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Written Testimony for Grifols

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Submitted to the Public Health Committee

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I am writing on behalf of Grifols to express our support for including language to address plasma collection issues in the State of Connecticut in S.B. 1083 An Act Concerning Various Revisions to the Public Health Statutes and H.B. 6666 An Act Concerning the Department of Public Health's Recommendations Regarding Various Revisions to the Public Health Statutes.

Grifols is a global healthcare company that since 1909 has enhanced the health and well-being of people around the world as an industry leader in producing plasma-derived medicines and transfusion medicine. We are a global leader in the development and production of plasma-derived medicines. Grifols operates the largest network of plasma donor centers in the United States with over 280 centers across 36 states. However, current regulations in Connecticut place unnecessary personnel burdens on potential plasma donor center operators such as Grifols.

Plasma donation is critical to helping save lives:

Plasma is a portion of the blood that is used as the starting material to make life-saving medicines. Plasma contains many proteins and antibodies known to be essential for human health. Collecting donations of plasma from health donors allows Grifols to produce plasma-derived medicines, which help replace missing or deficient protein levels in patients with a variety of rare, and often chronic, diseases.

For example, immunoglobulins are used to treat patients with primary immunodeficiencies, and a neurological condition called chronic inflammatory demyelinating polyneuropathy (CIDP). Clotting factors are still used to treat a variety of bleeding disorders, and Alpha-1 antitrypsin is used to treat patients with a genetic form of COPD.

Because plasma is mostly water, the proteins needed to produce plasma-derived medicines make up such a small percentage of human plasma, it takes hundreds, even thousands, of donations to produce enough product to treat a single patient for a year. Patients with no alternative treatments to plasma-derived medicines rely on the generosity of plasma donors to lead a more normal life.

Convalescent Plasma:

While the need for existing FDA approved medicines remains, this last year has also led to an interest in the collection of convalescent plasma to produce a potential treatment for COVID-19. Grifols is collecting convalescent plasma from donors who have recovered from COVID-19 to produce a highly concentrated hyperimmune globulin product, which has recently completed a Phase 3 clinical trial in partnership with the NIH.

Need for Increased Donations:

Prior to the COVID-19 pandemic, the global demand for plasma-derived medicines was growing at roughly 7% annually Because plasma donations are the essential first step in the production of plasma-derived medicines, meeting the demand for product is only possible by increasing donations and building centers in new locations.

However, rather than growing plasma donations in 2020, the COVID-19 pandemic reduced donation levels. That need for increased donations has become more urgent in light of the COVID-19 pandemic due to short-term reductions in plasma collections due to COVID restrictions across the United States. Collections have been impacted by stay-at-home orders and social-distancing measures. Plasma donors are needed now more than ever to make these medicines.

Economic impact of plasma donor centers:

In addition to the necessity of plasma donor centers for patients, centers also have a significate impact to the local economy. Grifols plasma donor centers operate like small businesses in the community. Grifols donor centers on average employee 40 individuals, with a range of jobs from entry level to medical professionals. In total, the average plasma donor center contributes over $4 million to the local economy each year, and Grifols' prides itself in having donor centers committed to community engagement.

Need for Legislation:

Using this opportunity to update Connecticut regulations to conform with federal standards as it relates to the credentials and qualifications of personnel in supervisory roles within donor centers, will make it easier for companies like Grifols to find employees and open plasma donor centers in the state. These changes will allow donor centers to employ qualified individuals to serve in positions without requiring overqualification. The plasmapheresis process and associated activities within a donor center are largely automated and do not require the same level of expertise and oversight currently demanded by old state regulation.

Conclusion:

Grifols has an unparalleled history and record of exceeding industry standards. We are committed to the health and safety of donors, the quality of the plasma we collect, and ultimately the health of the patients who rely on our medicines. Thank you for your consideration of changes to the regulations pertaining to the collection of source plasma in Connecticut.

Sincerely,

Dr. Mark Becker
Corporate Medical Director
Grifols