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Testimony Introducing

LD 1577, An Act to Require Health Insurance Coverage for Biomarker Testing

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Senator Bailey, Representative Perry and esteemed committee members, thank you for hearing LD 1577, 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.

You may be wondering, what exactly is a biomarker? Lines 6-11 of the bill offer an elaborate statutory definition, but a simpler version based on the U.S. National Cancer Institute definition is: 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 insurance providers and Mainecare cover biomarker testing. And it's likely cost neutral.

States as diverse as Arizona, Illinois, Louisiana, Rhode Island, Kentucky, New Mexico, and Georgia have passed biomarker legislation akin to this bill. In Maryland, the bill is on the governor's desk, and in Illinois, biomarker coverage is already in effect.

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[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.

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.

The historical context of this bill centers on the age-old question, how do we know what things will help us feel and be healthy?

The oldest approach to that question, is anecdotal; simply do what someone else has done and found effective, at least sometimes. While it was crude compared to what we expect today, this process worked to some degree. A few medicines we still use today were so identified.[2]

A newer approach is to put ideas to a test. In recent centuries, we've been able to greatly improve on the previous anecdotal approach by objectively *testing* our notions.[3] If you wanted to know if a particular thing (a medicine, device or other intervention) actually improves a health outcome, one could try it in a bunch of properly consented people and compare that to *not* trying it.

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 made 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.

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[2] https://www.mdlinx.com/article/ancient-medicines-and-procedures-still-used-today/lfc-4453

[3] The approach was elaborated and now is called the "scientific method." The scientific method was developed in the last couple centuries, and goes beyond observation; it starts to consider how to rigorously test suppositions based on observations ("hypotheses").

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. All that would be great.

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

- In the setting of Medicaid, requiring biomarker test coverage likely would have minimal if any fiscal impact. Consider Arizona, a state that has started to use *dynamic* fiscal notes; they look at the financial impact of the policy, not just the up-front costs as we do in Maine.[4] The Arizona legislature's fiscal note on their version of this bill found no fiscal impact.[5]

- A study by researchers in the US, published just a few weeks ago corroborated that finding 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.[6]

- 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."[7]

Even though it's a relatively small number of people who have conditions amenable to biomarker testing, the cost per course of treatment can be very high. So, guiding people to the right treatments with biomarkers is crucial.

In summary, passing this bill would greatly improve the quality of care, greatly improve equity and fairness in care, and seems approximately net neutral regarding costs. Mainers would be well served by LD 1577.

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.

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[4] https://cslf.gsu.edu/files/2019/04/cslf1911.pdf
[5] https://www.azleg.gov/legtext/55leg/2R/fiscal/HB2144.DOCX.pdf
[6] https://www.futuremedicine.com/doi/10.2217/fon-2023-0094
[7] 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/

Appendix

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

More on molecular mechanisms:
Many medicines work by having the medicine molecule fit with a receptor molecule on the surface of a cell. In the case of cancer, it's a whole lot of rogue cells that are reproducing out of control and causing all sorts of havoc. But not every cancer cell has the same receptors, or the same variant of the receptors. The medicine molecule literally might not fit. Those receptors are made out of (protein) molecules. They are derived from genetic "recipes" in a person's original DNA[8] code, or an aberrant cancerous code.[9]

[8] DNA stands for deoxyribonucleic acid, a very long molecule with a characteristic double helix shape. As far as we know, practically all living things on earth have their genetic code written in DNA. Some viruses use another long molecule called ribonucleic acid (RNA).

[9] Such aberrations in the genetic code of a cell can spontaneously happen due to a "copy error" as cells reproduce. It also can be related to something external, like asbestos, Agent Orange, or nuclear radiation (e.g. lymphoma among those who survived the atomic bombings of Hiroshima and Nagasaki in 1945, or the Soviet Chernobyl nuclear power plant disaster in 1986). Sometimes the thing that induces cancer it can be too much of a good thing, like sunshine over the course of a person's lifetime (e.g. squamous cell skin cancer in an avid beach-goer who doesn't use sunscreen).