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Testimony of Rep. Same Zager presenting
LD 107, An Act to Require Health Insurance Coverage for Biomarker Testing
Before the Joint Committee on Health Coverage, Insurance and Financial Services

Senator Bailey, Representative Mathieson, esteemed committee members, thank you for hearing **LD 107, An Act to Require Health Insurance Coverage for Biomarker Testing**. I'm Sam Zager, representing House District 116 (part of Portland). I'm proud to present this very *bipartisan* bill. It passed the Legislature last session, but was one of the three dozen bills that got caught up in the cross winds at the very end of last session.

What's the problem to solve? We are leaving many Mainers to suffer more and die earlier than if they had access to biomarker testing to guide treatment. We can do better, particularly for rural Mainers.

What is a biomarker? Some of the earliest biomarkers commonly discussed in society in the 1990s were the breast cancer genes BRCA1 and BRCA2 and Her-2. A biomarker is a biological molecule portion that indicates a normal or abnormal process in a living thing, or *how well a living thing might respond to a treatment.*[1]

In a nutshell, this bill would help Mainers with cancer or other conditions use the medicines that are most likely to help them. It helps match an individual with the right treatment for their unique situation, by requiring that private

[1] National Cancer Institute Dictionary of Cancer Terms. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biomarker. Mutation testing, genomic testing, molecular testing, molecular profiling, and tumor profiling are all terms for biomarker testing.

insurance providers and Mainecare cover biomarker testing. It's a bargain too.

It repeats essentially the same substance in Title 22 (MaineCare) and Title 24 (Insurance Law) in the Maine Revised Statutes.

By enacting this bill, fewer Mainers likely would suffer and die prematurely. This committee asked the Bureau of Insurance for a Mandate Review in June 2023. In the section on medical efficacy, the BOI's report found that "biomarker-guided therapies are associated with a reduction in premature mortality."[2] That's not what was highlighted for this committee, but that's what the cited paper says. Real people. Real Mainers. Less premature death, because of biomarker testing.

Randomized controlled clinical trials, like the TAILORx trial, have demonstrated how biomarker testing can guide clinicians and patients away from treatment options that would have no benefit for their particular type of cancer--saving those folks and their families from often difficult-to-tolerate treatment, too often hours from home.[3]

Another study of lung cancer showed that "patients with a more advanced initial diagnosis, where biomarker testing is well-specified in the guidelines, the risk of mortality was reduced by 20%."[4]

There are many other studies showing how biomarkers can improve outcomes, when utilized in the right settings. Biomarker testing can reduce both suffering and premature death. LD 107 would thus be an important step forward.

Nearly have the states in our country have recognized this. States as diverse as Arizona, Arkansas, Illinois, Louisiana, Rhode Island, Kentucky, New Mexico, and Georgia have passed biomarker legislation akin to this bill. "Although use of biomarker testing is increasing, barriers to access persist. Cost and lack of

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[2] D Avo Luis AB, Seo MK, Has the development of cancer biomarkers to guide treatment improved health outcomes? Eur J Health Econ 2021 July; 22(5):789-810. https://pmc.ncbi.nlm.nih.gov/articles/PMC8214594/ [accessed 1/27/25]

[3] Sparano JA et al, Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer, N Engl J Med 2018; 379:111-121. https://www.nejm.org/doi/full/10.1056/NEJMoa1804710 [accessed 1/27/25]

[4] John A, Yang B, and Shah R et al, Clinical Impact of Adherence to NCCN Guidelines for Biomarker Testing and First-line Treatmetn in Advanced Non-Small Cell Lung Cancer Using Real-World Electronic Health Record Data. Adv Ther. 2021; 38:1552-1566. https://pmc.ncbi.nlm.nih.gov/articles/PMC7932942/ [accessed 1/27/25]

insurance coverage are common barriers to testing because insurance coverage varies across commercial payers, Medicare, and Medicaid."[5]

In the American Cancer Society's storybook, there are beautiful examples of Mainers who benefited from biomarker testing. There will be testimony today illustrating how biomarker testing improves real people's lives in this state.

But, you may be wondering if this would be a huge cost that would be expensive and drive up overall healthcare costs? Fortunately, it appears not.

- The BOI estimated in its January 2024 report to this committee that the defrayal note last time ranged from $25,000 to $340,000. This represents 4 cents to 61 cents per Mainer who would receive protections.[6]

- The same BOI report 2024 noted, "CMS proposed that any mandated benefits included in a state's benchmark plan in 2024 would **not** require defrayal." Indeed, three months later, CMS published it's final rule, stating that "state-mandated benefits are **not** considered 'in addition to Essential Health Benefits (EHB)' under CMS's defrayal policy if the mandated benefit is an EHB in the state's EHB-benchmark plan. If Maine's BOI includes biomarker coverage, no defrayal might be needed--and hence no fiscal note.

- The consultants from NovaRest in the BOI report assessed that this bill would increase insurance premiums by less than 0.1%. This is a bargain compared to *other important* things that health insurance is required to cover. Page 35 of the same BOI report shows that coverage for mammograms is 6x more expensive, and treatment for alcohol and substance use disorder is 11x more expensive. If we don't think twice about those things, then what's holding us back from covering biomarkers?

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[5] Lin GA, Coffman JM, Phillips KA, The State of State Biomarker Testing Insurance Coverage Laws. JAMA. 2024 Jun 11;331(22):1885–1886. [accessed 1/27/25] https://pmc.ncbi.nlm.nih.gov/articles/PMC11590753/#:~:text=Four%20states%20(Arkansas%2C%20California%2C,diagnosis%2C%20management%2C%20and%20monitoring. [accessed 1/27/25]

[6] The BOI report noted that the biomarker bill in the 131st Legislature (LD 1577) would not apply to self-insured pool, and that it would apply to MaineCare, fully insured large group, fully insured small group, and individually insured Mainers. According to the Maine Office of Affordability in Healthcare's presentation to Health and Human Services on 9/29/24, this would constitute 42% of Maine's population, approximately 588,000 people.

In summary, passing this bill again, and getting it over the finish line would reduce suffering and premature death; it would bring more fairness to a rapidly changing healthcare system, especially for rural Mainers; and it is a bargain.

For the sake of time, I moved some testimony to the appendix. I'd be happy to answer questions, but I know a lot of other people have important things to say.

There's more in my written testimony, but I'll stop here. I could take questions, and I will be followed by a fair number of experts, and other Mainers telling how biomarker testing helped them through very challenging times. Thank you.

Appendix

1. Video summary of biomarkers and policy (less than 3 min)
https://www.fightcancer.org/what-we-do/access-biomarker-testing

2. A hypothetical vignette to illustrate how the field of medicine is changing, and why insurance coverage for biomarker testing matters:
Suppose that for every ten people with a terrible disease, only six people survived a decade after diagnosis if left untreated. Now, suppose a team of researchers found that a new medicine increased that to nine of ten. That's a huge improvement, and well worth considering, as long as people tolerated the medicine, and that society made it possible to pay for the medicine, and to make it available in a fair manner.

But even that only gets us so far. Remember, one of ten would still succumb, even with the medicine. And even though it didn't *help* that person, that individual would still suffer the downsides -- physical side effects, the treatment's impacts on their life and that of their loved ones (such as traveling from rural Maine for hours to a treatment facility several times a week for many weeks or months), and the cost which may or may not be shared with others through insurance. Moreover, because they used this medicine, they're not in a condition to withstand a different medicine that actually would have helped. Wouldn't it be great to know which patient is likely to benefit from which medicine?

That's where biomarkers come in. They help treatments hit their targets better. They foster better outcomes, like improved quality of life, fewer side effects, and increased survival rates. They also reduce waste in the system. And just think how it would improve equity in terms of socio-economic status, or rurality.

3. More financial benefit evidence.
- A study by researchers in the US, published in 2023 corroborated the cost stewardship in the private market. They found minimal, if any, increased cost to private insurance for biomarkers in three common cancers. They looked at lung cancer, melanoma skin cancer, and colorectal cancer.[7]
- Another biomarker study anticipated "testing costs were projected to increase...and chemotherapy use to decrease...resulting in...a *net savings of $49 million (1.8% decrease)*. A small net savings was seen under most assumptions."[8]

[7] https://www.futuremedicine.com/doi/10.2217/fon-2023-0094

[8] Mariotto A, Jayasekerea J, Petkov V, Schechter CB, Enewold L, Helzlsouer KJ, Feuer EJ, Mandelblatt JS. Expected Monetary Impact of Oncotype DX Score-Concordant Systemic Breast Cancer Therapy Based on the TAILORx Trial. J Natl Cancer Inst. 2020 Feb 1;112(2):154-160. https://pubmed.ncbi.nlm.nih.gov/31165854/