

**Testimony of Hilary Schneider, Maine Government Relations Director,
American Cancer Society Cancer Action Network**

In Support of LD 1577 "An Act to Require Health Insurance Coverage for Biomarker Testing"

May 8, 2023

Good afternoon, Senator Bailey, Representative Perry, and members of the Health Coverage, Insurance and Financial Services Committee. My name is Hilary Schneider, and I am the Maine Government Relations Director for the American Cancer Society Cancer Action Network (ACS CAN). ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, advocates for evidence-based public policies to reduce the cancer burden for everyone. As the nation's leading advocate for legislative solutions that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

On behalf of ACS CAN, I would like to thank you for this opportunity to submit the following testimony in strong support of LD 1577. We thank Representative Sam Zager for his hard work on this bill. We ask you and the members of your committee to pass this critical legislation that 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 potentially help achieve the triple aim of health care: better health outcomes, improved quality of lifeⁱ and reduced costs.^{ii,iii}

This legislation will ensure Mainers covered by Medicaid and state regulated insurance plans have coverage for biomarker testing when medically appropriate.

Progress in improving cancer outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to prevent, diagnose or treat diseases like cancer. Biomarker testing analyzes tissue, blood, or other biospecimens to identify mutations that may impact treatment decisions. This 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.^{iv} There is currently limited and disparate access to biomarker testing.^v According to a recent ACS CAN Survivor Views survey of oncology providers, 66% reported that insurance coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.^{vi}

Improving access to biomarker testing, and thereby access to targeted therapies, is a strategy to reduce health disparities and improve outcomes for cancer patients. In Maine, 83 percent of



policies reviewed were “more restrictive” than NCCN guidelines for biomarker testing for advanced breast cancer, non-small cell lung cancer, melanoma and/or prostate cancer.^{vii} This is evidence that there are likely Mainers that could benefit from biomarker testing that are being left behind.

Not all communities are benefitting from the latest advancements in biomarker testing and precision medicine. Communities that have been marginalized, including communities of color and individuals with lower socioeconomic status, are less likely to receive biomarker testing. People in rural communities and those receiving care in nonacademic medical centers are also less likely to benefit from biomarker testing. One jarring example of the current disparities in access to biomarker testing: a recent study showing patients with Medicaid diagnosed with advanced non-small cell lung cancer are not only at a 19% higher risk of not receiving biomarker testing and a 30% higher risk of not benefiting from precision medicine; they also have a 23% higher risk of mortality when compared to commercially insured patients.^{viii} Ensuring equitable access to biomarker testing by improving coverage for and access to testing across insurance types is key to reducing health disparities. Indeed, without action like this to expand coverage for biomarker testing – including Medicaid – advances in precision oncology could increase existing health disparities.^{ix}

To be clear, biomarker testing is not indicated or appropriate for all cancer patients. We are not advocating for universal biomarker testing; rather, this legislation is tied to rigorous sources of medical and scientific evidence that guide who should receive this testing. In addition, as demonstrated in the stories you will hear today and read in the attachment to my testimony, there are countless examples of cancer patients in Maine where biomarker testing led to decisions to forego unnecessary care like chemotherapy and radiation or resulted in transitions away from ineffective treatments. When patients forego unnecessary care there are direct and immediate results in the individual’s out-of-pocket costs, systemwide costs, and often in terms of improved quality of life. Avoiding unnecessary side effects of ineffective treatment also can result in cost savings and can better support a patient’s ability to work, support their family, and engage in their community.

Another important factor to consider during deliberations on this bill are multiplier effects, not only in terms of economics, but also in terms of impact on families and loved ones. The truth is a cancer diagnosis does not just impact the patient, but also families and communities. My mom was diagnosed with breast cancer for the second time when I was 11 years old. She died one year later. The trauma I experienced from my mom’s battle with cancer is not just a result of her death, but also witnessing the grueling side effects of her treatment, which included several rounds of chemotherapy and radiation. My mom experienced significant pain and nausea. To this day, I have vivid memories of her crying out in pain, seeing her not be able to keep food down, and watching her lose a significant amount of weight and becoming so weak that she needed to use a walker and wheelchair. One of the most traumatic experiences happened one day when my family took a trip from the Massachusetts suburbs into Boston to get outside and spend some precious time together. While my dad was taking care of a quick errand, my sister and I pushed my mom in her wheelchair down Newbury Street. I remember us laughing and enjoying our time together and then I remember my mom falling from her wheelchair, her wig falling off and my sister and I realizing she was having a seizure. My sister and I screamed for help. Fortunately, a doctor was nearby and ran to help us. Soon an ambulance was called, and we spent the rest of the day in the hospital as they ran tests and soon determined the seizure was likely a side effect of either the chemotherapy or her cancer. Despite living, working, and going to school in or near Boston in my late



teens and early 20s, it took me nearly 15 years to be able to walk down Newbury Street again.

I cannot help but think about how different my mom's cancer journey could have been if targeted therapies had been available to her. I also think about the serious impact of side effects of cancer treatment not just on patients, but on their families. Providing access to effective, targeted therapies that can have better outcomes and often fewer side effects, as well as providing patients with information that can lead to avoiding unnecessary treatment and its side effects, can be life changing and have significant positive impacts for cancer patients and their families.

The power of access to biomarker testing is truly a "gamechanger" for many cancer patients. LD 1577 would make it possible for more patients to get the right treatment at the right time. For these reasons, we ask you to vote "ought to pass" on LD 1577. I would be happy to answer any questions you may have about this testimony.

ⁱ ACS CAN. Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care. September 2020. <https://www.fightcancer.org/sites/default/files/Improving%20Access%20to%20Biomarker%20Testing.pdf>

ⁱⁱ Biomarker Testing Can Direct Care, but Only If Clinicians Perform the Right Tests. Evidence-Based Oncology, February 2020, Volume 26, Issue 2. <https://www.ajmc.com/view/biomarker-testing-can-direct-care-but-only-if-clinicians-perform-the-right-tests>

ⁱⁱⁱ Mikyung Kelly Seo & John Cairns. Do cancer biomarkers make targeted therapies cost-effective? A systematic review in metastatic colorectal cancer. PLOS. September 26, 2018 <https://doi.org/10.1371/journal.pone.0204496>

^{iv} ACS CAN. Improving Access to Biomarker Testing: Advancing Precision Medicine in Cancer Care. September 2020.

^v ADVI. Payer Coverage Policies of Tumor Biomarker Testing. September 2020. https://www.fightcancer.org/sites/default/files/ACS%20CAN%20and%20LUNGEvity_Payer%20Coverage%20Policies%20of%20Tumor%20Biomarker%20Testing.pdf

^{vi} ACS CAN "Survey Findings Summary: Understanding Provider Utilization of Cancer Biomarker Testing Across Cancers." December 2021.

https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf

^{vii} 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.

^{viii} Gross, C. P., Meyer, C. S., Ogale, S., Kent, M., & Wong, W. B. (2022). Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC, *Journal of the National Comprehensive Cancer Network*, 20(5), 479-487.e2.

^{ix} Ryan W. Huey, MD, Ernest Hawk, MD, MPH, and Anaeze C. Offodile II, MD, MPH. Mind the Gap: Precision Oncology and Its Potential to Widen Disparities. *Journal of Oncology Practice*. May 21, 2019: DOI <https://doi.org/10.1200/JOP.19.00102>



EXPAND ACCESS TO BIOMARKER TESTING IN MAINE

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 and autoimmune disease, there is research underway to benefit patients with other conditions including heart disease, neurological conditions like Alzheimer's disease, infectious disease and respiratory illness.

THE IMPORTANCE OF BIOMARKER TESTING



60%

Of oncology drugs launched in the past five years require or recommend biomarker testing prior to use¹

In 2000:



15%

Of cancer clinical trials involved biomarkers²

In 2018:



55%

BIOMARKER TESTING & HEALTH EQUITY

- **Not all communities in Maine 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.

Arizona, Illinois, Louisiana, Rhode Island, Kentucky, New Mexico, Georgia, & Maryland have passed comprehensive biomarker testing coverage laws.



66%

Of oncology providers reported that insurance coverage is a **significant or moderate barrier** to appropriate biomarker testing for their patients³

In Maine:



83%

Of commercial insurance plans provide coverage that is more restrictive than National Comprehensive Cancer Center guidelines⁴

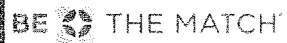
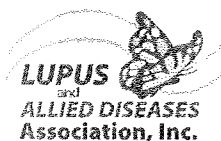
BENEFITS OF BIOMARKER TESTING FOR MAINE PATIENTS

"I did not expect that three months into chemotherapy, my cancer would be back and spread to my lymph nodes. My prognosis was very poor; I had few options. My doctor ordered biomarker testing, and the results I received opened-up treatment options I did not previously have. Thankfully, I felt better within one treatment."



Diane Davis | East Millinocket

SUPPORTERS OF MAINE BIOMARKER TESTING LEGISLATION (LD 1577)



¹Global Oncology Trends 2021. IQVIA Institute; June 2021.

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

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

⁴Wong 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 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.ⁱ
- 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)ⁱⁱ and decreased expected testing procedure costs to the health plan by \$24,651.ⁱⁱⁱ
- Some studies have found minimal cost increases as a result of the costs of more effective treatment and prolonged patient survival.^{iv,v}

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).^{vi} 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.^{vii}

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.^{viii}

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ⁱ Brito RA, Cullum B, Hastings K, et al. Total cost of lung cancer care associated with broad panel versus narrow panel sequencing. *Journal of Clinical Oncology* 2020; 38, no. 15_suppl; 7077.

https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.7077

ⁱⁱ Economic Impact of Next-Generation Sequencing Versus Single-Gene Testing to Detect Genomic Alterations in Metastatic Non-Small-Cell Lung Cancer Using a Decision Analytic Model

DOI: 10.1200/PO.18.00356 *JCO Precision Oncology* - published online May 16, 2019.

ⁱⁱⁱ Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non-Small Cell Lung Cancer

<https://doi.org/10.1016/j.jval.2018.04.1372>

^{iv} Budget Impact of Next-Generation Sequencing for Molecular Assessment of Advanced Non-Small Cell Lung Cancer

<https://doi.org/10.1016/j.jval.2018.04.1372>

^v Budget impact analysis of comprehensive genomic profiling in patients with advanced non-small cell lung cancer

Source: James Signorovitch, Zhou Zhou, Jason Ryan, Rachel Anhorn & Anita Chawla (2019) Budget impact analysis of comprehensive genomic profiling in patients with advanced non-small cell lung cancer, *Journal of Medical Economics*, 22:2, 140-150, DOI:

10.1080/13696998.2018.1549056

^{vi} 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-](https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx)

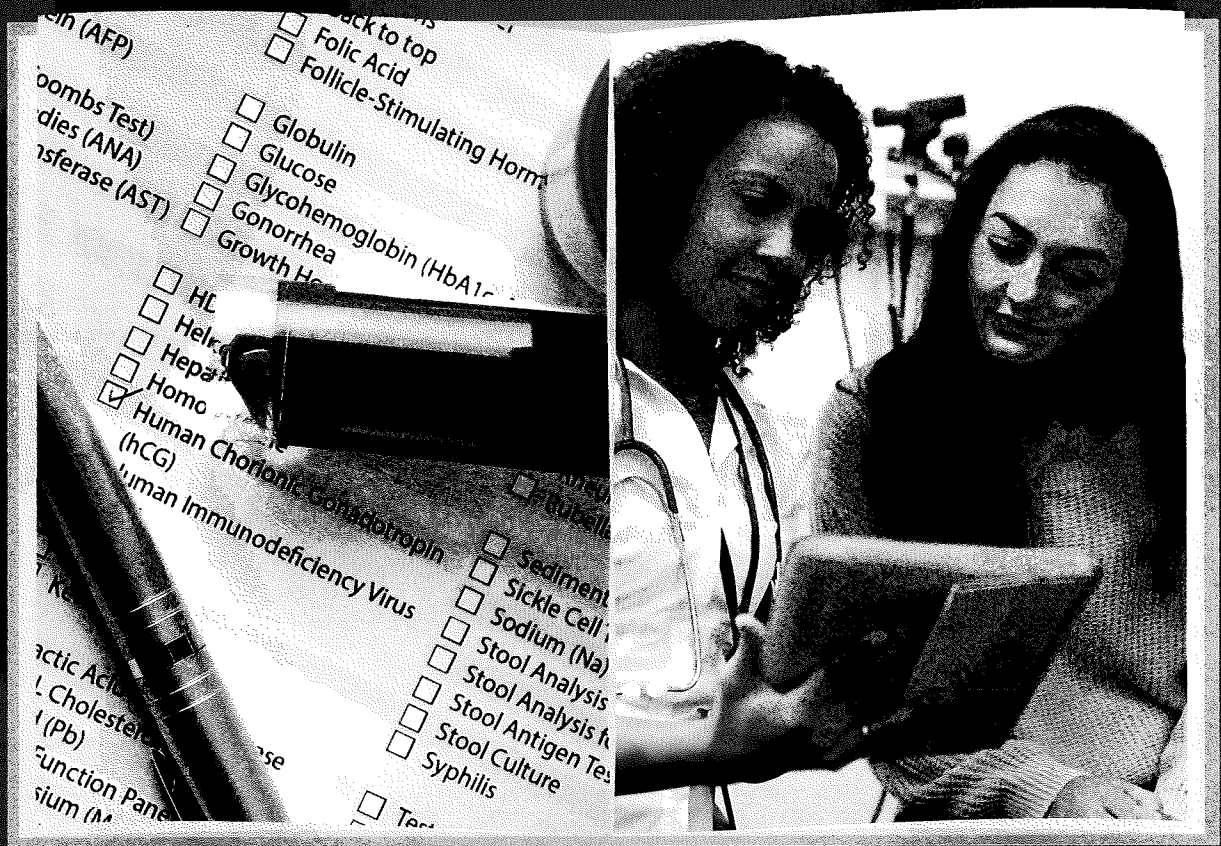
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^{vii} Survivor Views: Biomarker Testing. ACS CAN. Sept. 2020.

<https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf>

^{viii} 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-](https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx)

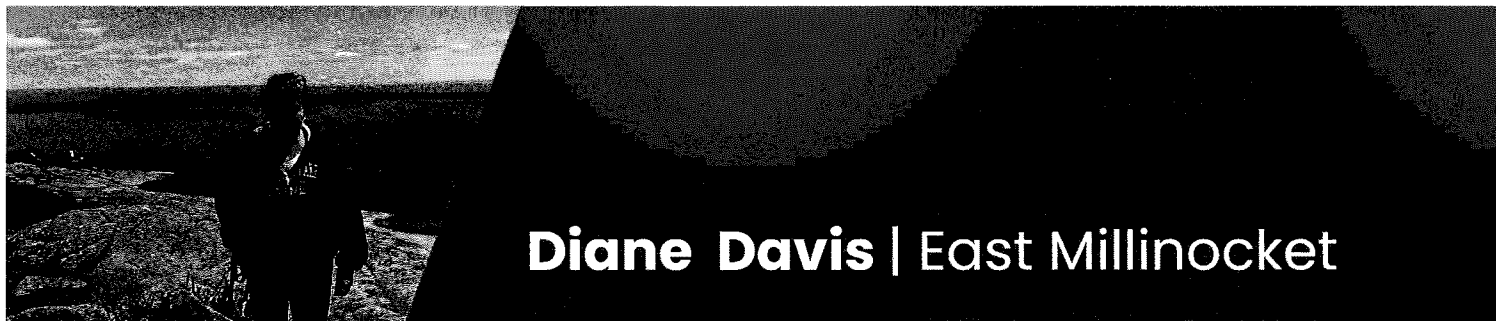
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Biomarker Testing in Maine: A Storybook

Introduction

Progress in improving cancer outcomes increasingly involves the use of precision medicine, which uses information about a person's own genes or proteins to diagnose or treat diseases like cancer. Biomarker testing opens the door to precision medicine, including targeted therapies that can result in improved survivorship and better quality of life. **Maine has the opportunity to expand residents' access to this potentially lifesaving testing.** LD 1577 would make it possible for more patients to get the right treatment at the right time. The following stories highlight the benefit of biomarker testing on patient care.



Diane Davis | East Millinocket

“

I was initially diagnosed with cancer at age 44. If I had biomarker testing then, I may have been able to avoid: the further spread of my cancer, the chemotherapy, and everything that came with it.

Diane is a three time cancer survivor. She was first diagnosed with uterine cancer at age 44, and she was treated with surgery. But years later, Diane was again in pain and knew something wasn't right. She and her health care providers investigated, and she was diagnosed with ovarian cancer. She began a treatment plan that many cancer patients may expect: her providers surgically removed the tumor, and she began standard chemotherapy after the surgery. But Diane did not expect that three months into chemotherapy, her cancer would be back and have spread to her lymph nodes. Her prognosis was very poor, and she had few options.

Her doctor ordered biomarker testing, and the results she received opened up treatment options Diane did not previously have. Her biomarkers showed she was a good fit for immunotherapy, and thankfully, Diane felt better within one treatment. She finished immunotherapy three years ago, and she is stable and cancer-free. Unfortunately, this effective treatment did not come without a cost. Diane's Marketplace health insurance denied coverage of her biomarker testing, and she received a bill for \$20,000. Luckily Diane received assistance from her testing provider for her life-saving biomarker testing, but not all cancer patients are so lucky.

Helen Roy | China



“

I will never forget getting the call from my oncologist once the biomarker test results were back. She told me the results showed I would not need to do a course of chemotherapy. My relief at this news was incredible.

In 2013, after transferring to Husson University to complete her degree, Helen was diagnosed with breast cancer at her routine screening. She underwent a lumpectomy to remove the tumor. Helen's doctor ordered biomarker testing on her tumor cells, and she told Helen that the lab doing the test would give her a call to discuss the cost, insurance coverage, and possibility of financial assistance. Helen was managing a heavy courseload at Husson and a time-consuming commute to Bangor, and it was stressful for her to consider the need to juggle chemotherapy and on-going health care costs in addition to that.

Thankfully, her test results revealed that she had a low chance of cancer recurring and would *not* benefit from chemotherapy. If not for biomarker testing, it could have been impossible for Helen to finish a degree and progress her career at the same time as investing her time, energy, and money into more intensive treatment such as chemotherapy. Instead, her doctor ordered a round of radiation treatments for the late spring of 2014, and Helen takes oral medications to treat her breast cancer and prevent it from spreading. She graduated from Husson in May 2016, and she is happy and fulfilled in her career. She feels blessed to have the cancer journey she had thanks to biomarker testing.



Mary Ann Cumming | Standish

“

Biomarker testing should be covered for every person who could benefit. I wonder how many women suffered through chemo and radiation when there might have been other options; I wonder how many women gave up believing those were their only choices.

When Mary Ann was diagnosed with breast cancer in 2016, she was all too familiar with the realities of living with cancer, having grown up as a caregiver to her father during his cancer treatment. Her cancer was discovered because of her recommended screenings, and she had her tumor surgically removed. Her breast cancer was treated with internal radiation, and she regained her health. But years later in 2022, her breast cancer came back. She underwent her second surgery, and this time her doctor ordered biomarker testing on the tumor to learn more about Mary Ann's cancer and her treatment options.

Her test results indicated that Mary Ann would *not* benefit from additional chemotherapy or radiation, and she was so grateful that she did not elect to participate in those taxing procedures. Despite her biomarker testing results saving her from receiving ineffective, costly chemotherapy, one of the tests was not covered by her insurance. Thankfully, the biomarker testing company decided to cover the remainder of Mary Ann's bill and save her from the great expense of preserving her livelihood, and she has become an advocate to ensure more cancer patients can access biomarker testing and understand their options.



Alex Babcock | Portland

“

My insurance denied coverage of the biomarker testing on the grounds that it wasn't necessary, when it literally saved my life.

Alex is a hardworking member of her community, who tends to put her health on the backburner in favor of her career. When she started experiencing symptoms in 2018, she all but wrote them off - thinking “I’m just exhausted and stressed from work.” But finally, she visited her primary care provider later that year. After a chest x-ray revealed a mass on her lung, she had an emergency CT scan. Alex’s pulmonologist said based on her age and lack of risk factors that she likely had lymphoma, but if she had lung cancer there are tests that could help access the best treatment option and prognosis. Unfortunately, she was diagnosed with stage IV lung cancer.

Her pulmonologist recommended biomarker testing. The results didn’t come for weeks, and in that time Alex had started traditional chemotherapy and received a bill for \$10,000 when her insurance denied coverage of her biomarker testing. While biomarker testing was deemed not necessary by her insurance company, it allowed Alex to access the right treatment for her. Her biomarker testing helped to identify the medication to treat her cancer, and it saved her life. Alex is still on that medication today, and she is stable. She is able to be the best mother and community member she can be thanks to her biomarker testing and the targeted treatment it led to.

Corinne Pert | Blue Hill



“

With the initial diagnosis, I was feeling pretty hopeless – until they did biomarker testing. Later when the cancer progressed, I was prepared; I knew there were other drugs, other treatments, other possibilities for me. It was much less scary. Because I knew about my biomarkers.

In 2015, Corinne developed a severe cough and other symptoms that led to more frequent visits to her doctor's office. At first she didn't think much of her symptoms, believing they may be a response to a recent house fire.

Unfortunately by early 2016, Corinne's condition had worsened. She went to a walk-in clinic for an x-ray, and the next day her doctor ordered a CT scan. It took a few weeks for Corinne to get a diagnosis, which caused significant distress. After further testing, she was diagnosed with lung cancer. Corinne called Dana-Farber Cancer Institute right away, and there she was able to get more detailed information about her cancer cells by undergoing biomarker testing.

She simultaneously received radiation as palliative care; her doctors were hoping it would shrink the tumor enough so that she could breathe easily. Unfortunately, due to her receiving that essential palliative care, insurance denied coverage of biomarker testing on the basis that she was already receiving treatment. But really, Corinne's biomarker testing results guided her to begin treating her cancer with an effective targeted therapy drug that gave her life back. And over a year later when cancer spread to her brain, Corinne already had valuable information about her biomarkers that qualified her for the medication that has allowed her to live a happy life.



Kate Knox | Portland

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Biomarker testing is an important part of the process for many patients. It should be covered. You and your doctor need that information for your treatment, recovery and quality of life.

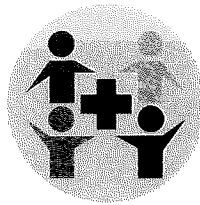
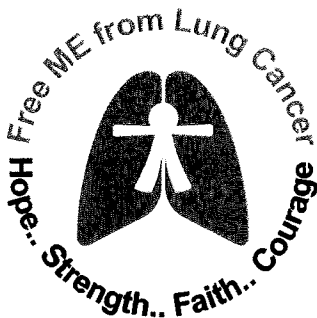
In 2021, at the same time as Kate and family welcomed a third child, she was diagnosed with breast cancer. She underwent surgery to have the tumor removed, and Kate vividly remembers one major decision made prior to the lumpectomy. There was a form that stood out. She recalls how the hospital took extra time explaining that the biomarker tests that could help inform her treatment "were expensive" and if their insurance did not cover the testing, they'd have to pay out-of-pocket. Without much discussion, they agreed, the risk not to have the test could be lifechanging.

Kate is not easily overwhelmed, but waiting for test results that would inform her cancer treatment protocol was difficult. Finally, the results became available, and they provided an essential roadmap for Kate's treatment plan - chemotherapy was not needed. Kate's treatment, after removal of the lump, was eight weeks of radiation and five years on an estrogen receptor medication. Kate's treatment plan was the solid footing that she had longed for since her diagnosis. The biomarker testing provided the details needed to survive her breast cancer.

Acknowledgements

Thank you to the cancer survivors across Maine who have shared their stories to contribute to this storybook.

Thank you to our partners at *Free ME from Lung Cancer* and *Consumers for Affordable Health Care* for helping to reach Mainers who have benefitted from biomarker testing and have important stories to share.



**Consumers for
Affordable
Health Care**