Regulatory Constraints

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Source Plasma Definition

21 CFR 640.60 Source Plasma

The proper name of the product shall be Source Plasma. The product is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.

3/12/76 amended 1/29/85

Recovered Plasma Definition

"Recovered plasma (RP) is a by-product derived from WB collection… RP may be separated from individual units of WB … up to 5 days of after expiration"

Issue Summary, BPAC, June 19-20, 2003

Literally *recovered* from expired WB

Short Supply Agreements

21 CFR 601.22 Products in short supply; initial manufacturing at other than licensed location

At the June 2002 BPAC meeting, FDA called SSA ‘a boondoggle’ that allows for interstate commerce of this unlicensed product

Because the plasma derived products are in short supply, the fractionator is able to purchase the raw material under SSA

Source is a Licensed Product Recovered is Not

	Source	Recovered
collection	plasmapheresis	WB
freeze	immediately	SSA
freeze temp	≤ -20 ° C	SSA
storage	≤ -20 ° C	SSA
expiration	10 years	none/SSA
ship temp	≤ -5 ° C	SSA

FDA: Intent of Collection

Eloquently described by Dr. Epstein at the 2002 BPAC Meeting

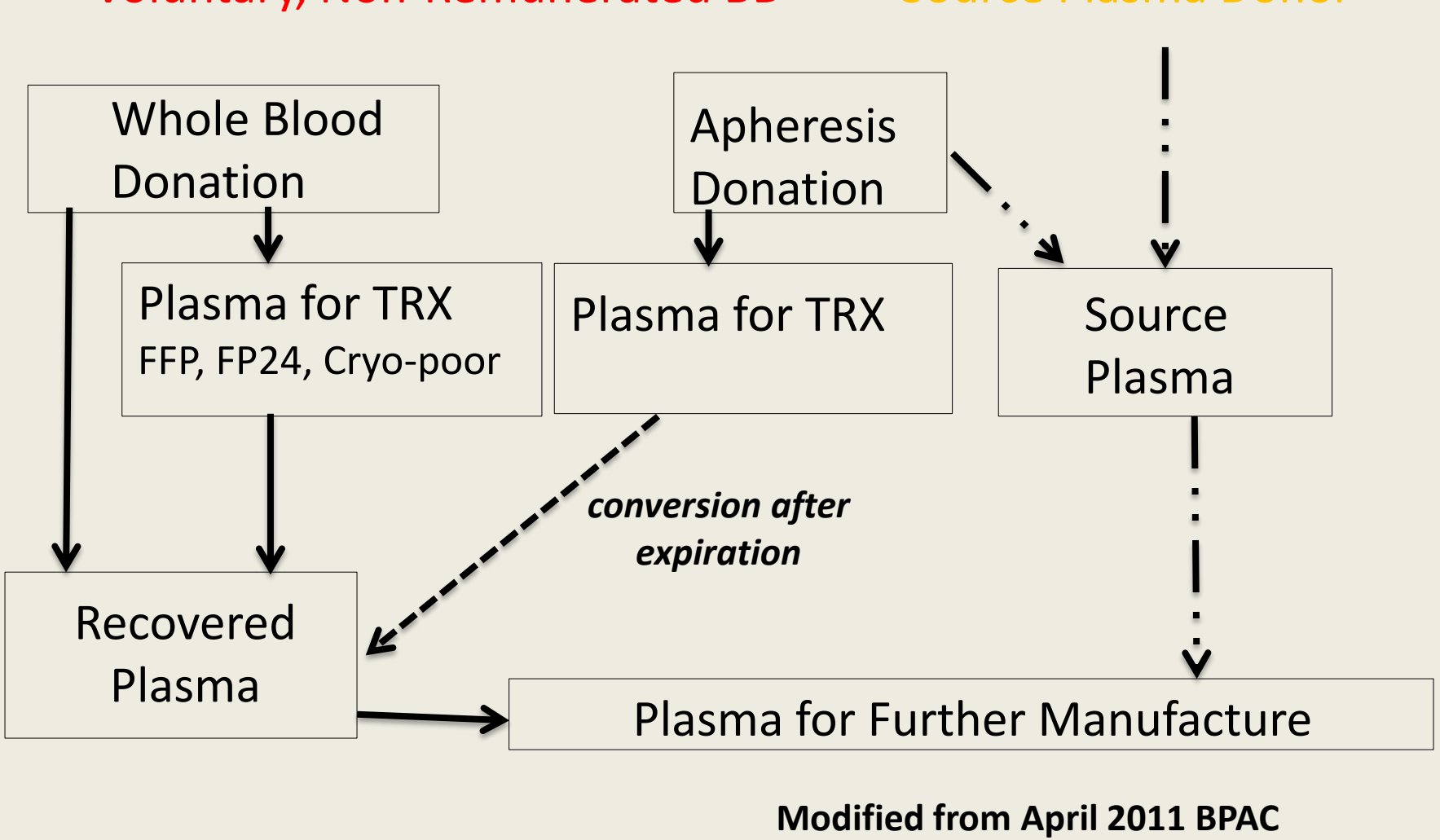
Source plasma is a deliberately collected raw material for further manufacture

- Both donor and collector are aware upfront

Recovered plasma is legally regarded as an incidental by-product which became useful

- Donor assumes transfusable products

Current Origins of Plasma for Further Manufacture



Modified from April 2011 BPAC

FDA and Increased Oversight of Recovered Plasma

Asked if standards governing the manufacture and shipping of recovered plasma should be developed - proposed to BPAC at the June 2002 meeting

Committee voted unanimously in favor of standards for storage, labeling and expiration

Issue was revisited at June 2003 BPAC

FDA and Increased Oversight of Recovered Plasma

June 2003 BPAC: FDA proposes changing the name of recovered plasma to **component plasma** defined as plasma collected manually or by apheresis, either separately or concurrently from donors who meet all WB donor suitability requirements

2004 – FDA sponsors workshop on plasma quality and industry practices

FDA and Increased Oversight of Recovered Plasma

April 2009 BPAC: 2 new plasma products

component plasma from one time relabeling of plasmapheresis FFP or FP24

concurrent plasma collected concurrently with a cellular product either by WB or apheresis donation

- Committee wants impact on voluntary donor pool studied

FDA and Increased Oversight of Recovered Plasma

April 2011 BPAC: revised proposal for component plasma and concurrent plasma

FDA believes that plasma derivatives made under current practices are safe and effective

Recent Dialogue with FDA

May 2016 – AABB/FDA Liaison Meeting

October 2016 – Ask the FDA session at the AABB Annual Meeting

Jan 2017 – AABB/FDA Liaison meeting

- Conflict with proposed concurrent plasma definition and existing Source plasma regs
- Rulemaking to establish this new product will be necessary

Recent Dialogue with FDA

Jan 2017 – AABB/FDA Liaison meeting

21 CFR 640.69(b) *Storage*. Immediately after filling, plasma intended for manufacturing into injectable products shall be stored at a temperature not warmer than -20 ° C

Request to extend the time until freezing based on worldwide practices, appropriate handling by fractionators via contracts with collectors

Recent Dialogue with FDA

June 2016 – 1st IPFA/FDA Liaison Meeting

September 14, 2017 - IPFA/FDA Liaison Meeting