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SPRING 2016

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In My View

BY JAN M. BULT, PRESIDENT & CEO

During my recent trip to China, I read an interesting article in a Chinese newspaper that started my thinking about the consequences of some important changes that are happening as I write this. Though there is a lot of anxiety in the world about the reduction of economic growth in China, we have to realize that the growth numbers in this country with an enormous population are still higher than we see in most other countries. The GDP (gross domestic product) is rising and the increase in wealth is noticeable. The traffic jams in the big cities create interesting challenges. In addition to this growth there is another one that is interesting.

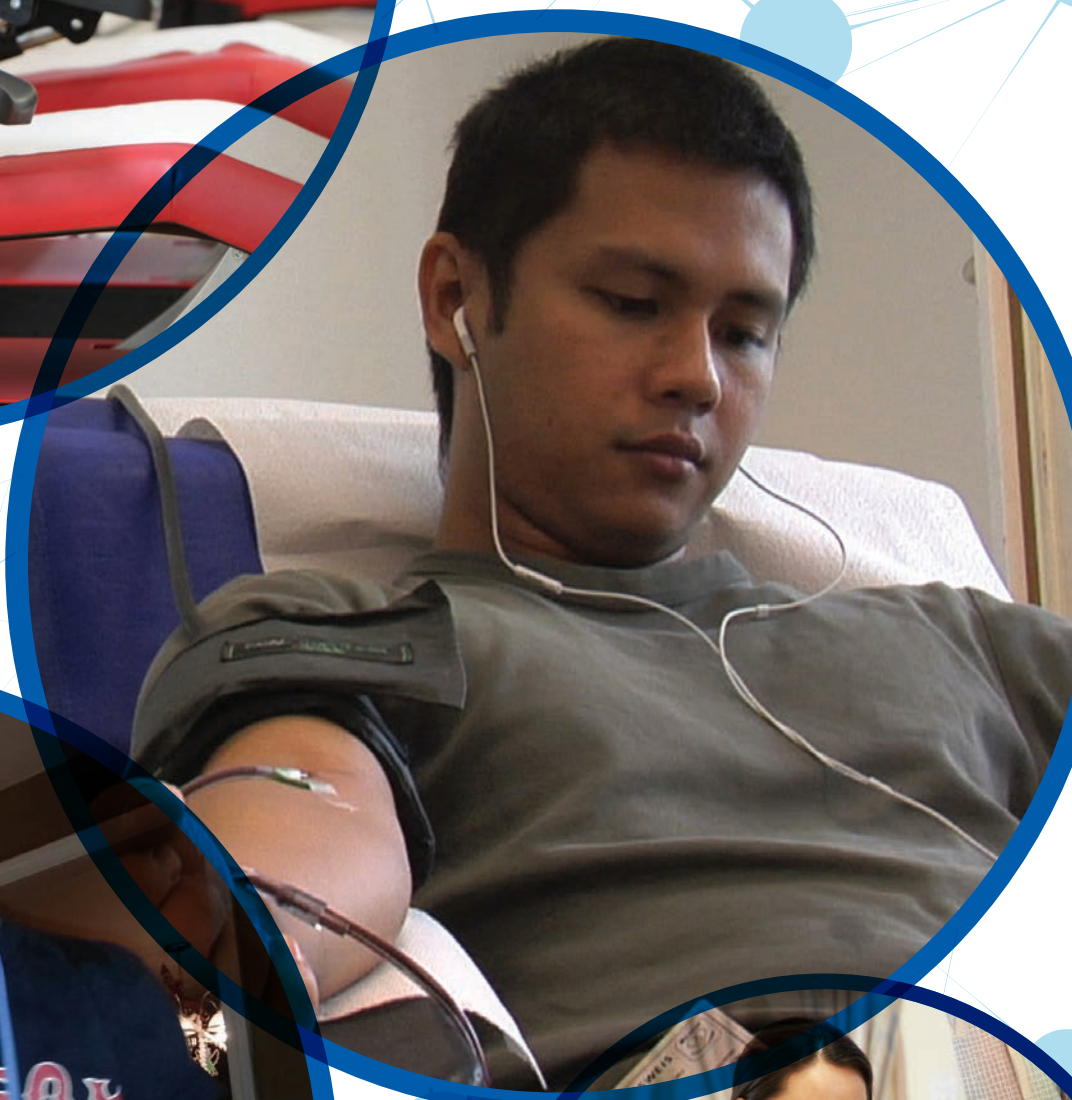
The article that I read was about the policy change from a single child to a two-child policy. The new policy that encourages all couples to have two children took effect on Jan. 1, 2016. "An additional 90 million women in China will be eligible to have a second child under the policy according to the National Health and Family Planning Commission. The commission said that 60% of the 90 million will be 35 years or older, which will result in increased risk of complications in pregnancy." The article gives a lot of information about the need to have more obstetricians, pediatricians, and midwives and also mentions that hospitals will have to open night clinics to handle the increase of patients. In Beijing alone, over 2.3 million women could have a second child and a birth rate peak is expected over the next five years.

This new policy has far reaching consequences. In many places, couples faced problems in obtaining a residence permit when the woman was unable to prove that she was using intrauterine devices (IUD's). But I am thinking of other consequences.

There will be an increase of patients with genetic disorders based on the known prevalence data. If we assume that 50 percent of the 90 million women will have a second child, then you can start the calculations. 45 million newborns = 22.5 million male newborns = 2250 boys with hemophilia A.

As we all know, there is already a problem with hemophilia care and regular shortages in China since the local companies cannot produce sufficient Factor VIII to meet the clinical need. The addition of a few more thousands of persons with hemophilia requires thinking how these future patients can be best helped. If we think about the clinical need for immunoglobulins and other plasma protein therapies, then we know that the problem will just be bigger unless the current restriction to import plasma-derived plasma proteins (with albumin as an exception) is reconsidered. I personally believe that it is a matter of time, more than a matter of principle. •

Jan M. Bult, *PPTA President & CEO*



COMPENSATING DONORS IN 2016

BY JOSHUA PENROD

The debate regarding compensation of donors evolves with each new year. Over the past several issues of *The Source* and elsewhere, we have seen different perspectives on the question of compensation, contributed by PPTA staff, representatives of industry, patients, and academics. There have been several common refrains and consistent arguments, which began long before our work to discuss the practice of compensation was ever initiated. At the same time, healthcare systems have experienced improvements and changes within the context of patient treatment that also work to underline what is at stake when it comes to donor compensation.

PREVIOUS DISCUSSIONS

The arguments put forward regarding compensation have taken two general forms: one being response to an existing policy initiative, and the other being a proposal for a future policy initiative. Invariably, the policy initiative is to eliminate, reduce, or tamper with the practice of donor compensation in some way so as to make it more difficult to secure enough plasma for manufacture into life-saving therapies. This seems to be an odd type of initiative coming from jurisdictions that have striven to improve access to health care for their citizens. Nonetheless, it occurs with alarming regularity.

The anti-compensation initiatives are almost always clothed in arguments of righteous concern; concern for bodily autonomy, concern regarding exploitation, concern regarding safety of the donor and his plasma, and concern about self-sufficiency. All of these questions are of extremely high importance. Yet, given the high importance, staging a ban against donor compensation is *exactly* the way to ensure that the goals of maximizing diagnosis and access are not met.

THE REALITY ABOUT COMPENSATION

The United States supplies the vast majority of source plasma for use in therapies distributed around the world. Source Plasma donation is largely compensated while, at the same time, the United States is wholly self-sufficient both for labile blood components and for plasma for fractionation. At the highest level, one can say that a system of both compensated and non-compensated donation can co-exist, using the United States as an example.

However, there remains a striking reality with which we should first grapple; the decline of the whole blood sector over the past several years. Some blood industry estimates have illustrated a decline in the need for whole blood to be approximately 30 to 35 percent per year in the recent past. This is more than a significant reduction and it has everything

In the European Union, certain countries have systems wherein donors are recognized for their donations; in Italy, for example, a blood donor receives a paid day off work, subsidized by the state, in return for a donation.

to do with changes in surgical practice, blood management for patients, and a host of other factors. That is to say, the practice of compensating plasma donors by itself is not relevant to the more complex national picture of blood donation. Practices, technologies, and techniques all change over time, which may have broad impacts on several industry sectors.

However, any picture like this is, like all high-level overviews, a bit too simple. What emerges upon closer study is an interesting patchwork of different practices within the context of donor compensation and which generate far more questions than answers. It is much more complex than a picture of non-compensated blood donation versus compensated plasma donation.

Several U.S.-based blood donation systems have reward programs that allow donors to receive prizes in return for component donation. Such systems basically utilize "points" given to a donor over a period of time, such as a year or per a number of donations. The points can then be redeemed through the blood center's system and, in return, the donor can receive movie tickets, gift cards to retailers such as Amazon.com or a department store, jewelry, or household items. In the European Union, certain countries have systems wherein donors are recognized for their donations; in Italy, for example, a blood donor receives a paid day off work, subsidized by the state, in return for a donation. Assuming an average annual individual income of €28,000 per year and 220 working days per year, this amounts to €127 per donation value in recognition of the donor's commitment. This is, however, considered a non-remunerated donation by the Italian and other authorities.

In the U.S., the FDA enforces the Code of Federal Regulations and uses associated policy guides and Guidance Documents to illustrate practices and principles that accord with legal requirements. In terms of donor compensation, the FDA's enumerated policy is that a donor is considered "unpaid" so long as the donation is not exchanged for an item "readily convertible to cash." This requirement is listed clearly in 21 CFR S. 606.121 and also has exceptions such as time off from work. To better illustrate, the FDA's Compliance Policy Guide 230.150 also states that the amount rendered is unimportant and that such a practice is considered paid; also irrelevant is whether the donation was actually performed or whether a potential donor presented for donation but, for whatever reason, was unable to do so. The FDA considers these "paid" donations period... or, at least, insofar as the written guide states.

The FDA provides a host of factors which are considered in making a determination of payment or not. These include whether a market exists for the incentive, transferability of the incentive, and the redeemability of the incentive. It can be

A whole blood incentive system might include a donor performing a donation of blood components three times in order to attain enough “points” for a $50 gift card.

difficult to make the case that certain incentives are in fact payment, such as for rewards of an audio CD or food and beverage. Other examples, such as the offer of an Amazon.com gift card for an amount of $20-$50, seem to be much easier to understand. What is the purpose of a gift card, after all, if it is not transferable, not redeemable, and not a participant in a market? The card is clearly marked with a monetary value, anyone can use it, and it is expected to be redeemed. And yet, such cards are widely used in the non-compensated sector.

A whole blood incentive system might include a donor performing a donation of blood components three times in order to attain enough “points” for a $50 gift card. This would be the equivalent of $16.67 per donation. However, a blood donation lasts for 20-30 minutes. Doing the math, the donation would actually be valued at an hourly rate of just over $33-$50 per hour. Therefore, a plasma donor who can receive $30-$40 in return for a single donation of 75 minutes, is actually being paid less per hour than a blood donor. Yet, currently, FDA considers the whole blood donation unpaid and the plasma donation paid even though the two scenarios are fundamentally equivalent in terms of participation in a market. It is also worthwhile to note that most source plasma collectors operating within the FDA jurisdiction today use pre-paid debit cards or something similar, which are again

The inconsistency of treatment in policies for blood and plasma–under such impenetrable and ultimately random reasoning—creates a system of favorites. This is not sound policy.

fundamentally equivalent to the gift cards—in size, shape, and amount. For some unarticulated reason, gift cards from a blood bank are not currently considered to be "operating in a market, while debit cards issued by a plasma collection center are."[1]

The inconsistency of treatment in policies for blood and plasma under such impenetrable and ultimately random reasoning creates a system of favorites. This is not sound policy, nor a strong basis upon which reasoned decisions can be made in order to identify any sound policy. And yet, the difficulty is not necessarily with the fact that distinctions are difficult, the difficulty is that the distinctions are pointless and yet still pursued despite the very real consequences of stigma and shame about a "paid" donation. These same two strong feelings cost donations and can prevent sufficient therapies from being produced.

With this, we come full circle. The avowed goal of the self-sufficiency camp is to ensure that patients receive treatment. It seems that the opposite outcome is effected instead, and the response to the effect is to trim appropriate diagnosis, a case that has been argued for by others, such as in the 2013 Rome Declaration and appears to have been put into practice in certain countries, such as Japan. At what cost? This is the question that needs to be answered, but the answer comes not in terms of television sets, t-shirts, mugs, or cash. The cost comes in lives. With this, choices between compensation policies become starkly clear: when it comes to sufficiency, regressive policies and rhetoric have no place in patient treatment. All donors deserve better, and all donors deserve recognition. •

JOSHUA PENROD,
PPTA Vice President, Source & International Affairs

References

1. The above-mentioned policy guide uses the example of a television set, and expressly notes that the receipt of a television set in response to a donation would mean that the donation should be labelled as "paid." In the words of the policy guide, "[t]he blood collected at the donation at which the donor received a television set would generally require a 'paid donor' label statement, because a television set is usually readily convertible to cash." Despite the tortured grammar, this seems to offer a more definitive demarcation for payment. Right now, at the time of this writing, Best Buy is offering a 19" Insignia flat panel television set for $89.99, which, using the same 20-30 minute metric, could be that a donor is paid $180-$270 per hour, which can be over 10 times more than what a source plasma donor would receive. Even still, a $90 television is only $15 more than a $75 gift card (also offered in a rewards program for an unpaid donation.)

German Haemophilia Registry Stakeholder Meeting

BY SÁNDOR VON TOTH

On Dec. 15, 2015 the German Haemophilia Registry Stakeholder Meeting took place at the Paul-Ehrlich-Institute (PEI) in Langen, Germany.

The PEI invited representatives from various stakeholder groups to present their perspective on the current status of the German Haemophilia Registry and on potential future developments. The group of participants included members of the Society for Thrombosis and Haemostasis Research (GTH, Gesellschaft für Thrombose- und Hämostaseforschung), the Patient Advocacy Groups DHG (Deutsche Hämophiliegesellschaft) and IGH (Interessengemeinschaft Hämophiler), Payers, IQWiG (Institute for Quality and Efficiency in Healthcare), members of the PEI, the Registry Steering Committee, and the industry represented by PPTA and IPFA (International Plasma Fractionation Association)

The meeting was intended to collect the perspectives of all stakeholders and provide a forum to discuss stakeholder needs and requirements, the pros and cons of the current status, and to assess current and future challenges to further development of the registry.

To set the stage, Prof. Wolfgang Schramm, representing the Rudolf-Marx Foundation and one of the drivers from the very beginning, gave an outline of the history of the German Haemophilia Registry. In 1998, the members of the GTH Haemophilia Commission recognized the need for the collection of comprehensive patient data from all treatment centers in Germany. In 2008, the registry started with a pilot program and, since 2010, the registry has been online, operated by GTH, DHG, and IGH, hosted by PEI, and supported by the German Ministry of Health. One of the original goals was to get an overview of patient numbers and factor consumption to estimate the prospective need and to ensure the availability of therapies. Two challenges turned out to be of major importance: fulfilling the requirements of the German data protection law and making data entry as easy as possible. Both challenges are still commanding attention today.

Two challenges turned out to be of major importance: fulfilling the requirements of the German data protection law and making data entry as easy as possible. Both challenges are still commanding attention today.

Next, the results of the IQWIG Rapid Report about the treatment of hemophilia patients was presented. The current level of clinical evidence in hemophilia was discussed. Rare diseases like hemophilia present some common challenges with regard to patient data:

Because of the relatively low numbers of patients and at the relatively high number of new hemophilia treatments, which

need to be assessed in clinical trials, it will presumably be increasingly difficult to recruit a sufficient number of patients eligible for these trials.

On the other hand, registries can provide large sample sizes (higher number of patients) but, as of today, leveraging registry data for creating scientific evidence or safety reports is limited due to multiple reasons, such as poor data entry, inconsistent data, double counting of patients in different registries, etc.

Nevertheless a well-designed, well-run registry could provide a large sample of real-life data of sufficient quality, adding information to the data derived from clinical trials.

There was agreement that the current German Haemophilia Registry should be adjusted to meet current and future needs. A consensus is needed about what these requirements are and how they should be met.

The amount and quality of the collected data still needs to be improved. One important point is that each patient should be entered into the registry individually and not via collective reporting.

The GTH Outcomes Working Group has already started to reassess what kind of data should be collected, what kind of data are essential in terms of a minimum data set, and what kind of data are needed for scientific research. The group is focusing on three subgroups of outcome data: clinical outcome, patient reported outcome, and economic outcome.

It would be beneficial to harmonize the different existing national and supra-national approaches like the German Registry, EUHASS (EUropean HAemophilia Safety Surveillance), PedNet (European Paediatric Network for Haemophilia Management), and others based on an agreed minimum data set and protocol.

Ideally, all patients should be entered into registries including patients in clinical trials.

Dr. Dorothea Stahl, member of the PEI and Head of the Section Transfusion Medicine, presented possible options for the development of the registry with a special focus on the German Oncology Registry as an example of a well working registry in Germany.

Scientific independence of the registry was regarded as essential to ensure the compliance of all participating centers, as well as improved transparency for and collaboration of all stakeholders including the industry. •

SÁNDOR VON TOTH, *PPTA Senior Manager, Germany*

1 PLUS 1 = 3

BY BRUNO SANTONI

The Platform of Plasma Protein Users (PLUS) Consensus meeting has put together all the interest groups from the blood and plasma community. It is an important platform to create common views on key aspects of the sector.

On Jan. 14-15, 2016, PLUS organized a consensus conference in Estoril, Portugal in order to address several important ongoing issues for the Blood and Plasma community. The EU Blood Directive and its potential future evolution as well as the latest MSM (men who have sex with men) deferral policy changes were among the topics discussed during the meeting.
The meeting was chaired by Brian O'Mahony from PLUS and William Murphy from the Irish Blood Transfusion Service. PLUS was represented at the meeting by Alpha 1 Global, EHC (European Haemophilia Consortium), HAEI (Hereditary Angioedema International), IPOPI (International Patient Organisation for Primary Immunodeficiencies), and WFH (World Federation of Hemophilia). The different stakeholders invited were: the American Plasma Users Coalition (A-PLUS), represented by HAEI and the National Hemophilia Foundation (NHF); the European Blood Alliance (EBA); the European Plasma Collectors Committee (EPCC); the International Federation of Blood Donor Organizations (IFBDO), the International Plasma Fractionation Association (IPFA) and the Plasma Protein Therapeutics Association (PPTA).

The dialogue among the stakeholders was open and productive. While consensus statements were published in 2010, 2011, and 2012,[1,2,3] the goal of this meeting was not to publish a paper but to find common ground to establish recommendations. The concept of the meeting is, of course, to leverage the knowledge and views of all participants in order to develop and deliver messages with one voice. This perfectly

illustrates the principle that the effect of a joint action is stronger than the sum of isolated separate actions. Follow up meetings will be conducted in May 2016 and January 2017.

THE EU BLOOD DIRECTIVE

Although there is not yet a revision of the Blood Directive 2002/98/EC (the famous one setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components) adopted 13 years ago, there are ongoing questions in the sector and at the EU Commission level on the future of this Directive. Does the Directive still meet its purpose? Does it meet the needs of the sector (donors, patients, collection centers, industry) and does it still match with the current status of knowledge and science?

Sebastian Rohde from Rohde Public Policy started this section of the meeting by providing visionary insight into the EU health care policy environment, explaining the changing public health environment and the possible consequences of a future revision. Mr. Rohde provided an excellent overview of this environment in the Fall 2015 edition of The Source in his article, "The Continuous Path of Changes in Healthcare: EU Member States." Following Mr. Rohde's presentation, a representative from each group presented their viewpoint on the current Blood Directive and its potential evolution. Specifically, each group talked about the need to better differentiate between blood and plasma in the Blood Directive.

During the discussion, PLUS specifically highlighted the disparities in diagnosis, treatment, and care within the EU. Throughout the different presentations, it was quite clear that all interest groups believed that improvements can and need to be made in the EU to contribute to the global plasma supply while keeping in mind the growing clinical demand. This was already mentioned in the 2011 consensus paper but the recommendations of this session will focus on how this can be addressed in the Blood Directive. There were also several interest groups highlighting the need for an improvement of definitions (e.g: plasma, plasma for transfusion, plasma for manufacturing, plasmapheresis) and policy concepts (e.g: voluntary unpaid donation, sufficiency). It was also quite obvious that the Blood Directive isn't a tool that allows regular and easy revision of technical requirements.

Since its launch, operations have been impacted locally according to how the Blood Directive has been implemented by the member states, creating different levels of satisfaction among the different blood and plasma collectors. On the national level, the different choices made by the member states in terms of establishing plasma collection standards or policies did not move in the direction of more harmonization. Although the goal of the EU Commission is obviously to improve in the EU, the reality is often different. This is due to the subsidiarity principle[4] allowing countries to implement different policies in some specific domains. This was well illustrated during the meeting by the differences in MSM policies in the EU Member States.

PLUS specifically highlighted the disparities in diagnosis, treatment, and care within the EU. Throughout the different presentations, it was quite clear that all interest groups believed that improvements can and need to be made in the EU

Of course, the participants noted if the Blood Directive is revised, there is always a certain significant amount of uncertainty about how the EU Parliament will vote, the Blood Directive's finished form, and what the consequences will be for the sector and particularly for patients.

While keeping all of this in mind, the group committed to continue its work to finish a set of recommendations in the coming months.

The next steps will focus on consolidating the input of the different groups so that the consensus document can be finalized. The PLUS stakeholder group represents the most comprehensive set of experts with regard to the EU regulations and its effects on their specific area. All are motivated to deliver the best quality and the best care. This group has overcome its differences to develop several consensuses over the years - their voice and message should be heard. •

BRUNO SANTONI, *PPTA Executive Director, Europe*

References

1 The Dublin Consensus Statement on vital issues relating to the collection of blood and plasma and the manufacture of plasma products B. O'Mahony & A. Turner. Volume 98, Issue 3p2, pages 447–450, April 2010.

2 The Dublin Consensus Statement 2011 on vital issues relating to the collection and provision of blood components and plasma-derived medicinal products. O'Mahony B., Turner A. Vox Sang. 2012 Feb;102(2):140-3.

3 The Dublin Consensus Statement 2012 on optimised supply of plasma-derived medicinal products. Brian O'Mahony, Blood Transfus. 2013 Oct; 11(4): 623–626.

4 http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:ai0017&from=EN

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French Regulation on "Ethical" Labeling for Blood Products Triggers PPTA Legal Opposition

BY JOHN DELACOURT & KARL PETROVSKY

In spring 2015, the French government gave notice of its intent to implement a regulation on the "ethical" labeling of blood and plasma products. The regulation in question would permit manufacturers of plasma-derived pharmaceuticals made exclusively from uncompensated donations to label those products as "ethical," in contrast to other products which would then presumably be viewed as "unethical."

The French initiative is not entirely novel, but rather bears strong similarities to an ethical labeling initiative that was considered, but ultimately rejected on both health policy and legal grounds, by the Dutch government in 2004. Given the potential negative impact of the regulation, as well as the possibility that similar approaches could emerge elsewhere in the European Union (EU), PPTA filed a legal opposition with the European Commission. Among other concerns, PPTA asserted that the French regulation violates provisions of the Pharma Code on product labeling and strict prohibitions on Member State rules that impede the free movement of goods within the Internal Market.

THE FRENCH REGULATION

The French regulation came to PPTA's attention as a result of mandatory notification through the Technical Regulation Information System (TRIS) procedure.[1] Under EU law, a Member State must inform the European Commission of any draft technical regulation prior to its adoption. This provides the Commission, Member States, and other interested parties with an opportunity to raise any objections to the regulation–most notably, whether it will potentially create a barrier to the free movement of goods.

On May 15, 2015, France filed TRIS notifications[2] regarding a new provision of the French Health Code[3] that would

specify the conditions for manufacturer use of an ethical label pictogram. As the TRIS notifications explained, any blood- or plasma-derived product could be labeled as "ethical" provided that the products were manufactured from source material that satisfied the criteria for voluntary, non-remunerated donations spelled out elsewhere in the Health Code.[4] Specifically, this would require that the blood or plasma donors at issue be "unpaid, over the age of consent, anonymous, and consent freely." The notifications further explained that, as long as the criteria were met, the ethical label was available for use by any manufacturer and that, although use of the label was voluntary, it would be a "criterion for gaining access to a public hospital market."

PPTA'S OPPOSITION

Despite the French government's insistence to the contrary, PPTA argued that the new regulation would, in fact, impede the free movement of goods within the EU. PPTA also argued that the "ethical" label would have an adverse impact on public health by providing physicians and patients with potentially misleading information. As the legal grounds for its objections, PPTA pointed to the Pharma Code's labeling requirements,[5] which preclude the inclusion of information outside specified categories, and the Internal Market rules, which prohibit Member States from providing domestic undertakings with a competitive advantage.

PHARMACEUTICAL LABELING REQUIREMENTS

In its TRIS filing, France cites Article 110 of the Pharma Code[6] as authority for implementing the labeling regulation. Article 110 encourages Member States to promote EU self-sufficiency in the production of blood and plasma derivatives, and to do so by encouraging voluntary, unpaid donations (VUDs). As PPTA points out in its opposition, however, while Article 110 might provide adequate legal grounds in other circumstances, it cannot be used to justify a labeling requirement. Labeling requirements are an area of full harmonization under the Pharma Code[7] and, consequently, Member States may not enact their own requirements that are more or less restrictive. The Pharma Code specifies extremely precise categories of information that may be included–ranging from active ingredients and necessary warnings to price and pedigree detail[15]–but says nothing about a product's "ethical" status. The Pharma Code is equally clear that promotional material may not be included on the label.[8] This is, of course, directly at odds with Article 110, the express purposes of which is to promote EU self-sufficiency and VUDs.

Furthermore, even if Article 110 were a valid legal basis for the regulation, the specific requirements of the French Health Code regarding which donations qualify as VUDs are far more restrictive than Article 110. In particular, the Health Code considers any monetary compensation whatsoever as incompatible with the principle of VUD. The principle of VUD incorporated in Article 110, in contrast, contemplates

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reimbursement of expenses, monetary payments for time and inconvenience, and small tokens that can include cash. Indeed, a Commission-sponsored independent study recently concluded that such practices are common in many Member States.[9]

BARRIERS TO THE FREE MOVEMENT OF GOODS

The French regulation is also inconsistent with the principle of a common Internal Market[10] and would function to restrict the free movement of goods between Member States. In practice, the proposed ethical label would benefit only one company, Laboratoire Français du Fractionnement et des Biotechnologies (LFB), which is wholly owned by the French government and, more importantly, has a legal monopoly on the fractionation of plasma collected in France. Because it has exclusive access to French plasma, which is already being collected in compliance with the French Health Code's requirements for VUDs, LFB alone automatically qualifies to use the "ethical" label. In contrast, competing manufacturers outside France would have to prove that they satisfy the French VUD requirements, and would need to do so by means of a regime that, currently, is still completely unclear regarding both the evidence that will be required and the audits and controls that will be established to verify compliance. The fact that use of the ethical label is optional does not cure these defects, as the European Court of Justice has held that optional measures can be just as restrictive as legal or regulatory requirements.[11] The use of the label as a "criterion for gaining access to a public hospital market" raises legitimate doubts regarding whether it is truly "optional" anyway.

Supporters of the French regulation will likely point out that there are a number of exceptions to the principle of a common Internal Market, one of which is the protection of health.[12] As a technical matter, however, that exception is not available here. This is because deviations from the prohibition on barriers to the free movement of goods are not permitted in an area of full harmonization,[13] and the Pharma Code's provisions on product labeling are an area of full harmonization. More importantly, even if this were not the case, there is no evidence that the ethical label will protect health because there is simply no support for its underlying premise – that VUDs are safer than compensated donations. Indeed, this premise has been rejected by both the European Medicines Agency–which stated that "[t]here is no evidence from clinical studies and pharmacovigiliance that donor remuneration increases the risk of viral transmission via plasma derived products[14]–and the European Court of Justice.[15]

EU MEMBER STATE REACTION

In response to the TRIS notifications filed by the French government, a number of other stakeholders, in addition to PPTA, took action. Most notably, the European Commission and Member States Germany and Austria all filed comments. Because there are substantial plasma collection and fractionation operations in Germany and Austria that would potentially not have access to the "ethical" label, unsurprisingly, the German and Austrian comments opposed the French regulation on grounds similar to PPTA's

This is not to suggest that the regulation is without supporters outside of France. At least one Member State–Italy–is currently considering a similar regulation. On Sept. 14, the Italian association of blood donors–Associazione Volontari Italiani Sangue (AVIS) – called on the Ministry of Health to develop an "ethical" label for plasma-derived medicinal products. AVIS explained that the express goal would be to differentiate between products manufactured

The French regulation is also inconsistent with the principle of a common Internal Market and would function to restrict the free movement of goods between Member States. In practice, the proposed ethical label would benefit only one company.

...there is simply no support for its underlying premise – that VUDs are safer than compensated donations. Indeed, this premise has been rejected by both the European Medicines Agency – which stated that "[t]here is no evidence from clinical studies and pharmacovigiliance that donor remuneration increases the risk of viral transmission via plasma derived products – and the European Court of Justice.

from remunerated donations and those made with VUDs. In addition, on Oct. 6, the French government filed TRIS notifications regarding a new regulation that would authorize a "Europe label" on pharmaceuticals regarding the origin and the place of the manufacturing steps.[17] It appears that at least one objective of the new regulation is to promote differentiation between products that are sourced and manufactured exclusively in Europe and products that are sourced and manufactured globally, which would include plasma protein therapies manufactured with compensated donations from the U.S..

WHAT'S NEXT?

By the rules of the TRIS procedure, the filing of comments by Germany, Austria, and the European Commission in the "ethical labeling" case triggered a three-month stand still period during which France was prohibited from implementing the labeling regulation. Now that the stand still period, which expired on Nov. 17, has ended, France must respond to those comments. This essentially leaves the French government with three options: (1) withdraw the regulation, (2) modify the regulation in response to the comments, or (3) enact the regulation without modification. By the time this article went to print, France had not yet officially responded. Should France choose the third and most provocative option, it could trigger further action by the European Commission, including filing an action to block the regulation in the European Court of Justice. •

JOHN DELACOURT, *PPTA Vice President, Legal Affairs & Global Operations*
KARL PETROVSKY, *PPTA Senior Manager, Health Policy*

References

1. Directive 98/34/EC.
2. TRIS notification numbers 2015/252/F and 2015/253/F.
3. Article R. 5121-139-1.
4. Articles L. 1221-3 to L. 1221-7.
5. Directive 2001/83/EC
6. ibid.
7. Because Directive 2001/83/EC is based on Article 114 of the Treaty on the Functioning of the European Union ("TFEU"), it is a Directive of full harmonization.
8. See Articles 54 and 57.
9. See Article 62.
10. See Creativ Ceutical, An EU-Wide Overview of the Market of Blood, Blood Components and Plasma Derivatives Focusing on Their Availability for Patients (Apr. 8, 2015), at http://ec.europa.eu/health/blood_tissues_organs/docs/20150408_cc_report_en.pdf.
11. See Article 34 of the TFEU.
12. See, e.g., Case C-325/00, Commission v. Germany [2002] ECR I-09977, at ¶ 24 (optional measures a barrier to free movement if "their use promotes or is likely to promote the marketing of the products concerned as compared with products which do not benefit from" their use).
13. See Article 36 of the TFEU.
14. See Case C-473/98 Toolex [2000] ECR I-5681, at ¶ 25.
15. EMA, CPMP Position Statement, Non-Remunerated and Remunerated Donors: Safety and Supply of Plasma-Derived Medicinal Products (May 30, 2002), at http://www.ema.europa.eu/ docs/en_GB/document_library/Position_statement/2009/10/WC500004488.pdf.
16. Case C-429/09, Humanplasma GmbH v. Republik Österreich [2010] ECR 12869, at ¶ 43 ("the obligation that the blood donation must have been made without any of the costs incurred by the donor being reimbursed is . . . not necessary in order to ensure the quality and safety of the blood and blood components").
17. TRIS notification numbers 2015/561/F and 2015/562/F.

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PPTA Interview: David Ian Bell

David Ian Bell is the newly elected Chair of the Global Board of Directors for PPTA and a Vice President at Grifols, S.A.

Q You bring decades of experience. How did you get involved in this industry?

My initial college training was in psychobiology, which today is called neuroscience. Ultimately I ended up in law school. The result is that, by training and experience, I am both a scientist and a lawyer. I first became involved in the Plasma Industry when I was asked to help with some regulatory and legal issues faced by one of the early members of the plasma industry. My involvement evolved from there. I've always looked for challenging work and I certainly found it here. I joined Grifols when they entered the U.S. market and found a home with truly rewarding work but also a group of people who I enjoy being with and feel honored to call my friends.

Q What are your proudest career achievements?

I have had many opportunities for success in my career, but what I feel most proud about is the ability to give back at least some of what I have enjoyed. Most recently, I have been involved in a project at Grifols focused on fighting emerging viruses in Africa. What makes me proud is that this is not a commercial project or something done for publicity. It is simply that we have knowledge that can help others less fortunate and we do so without hesitation.

We are at an important crossroad in the history of our Industry. We have the knowledge and capability to treat people on a global basis. However, we are faced with limitations and capacity constraints for our most critical raw material – plasma.

Q What motivates you?

Being challenged intellectually and creatively. Working provides the intellectual challenge; building things provides the creative challenge. I like to tinker – in my "spare" time I enjoy woodworking and building guitars. I am always thrilled with a finished product that exceeds my expectations.

Q What are your goals as the new Chair of PPTA's Global Board of Directors?

My primary responsibility is to continue PPTA's role as a leading industry representative that is viewed with confidence as a knowledgeable and credible source of information and insight. In its most simple form, this can be realized by focusing PPTA's resources in two areas: Technical standards and education. Certainly, within these general areas, there are many subparts such as access to care, reimbursement, donor and patient safety, and advocacy. However, I like to keep things simple; delivering a clear and consistent message. We work with lifesaving products that make a true difference in people's lives. We can never lose sight of how important these therapeutics are to the patients that use them and that the steps we take to ensure safety and efficacy are fully understood.

Q What do you see as challenges and opportunities for this industry?

We are at an important crossroad in the history of our Industry. We have the knowledge and capability to treat people on a global basis. However, without sufficient plasma resources, global access to these lifesaving therapeutics will always be compromised. Patients with need for our products are often outside of our reach. There are a number of reasons for this. Oftentimes, plasma resources are limited by "well-intentioned" advocates of self-sufficiency. Ethical and moral questions are thrown around to limit the collection of plasma in sufficient quantities to support demand and need. PPTA's greatest challenge and opportunity is to test the underlying premise of these advocates and educate the global community that Source plasma is safe, that Donors should treated with respect and that these Plasma Donors give much of themselves, including time, to help build an adequate supply of plasma for processing into therapeutic products. To value a Donor's time and effort as non-compensable is itself disrespectful and ensures that we will never have an adequate supply of plasma to treat those in need of these lifesaving products.

Another opportunity is to regain the confidence of the treating community in using IVIG as a frontline treatment for infectious disease. IVIG was initially developed to combat infectious diseases, and has been shown to be efficacious in the treatment of infections by known agents as well as certain emerging viruses when IVIG is made from convalescent plasma containing neutralizing antibodies.

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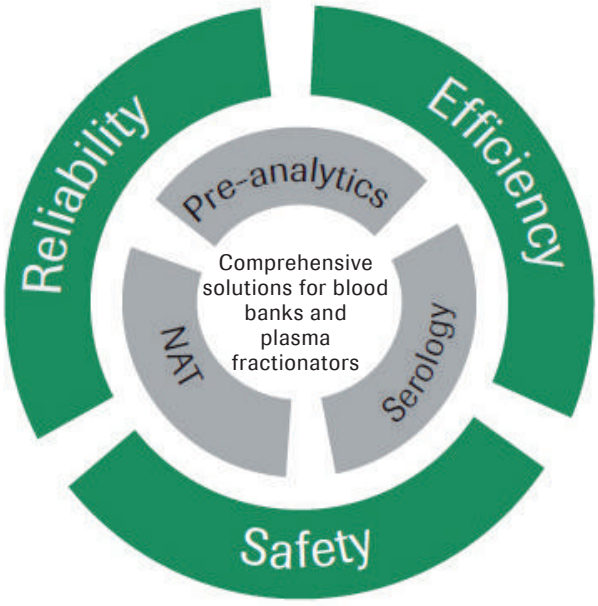

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EU Rare Disease Policy:

THE IMPLEMENTATION AT EU—AND MEMBER STATE LEVEL—STATE OF PLAY

BY KARL PETROVSKY

Rare diseases are a key health policy priority in the European Union (EU) due to the limited number of patients and scarcity of relevant knowledge and expertise regarding particular diseases. Patients with rare diseases, some of them suffering from primary immune deficiency and other conditions treated by plasma derived medicinal products, often spend years of uncertainty waiting for their disease to be diagnosed, and for an appropriate treatment to be found.

The medical expert who can diagnose a rare disease may practice in another region or even in another Member State. Scientific knowledge on a specific rare disease is likely to be insufficient and scattered. This is why the EU and cooperation between Member States can make a difference in pooling together knowledge and expertise, in fostering research and cooperation, and in granting the authorization of the best possible medicines for the whole European Union. EU action on rare diseases provides high added value.

Since the European Commission's (EC) "Communication on Rare Diseases: Europe's challenge of 2008"[1] and the Council's "Recommendation on an action in the field of rare diseases of 2009,"[2] significant gains have been made and initiatives launched to improve rare disease diagnosis and care in EU Member States. The EC Communication aimed to enhance recognition, support Member State policy, and develop EU harmonization and regulation in the field of rare diseases. The Council's Recommendation appealed to Member States to implement national plans on

rare disease management and aimed to define, code, and record rare diseases, increase research, build European Reference Networks, gather EU expertise, empower patient organizations, and develop sustainability.

The definition of a rare disease is a prerequisite for effective action in this field. Member States committed to use, for the purposes of Community-level policy work, the definition of rare disease from recital 55 of the Cross-Border Healthcare Directive:[3] a disease affecting no more than five per 10,000 people.

This definition confirms that most conditions treated with plasma protein therapies fall into the category of rare diseases and need a specific approach and policy.

In the end, it depends on whether Member States have or have not adopted rare disease plans. Member States with adopted plans or strategies comply with the EU definition for the Community level policy. Those without plans in place usually do not have any official definition of rare disease.

The EC published an implementation report on the "Commission Communication on Rare Diseases: Europe's challenges" in late 2014.[4]

There are several areas where it is important to have action taken with regard to rare diseases:

- EU Member States plans and strategies in the field of rare diseases.
- Definition, codification, and inventorying of rare diseases.
- Research on rare diseases.
- Centers of expertise and European reference networks (ERNs) for rare diseases.
- Gathering expertise on rare diseases.
- Empowerment of patients' organizations.
- Governance and European coordination.
- Actions to improve high-quality care for rare diseases.
- Global dimension of the rare diseases policy.
- EU Member State plans and strategies regarding rare diseases.

The EC has fostered the exchange of experiences to help Member States develop their national plans or strategies for rare diseases. This has helped a significant number of Member States to put in place dedicated plans to address rare diseases. Sixteen Member States had rare disease plans in 2014 as compared to only four in 2008. Despite some encouraging progress, there is still a long way to go to ensure that people suffering from a rare disease can obtain the right diagnosis and best possible treatment throughout the EU. There are still Member States that do not yet have a national plan or strategy.

The EC Communication aimed to enhance recognition, support Member State policy, and develop EU harmonization and regulation in the field of rare diseases.

In those Member States that do have a national plan or strategy in place, implementation has, for the most part, started only recently and needs to be monitored.

PATIENT REGISTRIES AND DATABASES

Patient registries and databases constitute important instruments to improve patient care and healthcare planning. They are also vital in assessing the feasibility of clinical trials, facilitating the planning of appropriate trials, and supporting the enrollment of patients. As of January 2014, there were 588 rare disease registries distributed as follows: 62 European, 35 global, 423 national, 65 regional, and three undefined. Most of the registries are managed by public and academic institutions. A minority of them are managed by pharmaceutical or biotech companies, while others are being run by patient organizations. The lack of interoperability between rare disease registries is severely jeopardizing the registries' potential. This is why the EC's Joint Research Centre is currently developing a European Platform on rare diseases registration. The objectives for this platform are to provide a central access point for information on rare disease patients' registries for all stakeholders,

to support new and existing registries in view of their interoperability, to provide IT tools to maintain data collection, and to host activities of the surveillance networks.

POPULATION SCREENING FOR RARE DISEASES

The EC continues its efforts to evaluate current population screening (including neonatal screening) practices and strategies for rare diseases, including the number of centers, an estimation of the number of infants screened, and the number of disorders included in the newborn screening, as well as reasons for the selection of these disorders. The majority of Member States have a body which oversees newborn screening. The numbers of diseases screened vary substantially between Member States, from one in Finland to 29 in Austria.

Finally, in order to continue efforts to provide improved diagnosis and care for people suffering from a rare disease, the following EU actions are key to supporting the activitives of EU Member States:

- Maintain the EU's coordinative role in the development of the EU policy on rare diseases and to support Member States in their activities on the national level.
- Continue to support the development of high quality National Rare Diseases Plans/Strategies in the EU.
- Provide continued support for the International Rare Disease Research Consortium and initiatives developed under its umbrella.
- Work to further decrease inequalities between patients with rare diseases and patients suffering from more common disorders and to support initiatives promoting equal access to diagnosis and treatment.
- Ensure proper definition and codification of rare diseases.
- Make use of Directive 2011/24/EU on the application of patients' rights in cross-border health care to bring together ERNs on rare diseases. Support the development of the tools facilitating cooperation and interoperability of the ERNs for rare diseases.
- Implement and continue support for the European Platform on rare diseases registration. •

KARL PETROVSKY, *PPTA Senior Manager, Health Policy*

References

1. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on Rare Diseases: Europe's challenges, Brussels, 11.11.2008. COM(2008) 679 final
2. Implementation report Health and Consumers on the Commission Communication on Rare Diseases: Europe's challenges and Council Recommendation of 8 June 2009 on an action in the field of rare diseases, Implementation report on the Commission Communication on Rare Diseases: Europe's challenges [COM(2008) 679 final]
3. DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
4. of 9 March 2011 on the application of patients' rights in cross-border healthcare
5. http://ec.europa.eu/health/rare_diseases/docs/2014_rarediseases_implementationreport_en.pdf

The lack of interoperability between rare disease registries is severely jeopardizing the registries' potential.

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Inside PPTA

NEWS FROM AROUND THE GLOBE

International Developments

BY SONIA BALBONI

PPTA has engaged in international issues since the organization's inception. We have advocated for patient access in Latin America, conducted workshops and advocacy in China, and met with regulators and legislators to discuss prohibitions on plasma collection in Canada. In addition, PPTA has been asked to engage in regulatory issues in Argentina, Brazil, China, Mexico, Turkey, and Malaysia. We have addressed self-sufficiency questions and advocated for access to care in Colombia, Ecuador, China, India, Japan, and Canada. These countries are located in areas where PPTA did not have dedicated staff or a formal plan of work. PPTA has always had multilingual staff with an impressive skill set, enabling us to address issues as they have arisen. However, during the past few years, the need for PPTA engagement has increased.

The Global Board of Directors recognized a growing need for industry attention in regions where, before, there was little or no Association presence. In response, PPTA developed a new department to address international issues in a more formal manner. The result is PPTA's International Affairs Department whose mission is to advocate for PPTA membership in underserved regions so that industry can better meet patients' needs for access to care.

One of the priorities for the department is leveraging international trade agreement negotiations like the Transatlantic Trade and Investment Partnership, or TTIP. The United States government and European Commission are working on a trade deal designed, among other things, to break down barriers to market access between the two economies. The International Department staff are working to persuade negotiators to include provisions that would help member companies provide life-saving therapies to patients more easily, in both the United States and Europe. These provisions include mutual recognition of inspections, breaking myths related compensated donation and self-sufficiency, and regulatory convergence, to name a few.

The Global Board of Directors recognized a growing need for industry attention in regions where, before, there was little or no Association presence.

Another undertaking for the International Department is to address industry's interests in China. For some years PPTA has organized a steering committee of members to evaluate and conduct Association activities through a variety of pathways. PPTA has also sponsored educational seminars in China and sent speakers to participate in fora about safety and efficacy, clinical need for therapies, and the importance of addressing rare diseases. Now with dedicated international affairs staff, the Association has greater and more focused resources. PPTA can research issues more thoroughly, increase industry outreach on behalf of access to care, and generally devote more time to address issues of international strategic importance.

One of the department's initial projects has been to build informational profiles for each country with patients using plasma protein therapies. These profiles contain current information on a country's economic, political, and health policy status, as well as details like patient populations, patient organizations, and general information relating to the plasma protein therapy industry in country. PPTA also is building a customized database to provide staff with thorough and up-to-date information on legislation, regulation, and policies relating to the plasma protein therapeutics industry. The database will be sourced through a web portal run by Tarius®.

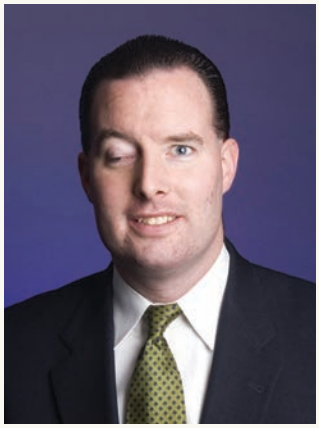
Staff working in the International Department include:

- **Julia Fabens,** Manager, International Affairs
  Ms. Fabens joined PPTA from the U.S.-Russia Business Council where she was Director of Membership. In that role, she had extensive experience with the intricacies of trade associations, as well as the issues of importance to companies operating internationally. Ms. Fabens graduated from Colby College with a B.A. in International Relations and a minor in Russian.

Julia Fabens

Joshua Penrod

Sonia Balboni



John Delacourt

In addition to bringing on Ms. Fabens, three existing staff members will commit their expertise to the Department on a part-time basis.

- **Joshua Penrod**, Vice President, Source & International Affairs
  Mr. Penrod has worked for the Association for thirteen years. In addition to his wealth of knowledge on industry practices, he led a steering group to address member interests in China and has conducted advocacy actions in Canada and Asia. Mr. Penrod has a Juris Doctor (*cum laude*) from the Thomas M. Cooley Law School, an LL.M. in International and Environmental Law and an M.P.H. from the George Washington University. He also earned a Master of Business Administration from the Merrick School of Business at the University of Baltimore.
- **John Delacourt,** Vice President, Legal Affairs & Global Operations
  Mr. Delacourt, an attorney, has been with the Association for more than six years and represented PPTA as outside counsel for several years prior to that. Mr. Delacourt is responsible for legal issues arising from the Association's mission and also has reporting responsibility for finance and operations within the organization. He has written articles in *The Source* magazine about trade barriers and the TTIP. Mr. Delacourt has a Juris Doctor (*cum laude*) from Harvard Law School, and a B.A. from Georgetown University (*summa cum laude*).
- **Sonia Balboni,** Senior Manager, Source & Standards
  Ms. Balboni has been with the Association for six years. At PPTA, she recently led a project to enhance the global applicability of the industry standards program. Prior to joining the organization, Ms. Balboni worked in Latin American business development and international medical device standardization. She has a Masters Degree from the University of California, San Diego School of Global Policy and Strategy (IR/PS), focusing on international trade and business management, concentrating on Latin America and the Pacific Rim. She also holds a B.A. in international political science from Trinity College in Connecticut.

While the department holds primary responsibility for issues affecting new markets, because of the industry's global nature, staff will work in a matrix fashion, with subject matter experts throughout the Association contributing their skills as needed.

With the departmental staff's strong knowledge of issues, breadth of experience, and global bank of information, PPTA is well equipped to assess industry's needs for engagement. While the full spectrum of countries or regions for engagement has not been formalized yet (a decision the Global Board of Directors will make), the scope of the International Department extends to any area outside of Europe and the United States. Staff from PPTA's offices in Brussels and the United States will continue to manage issues and access to care considerations in those more established regions. •

SONIA BALBONI, *PPTA Senior Manager, Source & Standards*

Donating Plasma . Saving Lives

INTERNATIONAL PLASMA AWARENESS WEEK
OCTOBER 9 - 15, 2016

INTERNATIONAL PLASMA AWARENESS WEEK 2016 IS COMING!

OCT. 9-15, 2016

International Plasma Awareness Week (IPAW) will be Oct. 9-15, 2016. Help to tell the story of why plasma donation is important, how it helps patients who need lifesaving therapies, and the importance of plasma donors.

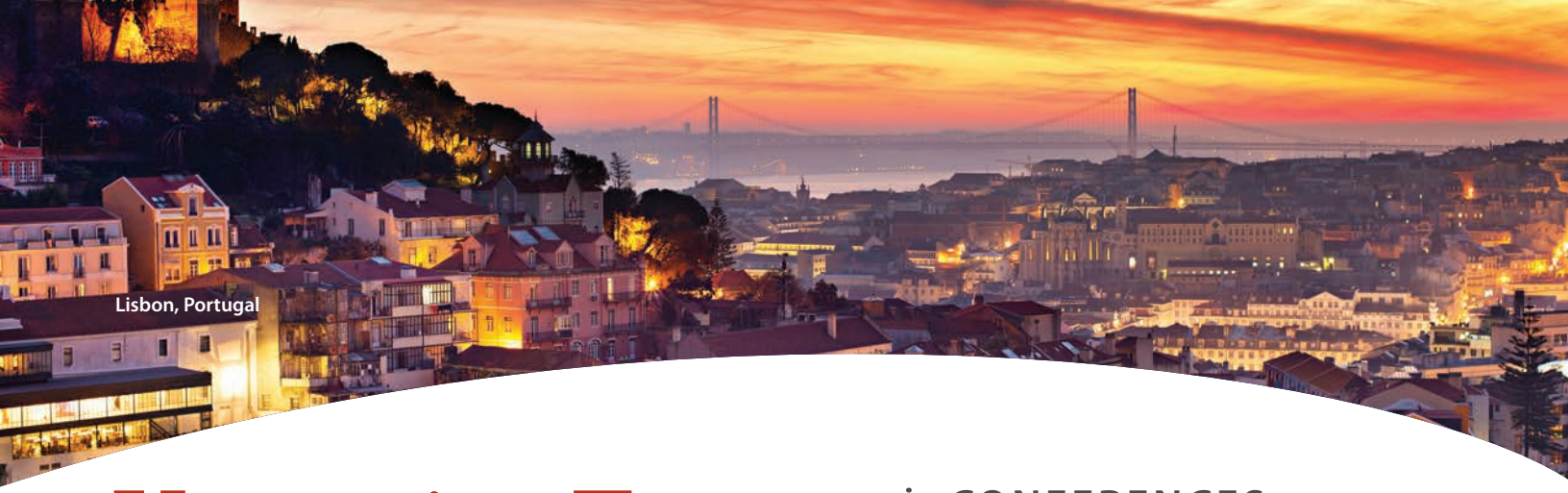
IPAW is an ideal opportunity to highlight plasma protein therapies, the role your organization plays in making lifesaving therapies available to those who need them, and your role in caring for and honoring the donors who make it possible.

Past successes include a 2014 event in Berlin in cooperation with the German Arbeitsgemeinschaft Plasmapherese (ARGE). Martina Stamm-Fibich (SPD), member of the German Parliament and of the Health Committee, was invited to give the keynote.

In 2015, PPTA staff conducted Capitol Hill visits with all 100 United States Senate offices to educate on the importance of plasma protein therapies and source plasma collection.

In 2016, PPTA seeks to add to these successes by engaging with donors, patients, patient groups, legislators, and others.

Stay tuned for information on how PPTA can help you promote International Plasma Awareness Week. •


Lisbon, Portugal

Upcoming Events

CONFERENCES & SYMPOSIUMS

March

31 – April 2 Hemophilia Federation of America (HFA) Symposium
Las Vegas, Nevada, U.S.

April

17 World Hemophilia Day 2016

22 – 29 World Primary Immunodeficiencies Week (WPIW)

23 – 24 8th International Conference on Primary Immunodeficiency (PI)
Tehran, IRAN

May

4 – 6 24th Biennial International Congress on Thrombosis
Istanbul, TURKEY

16 Hereditary Angioedema (HAE) Day

25 – 26 International Plasma Fractionation Association (IPFA)/Paul-Ehrlich-Institut (PEI) 23rd Annual International Workshop on "Surveillance and Screening of Blood Borne Pathogens"
Lisbon, PORTUGAL

26 – 28 8th European Conference on Rare Diseases & Orphan Products
Edinburgh, UK

June

14 – 15 PPTA Plasma Protein Forum
Washington, D.C., U.S.

24 – 26 25th Annual Alpha-1 National Education Conference
Miami, Fla., U.S.

July

8 – 10 Immune Thrombocytopenia (ITP) Conference
Orlando, Fla., U.S.

21 – 23 National Hemophilia Foundation (NHF) 68th Annual Meeting
Orlando, Fla., U.S.

24 – 28 World Federation of Hemophilia (WFH) 2016 World Congress
Orlando, Fla., U.S.

August

23 – 26 2016 National Ryan White Conference on HIV Care and Treatment
Washington, D.C., U.S.

September

21 – 24 17th Biennial Meeting of the European Society of Immunodeficiencies (ESID)
Barcelona, SPAIN

23 – 24 Guillain-Barré Syndrome (GBS)/Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Foundation International Symposium 2016
San Antonio, Texas, U.S.

October

9 – 15 International Plasma Awareness Week (IPAW)

GLOSSARY OF TERMS

A-PLUS – AMERICAN PLASMA USERS COALITION

ARGE - ARBEITSGEMEINSCHAFT PLASMAPHERESE

DHG - DEUTSCHE HÄMOPHILIEGESELLSCHAFT

EBA – EUROPEAN BLOOD ALLIANCE

EC – EUROPEAN COMMISSION

EHC - EUROPEAN HAEMOPHILIA CONSORTIUM

EPA – EUROPEAN PLASMA ALLIANCE

EPCC – EUROPEAN PLASMA COLLECTORS COMMITTEE

ERN – EUROPEAN REFERENCE NETWORK

EU – EUROPEAN UNION

EUHASS - EUROPEAN HAEMOPHILIA SAFETY SURVEILLANCE

GTH - GESELLSCHAFT FÜR THROMBOSE- UND HÄMOSTASEFORSCHUNG

HAEI - HEREDITARY ANGIOEDEMA INTERNATIONAL

IFBDO – INTERNATIONAL FEDERATION OF BLOOD DONOR ORGANIZATIONS

IGH - INTERESSENGEMEINSCHAFT HÄMOPHILER

IPAW - INTERNATIONAL PLASMA AWARENESS WEEK

IPFA - INTERNATIONAL PLASMA FRACTIONATION ASSOCIATION

IPOPI - INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES

IQWiG - INSTITUTE FOR QUALITY AND EFFICIENCY IN HEALTHCARE

MSM – MEN WHO HAVE SEX WITH MEN

NHF – NATIONAL HEMOPHILIA FOUNDATION

PDMP – PLASMA-DERIVED MEDICINAL PRODUCT

PEDNET - EUROPEAN PAEDIATRIC NETWORK FOR HAEMOPHILIA MANAGEMENT

PEI – PAUL-EHRLICH-INSTITUTE

LFB - LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES

AVIS - ASSOCIAZIONE VOLONTARI ITALIANI SANGUE

PLUS - PLATFORM OF PLASMA PROTEIN USERS

PPTA – PLASMA PROTEIN THERAPEUTICS ASSOCIATION

TRIS – TECHNICAL REGULATION INFORMATION SYSTEM

TTIP – TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

VAT – VALUE-ADDED TAX

VUD – VOLUNTARY UNPAID DONATION

WFH – WORLD FEDERATION OF HEMOPHILIA

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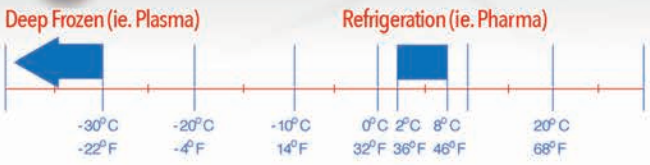

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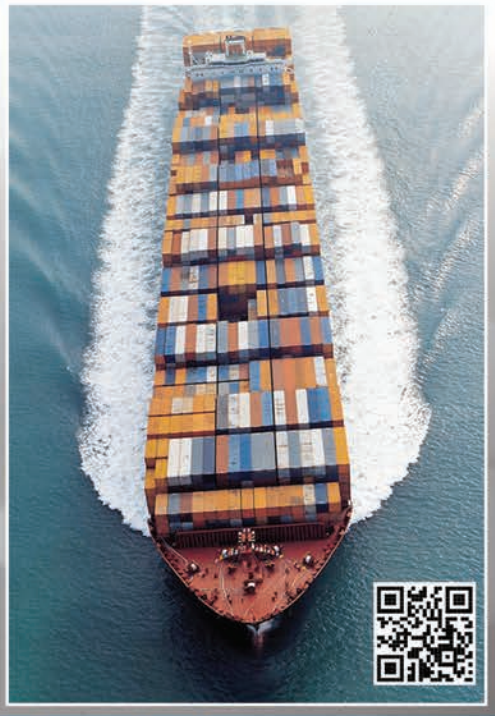

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Aurora is the automated system that streamlines plasma collection procedures, produces virtually cell-free plasma and provides an improved experience for both operators and donors.

- Intuitive touch screen display
- Data Management with Aurora provides easy, accurate data collection, remote procedure setup and paperless documentation
- Designed to improve plasma center efficiency

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