DALE KOOYENGA
STATE SENATOR · 5TH DISTRICT
State Capitol · P.O. Box 7882 · Madison, WI 53707-7882 · (608) 266-2512

November 20, 2019

TO: Senate Committee on Health and Human Services
FR: Senator Dale Kooyenga
RE: support for Senate Bill 489 – cancer clinical trials

Thank you for holding a hearing on this potentially life changing bill. Cancer is one of the leading causes of death in Wisconsin. Senate Bill 489 will allow for reimbursement of certain expenses for patients who participate in cancer clinical trials.

Cancer clinical trials provide the best evidence of the effectiveness of potential new life-sustaining treatments. Unfortunately, only a small fraction of patients willing to participate in a trial actually enroll due to barriers making participation possible. This bill addresses economic barriers and provides patients equal access to cancer clinical trials.

Cancer clinical trials rely largely on having robust and diverse patient participation and that participation depends, in part, on whether people can afford the out-of-pocket costs during their trial. However, some of the barriers preventing people from participating in clinical trials include out-of-pocket costs such as transportation, lodging and other expenses that are not covered by the cancer clinical trial site or sponsor. Two recent national studies found that patient households making less than $50,000 a year were about 30 percent less likely to participate in clinical trials, and limiting income disparities is important for ensuring enrollment and equitable access to trials.

Concurrently, some corporations, individuals, public and private foundations, health care providers, and other stakeholders are hesitant to contribute to, or accept funds from, programs that are organized to alleviate financial burdens faced by patients who wish to participate in clinical trials. This is in spite of the fact that the FDA issued guidance in 2018 that explicitly clarified that reimbursing patients for participation in a cancer trial is not considered coercion or undue inducement.

In order to address economic barriers that hinder trial access, encourage enrollment and retention of a more diverse participant trial pool and increase awareness of available expense reimbursement resources this legislation will:

- Specify that government, industry, public charities, private foundations, nonprofit organizations, associations, corporations, business entities, individuals and other legal or commercial entities may offer financial support to patient-subjects, or the family, friends,

or chaperones of patient-subjects to cover ancillary costs through their support of a reimbursement entity or program.

- Require reimbursement entities or programs disclose the nature of the ancillary support and general guidelines on financial eligibility to patient-subjects and employ a reimbursement process that conforms to federal law and guidance.

- Require sponsors of cancer clinical trials to provide language that must be submitted for review to the relevant federally designated institutional review board ("IRB") in conjunction with the review of the proposed clinical trial and included on the informed consent form approved by the IRB and that informs patient-subjects that reimbursement entities or programs that cover out-of-pocket expenses may be available.

- Define and establish a clear difference between what is considered to be inducement (paying a person money including a lump sum or salary payment) for a person to participate in a cancer clinical trial and the reimbursement of expenses for participating in a clinical trial. Under the bill, providing reimbursement to patients is not considered undue inducement or coercive to participate in a cancer clinical trial. Instead, reimbursement of out-of-pocket expenses is meant to accomplish parity in access to cancer clinical trials and to remove economic barriers to participation in cancer clinical trials for financially burdened subjects.

According to the National Cancer Institute, in 2018, an estimated 1,735,350 new cases of cancer will be diagnosed in the United States and 609,640 people will die from the disease. According to the Wisconsin Cancer Council, cancer is one of the leading causes of death in Wisconsin, and more than 80 people are diagnosed with cancer in our state each day. In recent years on average, approximately 11,420 Wisconsinites die from cancer each year. Given the statistics, it is hard to find anyone who has not been touched in some way by cancer, and cancer clinical trials provide the best evidence for showing the effectiveness of potential new life sustaining treatments.

This legislation is supported by the American Cancer Society Cancer Action Network, Marshfield Clinic Health System, the Medical College of Wisconsin and the UW School of Medicine and Public Health.

Thank you for your attention to this legislation. I respectfully ask for your support of SB 489.

BOB KULP

STATE REPRESENTATIVE • 69TH ASSEMBLY DISTRICT

TO: Senate Committee on Health & Human Services

FROM: Representative Bob Kulp

RE: Support For Senate Bill 489 / Cancer Clinical Trials

DATE: November 20, 2019

Thank you Chair Testin, Vice-Chair Kooyenga and fellow committee members for holding a public hearing on Senate Bill 489 ("SB 489"). I appreciate having the opportunity to register my support for SB 489 which allows for the reimbursement of certain expenses for patients participating in cancer clinical trials.

According to the Wisconsin Cancer Council, cancer is a leading cause of death in Wisconsin with approximately 11,420 patients dying from cancer annually. In addition, the American Cancer Society estimates that approximately 34,220 Wisconsinites will develop cancer in 2019. Given these statistics, cancer clinical trials remain critical to the advancement of new potentially life-sustaining cancer treatments.

Unfortunately, there are people who have been diagnosed with cancer that have had to make a decision about participating in a cancer clinical trial that could potentially increase their chance of living longer. Today, many people are traveling longer distances in order to reach treatment facilities to participate in cancer trials, and this travel can be especially challenging for residents living in remote areas of the state. In addition, expenses that aren't covered by the cancer clinical trial site or sponsor can be significant and can include airfare, parking fees and lodging during treatment.

The National Cancer Institute has confirmed that out-of-pocket expenses associated with cancer clinical trial participation can add up quickly and create a financial barrier that can discourage participation. In addition, recent national studies have found that patient households making less than $50,000 annually were about 30% less likely to participate in clinical trials. These financial barriers undermine equitable access and can result in low patient participation and a lack of diversity in clinical trials which may threaten the advancement of cancer clinical research.

In addition, some organizations and other stakeholders are hesitant to contribute to, or accept funds from, programs that aim to alleviate financial burdens faced by patients who wish to participate in clinical trials, due to concerns that federal regulators would view the payments made from those funds as prohibited inducements for patients to receive the health care services provided during clinical trials. This is in spite of the fact that the US FDA issued guidance in 2018 that explicitly clarified that reimbursing patients for participation in a cancer trial is not considered coercion or undue inducement. In short, the much needed FDA guidance confirmed it is appropriate for people not to have to pay out-of-pocket expenses to participate in clinical research trials.

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SB 489 is complimentary to the US FDA's 2018 guidance for Institutional Review Boards and Clinical Investigators. The bill is designed to improve access to and retention in clinical trials for those battling cancer by clarifying what are considered "undue inducements" (paying a person money including a lump sum or salary payment) for patients to participate in cancer clinical trial and the "reimbursement" of out-of-pocket expenses for participating in a clinical trial. SB 489 makes it clear that such funds are reimbursements to assist patients with the out-of pocket expenses associated with clinical trials rather than payments to encourage their participation. The bill will ensure that reimbursement to participants will not be considered coercive, or an inducement to participate, under Wisconsin law. I am confident SB 489 will help more patients to access the available funds and resources needed to participate in potentially life-sustaining clinical trials, and advance groundbreaking cancer research by broadening the scope of participation in such trails.

Thank you Senator Kooyenga for your assistance with this legislation and for your continued advocacy on behalf of cancer patients. SB 489 is supported by the American Cancer Society Cancer Action Network, Marshfield Clinic Health System, the Medical College of Wisconsin, the UW School of Medicine and Public Health, the Wisconsin Medical Society and the Wisconsin Nurses Association. I respectfully ask committee members to join me in supporting SB 489. Thank you again for scheduling the public hearing today, and thank you for your time and consideration.

UW Health
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UNIVERSITY OF WISCONSIN-MADISON

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Senate Committee on Health and Human Services
Wednesday, November 20, 2019
Testimony provided by Howard Bailey, MD
Re: Support for Senate Bill 489

Good morning Chairperson Testin and members of the committee. My name is Dr. Howard Bailey and I am a practicing cancer physician and researcher and have the honor to be the Director of the University of Wisconsin Carbone Cancer Center. Thank you for the opportunity to speak to you about my support for Senate Bill 489 related to reimbursement for some out-of-pocket expenses for patients participating in cancer clinical trials.

As one of the first in the country and the only National Cancer Institute-designated comprehensive cancer center in Wisconsin, we and all the hard-working cancer providers throughout the State know, cancer is a problem in all of our communities. While there have been great advances in cancer care leading to more people being cured there are still far too many of our family and friends dying of cancer. The only way to substantially change this is through research.

One of the Carbone Cancer Center's greatest strengths is rapidly applying cancer research discovery to our patients in groundbreaking clinical trials starting in the 1960's and 70's with the invention of one of the most commonly used anti-cancer drugs in the world (5FU) or the world's first successful bone marrow transplant. Currently, more than 250 clinical trials are available for patient enrollment at the Carbone Cancer Center and at community hospitals and regional cancer centers throughout the State both those affiliated and not affiliated with the Carbone Cancer Center. Given our focus on identifying new ways to treat and prevent cancer, I was pleased to see Sen. Kooyenga and Rep. Kulp introduce legislation that I believe may enhance our ability to improve everyone's access to innovative cancer treatments related to

clinical trials. Specifically, the bill before you may open the door to patients who face a hardship covering the costs that are often associated with participating in cancer clinical trials like airfare, gas and hotel stays. I understand the bill to allow for reimbursement to patients and in some cases family, friends or chaperones for out-of-pocket expenses like these without fear of allegations of coercion or undue inducement. This is an important factor in identifying research participants who struggle to travel great distances and accrue added expense which can in turn, limit the geographic and ethnic make-up of a cohort. Our goal in research in most instances is to assemble a robust and diverse pool of participants for each study so the results can be applied to as many patients as possible. This bill supports that goal. Of note, currently in our country, less than 5% of cancer patients participate in cancer clinical trials often times for reasons this bill would help correct.

I also endorse Senate Bill 489 because it would align Wisconsin law with guidance issued by the Food and Drug Administration in 2018 that clarified reimbursing patients who participate in cancer clinical trials is not coercion or undue inducement. This clarification in state law would help to alleviate any lingering concerns about defining coercion within the research community while at the same time, it would benefit patients.

For these reasons, I hope you see fit to join me in supporting Senate Bill 489. Thank you for your consideration and I would be happy to entertain questions at this time.

November 20, 2019

Good morning Chairman Testin, and members of the Senate Committee on Health and Human Services, my name is Sara Sahli. I am the Director of Government Relations for the American Cancer Society Cancer Action Network (ACS CAN) in Wisconsin. I am here today to express ACS CAN's thanks to Senator Kooyenga and Representative Kulp for their support of access to clinical trials and for recognizing the patient enrollment barriers which currently exist here in Wisconsin as well as nationwide.

ACS CAN pursues evidence-based policies at the local, state and federal levels that aim to reduce disparities and improve health outcomes for all individuals.

The objective of cancer research is to generate new knowledge that can be used to improve survival and quality of life for patients with cancer. Clinical trials are a critical part of cancer research. They allow researchers to test and study new treatments with the goal of improving cancer care. For a clinical trial to be successful, the trials need patients to participate.

In 2018, the American Cancer Society Cancer Action Network released a report entitled Overcoming Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer. This report identifies enrollment barriers and proposes ways they can be overcome. The report found only about one in four (27%) patients has access to clinical trials where they are being treated. Yet, if asked to enroll in an available trial, more than half of eligible patients typically agree to do so

Clinical trials are an essential step toward advancing promising new cancer treatments and while most patients are willing to take part, many trials struggle to find enough participants to successfully complete their research. Nearly 20% of cancer clinical trials fail due to insufficient patient enrollment, meaning potentially promising science is being delayed or deferred due to access barriers. Trial sponsors, institutions, patients and researchers need to work together to make sure trials are designed with patients in mind, meeting patients where they are, and that patients have all the information and resources they need to participate if they are interested.

Of the patients who actively decline participation, the main factors cited include, fear of side effects, loss of control in their treatment, logistical issues for participation and cost concerns.

The indirect costs of trial participation, such as travel, time off work, or day care needs, can be prohibitive, especially to lower-income individuals. ACS CAN supports Senate Bill 489 because it will address one of the many barriers by ensuring that reimbursement of these types of expenses will not be considered coercive, or an inducement to participate.

We urge you to vote yes on Senate Bill 489 and hope to continue this conversation with the goal of making sure that patients interested in clinical trials don't have anything standing the way of their taking part.

Thank you.

MEDICAL COLLEGE OF WISCONSIN

TO: Honorable Members of the Senate Committee on Health and Human Services

FROM: James Thomas, MD, PhD
Interim Co-Director, MCW Cancer Center
Medical Director, Cancer Clinical Trials Office
Associate Director, Translational Research
Medical College of Wisconsin

DATE: November 20, 2019

RE: Support for Senate Bill 489, Relating to: Allowing Reimbursement of Certain Expenses for Patients Participating in Cancer Clinical Trials

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The Medical College of Wisconsin (MCW) strongly supports Senate Bill 489 (SB 489), legislation which will help Wisconsin continue to lead the way in cancer research, clarifying that state law is not a barrier to enrolling participants into cancer clinical trials and providing financial reimbursement for any costs that may be incurred, such as expenses related to travel, lodging, or other associated costs.

Cancer is the leading cause of death in Wisconsin, and the American Cancer Society estimates that 34,220 Wisconsin residents will develop cancer in 2019, and nearly 12,000 residents will die from it this year. Receiving a cancer diagnosis is truly frightening, it can be economically crippling and creates fear and uncertainty. Cancer touches literally every family, and, for many, is devastating.

MCW has a deep commitment to fighting cancer. As the only academic health system in eastern Wisconsin, MCW is humbled each day by the opportunity to transform the lives of kids and adults diagnosed with cancer through research and the clinical trials developed to target cancer.

MCW's Cancer Center primarily serves a 24-county area representing over 3.4 million Wisconsin residents from the eastern Wisconsin/ Illinois boarder to Upper Michigan. However, we have patients from every part of the state. MCW offers more cancer clinical trials in the state than another other institution and many patients must travel significant distances in order to participate. This legislation will ensure that travel reimbursement for these participants will not considered coercive, or an inducement to participate, under Wisconsin law.

Cancer clinical trials are the most promising treatments available, they are tomorrow's standard of care, offered today. For example, in 2017, MCW-developed novel CAR-T cell clinical trial therapy which trains a patient's own immune cells to fight, kill lymphoma and continue fighting cancer cells. The very first participant in the trial had exhausted every other standard of care treatment, including chemotherapy, stem cell transplantation, and radiation and was told there was nothing else that could be done for him. He was told in October of 2017 that he probably had two months to live. He learned of the clinical trial offered at MCW in Milwaukee and traveled from Appleton to participate, and by Christmas, was completely cancer free and remains so today! Thus far, every participant within this promising new trial has gone into complete remission from their cancer. Every patient should have this chance at life and travel expenses should not be a barrier!

Curing cancer is MCW's top strategic research priority. Cancer research offers hope to our patients and their families and results in the development of ground breaking treatments, like the CART T Cell therapy . In fact, with the passage of the state budget and your support, the State of Wisconsin is

providing MCW with a $10 million State Building Commission grant to construct a new, state-of-the-art cancer research facility in southeast Wisconsin. This exciting endeavor will allow us to recruit many more world-class researchers to expand MCW's cancer research to speed in the development of treatments for our Wisconsin residents.

MCW is also working toward a National Cancer Institute (NCI) designation through the National Institutes of Health (NIH). MCW is likely to make its formal application for this highly competitive designation in the near future. Obtaining this designation would create many new opportunities for cutting-edge cancer clinical trials benefitting cancer victims across Wisconsin.

With that context in mind, MCW respectfully requests your support for SB 489. This bill is complimentary to the U.S. Food and Drug Administration's (FDA) 2018 guidance for Institutional Review Boards and Clinical Investigators entitled, "Payment and Reimbursement to Research Subjects." In short, this guidance states that the FDA does not consider reimbursement for travel expenses, along with associated costs, to raise issues regarding undue influence.

Ensuring that Wisconsin law effectively mirrors FDA guidance will ensure there are no barriers, from a state law perspective, from providing cancer clinical trial participants and their families with appropriate financial reimbursements. Many individuals and their caretakers struggle with the costs of traveling to participate in these trials, and when funding is available, MCW seeks to help ease this burden for participants.

Thank you for your time and consideration. Please feel free to contact Nathan Berken, MCW's Director of Government Relations, at 414.955.8588, or nberken@mcw.edu if you have any questions or would like additional information.