DUEY STROEBEL

STATE SENATOR • 20TH DISTRICT

Testimony on SB 1014/AB 1060

March 1, 2022

Thank you Chairman Nass and members of the Senate Committee on Labor and Regulatory Reform for holding a public hearing on Senate Bill 1014/Assembly Bill 1060, a proposal I authored with Representative Gundrum to address an issue that was brought to our attention by a contract research organization (CRO) located in our respective legislative districts.

To provide a bit of context, CROs conduct clinical trials in human volunteers through a contractual agreement with a client firm (e.g., a biotech or pharmaceutical company sponsoring a clinical research trial). The contract between the CRO and the client firm explicitly prohibits the CRO from enrolling employees in clinical trials in order to avoid potential conflicts of interest and the possibility of introducing bias in a controlled trial. Thus, in carrying out clinical trials, CROs recruit healthy adults to participate in early stage research and adults with particular co-morbidities to participate in late stage research. The clinical trials are short-term in nature, with an average length of 3-6 months. The average length of stay at the facility for the clinical trial participants is between 3-4 days, and participants may receive remuneration, a stipend, or some form of compensation from the CRO during the trial.

The individuals recruited for a clinical research trial are independent contractors, not employees of the entity that is conducting the trial. SB 1014/AB 1060 seeks to clarify this distinction in Wisconsin's minimum wage, worker's compensation and unemployment insurance statutes.

Earlier this year, it was brought to our attention that Spaulding Clinical, a CRO located in West Bend, was subjected to a Department of Workforce Development (DWD) audit and informed that they owed certain assessments to the state. It is believed that the audit resulted from an individual who had participated in one of Spaulding's clinical research trials submitting a claim for unemployment insurance after the trial had concluded.

As Wisconsin becomes a growing destination for the biotech industry, it is important that we ensure CROs will not be put at a competitive disadvantage with their counterparts in neighboring states with regard to the classification of participants in clinical research trials. While we appreciate the sacrifices made by individuals who step forward to participate in these trials, there is a mutual understanding between the trial sponsor, the CRO and trial participants that the arrangement is temporary in nature and does not constitute covered employment for the purposes of Wisconsin's minimum wage, worker's compensation and unemployment insurance laws.

Thank you again for your consideration of SB 1014/AB 1060. I hope you will join Representative Gundrum and me in supporting this legislation.

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RICK GUNDRUM
STATE REPRESENTATIVE • 58TH ASSEMBLY DISTRICT

Testimony on Senate Bill 1014

Senate Committee on Labor and Regulatory Reform| March 1, 2022 | Room 411S

Chairman Nass, and other honorable Members of the Senate Committee on Labor and Regulatory reform, thank you for the opportunity to testify on Senate Bill 1014 today. I am pleased to have authored this legislation with Senator Duey Stroebel to clarify that an individual who receives a stipend, remuneration, or compensation for participating in a clinical research trial is not considered an employee of the business who is conducting the trial.

Healthcare institutions, academic institutions, and private contract research organizations conduct clinical trials in human volunteers. In early stage research, these organizations recruit normal, healthy individuals to participate in the trials. In the later stage research, these groups recruit individuals with a specific condition or disease to participate in those studies in order to test the efficacy of the new product.

Spaulding Clinical, based in West Bend, is a private, contract research organization who, among other services, conducts early stage research trials for pharmaceutical or biotech sponsors/clients. Their typical volunteers/patients are younger individuals, usually anywhere from college-aged to 40 years old. Most of their studies require an overnight stay and the average stay is 3-4 nights.

I was made aware of the issue of the classification of clinical research trial participants (participants) recently and was surprised to learn that the Wisconsin Department of Workforce Development believes participants in clinical research trials are employees and not independent contractors.

I could not imagine a scenario in which someone who, in my readings of this issue, is clearly an independent contractor would receive unemployment insurance based on their participation of the study. We need to ensure that this misunderstanding does not happen again by clearly codifying what clinical research trial participants are with respect to the minimum wage law, workers compensation law, and unemployment insurance law and Senate Bill 1014 does just that.

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The requirements of the agreement with clients (the biotech and pharmaceutical companies) prohibit contract research organizations, such as Spaulding, from using employees for clinical trials due to the conflict of interest it would create. By allowing participants to be classified as employees, it puts clinical research organizations in Wisconsin at a disadvantage with similar entities outside of Wisconsin's borders. This is especially noteworthy given that Madison has recently become a preferred destination for the biotech industry.

Participants should not be able to seek compensation through Wisconsin's unemployment insurance fund because the trials are temporary, and the individuals are aware of that before they begin. Once the trials are completed, the participants depart. If individuals who request to participate in the trial are not accepted, it is due to not meeting requirements. Both of these scenarios do not allow any opportunity to collect money for Unemployment Insurance.

All of Wisconsin's 33 State Senators share a common goal, which is to see Wisconsin at its very best. Every one of you, I believe, would like to see business investments in America's Dairyland from new businesses. Wisconsin is quickly becoming home to an increasingly expanding biotech sector, and I want ensure that we continue to receive investment in that sector. Assuring Wisconsinites have the opportunity to continue participating in life changing medical advancements is important to me. I thank you, again, for the opportunity to testify on Senate Bill 1014 today.

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DWD
Department of Workforce Development

Tony Evers, Governor
Amy Pechacek, Secretary-designee

Date: Tuesday, March 1, 2022

To: Chair Nass, Vice-Chair Wanggaard, and Members of the Senate Committee on Labor and Regulatory Reform

From: Department of Workforce Development Secretary-designee Amy Pechacek

Written Testimony Regarding SB 1014 and AB 1060

Chair Nass, Vice-Chair Wanggaard, and Committee Members, thank you for the opportunity to provide written testimony for information only on Senate Bill 1014 and Assembly Bill 1060, regarding the non-employment status of participants in clinical research trials as it relates to minimum wage, unemployment insurance (UI), and worker's compensation (WC) laws.

As you may know, the Department of Workforce Development (DWD) relies on and defers to the Unemployment Insurance Advisory Council (UIAC) and Worker's Compensation Advisory Council (WCAC) to provide feedback on any legislation that affects eligibility and recipiency of unemployment insurance or worker's compensation benefits. In these councils, typically, any legislative changes to UI or WC programs are proposed through an "agreed-upon" bill process where council members who represent labor and management reach consensus on supporting statutory changes to their respective programs. In addition, DWD leadership defers to the UIAC and WCAC regarding support of or opposition to proposed legislation that have an impact on UI or WC laws or program administration. It should be noted that SB 1014/AB 1060 were not presented to the councils by the bills' authors or co-sponsors, so neither council has had the opportunity to formulate their support or opposition of the bills, nor provide feedback on improvements they would suggest regarding the effects of the bills.

Despite not having input from the UIAC or WCAC regarding SB 1014/AB 1060, DWD would like to raise a few issues for the authors' and committee's consideration. SB 1014/AB 1060 creates language in the worker's compensation and minimum wage statutes providing that those individuals who participate in clinical research trials and receive remuneration, stipends, or compensation for that participation, are not employees of the entities conducing the trials. The WC program interprets this as creating an exception to the nine-part test for determining employees/independent contractors for purposes of worker's compensation in Wis. Stats. s. 102.07(8)(a), which may erode the employee status test. Further, the current employee status test does not have industry-specific exceptions for individual criteria of the test. SB 1014/AB 1060 proposes a new approach to the employee status test and may result in other industries asking to have carveouts that could result in less coverage of fewer workers qualifying for WC benefits, UI benefits, and coverage by equal rights laws.

It is important to note that employees are entitled to benefits as defined in the Worker's Compensation Act of Wisconsin as their exclusive remedy. If SB 1014/AB 1060 were enacted, and such research participants are specifically excluded from the definition of employee for WC purposes, they will not be entitled to the no-fault, but limited, WC benefits. Because of the exclusion, these participants would no longer be limited to remedies under the WC Act, so they may instead seek redress in tort. Tort remedies can include compensation such as for pain and suffering, which would not be compensable under the WC Act.

SB 1014/AB 1060 creates language in the UI statutes, stating that clinical research trial participation is not considered covered employment. Entities conducting clinical research trials would not be subject to UI contribution requirements. Remunerations, stipends, or compensation paid would not be counted as base period wages for the purpose of determining UI benefits, which would potentially reduce an individual's UI benefit amount. In addition, claimants would still be required to report clinical trial earnings on their weekly claims, which would further reduce the claimant's weekly benefit amount.

Under current law, employers likely have clinical research subjects reported to UI as employees or were identified and found to be taxable employees. As a consequence of SB 1014/AB 1060 providing that participation in clinical research trials is not considered covered employment under UI law, amounts paid by employers for those services would not be subject to UI tax contribution requirements. This would have an impact on the UI trust fund. If enacted, DWD estimates that the changes under the bills would decrease the UI trust fund $2.8 million annually due to a reduction in UI tax contributions. And, since there is no corresponding exclusion for clinical research participants under Federal Unemployment law (FUTA), federal tax will likely still be owed by the employers.

Lastly, it is important to note that the bills, as drafted, would also apply to non-profit employers, and businesses that employ the clinical trial participants may be non-profits. FUTA requires state law to cover the services performed for employees of non-profits unless federal law specifically excludes the services under 26 USC §§ 304(a)(6)(A) and 3309(a)(1). DWD is not aware of a FUTA exclusion for participants in clinical trials, so excluding such services for non-profits may cause Wisconsin's law to fail to conform to federal requirements. Non-conformity with federal law could put UI administrative grant dollars and employer FUTA tax credits at risk. In a typical year, UI administrative grant funding is approximately $55 million. The Department strongly suggests that U.S. Department of Labor review the bill before it passes the legislature to ensure that the bill conforms to federal requirements.

Thank you for the opportunity to provide this information.