



STATE REPRESENTATIVE

SAMANTHA KERKMAN

Third-Party Logistics Providers

2021 Assembly Bill 120 and Senate Bill 163

Assembly Committee on Regulatory Licensing Reform
Senate Committee on Insurance, Licensing and Forestry
March 3, 2021

Pleasant Prairie, Wisconsin which Senator Wanggaard and I represent, is fortunate to be home to a Pfizer cold storage and distribution center, a facility that employs around 100 employees. The Pleasant Prairie center was expanded and updated in 20018 and has the potential for another multi-million dollar expansion and an additional 50-75 positions.

As one of three locations in the country and one of the main sites that is a distribution center for the Pfizer COVID-19 vaccine, the Pleasant Prairie location and its employees are playing a critical role in getting vaccine to vaccination locations and helping to meet the nation's need for the vaccine.

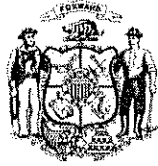
In addition to manufacturing and distributing the Pfizer COVID-19 vaccine, Pfizer would like to ship vaccine-administration related supplies that are not manufactured by Pfizer – a vaccination “kit” – along with the Pfizer vaccine. This would make Pfizer a third-party logistics provider (3PL) for those supplies.

The Drug Supply Chain and Security Act (DSCSA) directed the US Food and Drug Administration (FDA) to issue regulations establishing national licensing standards for 3PLs who are not required to be licensed in the states they do business. Until the FDA issues those regulations, DSCSA provides that any 3PL utilizing good handling and distribution practices shall be considered licensed, but provides no physical license that the 3PL may provide to a state that requires licensure.

Some states require 3PL licensure of a business in its home state as a prerequisite to a 3PL license in a second state. Currently, Wisconsin does not have a 3PL licensing process which creates obstacles to licensing the Pleasant Prairie logistics center in other states. As a result, Pfizer is currently unable to ship vaccination kits with the Pfizer COVID-19 vaccine from the Pleasant Prairie logistics center to states with that 3PL requirement.

The companion bills 2021 AB 120 and SB 163 remedy this situation by creating a 3PL license for Wisconsin. Senator Van Wanggaard and I have been working together since last fall to make sure that a legislative solution was ready if it was needed to ensure full utilization of Pfizer's facility in Pleasant Prairie. This legislation was originally included in AB 1 – the 2021 Wisconsin COVID response bill – but unfortunately, that bill was vetoed by the Governor in its entirety.

I appreciate your consideration of AB 120 and SB 163 today and ask for your support as it not only contributes to the economic vitality of our districts, but also the health of our nation.



Van H. Wanggaard

Wisconsin State Senator

TESTIMONY ON ASSEMBLY BILL 120

Thank you Mister Chair and committee members for today's hearing on Assembly Bill 120. I appreciate your willingness to hear this bill so quickly.

Pleasant Prairie in the 21st District is home to a state-of-the-art distribution facility owned by Pfizer. This facility is one of only two sites nationwide that Pfizer is using to ship its COVID vaccine, the other being in Kalamazoo, Michigan. Since December, Pfizer has been shipping the vaccine from Pleasant Prairie, and employment there has increased by 25% in just the last couple of months because of this activity.

I'm not going to get all technical on you, and so I'll simplify a legal spider web involving federal, Wisconsin, and California laws and the rule making and interpretations of each. At its base, California is requiring a state license for third party logistics providers to ship pharmaceuticals into the state, which Wisconsin does not offer. This bill creates an optional "Third Party Logistics Provider" license in Wisconsin, so that Pleasant Prairie's Pfizer facility can ship into California. The requirements and fee for the license are minimal and closely match the existing wholesale distributor license requirements. Senator Kapenga has an amendment that I support, which would require DSPS to determine if the optional license would still be required every two years.

This bill and the "Third Party Logistics" license is required because the "kits" being shipped along with the vaccine are manufactured by third party. That is, related items to the vaccine and shipped with the vaccine are not manufactured by Pfizer. Right now, this isn't a problem, but sometime in the next month or so, Pfizer will be shipping these third party materials along with the vaccine. And they'll have to stop at the California state line.

I want you to also know that Pfizer and DSPS have tried to work with California to avoid this legislation to no avail. Personally, I think California's law is a violation of the Interstate Commerce Clause, but that opinion doesn't allow Pleasant Prairie's facility to ship to California. This bill does.

I know Pfizer is here, and will be able to answer any technical questions you may have. I ask for your support for the bill.

Serving Racine and Kenosha Counties - Senate District 21

Testimony before the Assembly Committee on Regulatory Licensing Reform

Assembly Bill 120

Jim DeMay
Director of Pfizer State Government Affairs in the Midwest
March 5th, 2021

My name is Jim DeMay, Director of Pfizer State Government Affairs in the Midwest, covering Wisconsin. Pfizer is pleased to employ over 300 people in Wisconsin. We have two facilities in the State of Wisconsin:

1. Middleton WI Produces blood products.
2. Pleasant Prairie WI A Pfizer Distribution Center.

I am here today to speak about Pfizer's Pleasant Prairie facility. Pfizer employs about 110 personnel in the distribution facility, up about 30 employees since COVID-19 vaccination distribution started. Pfizer invested several million dollars in improvements at Pleasant Prairie in 2018-19 to make it one of two state of the art distribution facilities at Pfizer- the other one is in Memphis.

We have been successfully distributing COVID-19 vaccines out of the Pleasant Prairie facility and will continue to do so. At present, we ship deep frozen containers of about 1000 doses of the Pfizer vaccine to vaccination facilities. The distribution is working very well.

As we move forward, Pfizer will need additional licensing to ensure legal delivery of certain products for administering the Pfizer vaccine. In order to provide these additional products that I will refer to as a "vaccination kit," we will need the State of Wisconsin to grant us a 3PL license to allow for vaccination kits to be sent along with shipments of the Pfizer Covid-19 vaccine. The kits may have a solution mixture and other medical devices, which are not made by Pfizer. Because Pfizer will be shipping third-party product along with the Pfizer vaccine, certain states require that Pfizer obtain an additional license for our Pleasant Prairie facility, known as a "third-party logistics provider" license. The State of Wisconsin currently does not license third-party logistics providers, which means that third-party logistics providers can operate in Wisconsin, but do not need to obtain a license to do so.

Under the Drug Supply Chain and Security Act (DSCSA), enacted in 2013, the US Food and Drug Administration (FDA) was directed to issue regulations by 2015 establishing national licensing standards for third-party logistics providers (3PLs) who are not required to be licensed in the state(s) in which they do business (see section 584(a) and (d) of the Federal Food, Drug, and Cosmetic Act). The FDA has yet to issue such regulations. Until such time as those regulations become effective, DSCSA provided that any 3PL shall be considered "licensed" (as defined by DSCSA) provided FDA has not made a finding that the 3PL does not utilize good handling and distribution practices (section 582(a)(7)).

The key takeaway here is that while 3PLs may be considered "licensed" by FDA, because FDA has not issued regulations permitting licensure of 3PLs there is no physical license issued to a 3PL.

This creates a barrier to drug distribution when the Wisconsin 3PL must obtain a license to distribute into a state, but that state requires proof of licensure from Wisconsin. In California, for example, licensure of the business entity as a 3PL in its home state is a prerequisite to issuance of a 3PL license. Other states have recently inquired about the facility inspection and license.

Given that WI does not have a 3PL licensing construct, it creates obstacles to licensing our Pleasant Prairie, WI logistics center. As a result, we are not able to provide 3PL services out of our Pleasant Prairie, WI logistics center in some states.

Pfizer presently has acquired 3PL licenses for our Pleasant Prairie facility in several states and asks Wisconsin to enact a mechanism for issuing a 3PL license. We fully acknowledge that Wisconsin did not create this licensing issue, although we do need the state to help us fix it.

We would like to thank Representative Samantha Kerkman, Assembly Speaker Robin Vos, Senator Van Wanggaard, Senate Majority Leader Devin LeMahieu, Governor Tony Evers' office and the leadership at the Department of Safety and Professional Services for their support and assistance in working with us to address this matter.

Thank you.

James DeMay
James.demay@pfizer.com