

## Blood trail: Canada still lacks controls on plasma trade,inquiry told

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### Canada still lacks controls on plasma trade, inquiry told Country has 'unsavory reputation' in some international circles

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#### **TORONTO**

Despite its "unsavory reputation in some circles as the center of the international plasma trade, Canada still has virtually no regulations to control the lucrative and sometimes shady business, according to evidence at a public inquiry. The inquiry has heard that, for decades, Montreal served as a stopover point for plasma collected in so-called "vampire shops" of the third world- where plasma is purchased for a pittance- that was destined for giant pharmaceutical companies in developed countries. Montreal's only rival was Zurich, which offered tax-free status along with lax regulation.

The international plasma trade is worth \$7-billion a year. Plasma, the sticky part of blood, is broken down into specialized drugs, some of which can sell for more than \$1-million a gram. Brokers buy either plasma or blood products and resell to customers elsewhere, adding a markup of 20 to 100 per cent.

Earlier at the hearing, Melvyn Green, counsel for the Commission of Inquiry on the Blood System in Canada, said that "Canada, and in particular Montreal, has developed an unsavory reputation in some circles around the world as being the center of the international plasma trade."

The main reason, he said, is that the Food and Drugs Act specifically excludes regulation of "drugs not manufactured for consumption in Canada and not sold for consumption in Canada." That means international brokers do not have to be licenced and the federal Bureau of Biologics does not have the power even to inspect their facilities. The only requirement is that packages are marked "export." (In the United States, blood brokers are registered but have not been licenced since 1980, meaning they are subject to some regulations.)

Asked by Mr.Green if Health Canada officials took any action during the past 20 years to change regulations pertaining to blood brokers, Dr.John Furesz, director of the bureau from 1974 to 1992, said: "Not as far as I know."

Dr.David Pope, assistant director of the bureau from 1976 to 1989, told the inquiry that the government licencing agency "does not even have the authority to gather data" to determine if such businesses exist today.

According to documents filed earlier at the commission, federal health officials have been aware of shortcomings in the law since the early 1970's but have not acted to tighten regulations.

"It is recommended that actions by the branch include the development of appropriate regulation for control of blood products in transit in Canada or for export from Canada, " John Riou, chief of field investigations

for the bureau, wrote in a report dated Jan. 19, 1977.

**"It is evident we are dealing with more than technical violations, but rather a calculated and deliberate business designed to take advantage of legal loopholes providing possibly hazardous products onto the world market, which could include the Canadian market," he wrote.**

**It was estimated that one person, working part-time could enforce the regulations.**

At the time, the bureau was investigating several Montreal-based companies that were importing and exporting blood products. By 1975, there were also 10 private companies buying and selling blood in Canada that were unregulated. One estimate was that more than 600,000 liters of plasma were passing through Canada annually, with shipments traced to Germany, Spain, Israel and France.

One company, Alpha Diagnostics, was purchasing large quantities of plasma, but because it was using it for "diagnostic purposes," it was not subject to regulations.

**Another company, Continental Pharma Cryosan Ltd., was importing products from the United States, some of which were believed to have been past their expiry date- repackaging them and shipping them to Europe. It also had a vampire operation in Bogota. Cryosan was found to have imported blood that was extracted from cadavers in Russia and to have relabelled the product as having been collected in Sweden. In 1980, the company pleaded guilty to mislabeling and was fined.**

Cryosan left the plasma business several years ago, but is unclear if other blood brokers still are operating in Canada.

Thomas Asher, a long-time blood broker, said he is unaware of any blood brokers operating in Canada. The business has been cleaned up so radically since the AIDS crisis, he said, that there are only a handful of brokers left in the world.

The past summer, Italian health authorities seized more than 125,000 liters of plasma that were smuggled into the country by a blood broker. Much of the plasma was improperly tested, and some of it had expired.

And in June, 1994, U.S. health officials discovered plasma that had been smuggled into the country illegally and labelled as fruit juice and tropical fish.