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VIA E-MAIL

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Attention: Pandemic Influenza Vaccine Prioritization Guidance Comments

To Whom It May Concern:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Department of Health and Human Services (HHS) Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine [hereinafter, "Draft Guidance"]. PPTA commends the HHS for developing this Draft Guidance and considers it to be a step forward in the U.S. government's effort to assure preparedness for the American public. However, the failure to expand the definition of blood donation facilities to include Source Plasma donation leaves a portion of the population vulnerable. Source Plasma is used in the manufacturing of plasma protein therapies. These therapies are life-sustaining and are vital to the health of the consumers who rely on them. If employees of Source Plasma operations and fractionation facilities and their critical vendors¹ are unable to come to work due to illness caused by an influenza pandemic, access to life-saving therapies may be compromised.

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies (collectively, "plasma protein therapies"). Our member companies provide 80 percent of the U.S. needs for Source Plasma and plasma protein therapies. These include blood clotting factors for individuals with bleeding disorders, immunoglobulins to treat chronic diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these life-sustaining therapies. In order to ensure therapies are available, it is imperative that the plasma protein industry be considered critical in any pandemic plans.

Under the current Draft Guidance, employees of blood donation facilities are categorized as level A - outpatient and home health care providers. This category is

¹ These include transportation and testing facilities.

provided tier 1 status during all pandemic scenarios. PPTA agrees with this designation but believes further clarification of a blood donation facility is necessary. In January 2006, the HHS Advisory Committee on Blood Safety and Availability (ACBSA) recognized the importance of the plasma protein therapeutics industry. ACBSA stated the Secretary must take immediate steps to “establish national recognition of the blood and plasma systems (collection, processing, distribution and use) as key elements of the critical infrastructure under the HHS plan, specifically . . . facility staff.” (See attached) PPTA believes it is vital to public health that the HHS follow the recommendations made by its own committee and recognize the plasma protein industry as a key element of the critical infrastructure, including vaccine prioritization in the HHS Influenza Pandemic Preparedness Plan.

Plasma protein therapies are unique. They are unlike other pharmaceuticals. The ability to manufacture plasma protein therapies depends on the continuous supply of plasma from collection centers. Moreover, Source Plasma is not available on demand. It can only be provided through the donation process. Furthermore, the manufacturing process for these products is more complex than other small molecule pharmaceuticals. The fractionation process takes approximately nine months. The donation of the plasma and the fractionation of therapies are interdependent. Each process plays a vital role in the creation of life-saving therapies. Therefore, possible disruptions, due to illness during a pandemic, to the donation and manufacturing process will directly impact access to these life-saving therapies.

Those individuals that rely on plasma protein therapies cannot survive without them. These are not medications that are used to treat symptoms that are bothersome, like stomach aches, headaches, etc. These therapies change and save lives, similar to the important role cellular components achieve. The following are some examples of the people who depend on plasma protein therapies for survival: in the U.S. approximately 50,000 individuals suffer from a primary immune disease; worldwide approximately 400,000 people suffer from Hemophilia A and B; and lastly an estimated one in every 2500 Americans have Alpha-1 anti-trypsin deficiency.² It is also important to note that albumin is a critical therapy used in emergency rooms across the country to treat shock, trauma, and burns. Although this may seem like a small portion of the U.S. population, it is an important group that needs special consideration because they depend on plasma protein therapies to live. PPTA strongly encourages the HHS to adopt the recommendations made by its Committee and amend the Draft Guidance to specifically provide employees of Source Plasma operations and fractionation facilities and their critical vendors, vaccine prioritization during all scenarios of a pandemic.

² Primary Immune Deficiency Diseases in America, the First National Survey of Patients and Specialists – www.primaryimmune.org; (2) National Hemophilia Foundation – Fast Facts – www.hemophilia.org; and (3) Alpha-1 Foundation – www.alphaone.org

On behalf of thousands of individuals in the U.S. dependent upon life-saving plasma protein therapies, your attention is greatly appreciated. Again, PPTA thanks the HHS for the opportunity to comment on the Draft Guidance and commends the Department for recognizing the importance of this issue. Should you have any questions regarding these comments or would like additional information, please contact PPTA.

Sincerely,



Mary Gustafson
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