive appropriately intensified care, increasing the likelihood of positive outcomes for both mother and baby.

## Pharmacogenomic (PGx) Biomarker Testing

Pharmacogenomic (PGx) testing (also known as pharmacogenomic biomarker testing) is a component of precision medicine that involves examining a patient's inherited genes to detect variations that may impact the way a drug is broken down, absorbed and used within the body. Sometimes these variations can impact the safety and effectiveness of treatment. The same treatment given to patients with the same disease can produce different responses based on each person's inherited genes. There are a significant number of drug-gene pairs that can impact a patient's response to a medication, thus making PGx testing beneficial. These interactions are most common in oncology, neurology, cardiology, and infectious disease.

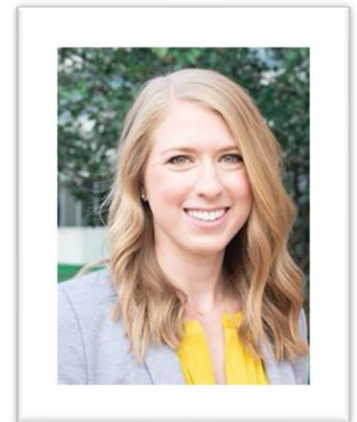
### PGx Testing in Depression

Depression is the number one cause of disability in the United States for individuals ages 15-44.<sup>xxxi</sup> PGx biomarker testing can be used to inform the selection of prescription drugs to treat patients. This type of testing can help a provider to understand the way a patient's genomic make up may affect an individual's response to certain psychiatric drugs – including those used to treat depression. Selective serotonin reuptake inhibitors (SSRIs) are the most commonly used drugs to treat depression in adults.<sup>xxxii</sup> There are several genetic variants that may impact the effectiveness or safety of SSRIs.<sup>xxxiii</sup>

PGx biomarker testing made the difference for Julie, who was suffering from postpartum depression. After having an adverse reaction to the antidepressant that she was prescribed, an SSRI, she underwent PGx biomarker testing. The results showed that SSRIs may not be a good fit for her. Her doctor prescribed a different medication, and Julie credits that new medication with helping her feel like herself again:

“ I felt defeated because these medications worked for others; why didn't they work for me? Now I know that's not how this works! Since being on a medication that is working for me, I am motivated, optimistic, and thriving – rather than trying to survive.

-Julie L., Indiana



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## Biomarker Testing and Cost Savings

**Timely access to guideline-indicated comprehensive biomarker testing can help achieve the triple aim of health care including better health outcomes, improved quality of life, and reduced costs.**

Comprehensive biomarker testing looks for all recommended biomarkers based on clinical guidelines. This testing can lead to treatments with fewer side effects, longer survival and allow patients to avoid treatments that are likely to be ineffective or unnecessary. Exposure to these ineffective treatments can exacerbate the physical, emotional, and economic burdens of disease.

### Spending on Biomarker Testing Can Yield Savings on Treatment Costs

There are several studies looking at the cost effectiveness of *single marker testing*, which are most likely to be covered by insurance plans currently, to more comprehensive testing, which isn't always covered. Comprehensive biomarker testing is often done with a *panel test* that assesses multiple biomarkers (e.g., genes or proteins) in one test as compared to single marker testing that assesses one marker per test. For many patients, panel testing is most appropriate. Examples include when there is limited tissue available for testing or as recommended by clinical practice guidelines to gain sufficient information to appropriately guide treatment decisions.

**Often paying more upfront for comprehensive testing can result in overall savings in treatment costs.**

- In a study sponsored by CVS Health looking at total cost of care for non-small cell lung cancer patients who received broad panel biomarker testing in comparison to narrow panel biomarker testing; broad panel testing had an average additional up-front cost increase of approximately \$1,200 in comparison to narrow panel biomarker testing. However, those patients who underwent broad panel biomarker testing experienced a savings of approximately \$8,500 per member per month in total cost of care, as a result of more optimal treatment.<sup>i</sup>
- Other studies have found upfront broader biomarker testing results in substantial cost savings for commercial payers (\$3,809; \$127,402; and \$250,842 less than exclusionary, sequential testing, and hotspot panels, respectively)<sup>ii</sup> and decreased expected testing procedure costs to the health plan by \$24,651.<sup>iii</sup>
- Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.<sup>iv, v</sup>

### Costs to Insurers

According to a 2022 analysis of biomarker testing coverage by Milliman, the average allowed unit cost to insurers per biomarker test ranges from \$78.71 (Medicaid) to \$224.40 (large group self-insured).<sup>vi</sup> When biomarker testing is not covered by insurance, patients can be on the hook for hundreds or even thousands of dollars in out-of-pocket costs.<sup>vii</sup>

This study also projected the impact of legislation requiring robust coverage of biomarker testing, projecting an impact of \$0.08-\$0.51 per member per month. This does not account for any potential cost savings from avoiding ineffective treatments.<sup>viii</sup>

American Cancer Society Cancer Action Network | 555 11th St. NW, Ste. 300 | Washington, DC 20004

 @ACSCAN |  @ACSCAN | [fightcancer.org](https://fightcancer.org)

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<sup>viii</sup> The landscape of biomarker testing coverage in the United States: Quantifying the impact of expanding biomarker testing coverage in the commercial and Medicaid markets. [https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22\\_the\\_landscape\\_of\\_biomarker\\_testing\\_coverage\\_in\\_the\\_us.ashx](https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx)



January 31, 2024

The Honorable Della Au Belatti, Chair  
The Honorable Jenna Takenouchi, Vice Chair  
House Committee on Health & Homelessness

Re: HB 2223 – RELATING TO INSURANCE

Dear Chair Belatti, Vice Chair Takenouchi, and Members of the Committee:

Hawaii Medical Service Association (HMSA) appreciates the opportunity to provide comments on HB 2223, which will require health insurers, mutual benefit societies, and health maintenance organizations to provide coverage for biomarker testing.

There already is a definition in statute for what is deemed medically necessary in Hawaii. While these tests can save lives if the right test is performed, unproven tests can be both harmful and costly. As an example, Arizona recently legislated coverage for an unproven and fraudulent biomarker test. The mandate resulted in unnecessary appointments, unneeded medication, invasive diagnostic tests, and eventually a \$4.65 million consumer-fraud settlement.

We, along with other health plans, are constantly monitoring scientific evidence of clinical benefit and update our policies regularly based on new information. While HMSA appreciates the intent of this measure, this bill creates a new mandate.

We respectfully ask that this bill be deferred to allow the State Auditor to first conduct an impact assessment report pursuant to Section 23-51 and 23-52 of the Hawaii Revised Statutes since it creates new mandated benefits which could increase costs for health plan members.

Thank you for the opportunity to provide comments on this measure.

Sincerely,

Dawn Kurisu  
Assistant Vice President  
Community and Government Relations

Testimony of  
John M. Kirimitsu  
Legal and Government Relations Consultant

Before:  
House Committee on Health & Homelessness  
The Honorable Della Au Belatti, Chair  
The Honorable Jenna Takenouchi, Vice Chair

January 31, 2024  
8:30 am  
Conference Room 329

**Re: HB 1966 Relating to Health Care**

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on HB1966 mandating coverage for biomarker testing.

**Kaiser Permanente Hawaii would like to offer comments.**

Kaiser supports biomarker testing to determine the best treatment options for patients, but requests that the legislative auditor conduct an impact assessment report since this is a new mandate for coverage, as statutorily required under Section 23-51 of the Hawaii Revised Statutes.

Should this bill move forward, Kaiser requests an amendment to include the nationally recognized “medically necessary” standard, which will ensure that the biomarker treatment is within the accepted standards in the medical community and also prevent coverage for unnecessary tests that increase costs without improving care:

"§431:10A- Biomarker testing; coverage. (a) Each individual or group policy of accident and health or sickness insurance issued or renewed in this State on or after January 1, 2025, shall provide coverage for the [medically necessary] services of biomarker testing for the policyholder or any dependent of the policyholder who is covered by the policy for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an insured's disease or condition to guide treatment decisions when supported by medical and scientific evidence, including but not limited to:

[added language]

Thank you for the opportunity to comment.



## Alliance for Patient Access

January 30, 2024

Representative Della Au Belatti  
Chair, House Committee on Health & Homelessness  
420 Hawai'i State Capitol  
Honolulu, HI 96813

Representative Jenna Takenouchi  
Vice Chair, House Committee on Health & Homelessness  
333 Hawai'i State Capitol  
Honolulu, HI 96813

### **RE: SUPPORT FOR HB 2223 – Biomarker Testing**

Members of the House Committee on Health & Homelessness:

On behalf of the Alliance for Patient Access (AfPA), I am writing to urge your support for HB 2223, 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.

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.

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>

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 Hawai'i face insurance coverage barriers for both biomarker testing and individualized treatments. This can cause delays in care that can be devastating for patients with diseases like advanced cancer. HB 2223 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.

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

<sup>2</sup> [doi:10.1001/jamaneurol.2023.5319](https://doi.org/10.1001/jamaneurol.2023.5319)

<sup>3</sup> <https://www.hcplive.com/view/wesley-mizutani-md-sb-496-expands-insurance-coverage-for-biomarkers>

HB 2223 supports the clinician-patient relationship by allowing clinicians to access appropriate medical tools for their patients and helping ensure patients can access testing. This will support optimal patient care by driving accurate diagnosis and effective treatment decisions. On behalf of the Alliance for Patient Access, I urge you to pass HB 2223 to ensure patients 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,

A handwritten signature in cursive script that reads "Josie Cooper".

Josie Cooper  
Executive Director  
Alliance for Patient Access



**COMMITTEE ON HEALTH & HOMELESSNESS**

**Rep. Della Au Belatti, Chair**

**Rep. Jenna Takenouchi, Vice Chair**

**Wednesday, January 31, 2024 – 8:30 AM Conference Room 329**

**Testimony in Support of House Bill 2223, Relating to Insurance**

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease, through research, education, and advocacy. The work of the American Lung Association in Hawai'i and across the nation is focused on four strategic imperatives: to defeat lung cancer; to improve the air we breathe; to reduce the burden of lung disease on individuals and their families; and to eliminate tobacco use and tobacco-related diseases.

**The American Lung Association in Hawai'i urges lawmakers to support House Bill 2223 to increase coverage of biomarker testing. This legislation will improve access to critical cancer care for patients in Hawai'i, including those with lung cancer.**

Comprehensive biomarker testing allows doctors to identify abnormalities in a cell's DNA, which in turn helps healthcare providers determine the best course of treatment for cancer patients. This is particularly important when treating lung cancer, as there are currently FDA-approved lung cancer treatments for tumor abnormalities in at least eight distinct genes.<sup>i</sup> Studies show that individuals with lung cancer who have access to biomarker testing and are thus able to receive targeted therapy treatments have better overall chances of survival.<sup>ii</sup> Biomarker testing is a crucial part of both cancer care and treatment of other chronic conditions and has been incorporated into many clinical guidelines so that doctors may make the best decisions for their patients' health.

Despite the evidence for the value of biomarker testing, most health coverage plans have been found to be more restrictive than the National Comprehensive Cancer Network's guidelines for biomarker testing.<sup>iii</sup> Many patients who should receive biomarker testing may be unable to do so because of insurance coverage restrictions and high out-of-pocket costs. Therefore, it is important that HB2223 increases coverage of biomarker testing and removes some of these barriers to care.

**The Lung Association recommends that an amendment be made to HB 2223 to ensure coverage of biomarker testing through our state's Medicaid program as well.**

Hawai'i has an opportunity to increase equitable access to healthcare by passing this bill. Current biomarker testing rates show significant racial disparities. For example, research shows that Black patients with non-small cell lung cancer are less likely to receive testing than white patients.<sup>iv</sup> The Lung Association supports HB2223 as a step towards closing these gaps. Treatment for many chronic diseases may also rely on biomarker testing, such as rheumatoid arthritis, diabetes, and certain rare diseases. The Lung Association urges lawmakers to broaden HB2223 so to ensure all patients in Hawai'i are receiving the best care that they can.

Increasing coverage of biomarker testing will improve health equity in Hawai'i and make cancer and chronic disease care more affordable and more accessible for patients. The American Lung Association in Hawai'i urges you to support House Bill 2223.

With gratitude,

Pedro Haro  
Executive Director  
American Lung Association in Hawai'i  
pedro.haro@lung.org

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<sup>i</sup> [Lung Cancer Biomarker Testing | American Lung Association](#)

<sup>ii</sup> [Value of Precision Medicine in Advanced Non-Small Cell Lung Cancer: Real-World Outcomes Associated with the Use of Companion Diagnostics - PubMed \(nih.gov\)](#); [The Effect of Advances in Lung-Cancer Treatment on Population Mortality - PubMed \(nih.gov\)](#)

<sup>iii</sup> [Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors \(futuremedicine.com\)](#)

<sup>iv</sup> Presley CJ, PR, Chiang AC, Longtine JA, Adelson KB, Herbst RS, Nussbaum NC, Sorg R, Abernethy AP, Agarwala V, and Gross CP. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology* 2017 35:15\_suppl, 6563-6563.





**Biotechnology Innovation Organization**  
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202-962-9200

January 30, 2024

The Honorable Della Au Belatti, Chair  
House Committee on Health & Homelessness  
Hawai'i State Legislature

Dear Chair Belatti and Members of the Committee:

The Biotechnology Innovation Organization (BIO) is pleased to support HB 2223, which would require health insurers to include coverage for biomarker testing, as specified. BIO supports timely, appropriate, and equitable access to biomarker testing as well as adequate coverage and reimbursement by public and private payers when backed by clinical guidelines or peer-reviewed scientific evidence. Delays in biomarker testing and coverage may lead to worse outcomes for patients.

Continuing advances in science and genomics are driving an increased understanding of human physiology and how diseases affect the body; these advances are helping researchers identify new biomarkers. As more biomarkers are identified, they have the potential to greatly enhance the drug development process by providing researchers with new ways to measure disease activity, reduce the amount of time required to show a medicine is safe or effective, and enable the development of more personalized, precision medicine—particularly where multiple biomarkers can inform the use of targeted drug combinations. Biomarkers can also allow researchers to better understand how effective a treatment is against a disease with endpoints that are difficult to define, providing clinicians with additional informative measurements in the early diagnosis of a disease and identifying differences in responses between individuals or subpopulations.

**The development of personalized medicines that are more tailored to the individual patient using biomarkers helps drive efficiencies and improvements in patient care.**

Biomarkers can help identify patients most likely to benefit from a specific treatment. For example, biomarkers are often used in cancer treatments to identify patients with tumors expressing certain genetic characteristics that indicate those patients are likely to respond to a targeted cancer therapy. In another example, they can be used to ensure that a certain patient with a rare disease will most likely benefit from a specific therapy, particularly gene therapy.

**Access to biomarker testing should not be delayed, as this may have detrimental effects on patient outcomes.** If patients do not have access to biomarker testing, they will not know about life-saving targeted therapies that can improve their overall health outcome. Additionally, it is important that if access to a particular therapy is dependent upon specific biomarker, coverage and testing policies must immediately reflect the new advances in treatment. Coverage policies should never stand in the way of access to treatment.

**The identification of biomarkers is not done through at home genetic DNA testing.** It is done in a medical setting by healthcare professionals and clinicians within the scope of their license and experience to identify appropriate biomarkers for clinical trials. In addition, genetic

counselors guide patients through proper clinical treatment guidelines and options. These health professionals must always have the ability to order all comprehensive biomarker testing panels necessary to ensure appropriate treatment and continuing care. Sadly, a February 2022 report by Milliman found that 48 states have no minimum coverage requirements for biomarker testing.<sup>1</sup>

**BIO supports the continual assessment of coverage requirements by public and private payers for novel biomarker testing that come to market.** Additionally, public, and private payers should regularly review clinical guidelines, existing medical compendia, CMS coverage guidelines, recommendations of health professional organizations, and consensus statements to update their testing policies.

**Biomarker testing should not be subject to lifetime limits.** As disease stages progress over time and can vary from patient to patient, biomarker testing should be covered for all relevant panels of tests at any time in the continuum of care, if determined necessary by a health care professional.

For these reasons outlined above, we respectfully urge your YES vote on HB 2223. If you have any questions, please do not hesitate to contact me to discuss this further.

Sincerely,



Brian Warren  
Senior Director, State Government Affairs

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<sup>1</sup> Dieguez, G., Carioto, J., *The landscape of biomarker testing coverage in the United States*. (2022).



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January 30, 2024

Honorable Della Au Belatti  
Chair, Committee on Health and Homelessness  
Hawai'i House of Representatives  
415 South Beretania St  
Honolulu, HI 96813

**RE: HB 2223 (Chun) – Support**

Dear Chair Belatti:

On behalf of AdvaMed, the MedTech Association, I am writing in support of HB 2223, legislation that will improve patient outcomes by ensuring access to vital biomarker testing.

AdvaMed is the world's largest association representing the full spectrum of medical technology innovators and manufacturers. AdvaMedDx, a division of AdvaMed, represents over 80 manufacturers of *in vitro* diagnostic (IVDs) tests and technologies. Our member companies produce advanced IVD tests and technologies that allow early detection of disease, facilitate evidence-based medicine, improve patient and public health, and enable precision medicine. AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers in the United States and abroad.

The significance of biomarker testing in patient care cannot be overstated. It is a game-changer in tailoring patient management and prevention plans by integrating individual medical histories and clinical symptoms. This approach is instrumental not just in cancer treatment but also across various medical fields like cardiology, neurology, infectious diseases, and autoimmune disorders. Conditions such as Alzheimer's Disease, Rheumatoid Arthritis, and Preeclampsia are just a few examples where biomarker testing can make a substantial difference.

Unfortunately, current health care coverage for biomarker testing is failing to keep pace with scientific advancements. HB 2223 aims to bridge this gap by requiring state-regulated health care plans to cover comprehensive biomarker testing when supported by medical and scientific evidence, including nationally recognized clinical practice guidelines. Timely access to appropriate biomarker testing will result in better health outcomes, advance health equity, and reduce costs. For these reasons, AdvaMed strongly supports HB 2223.



Your support can transform the landscape of patient care, and we look forward to your leadership in this critical healthcare initiative.

Sincerely,



Zach Rothstein  
Executive Director  
AdvaMedDx



Darbi Gottlieb  
Director, State Government and Regional Affairs  
Advanced Medical Technology Association (AdvaMed)

