Improving Access to Plasma-Derived Therapies for Neuropathy

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Improving Access to Plasma-Derived Therapies Requires Systems Thinking

Plasma-derived therapies are used to treat a wide range of life-threatening or rare diseases; however, the only current source of plasma is whole blood or plasma donated by humans. Developing plasma-derived therapies and ensuring access to those innovative therapies requires a more robust, national infrastructure to support safe and high-quality collection, storage, and ongoing supply of plasma. This paper explores several barriers to plasma supply in the current U.S. system and makes recommendations for change with the ultimate goal of enhancing access to plasma-derived medicines to address and treat life-threatening or rare diseases, such as neuropathy.

The Importance of Plasma Therapy for Patients with Neuropathy

More than 20 million people in the U.S. have some form of neuropathy. No single treatment works to address symptoms of neuropathy, but for patients with immune-mediated neuropathies, for example, chronic inflammatory demyelinating polyneuropathy, (CIDP), Guillain-Barré Syndrome (GBS), or multifocal motor neuropathy (MMN), plasma-derived treatments can be a therapeutic option. Currently, these treatments are produced by collecting human plasma from healthy donors that is repurposed to create medicinal products. The path from donation to medicine is lengthy and complex though, and making the path more linear would benefit researchers and patients alike.

What is plasma-derived therapy?

Human blood is a life-sustaining fluid and the basis of a broad spectrum of medical treatments, including replacing blood after major bleeding, but also utilizing different parts of whole blood for therapeutic uses. Whole blood contains red blood cells, white blood cells, platelets, and plasma. Plasma makes up more than half of whole blood and contains water, electrolytes, and a variety of proteins. In fact, there are at least "30 distinct protein products that can be isolated from human plasma." The isolation process, called fractionating, is when the plasma is separated so each individual protein can be used to produce medicine.

Plasma-derived medicinal products (PDMP) fall into various categories. The U.S. Food and Drug Administration (FDA) lists 34 medicines it regulates as Fractionated Plasma Products, including several in the most common categories of coagulation factors and immunoglobulins. Coagulation factors treat people who have blood clotting disorders, such as antihemophilic factors that treat people with hemophilia. Immunoglobulins treat people with immune conditions, including several types of neuropathy such as chronic inflammatory demyelinating polyneuropathy (CIDP), Guillain-Barré Syndrome (GBS), and multifocal motor neuropathy (MMN).

How are plasma-derived therapies created?

Human plasma is the foundation of plasma-derived therapy, and the current state of science requires healthy human donors as the source of plasma. Donation of plasma is somewhat similar to whole blood donation, in that humans are necessary, and systemic infrastructure is necessary to recruit, screen and host donors, then maintain the quality and security of donations both in storage and transit. Human donation processes are slightly different. For example, the American

Red Cross recommends whole blood donation no more than every 56 days, a frequency of up to six times per year. But a healthy person can donate plasma, no more than twice in a seven-day period, a frequency of up to 104 times per year. Additionally, the time commitment for donation is more intense for plasma. Whole blood donation typically takes about 10 minutes, whereas plasma donation takes an hour or more.

Plasma donation is only the first step in a complex manufacturing process that can take up to a year. Following collection and testing, donated plasma from pools of thousands of healthy donors undergoes fractionation and purification before it is processed and manufactured into a plasma-derived medicinal product. In the case of immunoglobulin, the medicine must also be formulated into a route of administration. There are three typical formulations:

- IMIg – intramuscular immunoglobulin
- IVIg – intravenous immunoglobulin
- SCIg – subcutaneous immunoglobulin

IVIg, specifically, is considered a breakthrough treatment for patients with immune-mediated neuropathies, such as CIDP, GBS, or MMN. The most common neurological disease treated with IVIg is chronic inflammatory demyelinating polyneuropathy (CIDP). Plasma-derived IVIg was first approved in 2008 to treat symptoms associated with CIDP and is now considered first line therapy with most patients responding withing six weeks of initiating therapy. Plasma-derived IVIg for Multifocal Motor Neuropathy was approved by the FDA in 2012 and is also considered first line treatment. Unlike patients with CIDP who may respond to other treatment options such as steroids or plasmapheresis, patients with MMN respond only to IVIg and need treatment for a much longer period of time than patients with CIDP.

Accessing Plasma-Derived Medicines

It has been nearly 25 years since the first plasma-derived intravenous immunoglobulin was approved for use with patients with certain neuropathic disorders. Still, there are a number of barriers to accessing plasma-derived medicines. Some of these are patient-facing barriers and affect whether and how a patient can obtain medical treatment. There are also barriers unique to PDMPs such as supply constraints and regulatory inadequacies.

The most common patient-facing barriers are those put up by health insurance companies seeking to manage their costs. Health insurance, both publicly sponsored such as Medicaid or Medicare, or privately sponsored such as plans offered through an employer, is often the payer of medical care. Health insurers collect premiums then manage how, where and under what circumstances a patient receives care. Managing utilization can take the form of medical necessity or coverage criteria, prior authorization, fail first criteria, quantity or frequency limits, provider networks, drug formularies, or cost-sharing requirements.

Insurance barriers for people needing access to plasma-derived medicinal products provided intravenously are common as IVIg “is one of the most expensive treatments in medicine.” Depending on the drug, the dose, and the care setting, a single PDMP infusion can cost up to $25,000 and annual costs can reach $250,000. Treatment denials are widespread, especially if

the PDMP does not closely match the clinical guidelines set forth by the health insurer or the FDA-approval does not exactly match the condition or disorder.

In addition to patient-facing barriers, there are several barriers to creating the plasma-derived medicine itself. First, plasma cannot be manufactured as the core ingredients of other pharmaceuticals can. As discussed previously, plasma must come from human donors so there is a biological limit on supply. Second, the demand for immunoglobulin is substantial and growing. Of the approximately 30 plasma proteins that can be fractionated, IVIg accounts for about half of the global plasma market. Additionally, the market is growing as IVIg can be used for a growing number of conditions and diseases. Third, manufacturing PMDPs is complex and takes nearly three times longer than making biologics. Fourth, the plasma supply chain is highly concentrated in the United States meaning shortages or disruptions anywhere in the world can slow or halt the collection, storage, and transport of plasma, in addition to disrupting manufacturing, production and delivery of final products for patient use. Many of these supply constraints can be addressed through policy changes at the state and federal level, but require thinking about the plasma ecosystem, not just single supply constraints.

Thinking in Systems: How Policy is Holding Back Progress

The United States supplies more than 70% of the world's plasma. Thinking in systems requires asking several questions about that fact:

1. If the U.S. is the world's primary plasma supplier, what benefits does that bestow?
2. What are the disadvantages to such a high concentration of plasma supply?
3. Is the U.S. collecting enough plasma to supply its own needs?
4. Does the existing system ensure safe and uninterrupted access to plasma?

Benefits of being the world's primary plasma supplier

In the U.S., blood products account for nearly 3% of the country's exports. As a comparison, this is more than the value of U.S. exports of farm and ranch products such as corn, soybeans, pork, and beef, and approaches the value of U.S. exports of automobiles. The plasma industry accounts for more than 70,000 full-time jobs and generates nearly $10 billion for communities across the country. Of course, being the world's primary plasma supplier also means hundreds of thousands of lives are saved or improved worldwide. Because so many people in the U.S. donate plasma, the entire world benefits: "Effectively, Americans donate to help Americans from New Year's Day until July 9th. Donations after July 9th go to save lives abroad."

Disadvantages of the high concentration of plasma supply

The reliance on a single country to supply most of the world's plasma means minor changes in the U.S. can have ripple effects across the world. Additionally, external disruptions that happen anywhere in the world can affect the supply chain in the U.S. Plasma donation depends not just on human donors, but also an enormous range of supplies and equipment. Donation and collection supplies include safety and cleaning supplies, tubing, filters, apheresis needles, collection bottles and bags, skin antiseptic supplies, solutions, shipping containers, and labels. Reusable equipment includes donor-screening instruments, plasmapheresis machines, tubing heat sealers, plasma freezers, and temperature-monitoring and alarm systems. Interruptions in

manufacturing, raw material or component shortages due to weather, political unrest, tariffs, or cybersecurity incidents can disrupt the supply of any of the hundreds of components that are required for the safe and high-quality collection, storage, and transport of human plasma. The high concentration of supply of plasma and supplies from the U.S. means limited capacity to overcome severe interruptions without also disrupting access to medications for patients. In fact, the high concentration of plasma supply in the U.S. was emphasized as a national security concern in an FDA roundtable, Strengthening the Supply Chain for Blood Manufacturing, held on September 29, 2026.

U.S. plasma self-sufficiency

Plasma self-sufficiency, meaning a country collects more plasma than it needs to produce the plasma-derived medicines it needs, is an essential part of maintaining a safe, adequate, reliable plasma supply. The U.S. FDA and the World Health Organization (WHO) consider plasma-derived medicines as essential medicines. In turn, WHO has advocated for more than 40 years that countries worldwide achieve self-sufficiency in the supply of blood components. However, because the WHO recommends such self-sufficiency based on voluntary blood donation, many countries do not achieve plasma self-sufficiency. For example, across countries in Europe, the plasma collected meets only 63% of their need. Self-sufficiency varies significantly by country: France is 33% self-sufficient, Spain is 43% self-sufficient and Italy is 70% self-sufficient. Outside of Europe, Australia provides only 48% of its plasma needs domestically and Canada is only 20% self-sufficient.

The U.S. as a country is more than 100% self-reliant in plasma for PDMP, meaning the country collects more plasma than it needs to produce medicines for the U.S. market. Some states don't have plasma centers at all due to logistical considerations, for example, Alaska and Hawaii, but in other cases, there are important regulatory differences discouraging plasma donation, collection and manufacturing. For example, three large states collect much less than they could based on the size of their populations (California, New Jersey, and New York).

The U.S. plasma supply system could work better

Variations in self-sufficiency across countries arise in part from different policies. For example, Austria and Germany collect more plasma than do France or Spain, in part because their regulations allow donors to be compensated. Similarly, variations in state policy in the U.S. mean some states supply well more than what would be required for self-sufficiency, and several states collect less than the 100% required to be considered self-sufficient. For example, the state of New Hampshire does not have any plasma donation centers. State regulations related to part of the finger-stick process needed to screen donors mean entities performing such tests must obtain full lab licenses and hire a credentialed laboratory director. Other states collect less than 100% of their needed supply because their regulations related to plasma collection are based on blood collection. Blood donation, storage, and supply oversight frameworks are a poor fit for plasma, however; policy changes are needed to make the existing system work better.

Progress in Accessing Plasma-Derived Medicines Requires Policy Change

Part of the reason the geographically uneven system of plasma supply in the U.S. doesn't work as well as it is could is the use of blood donation, storage and supply policy frameworks for the plasma used for plasma-derived medicines. There are two quite different uses of plasma: one is plasma used for direct transfusion, and the other is plasma used as a raw material in the pharmaceutical manufacturing of plasma-derived medicines, known as source plasma. While plasma intended for direct transfusion belongs within blood-banking oversight, source plasma is different in that it will be submitted to additional purification and processing before it is used in human medicine.

Federal oversight of plasma collection and use

Not only do federal statutes and regulations distinguish between the two types of plasma, the U.S. Food and Drug Administration (FDA) also oversees nearly all other aspects of the process of collecting, storing, transporting and manufacturing plasma-derived medicines using a regulatory framework specific to source-plasma. The FDA's Office of Blood Research and Review (OBRR) regulates blood establishments that manufacturer blood components, but they also regulate the products used in the manufacture of plasma-derived medicines, for example apheresis devices for red cells, plasma, or platelet collection, blood collection containers, such as bags and bottles, anticoagulants, and additive solutions, pathogen reduction devices, blood donor screening tests for relevant transfusion transmitted infections, immunohematology reagents and compatibility tests, hemoglobin measurement devices and blood establishment computer software.

A specific regulatory framework is needed for source-plasma for several reasons:

1. The end product and production processes are different
   Blood banks collect and prepare components of blood, including plasma for transfusion into patients. Source-plasma centers on the other hand collect material that undergoes further manufacturing into plasma-derived medicines. That distinction changes which activities a blood bank performs vs. what a plasma collection center performs. It also distinguishes which safeguards belong at a subsequent manufacturing stage instead of at the time of collection.

2. Clinical laboratory requirements can exceed the collection center's actual function
   A source-plasma center performs pre-donation screening to determine whether a person can safely donate. That is a narrower function than operating a clinical lab that performs a broad range of diagnostic tests. Requiring a separate, full clinical-laboratory license for the limited activities performed in a source-plasma center, similar to the requirements in New Hampshire, creates overlapping and unnecessary licensing and personnel obligations.

3. Storage rules must match the particular product
   Blood storage is not a single process. Red cells are generally refrigerated and plasma is generally frozen. For frozen-source plasma intended for injectable-product manufacturing, federal rules specify storage at certain temperatures, expiration rules and handling requirements that are not the same for whole blood.

State oversight of plasma collection and use

States retain authority over health facility and clinical lab licensure, professional scope of practice, building and sanitation standards, donor notification, and enforcement. State oversight of source-plasma collection and use varies substantially. Some states largely incorporate federal standards, while others require additional state licenses, inspections, specified licensed personnel or facility rules. Many of these requirements were developed for blood banks or clinical laboratories rather than source-plasma collection centers. Advocates for improving access to plasma-derived medicines point out that states that have regulations exceeding the federal requirements tend to have fewer plasma donation centers operating. A better framework for source-plasma policy begins with systems thinking. The strongest approach to improving donation and collection of source-plasma for its eventual use in PDMPs is a dedicated policy framework that preserves donor safety and product quality requirements specific to source-plasma while avoiding duplicative blood bank or clinical lab obligations. Two recent examples of state policy change are California and Connecticut.

State example: California

On September 27, 2026, California enacted AB 2009, modernizing the source-plasma regulations in the state. The Plasma Protein Therapeutics Association in its support for the bill explained "that because of these regulations, California lags far behind other states when it comes to plasma donation, ranking 39th in the country in terms of per capita plasma donation," and that "the existing regulatory framework is redundant, burdensome, and inappropriate for source plasma collection." The new law recognizes source-plasma centers as distinct from blood-bank depositories, clarifies medical-director and delegation of medical authority rules, and refines oversight of digital-refractometer protein testing. Before these changes, California was the only state in the country that required source-plasma centers to obtain and hold two distinct licenses to operate: a biologics license and a clinical laboratory license.

The passage of the California bill was especially important to the president of the Neuropathy Action Foundation, Dominick Spatafora, who shared his medical journey with as a patient with MMN, including fighting through barriers to access plasma-derived therapy in a powerful op-ed on August 13, 2026, in the California publication, Capitol Weekly. The article explained the importance of modernizing California's policy landscape by using systems thinking to analyze source-plasma from human donor to finished medicine in order to "strengthen the plasma ecosystem into a reliable, robust supply that patients depend on." A special note of congratulations to NAF for securing this important policy change in California!

State example: Connecticut

Connecticut passed SB 368, An Act Concerning Source Plasma Donation Centers, in May 2024. Where California separated licenses for blood and plasma operations, Connecticut used a more tailored approach to update its source-plasma policies. The Connecticut law requires a state source-plasma center license, but exempts a licensed center from obtaining a separate clinical-laboratory license when it performs only federally required plasma pre-donation screening tests. The law also directed the Department of Public Health to create regulations specific to source-plasma donation centers. These regulations were put in place in 2025 and replaced the overlapping licensing requirements with dedicated center licenses, while maintaining the safety rules tied to plasmapheresis.

Opportunities to boost supply and improve access to plasma-derived medicines

All of us have opportunities to boost the supply of source-plasma and improve access to plasma-derived medicines, including the following:

Be a donor

If this paper has made nothing else clear, the best way to boost supply and improve access to plasma-derived medicines is to become a donor! Human donors are the most important part of the complex process that leads to innovative and life-changing plasma-derived medicines for people who need them, including patients living with neuropathy. To find a donation center near you visit the GivingEqualsLiving website.

Support systems thinking state policy changes

Advocates can help policymakers understand how source-plasma collection rules connect to availability of plasma-derived medicines, such as IVIg. The strongest [proposals will identify specific operational barriers, identify how state policies are out of alignment with federal requirements and assist policymakers in matching their state's policies to those in states that are surpassing state plasma self-sufficiency.

Make the patient experience part of policy changes needed to support access

Patient stories reveal consequences that operational statistics do not capture. NAF President, Dominick Spatafora, shared his experience with the barriers he faced in trying to access a plasma-derived medicine his health provider prescribed that he had already had success using. Connecting insurance coverage of your medicine to how it supports daily function, independence, and the ability to work, volunteer or be a family or community member can be powerful components of policy change.

Ensuring continued access to innovative plasma-derived medicines for patients living with neuropathy requires thinking about the entire ecosystem that creates these medicines, from donor, to manufacturing, to patient. Developing plasma-derived therapies and ensuring access to those innovative therapies requires a more robust, national infrastructure to support safe and high-quality collection, storage, and ongoing supply of source-plasma. The barriers to plasma supply created by the present U.S. system can be addressed by policy changes with the ultimate goal of enhancing access to plasma-derived medicines to address and treat life-threatening or rare diseases, such as neuropathy.



Neuropathy Action Foundation
Awareness • Education • Empowerment

The Neuropathy Action Foundation (NAF) is a 501(c)(3) nonprofit dedicated to ensuring neuropathy patients obtain the necessary resources to access individualized treatment to improve their quality of life. The NAF increases awareness among providers, the general public and public policy officials that neuropathy can be a serious, widespread and disabling condition, which may be treatable when appropriate medical care is provided. The NAF's goals include:

Patient Empowerment
Educates and assists neuropathy patients on how to become informed advocates.

Public and Physician Awareness
Supports programs that create public and physician awareness of neuropathy, the use of IVIG and other treatments to improve patient care.