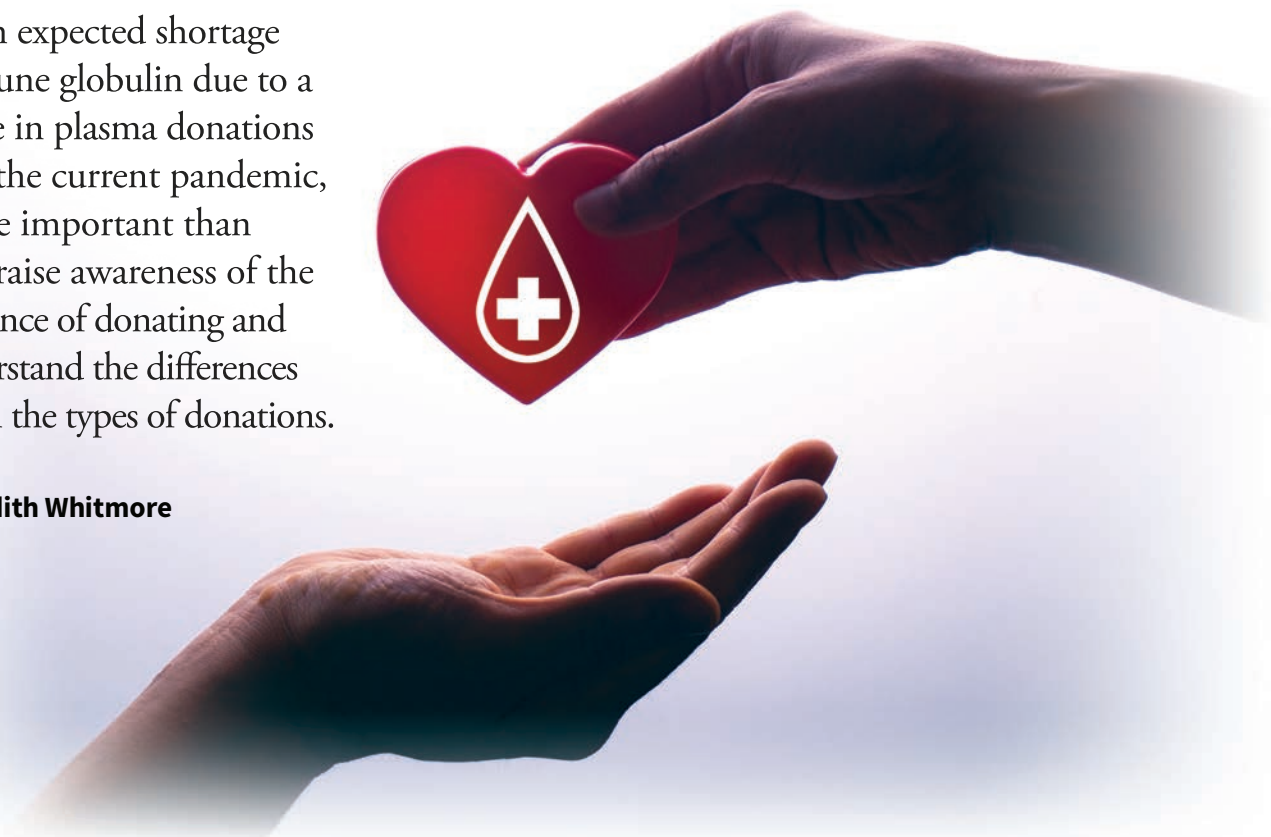
Plasma Donation and IG Supply:
An Interview with IDF President and CEO John Boyle

With an expected shortage of immune globulin due to a decrease in plasma donations during the current pandemic, it's more important than ever to raise awareness of the importance of donating and to understand the differences between the types of donations.



By Meredith Whitmore

EACH YEAR SEEMS to usher in varying degrees of uncertainty regarding availability of immune globulin (IG). With many people's lives dependent on IG, any shortage — or mere rumors of a shortage — can cause anxiety for patients and healthcare professionals. John Boyle, president and CEO of the Immune Deficiency Foundation (IDF), explains whether an anticipated scarcity of this precious drug is possible and, if so, why.

BSTQ: Is there an expected shortage of IG, and what would cause this?

Boyle: Based on the information our team at IDF has gathered, we anticipate some degree of IG shortage due to a drop in plasma donations at plasma collection centers. When the pandemic first occurred, all plasma collection centers had to alter their operations to ensure necessary social distancing and safety protocols were in place for donors and center staff. A small number of collection centers even closed temporarily. Added to that, there was reportedly confusion in some municipalities about whether collection centers could remain open even though they had been deemed essential by the Department of Homeland Security. But the greatest factor contributing to a shortage is the willingness of people to donate during a pandemic. Although donors are compensated for their time, for many, the time involved, the logistical challenges of safely getting to a plasma center, the perceived risk and other factors have shifted the risk/benefit calculations. Consequently, donations dropped starting in mid-March, and while there has apparently been significant recovery, the ongoing state-by-state spikes in COVID-19 cases mean there's no getting back to business as usual just yet. Even with most centers operating at capacity, there are still fewer donations.

Since it takes approximately nine months to manufacture plasma-based therapies from raw plasma, we anticipate a nine-month lag time between the decrease in donations of source plasma and probable therapy shortages. Furthermore, since the supply and demand levels for source plasma were perilously

close even when source plasma collection was at an all-time high prior to the pandemic, we're very concerned about the availability of IG beginning in January 2021.

BSTQ: What is being done to address the anticipated shortage of IG?

Boyle: IDF is galvanizing efforts to raise awareness of and encourage plasma donation, as well as to celebrate plasma donors as the heroes they truly are. We just launched our new Plasma Heroes campaign, and we are eager to see the positive impact it will have on donation levels in the short and long term.

Plasma collection and fractionation companies are opening source plasma collection centers around the United States as fast as they can, and happily, it appears the U.S. Food and Drug Administration (FDA) is working with them to minimize unnecessary barriers. Additionally, the executive and legislative branches of the federal government are addressing plasma-related issues. While they are primarily focused on convalescent plasma as a potential COVID-19 therapy, any interest in plasma serves as a "rising tide that lifts all boats" when it comes to encouraging people to donate plasma.

BSTQ: What are the pertinent statistics regarding plasma? For example, how much is the need for plasma outpacing supply?

Boyle: Unfortunately, a precise measurement of plasma supply and demand is not easy to ascertain since source plasma is collected and plasma-based products are manufactured by several different companies, each of which has its own data. And, while there are some useful aggregate data sets that exist such as those provided by the Plasma Protein Therapeutics Association (PPTA), there is no comprehensive repository for tracking supply and demand.

As a patient advocacy organization for people with primary immunodeficiency diseases (PI), IDF doesn't have access to data to track the number of people dependent on plasma-based treatments for other medical conditions. However, based on surveys of our PI patient community, as many as 50,000 people in the United States with PI require plasma-based products to remain healthy and alive. But, there are numerous diseases treated with plasma only temporarily. The difference between those and PI patients is treatment for PI is lifelong and lifesaving. PI patients simply can't live without it.

BSTQ: Are there alternatives to plasma for PI patients?

Boyle: There are no alternative treatments for PI patients. The IG infusions they receive are lifelong and lifesaving, and receiving IG is truly a life-or-death matter.

BSTQ: While this is a controversial issue, it has been rumored pharmaceutical companies sell plasma to researchers and for-profit agencies. If there is a plasma-for-sale loophole, is it contributing to plasma shortages, and are efforts being made to close the loophole?

Boyle: Classic blood donation and source plasma donation serve different purposes and populations, so I don't think there's a loophole to close, per se.

The classic blood donation system essentially serves everyone in the U.S., and since blood can be collected easily in almost any physical setting, it is easy to meet existing needs. Also, because the lifesaving nature of blood is well understood by the public and the volumes needed have historically been collected without incentivizing donors, no additional compensation has been needed. Additionally, the need for whole blood donations has decreased over time because of blood management in surgery and other areas of medicine.

Source plasma is collected only at certified collection centers to produce IG and other plasma therapies.

The source plasma donation system serves a comparatively small population: primarily those who have rare and chronic diseases who require plasma-derived therapy for survival. More than 100 source plasma donations are needed to treat one person with a PI for one year, and more than 1,000 donations are needed to treat those with other conditions. Experience has shown that without incentivizing plasma donors such as compensating them for their time, not enough people will go to the dedicated (and highly regulated) plasma centers to donate. Additionally, more and more people who need these therapies are diagnosed each year, and new uses for plasma-derived therapies are constantly being discovered. So, unlike the need for whole blood, the need for plasma and its component proteins is increasing each year.

In short, on one hand, the number of willing donors needed for whole blood donations is adequate. On the other hand,

the number of willing donors needed for plasma donations to treat the growing population whose lives depend on plasma-derived therapies can be met only by taking measures such as compensating donors for their time.

Because the need for plasma is so great, my understanding is just about every drop of source plasma collected becomes part of the plasma therapies. I believe the rumors you are referring to concern the practice of nonprofit blood collection organizations that then sell what's known as recovered plasma to plasma fractionation companies. Some of these companies purchase recovered plasma to supplement what they collect through source plasma centers. And, while this may be surprising to some, there's nothing inherently problematic with that as far as I can see. Recovered plasma helps to fill a gap needed to develop plasma therapies. It's all used for therapeutic use: saving lives.

Unfortunately, the disconnect between what is assumed and what is actual about blood and plasma collection generates alarm among those unfamiliar with it. People assume source plasma donors are being taken advantage of by a villainous plasma industry. Consequently, conversations surface about bioethics and donor safety that completely ignore prejudice or personal politics. Those conversations hijack the fact that there are people who rely on plasma-derived therapies. Since the process of creating plasma-derived therapies from source plasma is a complicated process and requires a donor to commit to regular, consistent donation, the utopian ideal of people donating plasma at levels that meet therapeutic needs with no incentive ends up failing each and every time. Canada and most of Europe are examples of this.

BSTQ: Are there misconceptions regarding a plasma shortage?

Boyle: There have been several plasma shortages over the decades that the PI community has dealt with, and each has its own unique causes. The most common misconception right now is caused by confusion about whole blood donations, convalescent plasma donations from people who have recovered from COVID-19, and source plasma donations used to make plasma-based therapies such as IG.

Whole blood, not source plasma, is donated at the Red Cross, and whole blood is not used to create plasma-based therapies. Convalescent plasma from COVID-19 patients only helps COVID-19 patients. Source plasma is collected only at certified collection centers to produce IG and other plasma therapies.

We hope the conversation and interest that surrounds convalescent plasma will help raise awareness for the importance of plasma donation in general. It's one of the many reasons we've launched the Plasma Heroes initiative.

Mitigating the Plasma and IG Shortage

Boyle and IDF's indefatigable efforts to ensure access to IG for those dependent upon it are reassuring to patients and healthcare professionals. As reported in a *BioSupply Trends Quarterly* plasma update, other organizations, including PPTA, are working with IG manufacturers to assist healthcare providers obtain specific products needed by patients. In addition, FDA is working to mitigate IG supply and is exploring ways to improve the manufacturing yield of IG products. The agency is also encouraging healthcare providers, hospitals and medical systems to proactively devise an evidence-based approach to deciding which patients will receive priority treatment. Beyond this, FDA has suggested hospitals and other medical systems consider a second IG product contract to improve resilience during and after the shortage.[1,2] While challenges in access will almost certainly remain due to life's unpredictability, those who strive to overcome the obstacles are, thankfully, steadfast in their work.

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References

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