



# DUEY STROEBEL

STATE SENATOR • 20<sup>TH</sup> DISTRICT

## Testimony on SB 387

January 10, 2024

Thank you Chairman Testin and committee members for holding a public hearing on Senate Bill 387, 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. SB 387 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 SB 387.



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# RICK GUNDRUM

STATE REPRESENTATIVE • 58<sup>TH</sup> ASSEMBLY DISTRICT

## Testimony on Senate Bill 387

Senate Committee on Labor, Regulatory Reform, Veterans and Military Affairs | January 10,  
2024 | Room 300SW

Chair Testin, Vice-Chair Nass, and other honorable members of the Senate Committee on Labor, Regulatory Reform, Veterans and Military Affairs, thank you for the opportunity to testify on Senate Bill 387 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 Senate Bill 387 does just that.

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 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 to 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 387 today.

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**Date:** Wednesday, Jan. 10, 2024

**To:** Chair Testin, Vice Chair Nass, and Members of the Senate Committee on Labor, Regulatory Reform, Veterans and Military Affairs

**From:** Department of Workforce Development Secretary Amy Pechacek

**Written Testimony Regarding SB 387**

Chair Testin, Vice Chair Nass, and committee members, thank you for the opportunity to provide written testimony for information only on SB 387, 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 SB 387. 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 reciprocity 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 SB 387 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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