DUEY STROEBEL
STATE SENATOR • 20TH DISTRICT

Testimony on AB 398

January 10, 2024

Thank you Chairman Moses and committee members for holding a public hearing on Assembly Bill 398, 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 on 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.

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 typically short-term in nature, 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 not employees of the entity that is conducting the trial. AB 398 seeks to clarify this distinction in Wisconsin's minimum wage, worker's compensation and unemployment insurance statutes.

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 AB 398.

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RICK GUNDRUM
STATE REPRESENTATIVE • 58TH ASSEMBLY DISTRICT

Testimony on Assembly Bill 398

Assembly Committee on Health, Aging & Long-Term Care | January 10, 2024 | Room 417N

Chair Moses, Vice-Chair Rozar, and other honorable members of the Assembly Committee on Health, Aging & Long-Term Care, thank you for the opportunity to testify on Assembly Bill 398 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.

When I was made aware of the issue of the classification of clinical research trial participants, I 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 Assembly Bill 398 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 from Unemployment Insurance.

All of Wisconsin's 99 state representatives 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 Assembly Bill 398 today.

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DWD
Department of Workforce Development

Tony Evers, Governor
Amy Pechacek, Secretary

Date: Wednesday, Jan. 10, 2024

To: Chair Moses, Vice Chair Rozar, and Members of the Assembly Committee on Health, Aging and Long-Term Care

From: Department of Workforce Development Secretary Amy Pechacek

Written Testimony Regarding AB 398

Chair Moses, Vice Chair Rozar, and committee members, thank you for the opportunity to provide written testimony for information only on AB 398, which creates language in the worker's compensation (WC), minimum wage, and unemployment insurance (UI) statutes to exempt individuals who participate in clinical research trials and receive remuneration, stipends, or compensation for that participation, from being considered employees.

Wisconsin's thriving economy rests on a long tradition of collaboration among employers, workers, government and educational institutions. Most recently, that collaboration has contributed to a string of historic successes, with a new record low unemployment rate of 2.4% and a new record high of 3,020,300 nonfarm jobs. Other milestones demonstrating the success of shared efforts to strengthen Wisconsin's workforce include a record high of 16,384 Registered Apprentices and a record high of 8,357 Youth Apprentices enrolled during the 2022-23 school year, with both programs also seeing record employer participation. Meanwhile, Gov. Evers' groundbreaking efforts to remove barriers to employment and address the worker quantity challenge have supported a growing labor force.

Other factors contributing to Wisconsin's economic vitality include foundational legal principles that respect and protect both workers and employers. An early example of Wisconsin's effective leadership in this regard dates to 1911, when Wisconsin passed the nation's first valid Worker's Compensation Act. Through this "grand bargain" between workers and employers, workers forfeited the right to pursue civil action against employers for injuries sustained on the job in exchange for access to compensation through employer-funded insurance. Thanks to these long-established principles, employers today can focus on running successful businesses and preventing workplace injuries while workers can focus on their jobs, knowing they're protected. If an injury does occur, workers can obtain care regardless of fault to return to work.

Proper worker classification represents another fundamental principle of an economy that works for everyone, ensuring that employees receive the rights and protections they have earned. Employers who misclassify workers as independent contractors gain an unfair competitive advantage over employers who play by the rules. To properly classify workers as either employees or independent contractors at the state level, employers routinely apply a series of tests related to the control workers have over their place of work, their schedules, their history of filing business or self-employment tax returns, and other tests.

Again, to maintain an even playing field, these tests are applied with consistency, across industries and occupations. It is also important to note that there is no explicit exclusion for clinical trial participants from the classification as employees under federal law.

To sustain Wisconsin's thriving economy, the department welcomes opportunities to collaborate on legislation that advances Wisconsin workers, employers, and job seekers. However, DWD has significant concerns regarding AB 398. Among the issues, as further described below:

- The proposal creates an exclusion from the definition of employee for a single industry, with negative implications for employees and employers. Specifically:
    - By reclassifying participants in clinical trials from their current status as employees, the proposal would exclude these workers from minimum wage, Worker's Compensation, and Unemployment Insurance benefits and protections.
    - The exclusion would diminish the grand bargain under the Worker's Compensation program.
    - In the Unemployment Insurance program, the proposal could result in estimated higher costs for businesses as a result of losing federal tax credits if the proposal does not conform to federal law.
- The proposal was crafted outside of established stakeholder engagement channels and the agreed-bill process with DWD's advisory councils.
- The proposal also carries negative state fiscal impacts.

This bill proposes a new approach to the employee status tests and may result in other industries seeking carveouts that could further result in reduced coverage or fewer workers qualifying for WC benefits, as well as the protections afforded under wage and hour laws.

In the Worker's Compensation program, the proposed exclusion of clinical research trial participants as employees creates an exception to the nine-part test for determining whether workers are employees or independent contractors for purposes of worker's compensation in Wis. Stats. s. 102.07(8)(a). Employees are entitled to benefits defined in the Worker's Compensation Act of Wisconsin as their exclusive remedy. As clinical research trial participants would be specifically excluded from the definition of employees for WC purposes under this bill, they would not be entitled to the no-fault, but limited, WC benefits, making it more difficult for injured employees to be entitled to a remedy and adding uncertainty to excluded employers as to the extent of remedies that may fall under tort law (e.g., pain and suffering compensation).

Further, the proposal impacts taxpayers under the Unemployment Insurance program. As described in DWD's previous fiscal estimate and testimony on 2021 AB-1060, the Federal Unemployment Tax Act (FUTA) requires state law to cover the services performed for employees of nonprofits 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 nonprofits may cause Wisconsin's law to fail to conform to federal requirements. Nonconformity with federal law could put UI administrative grant dollars and employer FUTA tax credits at risk. This year, the UI administrative grant funding is approximately $65 million. Nonconformity with federal law also could increase costs for employers because they would no longer benefit from a tax credit discount that is applied when a state is in compliance with FUTA laws and regulations.

Importantly, two crucial advisory councils have not taken a position on the bill. 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 important perspective on policy changes that affects eligibility and recipiency of unemployment insurance or worker's compensation benefits, respectively. 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. UIAC has not taken a position on AB 398 and it was not presented to the WCAC. A policy change such as an exclusion from coverage should go through the appropriate councils.

Finally, if enacted, the bill is projected to reduce UI tax revenues and the UI Trust Fund balance, but the amount of the reduction is indeterminate at this time. If no employers elect to cover clinical research trial participants under this bill, the fiscal impact would be estimated as a reduction to the UI Trust Fund balance of approximately $2.8 million annually. This was calculated based on the average annual tax contributions estimated to be attributed to clinical research participants between 2018 and 2021.

Again, the department remains open and available for collaboration on this legislation. Thank you for the opportunity to provide this information.

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Lab test subjects as employees

vforberger ⋮⋮ 1/9/2024

In late 2022 and early 2023, a few folks started contacting me about being disqualified or having to repay unemployment benefits they received during the Covid-19 pandemic because of their participation in lab testing studies.

Then at the July 2023 Unemployment Insurance Advisory Council meeting, a coalition of lab testing companies and Rep. Gundrum asked the council to support a change in the law to exempt lab testing as covered employment. According to the minutes of that meeting:

> State Representative Rick Gundrum addressed the Council regarding a proposed bill to clarify the employment status of participants in clinical research trials. Rep. Gundrum stated that participants in clinical research trials are volunteers and are not employees of the research organization. Participants receive a stipend for their participation. Rep. Gundrum stated that a clinical trial lasts between three and six months, with the typical participant's length of stay at the research facility being three to four days. Rep. Gundrum stated that he has heard that DWD considers research trial participants to be employees. Rep. Gundrum stated that the research companies cannot enroll their own employees as participants.
>
> Rep. Gundrum stated that that the draft of LRB 1462 seeks to clarify the relationship between participants and research companies. Under the proposed bill, participants would not be considered employees for purposes of Unemployment Insurance, Workers Compensation, and minimum wage. Rep. Gundrum stated that research organizations in Wisconsin are at a competitive disadvantage with similar firms in other states. The new bill addresses federal conformity issues raised by the Department in last session's version of the bill.
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> Ms. Knutson stated that a copy of the LRB Draft is included in members' packets.
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> Mr. Manley asked if a participant who is laid off and collecting UI benefits would lose their benefits.
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> Representative Gundrum stated that he does not think that participants would lose their benefits but will check further and get back to the Council.
>
> Ms. Knutson stated she would check with staff to determine if the stipends would be considered reportable wages.

At the September 2023 Advisory Council meeting, SB387 was introduced to council members along with the Department's fiscal estimate.

This bill proposes that a participant in a clinical trial is not an employee for purposes of state wage law and workers' compensation law and is not in covered employment for purposes of state unemployment law. The Department's fiscal estimate mostly indicates that the financial effects of the bill are indeterminate (other than an *annual* loss of $2.8 million in unemployment tax revenue to the unemployment trust fund).

This fiscal estimate also indicates that clinical lab companies would lose their FUTA tax credits because those companies would no longer be in compliance with federal unemployment law, unless those companies voluntarily agreed to have their clinical subjects listed as their employees for purposes of unemployment eligibility (and so, undoing the purpose of this proposed law).

As for unemployment purposes, this bill only addresses half of the problem — covered employment — and ignores the issue of employee status. As I wrote in an e-mail message to Rep. Gundrum in Sept. 2023:

> I don't think think SB387 will work as currently drafted. While it excludes employment for UI purposes, it does not address employee or wage coverage. Per the definitions of wages and employee in 108.02, a person qualifies for UI coverage if he/she performs services for pay for an employer/employing unit.
>
> So, even if there is no employment, these lab volunteers will still have to report their wages and any separations to DWD-UI for these lab experiments. So, while the employer may no longer be paying UI taxes for their lab volunteers, the employers will still have to answer questions about all of their lab volunteers and still report all of these employee issues and wages for anyone who is claiming UI at the time of these experiments.

That is, for this proposal to exclude lab participants in all unemployment matters, the exclusion needs to be in both covered employment and in whether laboratory participants still qualify as employees for purposes of unemployment law.

> *Note:* the definition of employee in Wis. Stat. § 108.02(12)(a) is expansive and applies to any person who performs services for pay for another. So, a lack of covered employment does not mean that unemployment is not involved. *See* Piontek v. Cooper Spransy Realty Inc, UI Hearing No. 09003831MD (17 March 2010), *aff'd* Piontek v. LIRC, 340 Wis.2d 742, 813 N.W.2d 248 (app. Ct. 2012) (a realty agent's decision to transfer brokerages — i.e., quit one brokerage — disqualified him from receiving unemployment benefits because of his prior layoff from a factory as he was also an employee of the brokerage despite his realty services to that brokerage being in excluded employment).

I also had questions about the $2.8 million in unemployment tax revenues and the FUTA tax coverage problem mentioned in this fiscal estimate. Federal unemployment law does not really address this issue/problem of FUTA tax coverage, and I suggested that specific directive/advice from Region 5 of US Dep't of Labor on this loss of FUTA tax credits question be sought out.

And, the $2.8 million figure in annual unemployment tax revenue seems much too large and is somewhat unbelievable. Understand that unemployment taxes only apply to the first $14,000 paid to an "employee."

So, a tax payment of $1000 per “employee” would be an extremely high 14% tax rate (for comparison, the highest tax rate applicable in the current Schedule D tax schedule is 12%, and the new employer tax rate for a large business in that schedule is 3.25%).

But, using that $1000 in unemployment taxes per employee figure would mean that clinical lab companies have 2,800 clinical lab “employees” for which unemployment taxes are being paid. The November 2023 jobs report for Wisconsin has all of 416,900 employees in health care and social assistance in the entire state (every hospital, doctor’s office, social worker, and other health-related employee). Using a 3.25% tax rate to get $455 in unemployment tax revenue means that there are nearly 6,200 clinical research subjects in Wisconsin based on the Department’s $2.8 million figure. And, a likely tax rate of 1.05% (for $147 in revenue per “employee”) means there are just over 19,000 participants in lab tests in Wisconsin.

All three of these numbers of clinical research subjects would make them a major job sector of the state economy. Maybe there are a few hundred clinical lab test volunteers every year in Wisconsin. But, are there 2,800 let alone 19,000 such volunteers every year? Given that laboratory research has never been seen as an economic engine in the state’s economy, something is off with the Department’s $2.8 million annual tax revenue figure.

Finally, this whole issue turns on the Department treating participants in lab tests as employees because they are allegedly performing services for pay for another. But, the Department also has explicit guidance that payments for blood and plasma donations do NOT qualify as income. I have yet to see any explanation from the Department that explains how a payment for blood in general is not income but a payment for blood for a laboratory test does count as income for unemployment purposes.

A hearing on AB398, a companion bill to SB387 is scheduled for January 10th before the Assembly Committee on Health, Aging and Long-Term Care. Here is hoping that some of these issues can be ironed out and some real change made with this bill.