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Plasma Therapeutics & Industry Economics
Role of Reimbursement

Presentation to
Advisory Committee Blood Safety and Availability
Department of Health and Human Services
August 26, 2004

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President PPTA

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Topics

- Changes since 1998
- Data collection and legal constraints
- Therapies and fractionation
- Recent developments
- Supply
- Economics of plasma fractionation
- Conclusion

Changes Since 1998

What has changed since 1998?

- Monitoring systems are in place to assess changes in supply dynamics
- Industry is better positioned to meet consumer demand
  - More companies providing broader product portfolios
- Companies must address current industry economics
  - Long-term viability of industry requires economic adjustments.

Commitment April 27, 1998

- …..we commit at this time to continue our data collection effort. We will collect and make public production data every three months, so that all parties will be able to understand the current production trends. …..
  - Monthly reporting
  - Published on website
  - Letters to patients when system indicated yellow
  - Still a need?

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Future Supply

Association can use publicly available information

Since it is a concentrated industry, we must be extremely sensitive to Anti-trust laws

We have to accept that certain things are unpredictable

Industry is only part of the chain

- No near term threat to supply
- Tightening as result of economic factors

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Legal Constraints

U.S. Anti-Trust Laws Treat Agreements Among Competitors to Limit Output the Same as Agreements on Price .

Illegal Are Agreements to:

limit production
reduce inventories
coordinate output
allocate capacity
set quotas
discontinue particular products
limit supply of particular products

No Facilitation of Information Exchanges Among Members.

American Column & Lumber Co, v. United States, 257 U.S. 377 (1921)

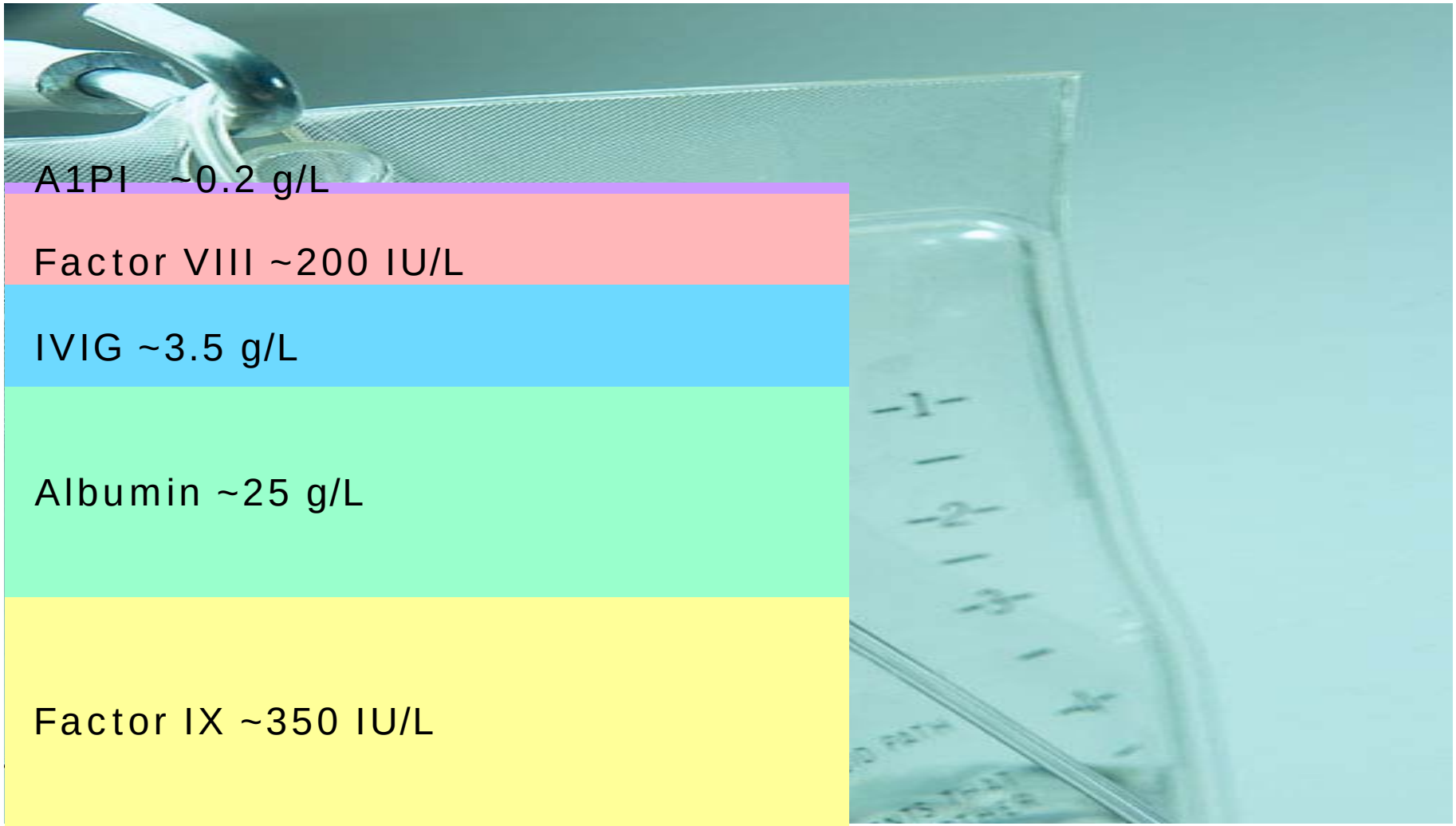
No Encouragement Public Announcements to Circumvent Limitations on Direct Exchanges.

…Particularly with relative small number of producers….

…Disclosures could be viewed as a means of signaling competitors and challenged as facilitating an unlawful agreement under the Sherman Act..

Stone container, 63 Fed. Reg. 10628, 10629 (March 4, 1998)

Plasma Therapy Portfolio



*Industry-wide Estimates

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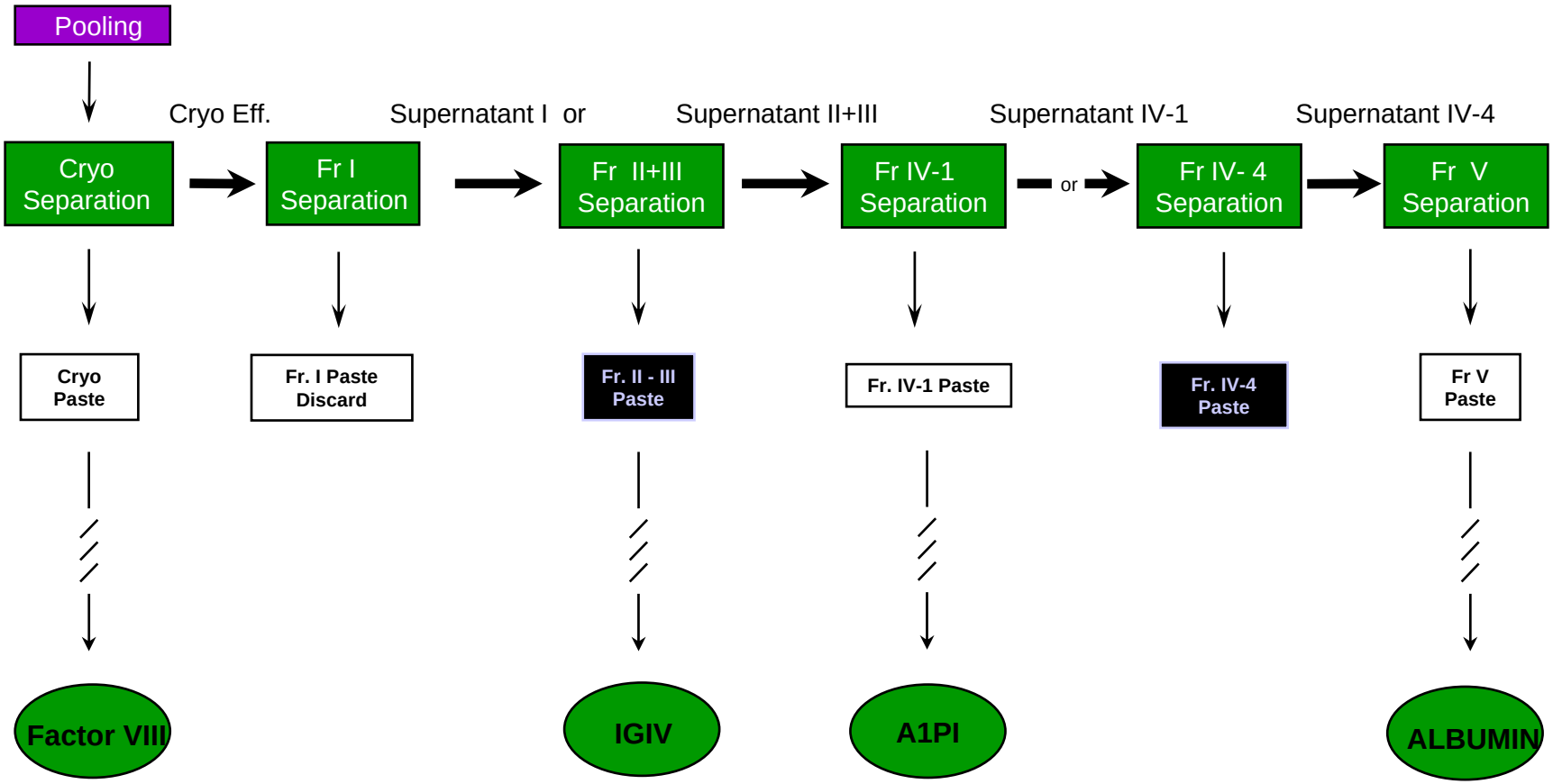
Fractionation Process



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Recent Developments

- Consolidations / Divestitures
- Plasma Center Closures
  Fractionation Facility Closures
- Reduced Volume of Fractionated Plasma
- Staffing Reductions

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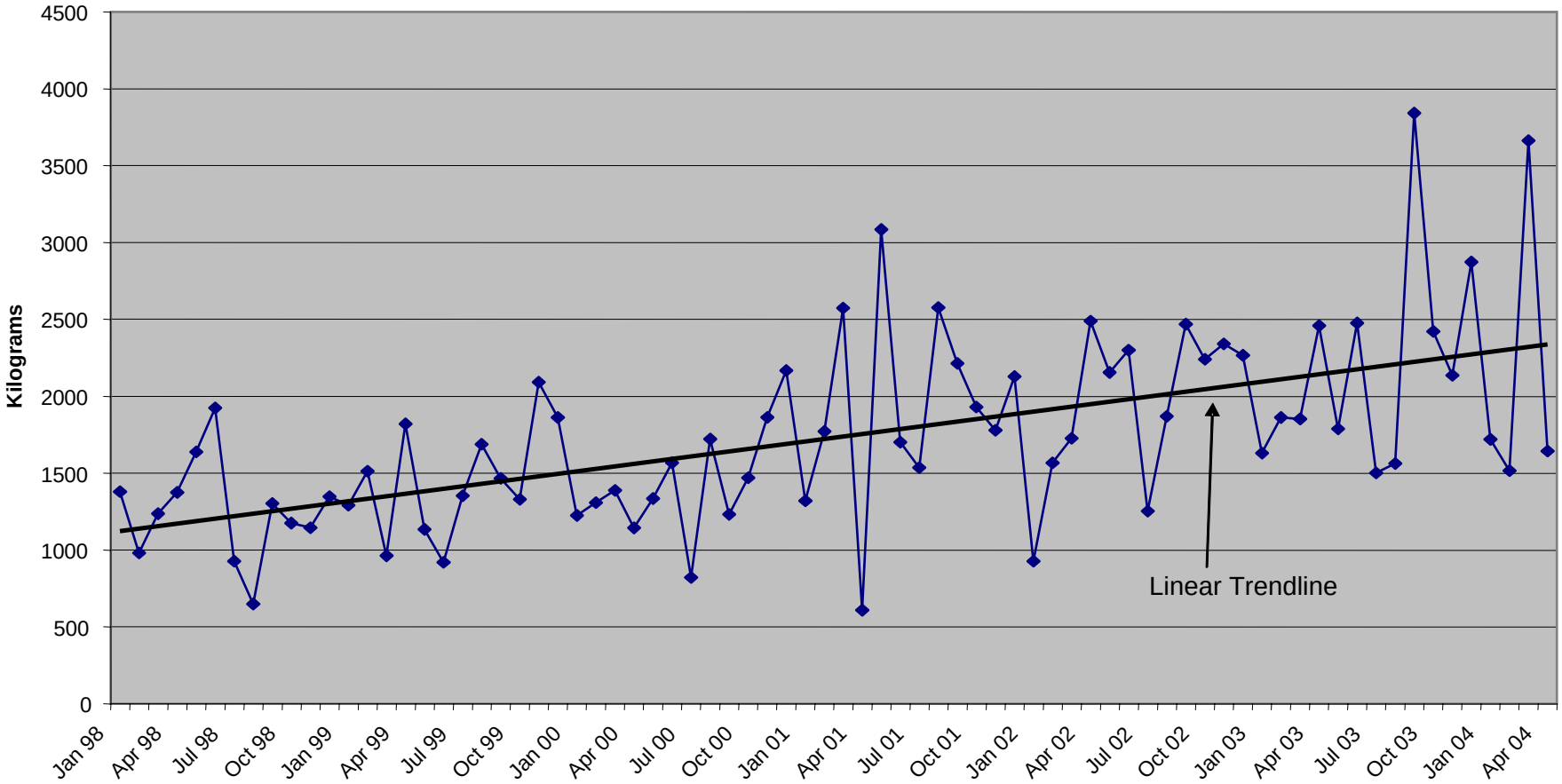
Recent Developments

- New Companies Entering Market
- New Product Approvals
- Facilities Upgrades and Build-outs
- Enhanced Technologies Resulting in Higher Yields
- Utilization of Both Source and Recovered Plasma

US Supply Trends

U.S. IVIG Availability
January 1998 - April 2004



Source: PPTA

Plasma Economics

Model with 5 proteins:

- Immuneglobulin
- Albumin
- Factor VIII
- A1P1
- Other Proteins

Plasma Economics

Drivers for plasma collection:

Albumin

Factor VIII

Immuneglobulins

Plasma Economics

Drivers for plasma collection:

Albumin

Factor VIII

Immuneglobulins

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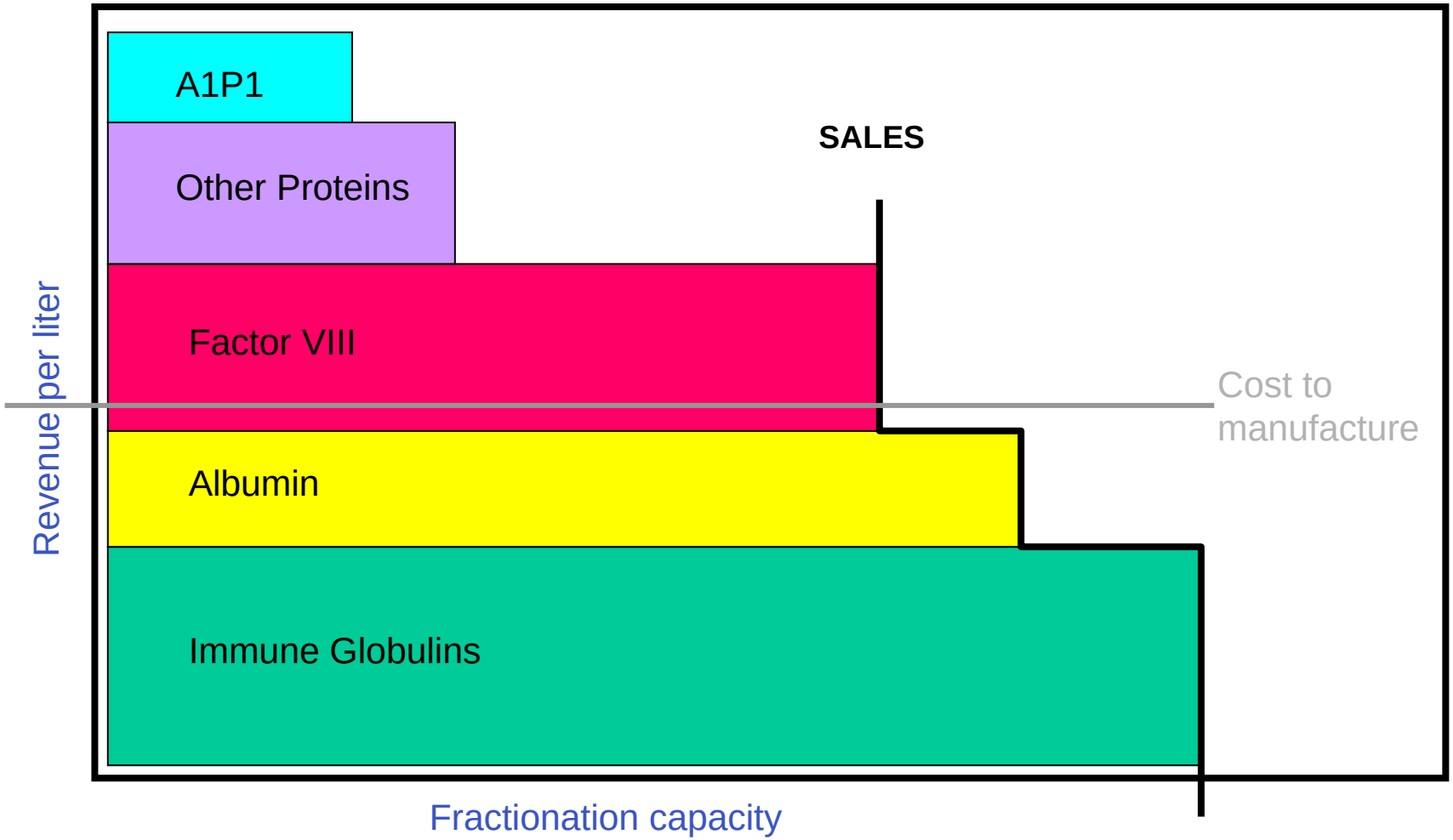

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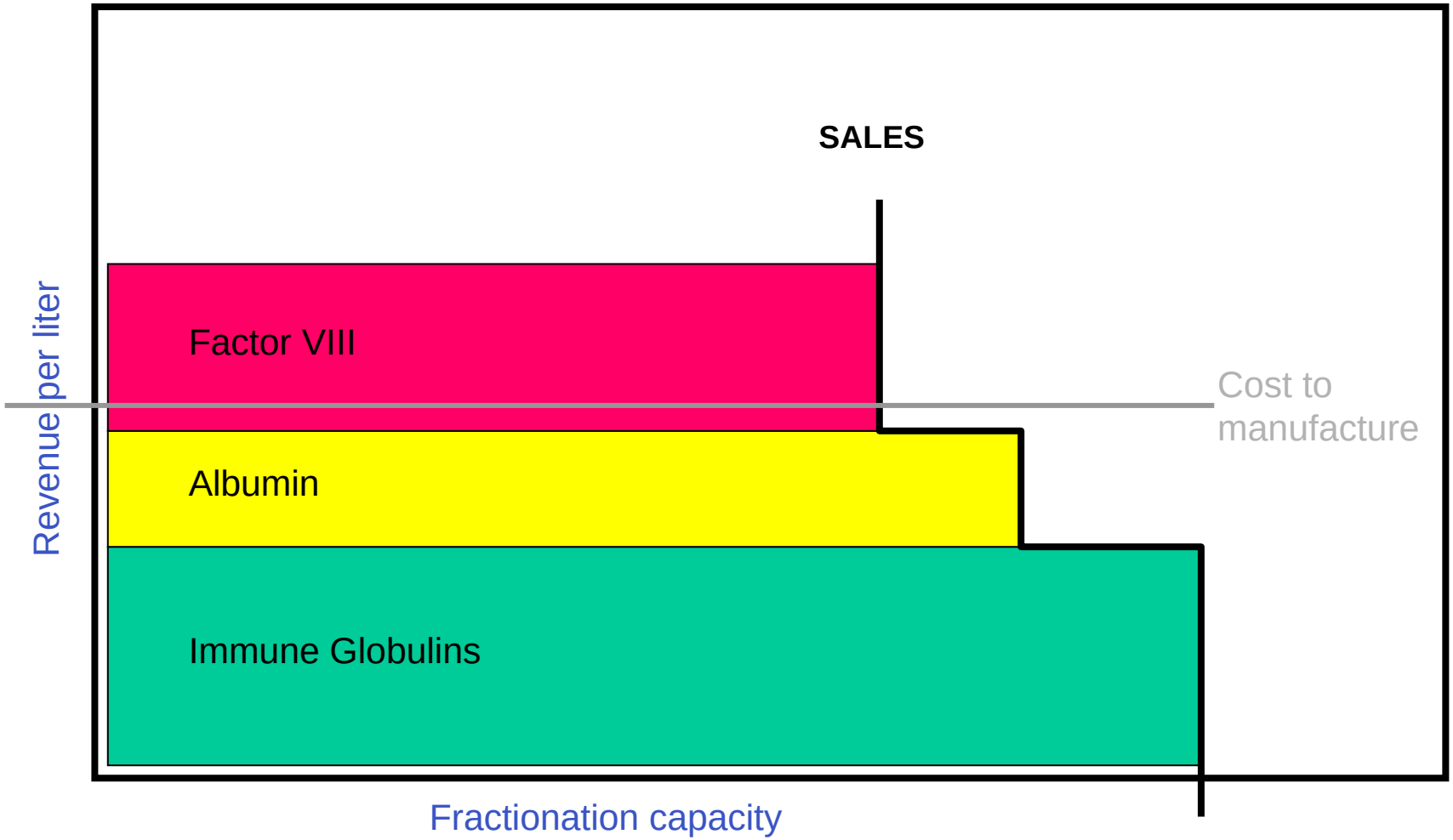

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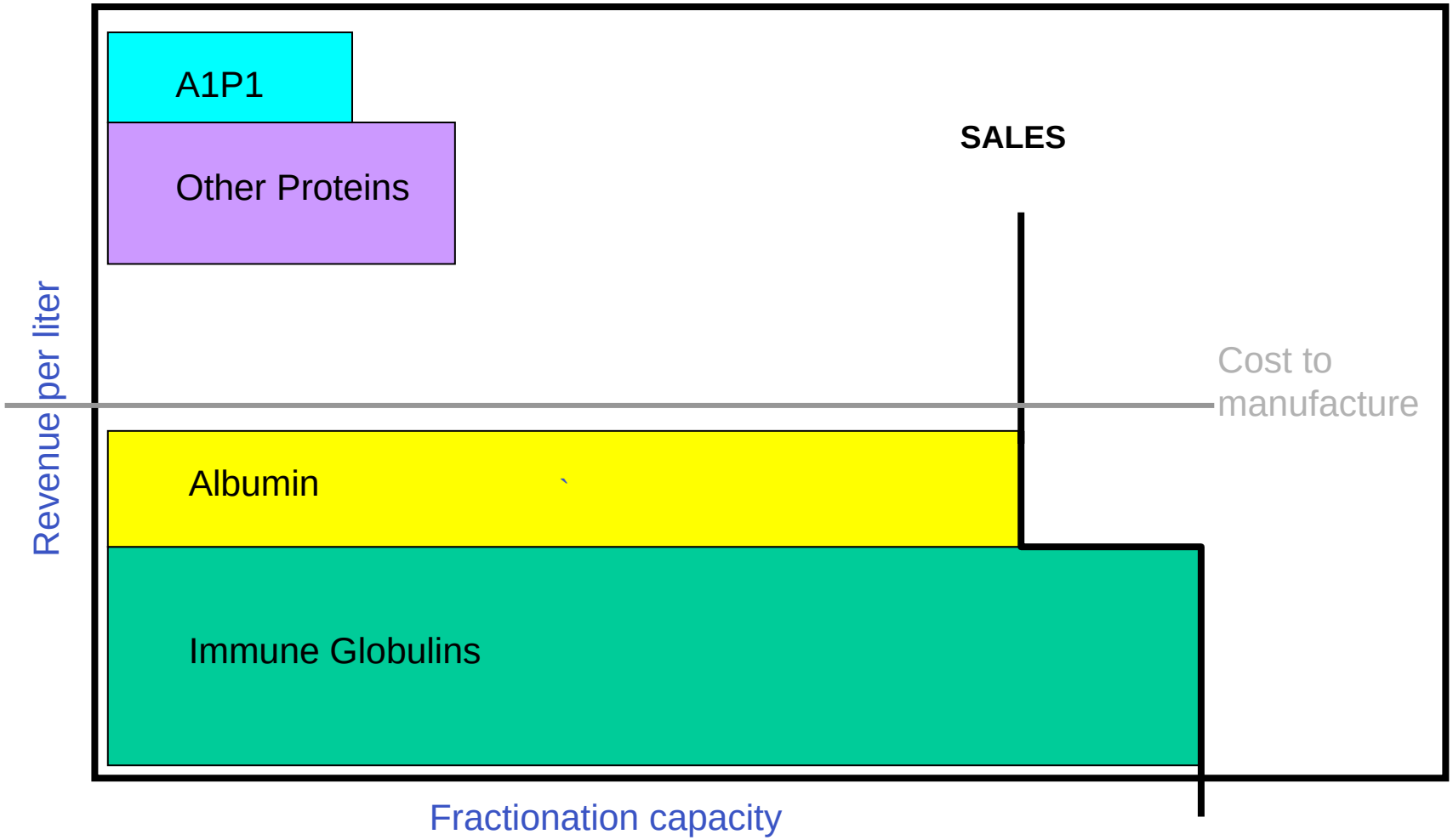

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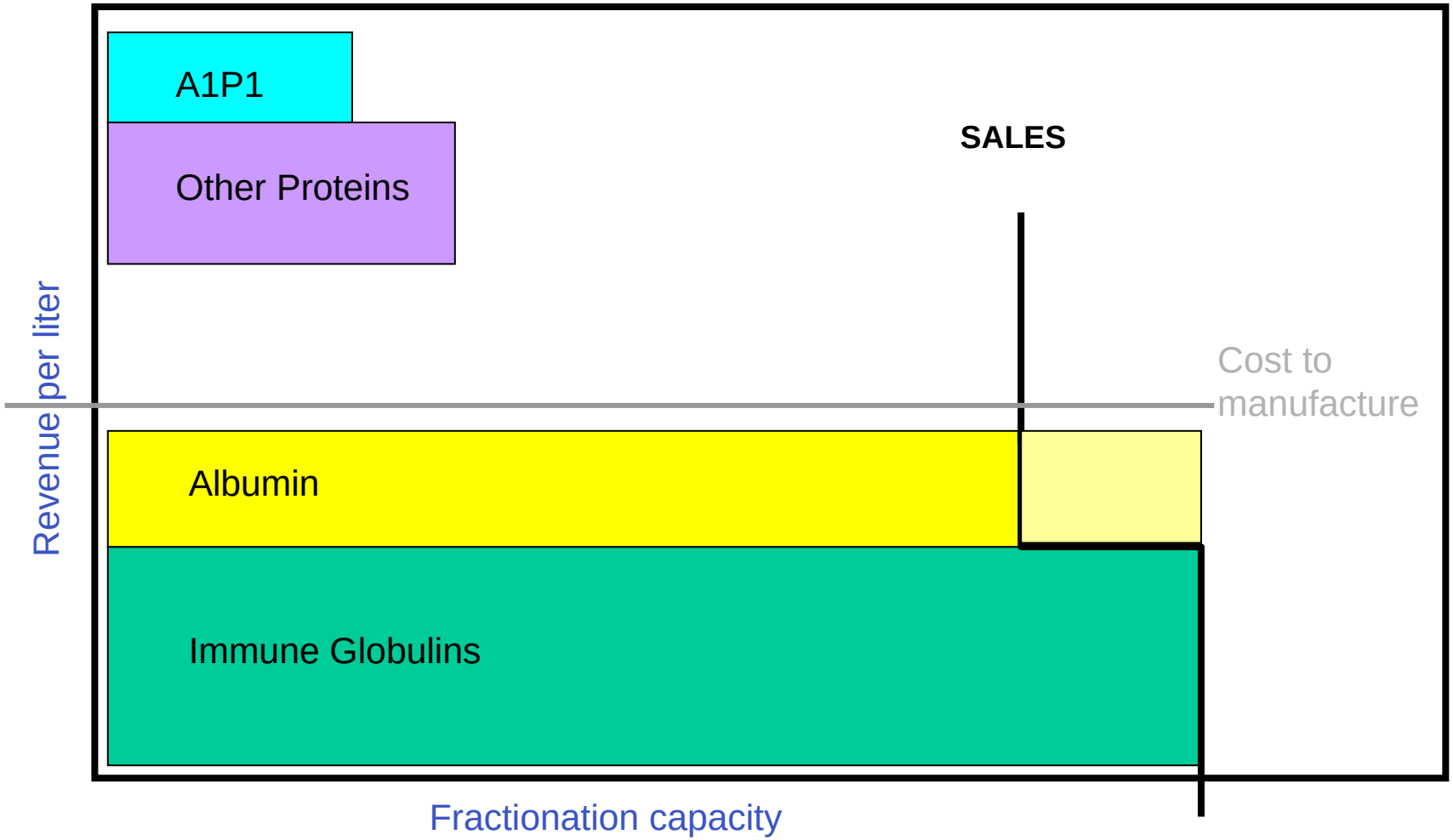

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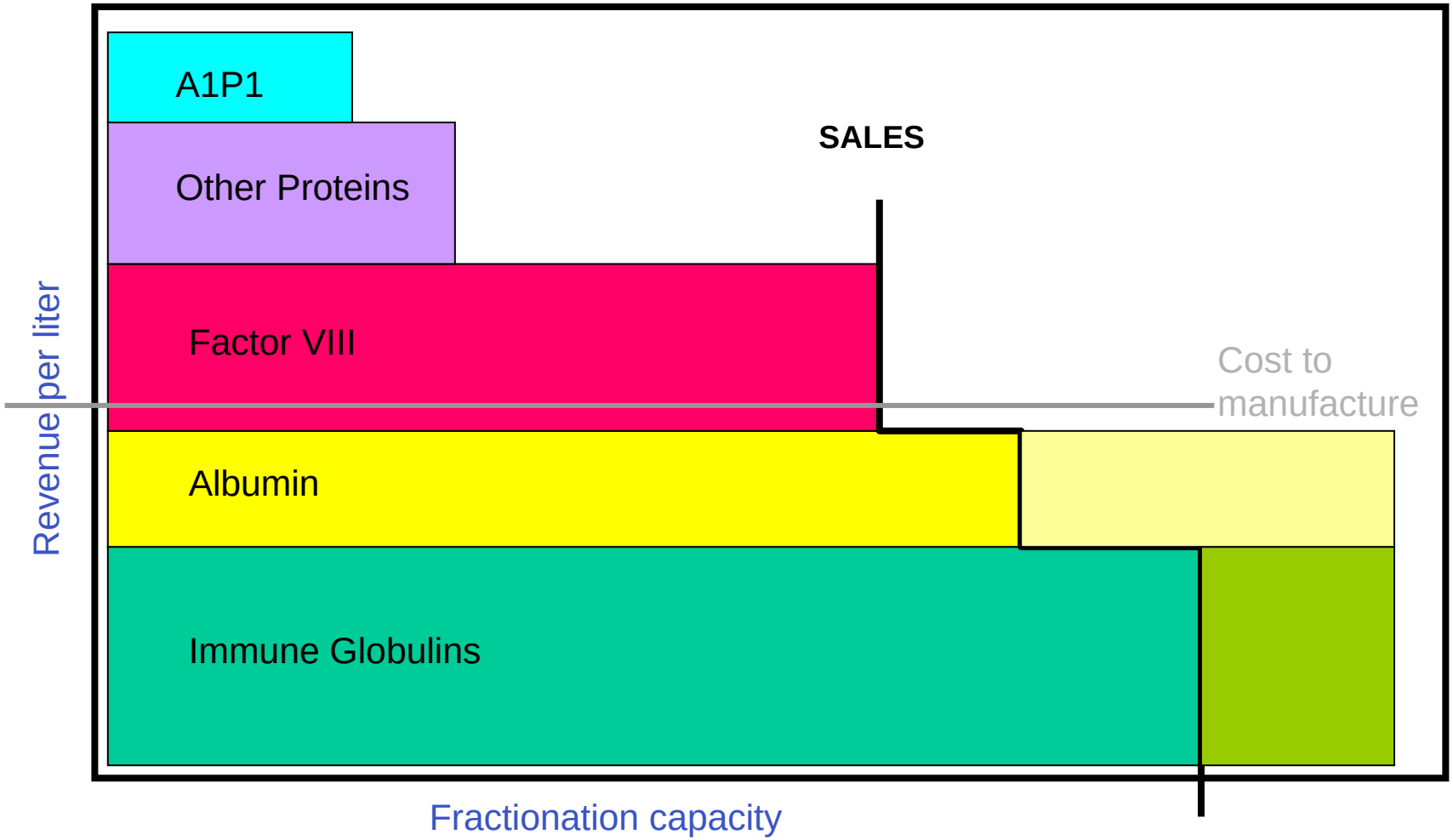

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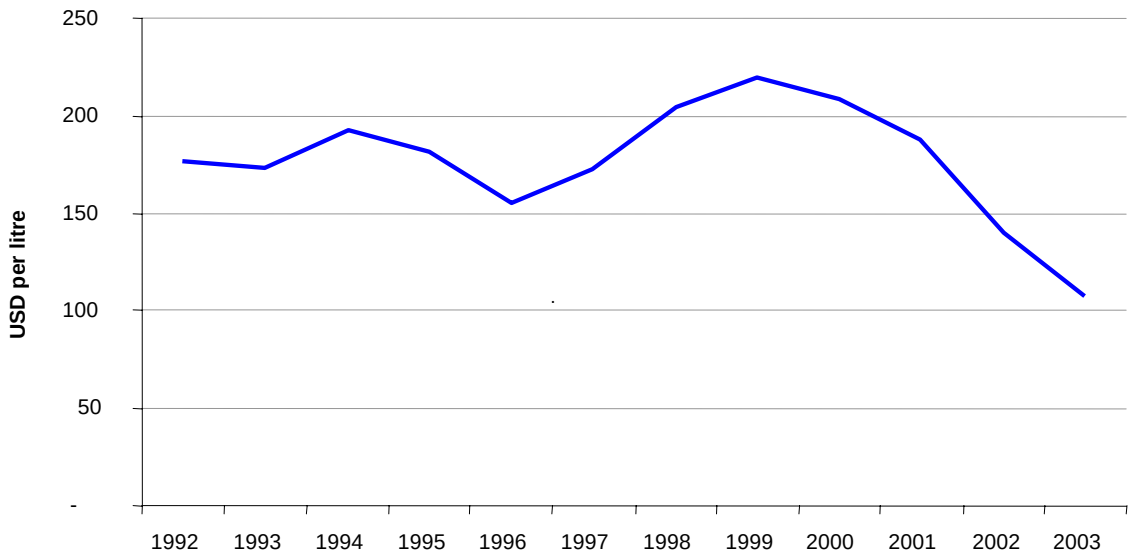
Real* Net Sales per liter



Net sales per liter are sales per liter less cost of plasma

*** prices and costs corrected for inflation**

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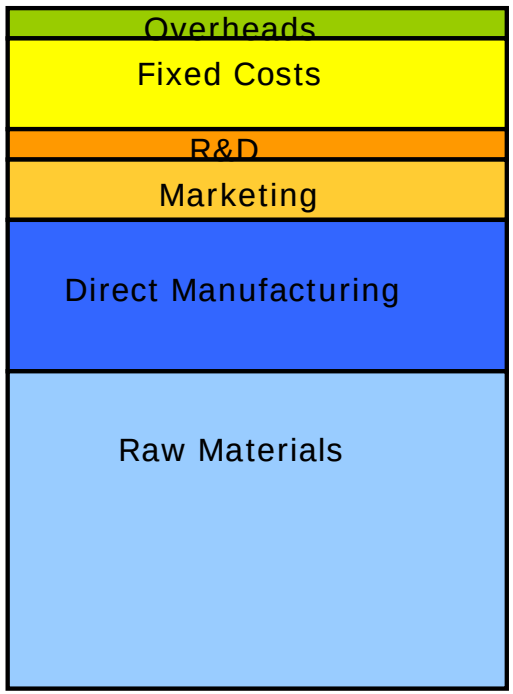
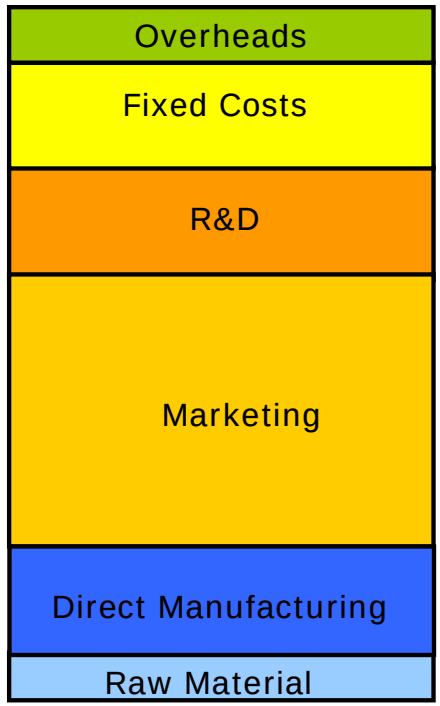
Plasma Industry
Cost Base



Pharmaceutical Industry
Cost Base



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Implications of Differences

- **Plasma Protein Therapeutics serve small patient populations unlike the mass markets for pharmaceuticals.**
- **We get “caught” in measures for pharmaceuticals.**
- **Plasma protein therapeutics are proprietary biologicals (non-generics, product life-cycle development and regulatory costs are high.**
- **Investment in working capital, plant and equipment to manufacture plasma protein therapeutics is significant.**
- **Emerging clinical trial requirements are very difficult to meet, so product development and new plasma protein therapeutics will diminish.**
- **Reduced reimbursement for plasma protein therapeutics and mandated price reductions will result in more company exits, further industry consolidation and reduction choice of products in future.**

Plasma Economics

Revenue Factors

- Declining Medicare Reimbursement
  - Significant reforms to lower expenditures
- Medicaid Budgets Being Slashed
  - Severe cost containment measures
- Private Sector Models Public Payors
  - Managed Care, PBMs, GPOs and others

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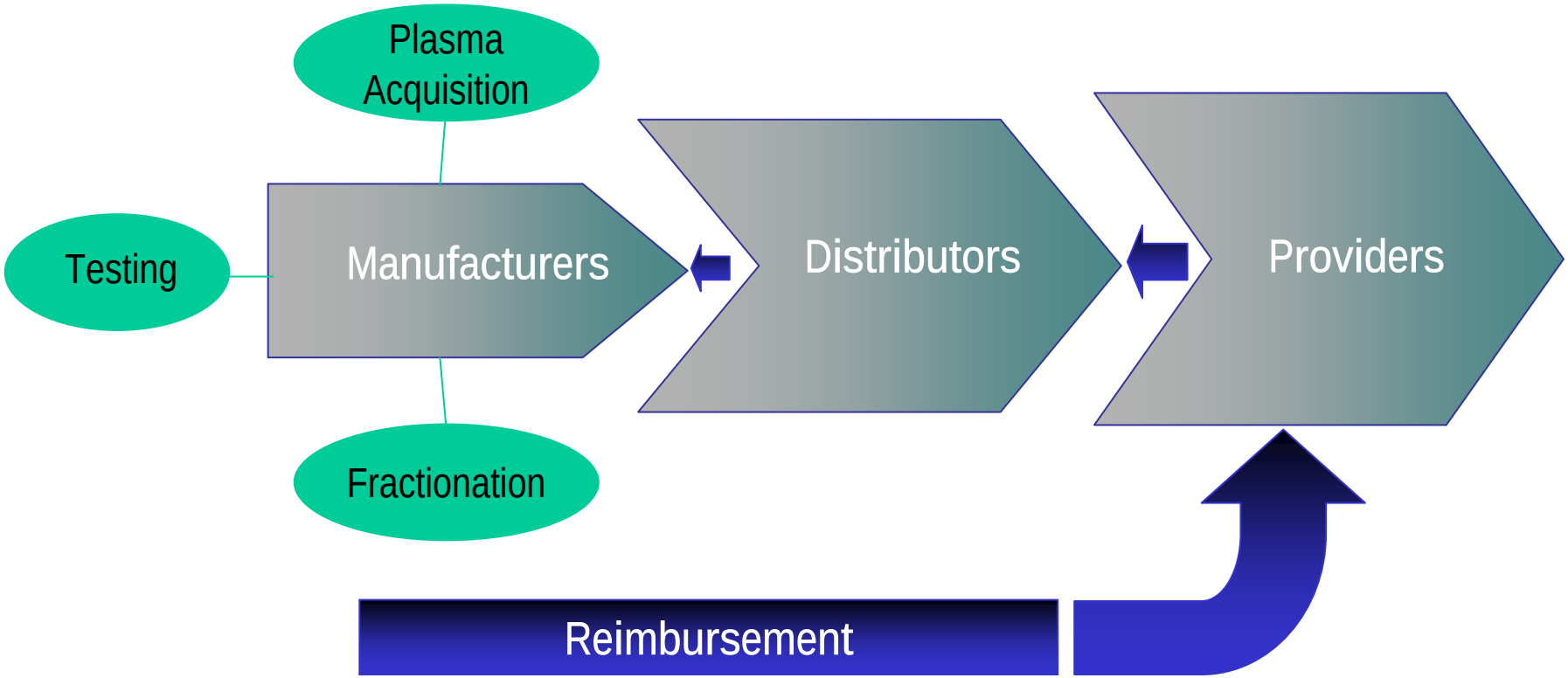
Value Chain



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Cost Challenges

- Regulatory Requirements
  - » Remove redundant and /or obsolete requirements
  - » Team Biologics: Balance costs of quality
  - » Complexity clinical trial requirements

Revenue Challenges

- Reimbursement policies
  - » Plasma Industry is different from “pharma”
  - » Reimbursement is not equal to industry revenue

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Ongoing Vigilance

- Supply Monitoring System
  - Inventory and distribution monitoring
- Emergency Supply
  - Company commitment to consumers / healthcare professionals
- Consumer and Health Professional
  - Regular communications

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Conclusion

- No Near Term Threat to the Availability of Plasma Therapies.
  - Current inventories and higher yields may off-set reductions in fractionated plasma.
- PPTA Will Remain Vigilant.
  - Economic adjustment is needed for long term health of industry.
- Access, Choice and Innovation Must Be Maintained.