Regulatory/Legal Issues and Barriers to Progress

Regulatory Harmonisation – Desirable Goals

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The Future for Blood and Plasma Donations

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Overview

• AABB Plasma Task Force
• Inconsistencies
  – manufacturing processes
  – regulations
• Identify areas for harmonization
Why the Need for a Plasma Task Force?

Plasma Collected by US Blood Centers

• Plasma for Transfusion
  – Frozen and liquid products, manual and automated methods

• Plasma for Further Manufacture – Injectables
  – Recovered Plasma using short supply agreements and contracts, manual collections
  – Source Plasma license, primarily infrequent collection schedule, automated collections

• Generally, Blood Center collections occur at fixed, satellite, and mobile sites
AABB Plasma Task Force - Goals

• Seeking pathway to licensure for Recovered Plasma
  – Currently shipped via short supply agreement

• Any product not needed for transfusion
  – Should be available for further manufacturing at any point in the shelf life of the product

• New Licensable Product
  – Labeling provides the conditions of storage/freezing
AABB Plasma Task Force

- Proposals submitted to the FDA
- Clarifications provided to the FDA
- Position statement provided to the FDA’s Blood Products Advisory Committee

http://www.aabb.org/advocacy/statements/Pages/statement042811.aspx
Donor Questionnaire

• Donor Questionnaire – products for transfusion and further manufacture
  http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx
  http://www.pptaglobal.org/safety-quality/donor-history-questionnaire

• Additional screening for cornea and xenotransplants are required by some plasma contracts
  – May 2015 Final Rule will require an assessment of all whole blood donors for xenotransplants

• HIV Risk Reduction draft guidance – male donors who report sex with other males assessed in a 12 month category rather than “since 1977”
  – Argentina, Australia, Brazil, Hungary, Japan, Sweden and United Kingdom
Donor Testing

“Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use”, 22 May 2015, Final Rule

• Defines testing algorithms for whole blood and source plasma donors

• Framed in context of relevant transfusion-transmitted infections (RTTIs)

• No real change to current testing requirements

• Makes provision for selective testing by amending 21 CFR 640.5

Specific Plasma Components

“Circular of Information for the Use of Human Blood and Blood Components”
http://www.aabb.org/tm/coi/Pages/default.aspx

PLASMA FOR TRANSFUSION

• FFP, PF24, PF24RT24
  – FFP → Cryo and Plasma Cryo Reduced
  – FFP and PF24 → Thawed Plasma (4 additional days)
  – Plasma Cryo Reduced → Thawed Plasma Cryo Reduced (4 additional days)

• Psoralen treated whole blood-derived plasma and apheresis plasma

• Liquid Plasma
Specific Plasma Components

PLASMA FOR FURTHER MANUFACTURE

• Current options that are commonly used by US blood centers
  – Recovered Plasma, manual collections shipped under short supply agreements
  – Source Plasma, automated, Infrequent collections shipped under license

www.aabb.org
Plasma for Further Manufacture

AABB Plasma Task Force - discussions with FDA since early 2000s

• Simplified algorithm

• Any plasma product not needed for transfusion could be labeled for use in further manufacturing

• Licensed product; SSAs would no longer be needed.

AABB and ABC continue to engage with the agency on this issue.
Plasma for Further Manufacture

FDA feedback – April 2011 BPAC, CY2015 Guidance Agenda, May 2015 Final Rule

• Concurrent Plasma (CCP) and Component Plasma (CMP) described at April 2011 BPAC

• Potential use for labeled product “Concurrent Plasma” – FDA working on a guidance.
  – “Component Plasma” – no indication from FDA that they are working on this pathway…

• Final Rule describes infrequent plasma collections
Harmonization (Harmonisation) Requested

- In the US we have a history of labeling plasma for transfusion
  - to indicate storage/freezing conditions
  - that enables the transfusion service/clinician to select the component
  - needed for particular protocols/patient populations.

- The AABB Plasma Task Force asked FDA to provide a similar pathway so that plasma for further manufacture could be labeled
  - to indicate storage/freezing conditions
  - that enables plasma fractionators to select the component
  - needed for particular protocols/manufacturing needs.
Harmonization (Harmonisation) Requested

• Canada, Europe – Source Plasma is placed in the freezer before 24 hours

• US – the requirement for placing in the freezer is described as “immediately”

• US Blood Centers collect at satellite and mobile sites – physically removed from freezers

• US Blood Centers have started a conversation with the FDA to see if a pathway is available to harmonize with European requirements.
Thank you!

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