Compensated

BY JOSHUA PENROD AND SONIA BALBONI

SOURCE PLASMA DONOR COMPENSATION should be separated from discussions about product safety. For the better part of two decades, there have been no reported transmissions of Hepatitis C, Hepatitis B, or HIV in any plasma product manufactured by a PPTA member company. Despite this lengthy record of safety, presumption and misinformation sometimes prevail when questions relating to compensated donation arise. Recent stories in the Canadian media have brought this to light. Many in the industry and our observers have taken note of recent public policy debates in Canada relating to the potential opening of plasma centers. The focus of the media reports has been donor compensation, with some critics assailing the possibility that the Canadian government could be disregarding the lessons on safety learned many years ago.

Nothing could be further from reality.

As is well-established through the peer-reviewed literature, exhaustive licensing and inspection procedures, and implementation of voluntary industry standards programs, the plasma protein therapeutics industry has demonstrated extraordinary leadership in helping ensure the highest possible levels of safety. Donor screening and selection, testing, physical assessment, computerized management, voluntary industry standards, production processes, and pathogen inactivation have all combined to create therapies of uncommon safety and high impact.

In Canada, if safety is consistently and truly the issue, that question has been well-settled for many years and the critics need only look to the volumes of data and publications underscoring the facts. The conversation would be better served if, instead, the issues themselves were discussed forthrightly and openly. To that end, we invite conversation about donor compensation and the practices of the industry.

Beyond the questions about safety, however, are politically-driven goals that actually do great harm to patients. Late last year, in a publication by the European Blood Alliance and republished in the America's Blood Centers newsletter, the World Health Organization again made headlines with its proclamation insisting on the "principle" of altruistic donations. The reasons given in the proclamation include safety and ethical concerns.

The ethical concerns have been discussed at length in many different publications, including a recent article in *The Source* (*see Penrod and Farrugia, Winter 2012*). Just as in the

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conversation about safety, volumes can be written about the debate over donor compensation—in fact, volumes already have been written. Without attempting to re-hash the debates, or again write what was already shown, we can say that our industry's detractors, or those who do not fully understand our industry, often conflate these concerns, creating a cloud of uncertainty. Sadly, the result is that worry and misunderstanding triumph over patient care. The results may occur in several forms, including international trade barriers; self-sufficiency policies targeted toward erroneous ends, and generalized concerns about safety.

For instance, political preferences can lead to obstructions to international trade, which may be cloaked by safety discussions. The true reason behind an obstruction could actually be a hasty reaction to public perceptions on the practice of compensated plasma, or even a regulatory or statutory deployment favoring protection of a domestic industry. It is sometimes difficult to isolate one rationale behind these measures, but it is simplified by knowing that whatever the reason, patients suffer.

Hand in hand with trade barriers comes a rationalization in the form of an avowed self-sufficiency policy. While from the public health and national security standpoint, a self-sufficiency policy makes sense for blood components with short shelf lives, the complexity of the global plasma protein therapeutic industry makes such policies result in availability issues. In turn, this increases government and payer pressure on diagnosis, substituting a political and economic goal instead of true patient need. When one speaks of ethics and systems favoring patient care, one must consider the need of patients and empirical medical findings.

As discussed above, viral safety has been and continues to be a top focus for the industry. Donor selection, examination, screening, assessment, and testing processes reduce risk by orders of magnitude. Companies participating in PPTA's International Quality Plasma Program (IQPP) have the added assurance of a third-party audit system and compliance with the Viral Marker Standard, the Qualified Donor Standard, the Community-Based Donor Standard, the Donor Education Standard, and others. All of these steps take place prior to the plasma even entering further production; during the fractionation process, robust and sophisticated pathogen inactivation steps occur which eliminate further risk. Companies adhering to the PPTA Quality Standards for Excellence and Leadership (QSEAL) further benefit.

The industry has earned a strong safety record for its robust practices including screening, testing and manufacturing. Concerns about compensation remain; however the practice will prevail as we continue to recognize the effort that it takes to be a committed, regular donor. To *not* recognize such commitment would be nonsensical. We are proud of our donors' dedication and for that reason compensation will remain a vital part of our industry.

Joshua Penrod, *Vice President, Source*
Sonia Balboni, *Manager, Source and Standards*