BOB KULP

STATE REPRESENTATIVE • 69TH ASSEMBLY DISTRICT

TO: Assembly Committee on Health

FROM: Representative Bob Kulp

RE: Support For Assembly Bill 542 / Cancer Clinical Trials

DATE: January 7, 2020

Thank you Chair Sanfelippo, Vice-Chair Kurtz and fellow committee members for holding a public hearing on Assembly Bill 542 ("AB 542"). I appreciate having the opportunity to express my support for AB 542 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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AB 542 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. AB 542 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 AB 542 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.

AB 542 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 AB 542. Thank you again for scheduling the public hearing today, and thank you for your time and consideration.

CINDI DUCHOW

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Committee on Health
Public Hearing, AB 542
January 7, 2020

A sincere thank you to Chairman Sanfelippo for holding a public hearing, as well as to the members of the Committee for being here to listen to the testimony on AB 542, relating to allowing reimbursement of certain expenses for patients participating in cancer clinical trials.

It is an unfortunate thing to say, but almost every person in this room has been impacted by cancer in some way. Whether it has been a personal diagnosis or the diagnosis of a loved one, cancer is one of the greatest evils in this world. For me, it is a topic I am passionate about and why I am advocating here today as the second author on this bill.

Unfortunately, for many families, the story of the fight against cancer does not have a happy ending. According to the Wisconsin Cancer Council, cancer is one of the leading causes of death in Wisconsin. While we have come a long way with different success in trials, we still have a long way to go, as evidenced by the staggering number of deaths – 11,420 a year in Wisconsin alone. AB 542 has the potential to improve the numbers and change lives.

Currently for some families, due to economic barriers, they have to decline a cancer clinical trial that could save their loved one. I can only imagine how heartbreaking it would be to have to decline a cancer trial that has already had success stories. While the trials themselves are paid for, personal expenses such as travel and lodging are not. These personal costs are ultimately hindering trial access to those who simply cannot afford it. This is all because of a false belief that programs that aim to alleviate these personal costs would be viewed by the federal government as prohibited inducements to participate in the clinical trials.

This false belief is simply that – false. The Food and Drug Administration (FDA) has issued specific guidance regarding this idea. Specifically, the FDA stated that it does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. Even with the statement that addressed the concerns, charities and stakeholders still remain hesitant to contribute.

As such, this legislation is necessary to clarify that reimbursement for these expenses are absolutely legal. It is my hope that the Committee support AB 542 to create equitable access to trials, encourage enrollment and retention in trials of more diverse participants, and increase awareness that reimbursement for expenses is available.

Thank you again for the opportunity to testify.

Representative Cindi Duchow

DALE KOOYENGA
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January 7, 2020

TO: Assembly Committee on Health
FR: Senator Dale Kooyenga
RE: support for Assembly Bill 542 – 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. Assembly Bill 542 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 small fractions 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 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 AB 542.

MEDICAL COLLEGE OF WISCONSIN

TO: Honorable Members of the Assembly Committee on Health

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: January 7, 2020

RE: Support for Assembly Bill 542, 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 Assembly Bill 542 (AB 542), 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 AB 542. 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.

UW Health

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Public Hearing of the Assembly Committee on Health
Tuesday, January 7, 2019
Testimony provided by Nataliya Uboha, MD, PhD
Re: Support for Assembly Bill 542

Good morning Chairperson Sanfelippo and members of the committee. My name is Dr. Nataliya Uboha and I am a board certified physician in Internal Medicine and Medical Oncology. I am an Assistant Professor at the University of Wisconsin Carbone Cancer Center. I am also a co-director of Wisconsin Oncology Network, which is a regional network of cancer clinics that aligns community and academic health centers to bring novel cancer treatments to patients in the community. Thank you for the opportunity to speak about my support for Assembly Bill 542 related to reimbursement for some patient-incurred expenses relevant to participation in a cancer clinical trial.

As a practicing oncologist and clinical researcher at UW Carbone Cancer Center, I am proud of the work we do to serve patients. Our cancer center is the only National Cancer Institute-designated comprehensive cancer center in Wisconsin. We see more than 30,000 cancer patients for diagnosis, therapy, and follow-up care annually at UW Carbone Cancer Center and our partner clinical locations regionally. One of the Carbone Cancer Center's greatest strengths is its involvement in groundbreaking clinical trials. In 1979, we were among a handful of centers conducting Phase I clinical trials, which are the first step in evaluating novel treatments. Currently, more than 250 clinical trials are available for patient enrollment at the Cancer Center or at community hospitals and regional cancer centers affiliated with the Carbone Cancer Center. The impact of this clinical research at UW is profound. It changes lives. Patients travel from all over the state, as well as neighboring states to get access to state-of-the art treatments that we are able to

offer through our research program. I personally have treated patients who have commuted from Northern Wisconsin, Iowa, Illinois, and even Colorado, to name a few, to get access to cutting-edge research available at UW.

I was delighted to learn about Representative Kulp and Senator Kooyenga's introduction of Assembly Bill 542 and Senate Bill 489, respectively. Specifically, the legislation before you will allow patients to get reimbursed for the costs that are often associated with participating in cancer clinical trials, such as travel expenses, hotel stays and meals. Under this bill, this type of financial assistance will not be considered coercive or as one exerting undue influence to participate in clinical trials.

Financial assistance is often essential to patients and their support network who struggle to cover the cost of traveling great distances and/or missing work to receive treatments. These financial constraints can limit study size as well as the geographic, socioeconomic and ethnic make-up of the research population. The proposed bill will remove significant barriers to clinical trial participation and will help us to enroll a larger and more diverse pool of participants for each study. Ultimately, our goal is to bring improved cutting-edge treatments to the public as safely and quickly as possible, and this bill will help us achieve that goal.

I also endorse Assembly Bill 542 because it aligns Wisconsin law with guidance issued by the Food and Drug Administration in 2018, which clarified that reimbursing patients who participate in cancer clinical trials is not coercion or undue inducement. The clarification in state law will alleviate any lingering concerns about financial support and coercion within the research community, while at the same time benefitting patients.

For all these reasons, I hope you see fit to join me in supporting Assembly Bill 542. Thank you for your consideration, and I would be happy to answer any questions at this time.

January 7, 2020

Good morning Chairman Sanfelippo and members of the Assembly Committee on Health, 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 Representative Kulp and Senator Kooyenga 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. And, if asked to enroll in an available trial, only 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 Assembly Bill 542 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.

Sara Sahli
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Date: January 7, 2020

Subject: WI Assembly Committee on Health Testimony re: AB 542

Submitted By: Paul Westrick - Cancer Patient & Volunteer Advocate

My name is Paul Westrick and I currently reside in Middleton, Wisconsin.

Thanks for the opportunity to offer some perspectives on the proposed cancer clinical trials patient expense reimbursement legislation.

I've had experience doing this at both state and federal policy levels as an active volunteer with the American Cancer Society and the Leukemia & Lymphoma Society.

It is a humbling honor to be a voice representing the many cancer patients and survivors in Wisconsin. But I do need to qualify my comments as I am atypical of most patients – in general and concerning those who would benefit most from this bill.

I am fortunate to have both the time and resources that many more busy, vulnerable people lack. As a retired empty nester and relatively healthy guy for my age, I have time, knowledge and financial resources that are not available for most patients and caregivers who have the added responsibilities of work and family.

I am also atypical as a cancer patient. I was diagnosed with an incurable blood cancer (multiple myeloma) with a 3-year median survival at the time. That was 22 years ago.

So I am here literally because of treatments produced by research and development; and people who participated in clinical trials before me. I've been around long enough to have experienced 4 distinct generations of therapies since 1997, and have been able to contribute to advances myself as a participant in six clinical trials. Ironically, these have been evenly split between UW Health and the Medical College of Wisconsin/Froedtert Health.

In fact today, I am about one-quarter through a Phase 2 trial that was initiated at the UW Carbone Cancer Center. In partnership with Cellectar Biosciences, a spin off company with local ties, this trial has recently been opened at another nine prestigious cancer centers in other parts of the country. I received great news last week on the first check in on progress and the markers used to track my level of cancer have already decreased by 75%.

Related to the benefits of the proposed legislation – this treatment protocol is relatively straightforward and requires the possibility of two overnight stays and weekly visits to an outpatient center over a 12-week period. Other Phase 3 trials I have completed were more demanding and involved one to two outpatient infusions weekly over 12-18 months. Although the trends in treatment settings have fortunately shifted dramatically towards outpatient centers, this exacerbates the cost problems addressed by AB 542.

Again, I am fortunate to live only 15 minutes from UW Hospital. But think of most people served by our multi-state regional systems like UW Health and the Medical College of Wisconsin/Froedtert Health – and all of the health systems in Wisconsin.

When patients are struggling with the unexpected news of a cancer diagnosis and then the added stress of making on the spot treatment decisions, the last thing they need is another practical barrier such as the unknown costs of travel, lodging and other logistics expenses for them and their caregivers.

The provisions of this bill would align at these moments the treatment and clinical trials opportunities with financial support information available through the health care provider and other supportive funding organizations.

We are in an unprecedented time of rapid progress in the war on cancer and other life-threatening illnesses. Yet as noted previously, only a fraction of eligible patients are now participating in the scientific process of evaluating the efficacy of emerging, less toxic and more targeted therapies.

On behalf of the thousands of Wisconsin patients and caregivers who would clearly benefit, I obviously and strongly encourage the support of this legislation by you today and by your colleagues further into the session.

Thank you and I'd be happy to take any questions.