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IN 2009, THE INDUSTRY AND PPTA SET ABOUT PERFORMING AN IN-DEPTH STRATEGIC REVIEW.

As a result of that process, the strategic objective of “plasma” was articulated as one of the priority areas for the Association. It was recognized as an underpinning for many of the challenges and opportunities faced by the industry, and it also encompasses a number of areas within the activities of PPTA Source. Some of the activities “touch” the area of the strategic objective of plasma, while others are fully involved in the discussion. Some of the areas implicated in the plasma objective are regulatory advocacy, safety, quality, standards, donor compensation, and industry image and credibility.

The most salient aspect of the discussion of plasma as a strategic objective is the recognition that plasma is truly what differentiates this industry from any other. The ultra rarity of the conditions that plasma therapies treat, the uniqueness of the patient groups who cope with these diseases, and the many other aspects that make up the conversations about our industry all stem from the foundation of what truly sets us apart: plasma.

With human plasma as the starting material, the issues managed and the challenges faced by the industry come from virtually every direction: safety, quality, access, ethics, standards, profile, trade, and so on. The use of plasma has a long history, and the industry’s efforts have resulted in extraordinarily safe and high-quality therapies. In addition, the distinction of “plasma” as a strategic objective has resulted in a number of high-profile initiatives and discussions. Some of these efforts have been long standing –and therefore underscore the long-term nature of plasma as a core strategy—and some have been created as a result of this renewed effort and focus.

In one sense, this discussion could revolve solely around our efforts at industry image and credibility—a project now four years in the running directed toward addressing some of the misconceptions about plasma. Plasma collection means many things to many different people, and the Association has endeavored to use the latest technology in an effort to bring coherent messages about our industry to as many diverse audiences as possible.

The focus of the work has been on education. This means dispelling myths, offering quality information for a variety of audiences, being able to address media inquiries, and many other important goals. The industry image projects have yielded a number of tangible tools and positive outcomes for the industry:

- ▶ English and German-language websites devoted strictly to plasma collection and boosting PPTA members’ profiles in various communities (www.donatingplasma.org and www.dieplasma spende.de and .at);
- ▶ Several campaigns that have utilized social media, particularly Facebook, to impart educational messages about plasma donation and plasma therapies; and
- ▶ Film, video, and interactive software to educate viewers about plasma, and center personnel on handling media inquiries.

These and other efforts have also resulted in increases in intangible benefits as well, such as an enhanced ability to distribute key messages to personnel in member companies responding to media inquiries. As a result of these new capabilities, negative media impact and misperceptions about the industry have been minimized and, in some cases, turned to positive messages about the importance of plasma.

But a project devoted toward improving perception of the industry and increasing education is only part of the discussion. The image must also have substance. If the industry had not made so many significant efforts (including the International Quality Plasma Program (IQPP) standards, regular stakeholder communications and outreach, improved safety and quality, and countless others), then industry image and credibility would be an empty shell. Fortunately, the plasma collection industry has tremendous substance and, through the strategic objective of plasma, can demonstrate it.

The cornerstone of the image and credibility project, as well as the larger strategic objective of plasma, is the IQPP voluntary standards program. Now celebrating its 20th anniversary, the IQPP has undergone significant improvements and optimization over the past several years. Every existing standard was reviewed in detail by a technical working group, and updated (along with accompanying documents) according to the determinations of the industry. In addition, the industry developed the Cross Donation Management Standard, which helps centers ensure that donors do not donate in excess of the regulatory requirements. The IQPP Standards stand as a testament to the industry’s commitment to stakeholders and PPTA is looking forward to taking them to the next level of excellence.


Moving beyond standards, PPTA has also undertaken a number of regulatory initiatives reflecting the importance throughout the industry. Examples include:

- ▶ The industry’s Donor History Questionnaire (DHQ). The DHQ is the end result of a long, painstaking process that will benefit all source plasma collectors. Despite the timeframe of the undertaking, Source members and PPTA realized that the benefit will be significant and that a change and project of this significance and scope would require long-term thinking and operations. We’re pleased to have been able to generate such a carefully considered, constructive result.

PLASMA STRATEGY

- ▶ Managing donor epidemiology issues in Europe. While this initiative is still very much in flux, its importance is well-understood by the participants. Formulation of the plasma strategic objective has brought focus to bear on this issue, and has been essential in developing creative and novel approaches.
- ▶ Responding to significant regulatory proposals. PPTA has been vigilant in monitoring draft guidance documents and proposed rules bearing on source plasma collection practices. Where appropriate, these messages include support for a risk-based approach to regulatory structures, differentiation from other industries, and recognition of the broader context in which our industry manufactures its life-saving therapies. The comments provided to the U.S. Food and Drug Administration (FDA) and other regulatory agencies may be brief or, in some cases, quite lengthy, as was the case with a recent proposal that advocated more than 100 separate changes to the regulatory structure for plasma collection. All of these efforts in accordance with a consistent application of sound regulatory policy to our industry are in accordance with the core principles of the plasma strategic objective.

Much of what our industry takes on in the global and international sphere is also reliant upon our strategic understanding of plasma. In the recent past, PPTA has engaged in workshops in China, as well as discussions in Japan, directly related to our industry's interests and advancement with regard to quality and safety. Sometimes, these forums are opportunities for clarifying misconceptions that exist. Examples include: the nature of compensated donation, the need for safe products and effective diagnosis and acceptable treatment levels. In this way, one can see the growth from a regional or national issue, either in terms of regulatory requirements or perception, to an area of global concern.

The developments and activities stemming from the plasma strategic objective are complex and more numerous than can be described in a brief article. As previously discussed, they run the gamut from standards and profile to regulatory policy and international trade. The strategic objective of plasma is a systematic and useful way of bringing all these issues together. Consequently though we have many issues and concerns that await resolution, a foundational framework and strategy are now firmly in place to get us where we need to go. 

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