

# INSIDE PPTA

PPTA NEWS FROM  
AROUND THE GLOBE

## ▼ 31<sup>ST</sup> ISICEM CONGRESS HELD IN BRUSSELS, BELGIUM

PPTA organized a satellite symposium during the 31st International Symposium on Intensive Care and Emergency Medicine (ISICEM) Congress on March 24 in Brussels, Belgium. This event is organized by the Department of Intensive Care Emergency Medicine of Erasme University Hospital, Université Libre de Bruxelles in association with the Belgian Society of Intensive Care and Emergency Medicine. Started in 1980, this meeting, held every March, is now one of the largest of its field and attracts up to 5,600 participants. During the satellite symposium, key opinion leaders, Prof. Simon Finfer (Australia), Prof. Timothy W. Evans (United Kingdom) and Dr. Pietro Caironi (Italy) presented the latest developments on the use of albumin in sepsis. The satellite symposium was chaired by Prof. Albert Farrugia, PPTA's Vice President, Global



## ▼ PPTA MEETS WITH EUROPEAN MEDICINES AGENCY (EMA)

PPTA met with European Medicines Agency (EMA) experts for its annual liaison meeting. The meeting has become a valuable event, as EMA outlines its priorities for the year ahead. Subjects covered in the briefing included: contract fractionation and the related revision to Annex 14 of the Good Manufacturing Practices (GMP) requirements, EMA Road Map and fee structure, review of guideline 269/95 (EMA believe the industry should be pleased with the new version), Plasma Master File and epidemiology reporting. A report of the meeting is in preparation. PPTA raised some issues including the need to tidy up certain regulations that mistakenly require plasma for fractionation to be tested for Human T-Lymphotropic Virus I and II (HTLV 1 & 2). Additionally, PPTA staff stressed the urgent need to review the albumin guidelines in light of the new findings and questions surrounding the veracity of the work of Dr. Joachim Boldt, which promoted a starch based alternative to albumin. Finally, PPTA learned of a new 'Blood Cluster' harmonization initiative supported by both the U. S. Food and Drug Administration and the EMA and not including the industry.



## ▼ PPTA HOLDS CONGRESSIONAL STAFF BRIEFING

The Association, in collaboration with the patient community, hosted a Congressional staff briefing on March 31 focused on the uniqueness of plasma protein therapies and the importance of access. Presentations were made by patients including Lisa Miller, who has primary immunodeficiency; Michelle Rice, who has two sons with hemophilia and works with the National Hemophilia Foundation (NHF); and John Walsh, who has alpha-1 and also is the founder, president and CEO of the Alpha 1 Foundation.

Dr. Craig Kessler, a hematologist/oncologist with Georgetown University Hospital and chair of NHF's Medical and Scientific Advisory Council also presented at the briefing and described the challenges with treating hemophilia. Julie Birkofer of PPTA moderated the panel. Staff from a number of Congressional offices attended including Reps. Pitts (R-PA), Frank (D-MA), Kinzinger (R-IL), Biggert (R-IL), Chu (D-CA), Walberg (R-MI) and Israel (D-NY) among others. Visit [www.pptaglobal.org](http://www.pptaglobal.org) and read the news release or listen to the audio of the one-hour briefing.



**PPTA collaborated with patient groups to host a Congressional briefing in March that focused on the unique nature of plasma protein therapies and the need to preserve patient access. Pictured from left to right are: John Walsh, Dr. Craig Kessler, Michelle Rice and Lisa Miller.**

# Anti-Tetanus toxoid immunoglobulin quantification



The accurate determination of Tetanus toxoid immunoglobulin levels in human serum and plasma is important both in the manufacture of Tetanus Hyperimmune Globulin and in the diagnosis of Primary Immunodeficiency.

Binding Site understands that the testing requirements of therapeutic immunoglobulin manufacturers and clinical laboratories are very different and is pleased to offer assays optimised for the needs of each.

Application:	Primary Immuno-deficiency Diagnosis	Plasma donor unit Screening	Plasma donor unit Screening
<b>Platform:</b>	ELISA	ELISA	Turbidimetry*
<b>Measuring Range:</b>	0.01-7 IU/mL	1.23-300 IU/mL and 0.25-60 IU/mL	1.56-50 IU/mL
<b>Calibrated to:</b>	NIBSC Tetanus antitoxin reference preparation 76/589	NIBSC Tetanus Immunoglobulin, Human TE-3	NIBSC Tetanus Immunoglobulin, Human TE-3
<b>Test per kit:</b>	1 x 96 well plate	10 x 96 well plates	5 x 200 tests
<b>Product Description:</b>	Tetanus toxoid IgG EIA kit	Tetanus toxoid IgG EIA kit	Tetanus toxoid latex SPAPLUS kit
<b>Product Code:</b>	MK010	MK010.4	LK710.S



\* **SPA PLUS**

**Specialist Protein Analyser**  
A turbidimetric, fully automated platform for measuring Tetanus toxoid immunoglobulin.

[www.bindingsite.com/spaplus](http://www.bindingsite.com/spaplus) for more information.

Please enquire regarding FDA status.

[www.bindingsite.com/manufacturers](http://www.bindingsite.com/manufacturers) for more information



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The Specialist Protein Company

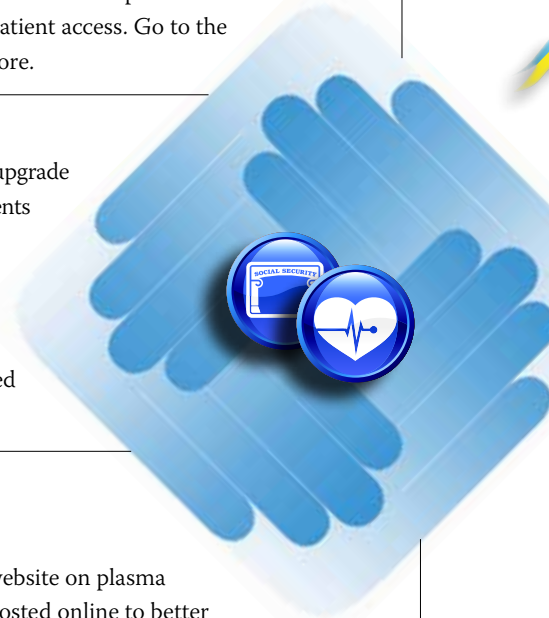


## ◀ 1099 TAX-REPORTING PROVISION REPEALED

On April 14, 2011, President Barack Obama signed into law the “Comprehensive 1099 Taxpayer Protection and Repayment Exchange Subsidy Overpayments Act of 2011.” For more than a year, PPTA strongly advocated for the passage of this new law, which strikes from 1099 tax reporting “amounts in consideration for property,” a provision added in health care reform. Because courts have held that plasma donations are considered “property” for the purpose of income taxes, repeal of the expansion of the 1099 reporting requirement is vital to the preservation of human plasma collection and is a victory for patient access. Go to the Newsroom on [www.pptaglobal.org](http://www.pptaglobal.org) to learn more.

## NDDR UPGRADED ▶

The National Donor Deferral Registry (NDDR) upgrade was rolled out on February 27, 2011. Enhancements such as Social Security Number encryption and software upgrades improve the donor screening process for all involved. The advanced system provides increased efficiency and functionality to the industry’s database of permanently deferred plasma donors in North America.



## ◀ NEW SPANISH LANGUAGE TRANSLATIONS AVAILABLE ON PPTA WEBSITES

PPTA recently updated the Association’s global website and its website on plasma donation with Spanish language translations of some materials posted online to better serve consumers. PPTA updated the websites to provide information about the plasma protein therapeutics industry to a Spanish-speaking audience and to provide information to a diverse audience. Users wishing to view the materials online in Spanish can now click on links provided “En Español” that will show the translation in the Spanish language of their current page. Information on plasma donation and lifesaving plasma protein therapies is now available as a resource to the Spanish-speaking community. To view the translated materials online, please go to [www.pptaglobal.org](http://www.pptaglobal.org) or [www.donatingplasma.org](http://www.donatingplasma.org).



## GLOSSARY OF TERMS

<b>ACA</b>	Affordable Care Act	<b>IPPC</b>	International Plasma Protein Congress
<b>A-PLUS</b>	American Plasma Users Coalition	<b>IPOPI</b>	International Patient Organisation for Primary Immunodeficiencies
<b>CEA</b>	Cost Effectiveness Analysis	<b>IPPIA</b>	International Plasma Products Industry Association
<b>CER</b>	Comparative Effectiveness Research	<b>IRS</b>	Internal Revenue Service
<b>CMS</b>	Centers for Medicare and Medicaid Services	<b>ISICEM</b>	Intensive Care and Emergency Medicine Congress
<b>CUA</b>	Cost Utility Analysis	<b>NDDR</b>	National Donor Deferral Registry
<b>CVID</b>	Common Variable Immune Deficiency	<b>NHF</b>	National Hemophilia Foundation
<b>EDQM</b>	European Directorate for the Quality of Medicines and HealthCare	<b>PhRMA</b>	Pharmaceutical Research and Manufacturers of America
<b>EMA</b>	European Medicines Agency	<b>PID</b>	Primary Immunodeficiency
<b>EU</b>	European Union	<b>PLUS</b>	Plasma Users
<b>FDA</b>	U.S. Food and Drug Administration	<b>PPACA</b>	Patient Protection and Affordable Care Act
<b>GMP</b>	Good Manufacturing Practices	<b>PPT</b>	Plasma Protein Therapies
<b>HHS</b>	Department of Health and Human Services	<b>QALY</b>	Quality Adjusted Life Year
<b>HTA</b>	Health Technology Assessment	<b>QSEAL</b>	Quality Standards of Excellence, Assurance and Leadership
<b>IMAB</b>	Independent Medicare Advisory Board		