Witness Statement **2/11/2025**

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I want to thank Chairman Buchanan, Ranking Member Doggett, and distinguished members of this committee, for the opportunity to be here today. My name is Jay Carlson, DO, MS. I am a gynecologic oncologist and currently serve at St. Louis-based Mercy as the Medical Director for the Oncology Service line and the Clinical Chair of Mercy Research. I am also a founding member of Mercy's Center for Precision Medicine.

Mercy is one of the 15th largest health systems in the US. It is a large community-based system primarily in Missouri with hospitals and clinics in Illinois, Kansas, Oklahoma, and Arkansas. Mercy Health has 33 acute care hospitals and 17 specialty hospitals. There are just under 3,000 physicians and another 2,500 advanced practice providers employed across the system. It has an operational budget of $10.6 billion and serves almost 3.6 million lives in Missouri alone.

It is Mercy's strategic goal to use the best-in-class genomic testing and artificial intelligence to screen and detect at-risk patients earlier in their disease course. It is well known that early disease detection and intervention results in longer survival and improved outcomes. Through AI and predictive algorithms, Mercy identifies high-risk cohorts for cancer screening and help them improve their quality of life and productivity even while being stressed by cancer treatments and chemotherapy.

To support its strategic goal, Mercy established a Center for Precision Medicine (CPM) to serve as the subject matter experts on genomic testing and the implementation of state-of-the-art screening. The CPM is staffed by a NP, RN and MA that have oversight by a Family Practice provider with considerable Precision Medicine experience.

Mercy's Center for Precision Medicine has implemented a broad screening program that focuses on Hereditary Cancer risk. This risk is linked to an autosomal dominant mutation, which means that some relatives may have a 50% risk of inheriting the same mutation. These mutations and their transmission may make the patients' problem into a family problem once others in the family get tested. The significance of this becomes evident when some of these mutations are associated with a 40-80% lifetime risk of cancer. The screening tools for discerning who should be tested are based on the National Comprehensive Cancer Network (NCCN) guidelines for hereditary cancer screening. This actual screening test is almost always covered by insurance if one meets the NCCN criteria. For patients with a harmful mutation (called deleterious), the NCCN has identified heightened screening tests or prophylactic surgeries or medications that can be offered to mitigate, or eliminate, the risk of cancer associated with these mutations. Again, these abnormal results are not an indication that there is a cancer present but rather identifies a mutation that elevates one's risk for cancer and the need for more sensitive screening. Because of its complicated nature, a lot of health systems do

not have a coordinated, system-wide, effort for these patients who are at exceedingly high-risk of cancer.

To support this screening effort, Mercy completed website development that gives patients access to a hereditary cancer screening tool that then digitally hands the at-risk patients off to the CPM team. We also send SMS texts to patients that link back to the survey tool, and ultimately the CPM team. The patients identified to have a serious or deleterious mutation are further managed by the CPM team for counseling, further testing, and coordination of their follow up care before being handed back to the primary care providers.

Mercy has an integrated vendor for genomics assays that has made it much easier for providers to order and track the results of these tests. In the last two years, our oncologists have tripled their utilization of genomic tests to help drive targeted therapy for our oncology patients, rather than just prescribing conventional chemotherapy. The genomic assays include the utilization of hereditary cancer testing for new cancer patients, which may then lead to the identification of at-risk family members, who subsequently receive interventions that mitigate their risk for a similar cancer.

Today, some cancers with appropriate treatment essentially become a chronic disease as we have slowed tumor growth or stopped it altogether. For patients on treatment, Mercy using an AI algorithm to discern a risk score for emergency room visits or inpatient admissions. We send SMS texts to those patients at highest risk to survey for symptoms such as pain, fever, nausea, or vomiting, etc. Those SMS text responses come back to our nursing triage team who can then reach out to the patient, allowing us to proactively manage these complicated patients to improve their oncology journey.

Mercy has also implemented a broad multicancer early detection (MCED) screening test. This committee is experienced with this test and has previously supported its utilization. Therefore, I will not necessarily speak to the assay, but rather speak to our implementation of this screening test. We knew our patients were already seeking out MCED tests through alternative pathways, often with suboptimal counseling or a poor understanding of the test. Mercy has hospitals that are close to the Coldwater Creek communities, a well-documented area in north St. Louis County where radioactive waste has been linked to a higher rate of cancer where this test may be of benefit. We also wanted to offer this state-of-the-art test to interested patients in our communities and other high-risk groups such as firefighters, or veterans, where there is a known high risk environmental exposure. Based on this strategic goal, Mercy decided to offer the MCED screening test across our entire health system. To be successful, we knew the deployment would require provider education, the utilization of the CPM team to facilitate the counseling and ordering, and patient education through website development and direct to consumer marketing.

We had a series of virtual educational meetings with providers at their section meetings and all physician meetings. During these meetings, the science of the test was reviewed.

We developed a provider order for “referral for MCED screening” in our electronic medical record (EMR) that was sent to and managed by the CPM team. The CPM team performed and documented the critical patient counseling for this test.

Mercy developed an extensive patient-facing website for the MCED screening test. A separate intranet educational section was developed for providers. We then leveraged AI and data extractions to identify a high-risk group for a targeted marketing campaign. We have been using this process for the last 2 years and have had approximately 3,000 provider referrals through our EMR and more than 9,000 patient self-referrals through our web interface. About one third ultimately proceeded to testing where – to date- we had 27 positive tests (22 confirmed malignancies and 5 false positives or pending evaluations). Each of these patients were asymptomatic at the time of their screening test. Those with a positive test received a virtual same-day peer review with me, a urologic oncologist, and the FP physician with operational oversight of the CPM team to formulate the diagnostic plan to be shared with the patient. The diagnostic plan rapidly ensued and we received support for all requested diagnostic imaging, including PET scans and MRI’s. For patients treated within our health system, the diagnostic evaluations were navigated by the CPM team and completed in a median of 15 days.

The current USPSTF screening tests have been available for years. They are well engrained into medical training and practice. We believe that the screening tests of the future will be more complicated, and frequently involve a combination of AI and some ‘omics’ assay making these clearly different than our historical standards.

As we have already experienced, many providers will be unfamiliar with these potential tests, their science, and the use of predictive algorithms that are deployed at scale. By engaging the CPM team we have been able to offer these services as a concierge lift to our providers. This meant that they only needed awareness of, not full knowledge in, the screening intent and test capabilities. The CPM team bridged the knowledge deficit and became the content experts in these areas. The centralized approach and standardized workflow we developed may be a model for other health systems to emulate for their deployment of new screening tests.

In summary, Mercy continues to explore new tests and services that combine the expanding science of genomics with the new benefits of AI, and deploy them at scale, to aide in the screening and earlier detection, and accurate diagnosis for a personalized treatment plan to improve the quality and value of the care we provide our patients.

I look forward to your questions.