




The quest for Holy Grail : could plasma be universal ?

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The Holy Grail : Source or Recovered ?



Introduction

- Plasma: a starting material for manufacturers;
  but a source of starting material that is diverse and volatile



- To avoid registration of each plasma / each product / each country





- The Grail



of an universal plasma

Impact of restriction of importing non US Plasma in the US



FDA accepts foreign APIs: Why not plasma ?

Restriction on US plasma for US PdMPs market / US patients

= Restriction on non US plasma import in US



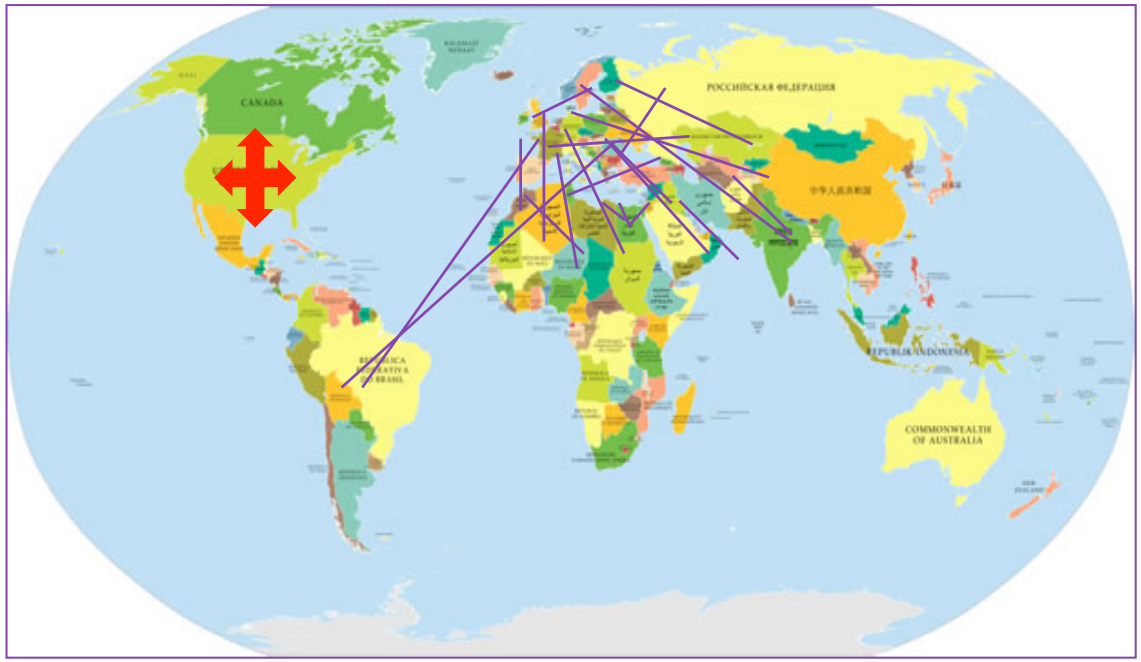
=> Huge industrial, quality and regulatory burden as compared to other pharmaceutical products
because US FDA inspects and approves foreign API

So our world is far from Free Trade on plasma

Acceptance of plasma by countries

	US	RoW
US plasma	OK	OK (1)
Non US plasma	~~OK~~	Locally dependent

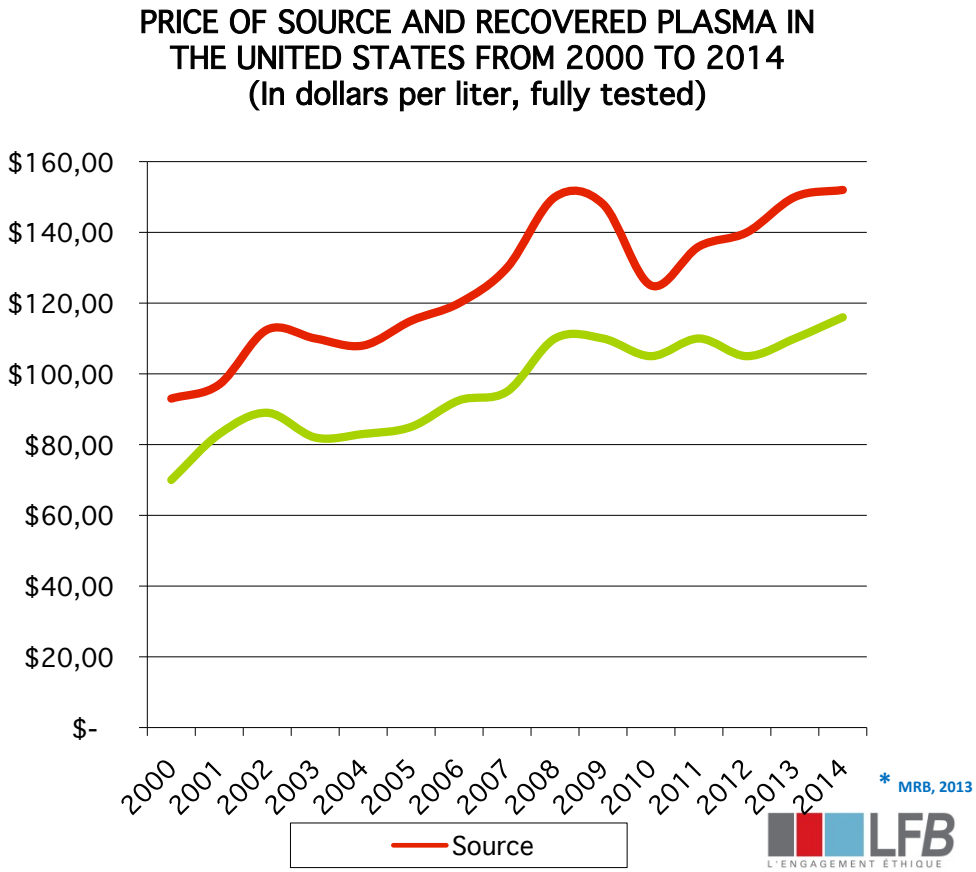
(1) Except few exception such Japan / China (non Albumin product)



Collection of plasma predominantly developed in the US for the US, creating great disadvantage to non-US companies and establishments

Consequences of US plasma as "The" universal one (I)

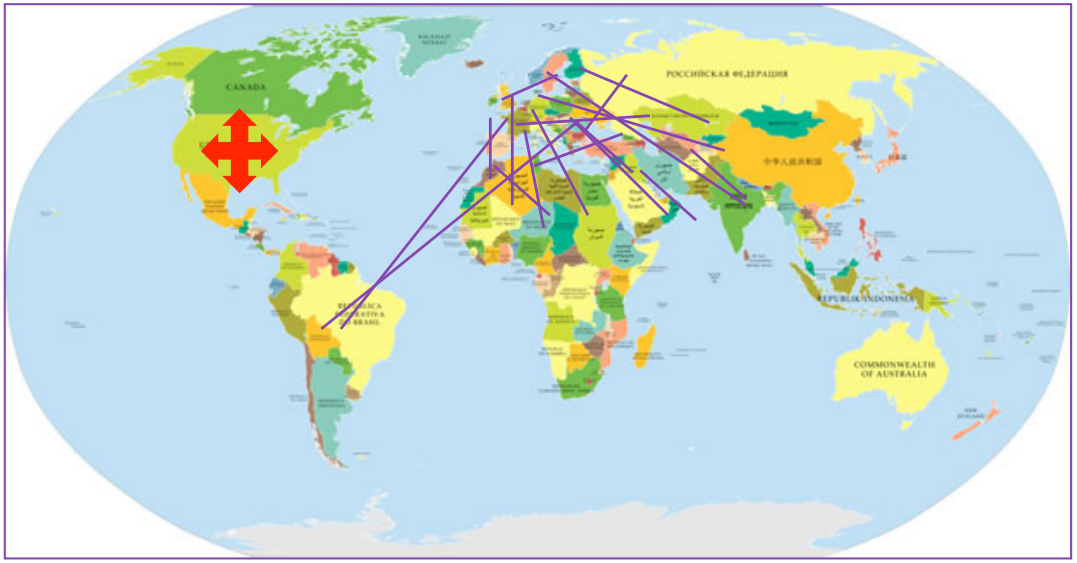
- In the US
- Higher prices: US can't use a plasma that is as safe but cheaper/
- Fight for the "universal" plasma
  - Concentration of industry
  - Concentration of collection
  - Reducing competition
  - Leads to intentional higher prices



Prominence of US plasma

- This leads to prominence of US source plasma (61% of WW supply)

Million Liters*	Recovered	Source	Total
US	1,950	24,153	26,346
UE	4,577	3,281	7,858
RoW	2,465	6,141	8,606



* MRB, Patrick Robert, Bioplasma Asia 2015

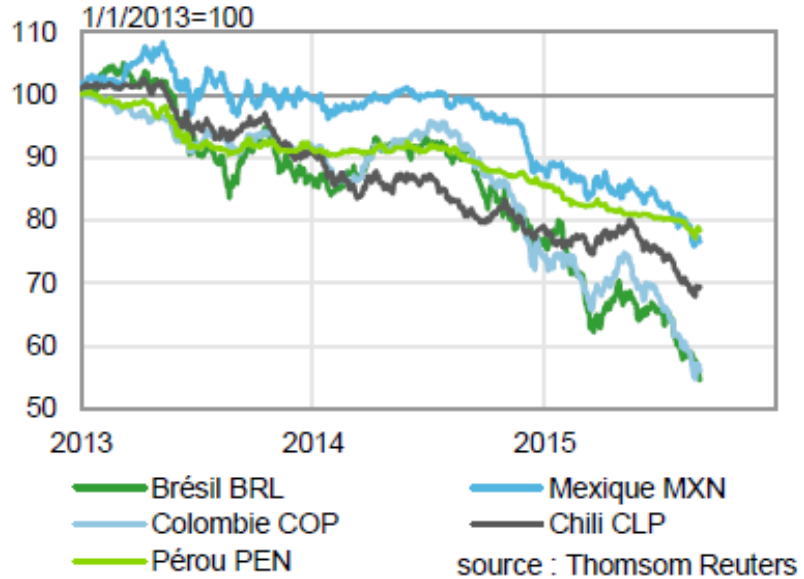
Consequences of US plasma as "The" universal one (II)

- In the RoW

- Dependence on US as a plasma supplier

- => price volatility on finished products because
  - exchange rate $ / local currency
  - plasma cost accounts for 20 to 30 % of final product price





source : Thomsom Reuters

* MRB, 2013

Impacts on safety

- Restriction on non US plasma import in US is grounded by FDA based on safety issues
- However,



France

Japan

Impacts on safety

- Is it true that you cannot collect plasma outside the US as safely as in the US?

  - Concerns are raising on US plasma, starting by EMA

  "*differences observed in trends of HIV and HCV positive donor rates between USA blood banks and European countries on one hand and USA plasmapheresis on the other hand. When going into details, it was observed that the rates evolved very differently between four US Plasmapheresis organisations whereas the trends were very similar between the nine European countries studied*."
  Report of PMF Epidemiology Workshop With Industry EMEA, 30-31 March 2009 / Report/2009/11/WC500015249.pdf

  - The new Grail : US plasma.

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Consequences

- Impact on sustainability
  - US can't be the worldwide "golden oil" field
  - Because of donors cost /donors safety
- Impact on patients
  - Less product availability by discouraging non US plasma fractionation
  - High cost for everybody

Conclusion

- How to solve the issue? => Stop the quest for the Grail

  - Developing non US source plasma to supply the RoW
  - FDA could accept mutual recognition of plasma collection center inspections by FDA selected health agencies
    - → TTIP good opportunity to start with
  - RoW health agencies could ease plasma mutual recognition
  - FDA to consider adopting a “European PMF”-like concept

- Thank you for your attention

- Questions?