The Story of Ontario:

POLICYMAKING AND MISUNDERSTANDINGS

BY JOSHUA PENROD

Questions on the ethics behind compensating plasma donors are as old as the practice itself. For the past decade the issue has clouded policy debates, particularly in Europe. But in 2014, the ragged edge of the discussion involving the appropriateness of a policy supporting compensation for donors has drifted outside the context of the European Parliament and the offices of European national policymakers.

In the United States, in 2013, nearly 29,000,000 source plasma donations were given and used around the world, including Canada; but this year in Ontario, the premise of allowing compensated donation on their own turf has come under scrutiny.

The Ontario case has been covered before in *The Source*; there's little need to repeat those events except to say that there was a legislative attempt to ban compensated donation in Ontario. This spring, Parliament dissolved over heated policy issues before hearings could be held. Following Parliamentary elections in June, a new government formed and soon thereafter announced its intent to re-introduce similar legislation aimed to produce a similar result. At the same time, news features and op-eds have run the press circuit.

Various groups may indeed differ on the issue as far as what constitutes an ethical practice, what constitutes safety, and many other concerns and problems that span the spectrum of plasma donation. But one characteristic common to the detractors of the practice is a lack of knowledge about plasma donation and why donor compensation has taken root in the US and elsewhere.

For several years now, PPTA and member companies have engaged in a public awareness campaign in an effort to dispel myths about the plasma collection process. This includes promulgating messages about the vital uses of plasma, how plasma is collected, how patients benefit from plasma, testing, quality, and safety, and why we compensate donors. The last question can be both simple and complex: plasmapheresis is a time-consuming process and the industry requires many donations in order to make finished plasma therapies. Also, it includes recognition of a regular donor's time and commitment to the process and allows reciprocity in the relationship.

The Ontario situation, in particular, has become a microcosm of the ongoing controversy and misunderstandings about plasma and plasma products. Many parties have expressed concern about safety, the meaning of compensation, how donors are treated, and what sort of people the donors are.

The questions stem from an historical image of the industry which has now become embedded as a stereotype of the plasma center and the plasma donor himself. The stereotype has its roots in the hypothetical "donor profiles" imagined by Richard Titmuss in his 1971 book, The Gift Relationship, wherein, without empirical data, plasma donors were boxed into the category of "paid donor." The stereotype has persisted for more than 40 years.

An offshoot of the cultural stereotype depicting donors, are concerns about safety. The discussion takes two major forms: the safety of the plasma itself, and the safety of the individual giving the donation. Ultimately, the layers of quality and safety put in place by industry provide further assurance of a donation process that is already proven safe. Testing, donor assessment and screening, and a fully integrated process for donors and donor management are an irreplaceable part of contemporary plasma donation. Because of current industry safeguards and practices, any argument that compensation leads to unsafe product is outdated. In fact, Canadian policymakers have stated that national concerns have nothing to do with plasma safety; they agree that products made from compensated donors or made in the United States, are safe. Recent quotes by newly-installed Ontario Minister of Health Eric Hoskins underscores this.

Rather than donor safety, the present Canadian argument seems to be that compensation is inherently unethical, and therefore, even if the fruits of compensation undertaken in other jurisdictions may be reaped in Canada, the practice of compensation in Canada should not be allowed. In other words, they seem to argue that Canadians may become tainted by donating plasma for compensation, although the plasma itself would still be unsullied. This position is such that any monetary value ascribed to any part of the human body stems from wrong assumptions about the nature of economics and demonstrates a lack of affinity for pro-social policy objectives. The argument relies on a very specific application of the concept, as working people constantly trade their bodies for value, in the sense of labor and salary. The "something different" is constructed as some other ineffable quality relating to the constituents of the body itself, however. The objections can be religious or sprout from other ethical systems in which the social is elevated further, and that the individual's determination of the value of their individual body is deferred in favor of the state's decision. This is typically described in terms of protection from exploitation, wherein an actor which is perceived to possess greater power overrides a lesser-powered party or individual. Oftentimes, this has rational benefit and protects basic freedoms; other times, however, it militates against individual volition and deprives fundamental rights of association and participation.

Interestingly, much of the most balanced and well-informed commentary emerged from the patient communities themselves who have intimate familiarity with plasma therapies and, of course, the serious conditions that are treated by products produced from human plasma. PPTA has also contributed discussion points and items for consideration in the policymaking process, as has Canadian Blood Services. All of these voices have advocated for a balanced and sensible approach which take into account a number of social factors involved. Shortly after several articles and the Ontario Ministry of Health's announcement, one Canadian patient group posted: "Does Anyone Care What Patients Think?"

One of the most pernicious and persistent aspects of the debate is the confusion between blood/plasma for transfusibles use versus plasma collected specifically for further manufacture. Among the foremost making this distinction has been the organization responsible for collection of transfusible components in Ontario: Canadian Blood Services. Time and again, efforts by CBS and others, including PPTA, have been directed toward education highlighting the discrepancy. This remains an important, basic fact that continues to be overlooked.

Differentiation between plasma and blood has long been an objective of the industry, and is often recognized by scientific authorities, both governmental and otherwise, as a path by which the most effective regulations can be promulgated. These outcomes include critical distinctions about policies involving donor deferral, product safety, blood component availability, and many other related items. All too often, however, policymakers are not aware of these important distinctions, and the product is unfortunately cookie-cutter regulations which hinder the availability of safe product. Thus, lumping transfusibles and source plasma products together demonstrates not only a lack of understanding, but a disregard for science and well-settled regulatory policy made by leading scientific bodies around the world.

The issues in Canada are the ingredients for a perfect storm. Most concerning- is that an honorable system created to effect meaningful policy may be subverted. The most adverse consequence is the harm that could be wrought for patients' health and the confidence they have in their medicines. Never before have so many patients been treated by safer and high-quality therapies. Yet, as shown by the Canadian situation, they still face these needless obstacles. Patients deserve better, as do the many millions of donors who have contributed to the availability of life-saving therapies today. •

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