

DISABILITY AND COMMUNICATION ACCESS BOARD

1010 Richards Street, Room 118 • Honolulu, Hawaii 96813 Ph. (808) 586-8121 (V) • Fax (808) 586-8129 • TTY (808) 586-8162

March 22, 2024

TESTIMONY TO THE SENATE COMMITTEES ON COMMERCE AND CONSUMER PROTECTION AND ON HEALTH AND HUMAN SERVICES

Senate Concurrent Resolution 159 – Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing

The Disability and Communication Access Board (DCAB) supports Senate Concurrent Resolution 159 – Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing.

Biomarker testing is an important diagnostic tool that may lead to early detection of many diseases. If insurance plans do not provide coverage, many people will not be able to afford it and the opportunity to mitigate potentially devastating health issues early on will be lost.

Thank you for considering our position.

Respectfully submitted,

KIRBY L. SHAW Executive Director



A nonprofit advocacy community fighting for treatment for all patients

Re: In Support of HCR 53 and SCR 159

March 19, 2024

Dear

On behalf of the infusion patients we represent across the state, thank you for your service and commitment to the people of Hawaii. The Infusion Access Foundation is a nonprofit advocacy community and public charity dedicated to ensuring that patients have access to provider-administered therapies for any and all complex diseases. The organization was created to serve as a supportive and inclusive community for the patients receiving these life-changing medications. We are writing in regards to HCR 53 and SCR 159. If passed, this bill will request the Hawaii auditor to assess the social and financial effects of mandatory health insurance coverage for biomarker testing.

Precision medicine is dramatically improving health outcomes by using information about a person's own genes or proteins (biomarkers) to prevent, diagnose, or treat <u>disease</u>. Advances in biomarker testing now allow for targeted therapies that can improve patient survival and quality of life. Testing patients for specific biomarkers is integral to precision medicine in cancer care, but despite evidence pointing to the benefits, testing rates lag behind clinical guideline recommendations. Research shows that there are socioeconomic inequalities in biomarker testing and targeted therapy utilization across disease types.

Using the traditional trial and error method, identifying an effective treatment for a particular patient can take months - even years. In chronic, degenerative diseases like rheumatoid arthritis, any length of time spent trying (and failing) ineffective treatments allows the disease to continue causing irreversible damage to the joints, increasing health care consumption and costs. In cancer care and some autoimmune conditions, the length of time it takes to identify an effective treatment can be a matter of life or death. In all cases, ineffective treatments exacerbate the physical, emotional and economic burdens of disease, and the price is paid by both the patient and the insurer.

Health care coverage for biomarker testing is failing to keep up with scientific advancements. HCR 53 and SCR 159 will take the first step for Hawaii to cover biomarker testing. Timely access to appropriate biomarker testing will result in better health outcomes, advance health equity, and may reduce costs. Please support HCR 53 and SCR 159.

Sincerely, Infusion Access Foundation Team





fightcancer.org

Senate Committee on Commerce and Consumer Protection Senator Jarrett Keohokalole, Chair Senator Carol Fukunaga, Vice Chair

Committee on Health and Human Services Senator Joy A. San Buenaventura, Chair Senator Henry J.C. Aquino, Vice Chair

Hearing Date: Friday, March 22, 2024

ACS CAN in STRONG SUPPORT of SCR 159 – REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

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

Thank you for the opportunity to be in **STRONG SUPPORT** of SCR 159. This resolution requests the State Auditor assess, in accordance with sections 23-51 and 23-52, Hawaii Revised Statutes, the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a person's disease or condition to guide treatment decisions when supported by medical and scientific evidence, as provided in House Bill No. 2223, House Draft No. 1, Regular Session of 2024, and to submit a report of its findings and recommendations, including any proposed legislation, to the Legislature no later than twenty days before the convening of the Regular Session of 2025.

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. On behalf of our constituents, many of whom have been personally affected by cancer, we urge your support of this important bill.

This critical legislation will improve patient access to care. Biomarker testing is the analysis of a patient's tissue, blood, or biospecimen for the presence of a biomarker, to identify mutations

that may impact treatment decisions. Timely access to guideline-indicated comprehensive biomarker testing will enable more patients to access the most effective treatments for their disease and can potentially help achieve the triple aim of health care: better health outcomes, improved quality of life and reduced costs. Comprehensive biomarker testing allows patients to avoid treatments that are likely to be ineffective. 60% of oncology drugs launched in the past five years require or recommend biomarker testing prior to use.

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 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 fiscal 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. Refer to fact sheet on costs and cost savings.

Legislation has been enacted in 14 states and is currently being heard in 12 others. We urge the committee to request the State Auditor to study biomarker testing impact in the state to 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 very 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.



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March 22, 2024

Honorable Joy A. San Buenaventura Chair, Committee on Health and Human Services Hawaii State Senate Hawaii State Capitol – Conf. Rm 229 415 South Beretania Street Honolulu, HI 96813

RE: SCR 159 – Support

Dear Chair San Buenaventura:

On behalf of AdvaMed, the MedTech Association, I am writing in support of SCR 159 legislation that will provide vital information on the impact of biomarker testing on patient outcomes.

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. The impact assessment required in SCR 159 could provide the necessary information 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 SCR 159.

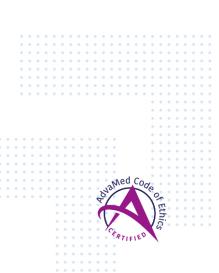
Your support can transform the landscape of patient care, and we look forward to your leadership in this critical healthcare initiative.

Sincerely,

Zach Rothstein Executive Director AdvaMedDx

Gottheto

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



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The Honorable Jarrett Keohokalole Chair Senate Committee on Commerce and Consumer Protection Room 205 Hawai'i State Capitol 415 South Beretania Street Honolulu, HI 96813

The Honorable Joy A. San Buenaventura Chair Senate Committee on Health and Human Services Room 213 Hawai'i State Capitol 415 South Beretania Street Honolulu, HI 96813

Re: SCR 159, Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing

Dear Chair Keohokalole, Chair San Buenaventura, and Members of the Senate Committee on Commerce and Consumer Protection, and the Senate Committee on Health and Human Services,

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.

Similarly, we respect the request for the Auditor's report, both as a matter of law, pursuant to Sections 23-51, and 23-52, Hawaii Revised Statutes, and as a matter of good fiscal prudence.

We wish to stress, however, that in assessing the fiscal impact of biomarker testing, the human impact needs to be considered



ICAN re SCR 159—Auditor Report—Biomarker Testing, March 20, 2024, page 2 of 3

alongside the fiscal impact, and the fiscal impact is not simply the costs of the testing.

The <u>human impact</u> is that more accurate testing sooner in the patient's journey both extends lives and saves many lives. The <u>full fiscal impact</u> must include two factors, a) the <u>long-term fiscal impact</u> of getting people on the right treatment sooner as this saves money for the health care system, including those systems managed by the state, and b) the <u>economic impact of the regained productivity</u> (and tax payments) of anyone who is or will be in the workforce. Extending lives, with a high quality of life, through better treatments, and saving lives through a cure—and both of these are direct impacts of increased biomarker testing—means that Hawaii will have more tax revenues from a healthier workforce.

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.

ICAN re SCR 159—Auditor Report—Biomarker Testing, March 20, 2024, page 3 of 3

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 <u>marcia@askican.org</u> 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 Phoenix, AZ 85021-7246

(602) 618-0183 marcia@askican.org https://askican.org

P. S. We realize there may be an effort to restrict biomarker testing to just cancer. Although ICAN is solely focused on helping cancer patients—specifically Stage IV cancer patients, the most serious stage—we strongly support biomarker testing for all diseases where it is medically appropriate.

Ask yourself this: if a loved one had a lethal or chronic disease, whether cancer or any other, wouldn't you want them to have access to the tests that can lead them to a better course of treatment and possibly be the difference in whether they survive?

If your answer is yes, then please ensure that the loved ones of others also have the ability to access biomarker testing for all diseases.

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Testimony to the Senate Committee on Commerce and Consumer Protection and the Senate Committee on Health and Human Services Friday, March 22, 2024; 9:38 a.m.

Hawaii State Capitol, Conference Room 229, and Videoconference

<u>RE: SENATE CONCURRENT RESOLUTION 159 – REQUESTING THE AUDITOR TO ASSESS</u> <u>THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE</u> <u>FOR BIOMARKER TESTING.</u>

Chairs Jarrett Keohokalole and Joy San Buenaventura, Vice Chairs Carol Fukunaga and Henry Aquino, and Members of the Committees:

The Alzheimer's Association–Aloha Chapter serves the residents of Hawaii to help all those facing Alzheimer's disease and other dementias by providing local support groups and educational resources while advancing crucial research and public policy initiatives. We testify in <u>SUPPORT of SENATE CONCURRENT RESOLUTION NO. 159</u>.

Alzheimer's disease is a public health crisis across the country. In Hawaii, approximately 29,000 individuals aged sixty-five and older live with Alzheimer's disease. This figure is projected to increase to over 35,000 by next year. In addition, many are experiencing subjective cognitive decline — one of the earliest warning signs of future dementia. In 2020, 6.7% of individuals aged 45 and over reported increased confusion or worsening memory loss, putting them at risk of later developing dementia.

This resolution, as received by your Committee, would request that the State Auditor assess, in accordance with sections 23-51 and 23-52, Hawaii Revised Statutes, the social and financial effects of mandating health insurance coverage for medically necessary biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a person's disease or condition to guide treatment decisions when supported by medical and scientific evidence, as provided in House Bill No. 2223, House Draft No. 1, Regular Session of 2024, and to submit a report of its findings and recommendations, including any proposed legislation, to the Legislature no later than twenty days before the convening of the Regular Session of 2025.

An early and accurate diagnosis of Alzheimer's can improve access to care and support

services, enhance the quality of life and reduce the financial impact of the disease. With the historic approval of treatments that slow the progression of the disease, early detection and diagnosis of Alzheimer's are even more critical to ensure individuals receive the most benefit at the earliest point possible in the disease progression.

Current diagnosis of Alzheimer's disease relies largely on documenting cognitive decline, at which point Alzheimer's has already caused severe brain damage. Experts believe that biomarkers (short for "biological markers") offer one of the most promising paths to improve dementia detection, diagnosis, and treatment.

Currently, there are some FDA-approved biomarker tools that, when applicable, can aid in diagnosing people with symptoms of Alzheimer's or other dementia (e.g., brain imaging). Some of these tools have a wealth of research and clinical data to support their use in a clinical setting (e.g., biomarkers in cerebrospinal fluid (CSF)), while other emerging biomarkers are promising but still under investigation (e.g., blood tests and genetic risk profiling). Continued progress around blood-based amyloid biomarker markers will likely lead to new diagnostic tools coming to market within the next few years. Insurance coverage for biomarker testing (including blood tests, saliva tests, imaging, etc.) is currently not keeping up with scientific discoveries and treatment progress. Existing healthcare disparities and challenges to obtaining a dementia diagnosis may be exacerbated if new biomarker testing opportunities cannot be accessed.

Without acting on this legislation, dementia diagnoses may take up to two years, increasing the long-term costs to the individual, family, and the state. Because diagnosis leads to lower costs of care for people living with dementia, access to biomarker testing can accelerate these cost savings. In a 2018 analysis, diagnosis led to projected cost savings of approximately \$63,000, of which \$30,000 was in Medicare savings, \$20,000 in Medicaid savings, and \$13,000 in other savings. (2018 Alzheimer's Facts and Figures)

The Alzheimer's Association requests your favorable consideration of this measure based on an earlier and faster diagnosis that offers individuals and families more time with their loved ones. <u>We ask you to pass</u> <u>Senate Concurrent Resolution 159</u>.

Mahalo for the opportunity to testify. If you have questions, please contact Ron Shimabuku at 808.451.3410 or <u>rkshimabuku@alz.org</u>.

himabuku

Ron Shimabuku Director, Public Policy and Advocacy Alzheimer's Association – Hawaii



March 21, 2024

Re: Support for HCR53/SCR159, Requesting the Auditor to assess the social and financial effects of mandatory health insurance coverage for biomarker testing.

Dear Members of the Committee:

On behalf of The Michael J. Fox Foundation for Parkinson's Research (MJFF), I write in support of **HCR53/SCR159**, which will request the Auditor to assess the social and financial effects of mandatory health insurance 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.¹

There are estimated to be more than 1 million Americans currently living with Parkinson's disease, with about 90,000 more diagnosed each year.² 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.

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

² "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, <u>https://www.michaelifox.org/news/new-study-shows-incidence-</u> <u>parkinsons-us-nearly-50-percent-higher-previous-estimates</u>.

For these reasons, MJFF strongly supports **HCR53/SCR159**. 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 <u>zhardy@michaeljfox.org</u>.

Sincerely,

Zach Hardy State Government Relations Officer



March 21, 2024

Hawai'i State Legislature Senate Committee 415 South Beretania St. Honolulu, HI 96813

Re: Senate Concurrent Resolution 159; Requesting the Auditor to Assess the Social and Financial Effects of Mandatory Health Insurance Coverage for Biomarker Testing

Dear Senate Committee:

I am writing on behalf of Aimed Alliance, a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers, to express our support for Senate Concurrent Resolution 159, requesting the auditor to assess the social and financial effects of mandatory health insurance coverage for biomarker testing. The passage of this resolution, alongside House Concurrent Resolution 53, is essential to pave the way for House Bill No. 2223. This bill carries significant potential in advancing medical diagnostics and personalized treatment options for individuals facing various health challenges through the coverage of biomarker testing.

Biomarker testing is a crucial mechanism for gathering individualized information essential for the prevention, diagnosis, and treatment of diseases.¹ This personalized data is derived by analyzing biological specimens, such as tissue and blood from patients, to detect key biomarkers such as genetic anomalies and molecular indicators.² Expanding insurance coverage for biomarker testing is a pivotal step toward enhancing accessibility to this indispensable diagnostic tool. The identification of specific biomarkers empowers practitioners to tailor treatments to individual patients, minimizing unnecessary interventions and maximizing therapeutic benefits.³

While significant strides in biomarker testing have been made in areas like oncology, its potential extends far beyond cancer diagnosis and treatment. There is a rapidly growing body of evidence highlighting its clinical benefits across a diverse spectrum of diseases and chronic illnesses, including conditions such as preeclampsia,⁴ cardiovascular diseases,⁵ diabetes,⁶

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

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

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

⁴ 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.

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

⁶ Brenda Dorcely et al., *Novel biomarkers for prediabetes, diabetes, and associated complications*, Diabetes, 10 Metabolic Syndrome and Obesity 345–61 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565252/



neurodegenerative disorders,⁷ and autoimmune diseases.⁸ For instance, the FDA recently approved a biomarker test for preeclampsia earlier this year, enabling health care professionals to identify pregnant individuals at the highest risk of preeclampsia, leading to better management of this condition and improved outcomes for both mothers and their newborns.⁹

These innovative applications of biomarker testing can contribute to improved patient outcomes, reduced healthcare costs, and enhanced quality of life.¹⁰ Spanning across a wide spectrum of medical conditions, biomarker testing offers significant contributions to disease prevention, early detection, and precision treatment strategies. We support the disease-agnostic language in House Bill No. 2223, recognizing its role in fostering a comprehensive approach to biomarker testing. This inclusive approach promotes innovation and progress across various medical specialties, ensuring that advancements benefit individuals across diverse healthcare needs.

In conclusion, we urge your support for the passage of S.C.R.159, which calls for an evaluation by the auditor to assess the social and financial impacts of mandating health insurance coverage for biomarker testing. This crucial step will clear the path for the enactment of House Bill No. 2223, thereby enhancing health outcomes for the residents of Hawai'i and ensuring that our health care system remains at the forefront of technological advancements.

Sincerely,

Ashira Vantrees Counsel

⁷ Blood Biomarkers in Neurodegenerative Diseases: Implications for the Clinical Neurologist, 101 Neurology (2023),

 $https://n.neurology.org/content/101/4/172 \#:\sim:text=The\%20most\%20rigorously\%20studied\%20blood, detect\%20AD\%20in\%20older\%20adults.$

⁸ 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%20qua ntify,of%20disability%20in%20clinical%20practice.

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

¹⁰ 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.

WRITTEN TESTIMONY BY AMY JACOBS – PATIENT ADVOCATE, FOR: 159 SCR REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING

Greetings:

My name is Amy Jacobs, I am a Stage 4 stomach cancer patient/survivor diagnosed June 13, 2018, with a grim 6-month statistical expectancy. The 5-year survival rate back then for a Stage 4 patient was 4%. I will reach my 6-year post diagnosis mark this coming June 13, 2024. Stomach cancer remains one of the 5 deadliest cancers on the planet, very under-recognized and underfunded for research and early diagnostic tools.

I am submitting my testimony as a Patient Advocate on behalf of Debbie's Dream Foundation: Curing Stomach Cancer ("DDF") - the leading USA-based nonprofit organization dedicated to stomach cancer awareness, patient resources, research funding, to name a few, I am also a DDF PREP Mentor for Stage 4 patient and caregivers internationally, DDF Board Member, and DDF's Regional Representative for New York's Long Island region. I participate in Advocacy on Capitol Hill for DOD research funding for stomach cancer, and also see the other side of that advocacy as I also have had the honor since 2020 to participate as a Consumer Reviewer in the Dept. of Defense's Peer Reviewed Cancer Research Program (PRCRP0 on behalf of DDF, reviewing applications for research funding for stomach cancers.

I would like to add that the Honorable Mazie Hirono (US Senator - HI) is a long time supporter of stomach cancer research funding and leads the US Senate Letter to the Appropriations Committee seeking to ensure stomach cancer remains an eligible disease to receive research funding under the Department of Defense's PRCRP.

Biomarker testing is crucial in determining any cancer patient's best treatment options. In simple terms: our cancers have certain "traits" (a/k/a biomarkers) and hopefully there are known and approved immunotherapy and/or targeted therapy drugs available to target them. Immunotherapy and targeted therapy drugs are the future for cancer patients, they seek to retrain the immune system to "see" the biomarkers the cancerous cells are hiding behind, and hopefully permanently destroy them.

I am living proof of that: my 3rd-line treatment was immunotherapy alone Pembrolizumab a//k/a Keytruda via my MSI-H(high) biomarker. Things were different back in 2018, a stomach cancer patient had to have two (2) failed lines of chemotherapy before having a chance at Keytruda as long as one of the biomarkers were present. Lucky for me I have 2 biomarkers: MSI-H(high) and PDL-1 (CPS: 80% which is exceedingly high for a stomach cancer patient, they are typically 0-5%, some are as high as 10%). I began Keytruda March 25, 2019 (after 8+ months of 2 different failed lines of highly aggressive, toxic chemotherapy drugs, so horrendous I was sure they would kill me before my cancer ever could).

What science knows today is that an MSI-H patient's cancer is resistant to chemotherapy, making it entirely toxic, highly toxic, and ineffective. Now in the present time, biomarker testing is done at diagnosis and the advanced/late Stage patient has hopeful options outside of chemotherapy. An MSI-H advanced/late-Stage patient will commonly go straight to immunotherapy, and less of a toll on their body. While immunotherapy and targeted therapy drugs have their own risks and possible side effects, they can be "curative" - whereas chemotherapy is merely "palliative" and geared to prolong life with virtually little to no "quality of life".

There are many types of stomach cancer including hereditary (genetic) type, and it is very common among Hawaiian citizens, as well as Pacific Islanders, indigenous citizens, and is abundant throughout Australia, New Zealand, Japan, South Korea, China, Singapore, Malaysia, to illustrate its closeness to Hawaii.

It would be a great service to your citizens to afford them access to biomarker testing, and please know that the major testing companies all have Patient Financial Assistance programs to help offset testing costs this can be arranged by the patient's oncology office or cancer center. This is definitely a crucial service to be covered by health insurance including Medicaid. The major testing companies are:

- 1. Foundation Medicine (Foundation One);
- 2. Natera (Altera, Signatera)
- 3. Caris Life Sciences (NGS)

Thank you for your courtesy and consideration of my testimony, and please feel free to contact me for more information or with any questions.

I certify that the foregoing statements made by me are true and accurate to the best of my knowledge, information and belief.

Best regards,

Amy Jacobs.

Amy Jacobs Email: amy.jacobs845@gmail.com Debbie's Dream Foundation: Curing Stomach Cancer PREP Mentor Board Member Chapter Leader: Long Island, New York {Nassau & Suffolk Counties}

Debbie's Dream Foundation: Curing Stomach Cancer Two South University Drive, Suite 326 Plantation, FL 33324 Toll-free number: (855) 475-1200 Toll-free Fax number: (855) 475-1201 Website: www.debbiesdream.org

~ Together we are dreaming BIG to make the cure for Stomach Cancer a reality ~

<u>SCR-159</u>

Submitted on: 3/20/2024 7:28:41 AM Testimony for CPN on 3/22/2024 9:38:00 AM

Submitted By	Organization	Testifier Position	Testify
Cheryl K. Okuma	Individual	Support	Written Testimony Only

Comments:

RE: Strong Support of SCR 159 REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

Chair, Vice Chair and Members of the Committee:

My name is Cheryl K. Okuma and I am an advocate for the American Cancer Society Cancer Action Network. I am in STRONG SUPPORT of SCR 159.

I am a breast cancer survivor. In my immediate family of 5, two others have endured other forms of cancer (prostate, colon). This causes me to wonder whether genetics is a factor. On my paternal side, my aunt is also a breast cancer survivor—twice. When I fill out forms for my check ups and exams I am asked if other immediate family members and those on my paternal and maternal side have had cancer, and what type.

Biomarker testing would provide a better way to determine what factors are involved, and in turn lead to the best treatment for cancer patients. Access to biomarker testing will lead to better health outcomes for cancer patients.

Progress in improving cancer outcomes increasingly involves the use of precision medicine, using information of a person's genes, proteins or other substances to diagnose and treat cancer in a targeted way. Biomarker testing is a personalized, important step to accessing precision medicine and therapies. This leads to improved survivorship and better quality of life for cancer patients.

Sincerely,

Cheryl K. Okuma

Wailuku, 96793

<u>SCR-159</u> Submitted on: 3/20/2024 10:46:48 PM Testimony for CPN on 3/22/2024 9:38:00 AM

Submitted By	Organization	Testifier Position	Testify
Deborah Michiko Fried	Individual	Support	Written Testimony Only

Comments:

RE: Strong Support of SCR159 – REQUESTING THE AUDITOR TO ASSESS THE SOCIAL AND FINANCIAL EFFECTS OF MANDATORY HEALTH INSURANCE COVERAGE FOR BIOMARKER TESTING.

Chair, Vice Chair and Members of the Committee:

My name is Deborah Michiko Fried and I am an advocate for the American Cancer Society Cancer Action Network. I am in STRONG **SUPPORT** of SCR159.

Two of my cousins died in their 40s of recurring breast cancer. As a registered nurse and now a nurse practitioner, I have witnessed great suffering caused by cancer unresponsive to treatment or recurring cancer.

Progress in improving cancer outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to better diagnose and treat diseases like cancer. Biomarker testing is an important step to accessing precision medicine which includes targeted therapies that can lead to improved survivorship and better quality of life for cancer patients.

Sincerely,

Deborah Michiko Fried