

Global Use of Plasma-Derived Medicinal Products

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The Marketing Research Bureau, Inc.

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Improving Access to Plasma and Plasma
Products in the Southern African Region**

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SOURCE OF THE DATA

The data used to develop the charts and tables shown in this presentation have been compiled from the Marketing Research Bureau's database, scientific articles, congress proceedings, companies' annual reports, publications and statistics published by national and international organizations, as well as by various plasma industry stakeholders.

GENERAL INFORMATION

All the data and information come from sources generally available to the public. Their accuracy is not guaranteed, and the Marketing Research Bureau assumes no liability for their use.



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- **Global Plasma Products Demand by Region**
 - **Global Plasma Products Demand by Product.**
- The Market Drivers**
- **Plasma Supply**



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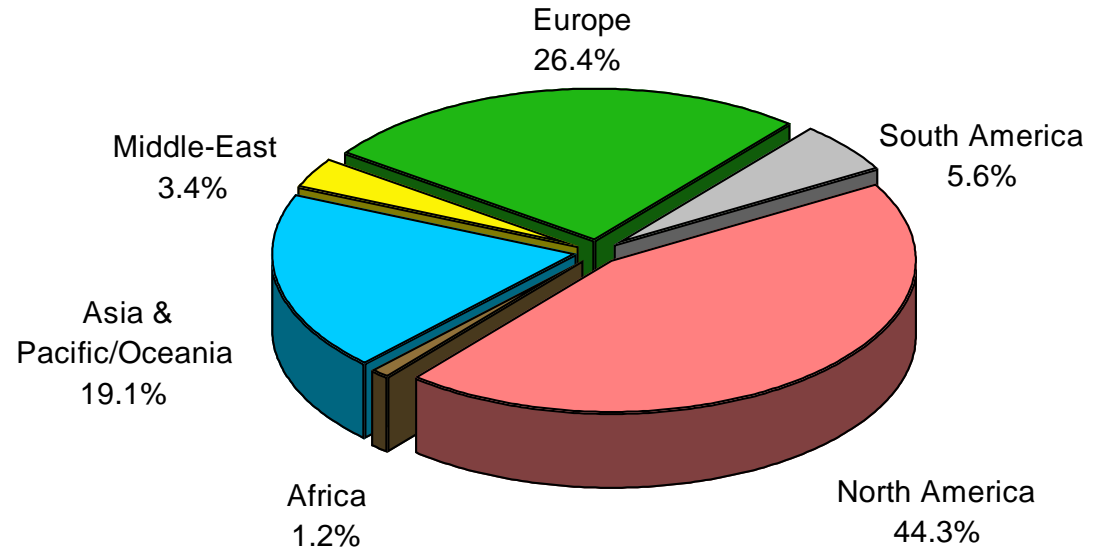




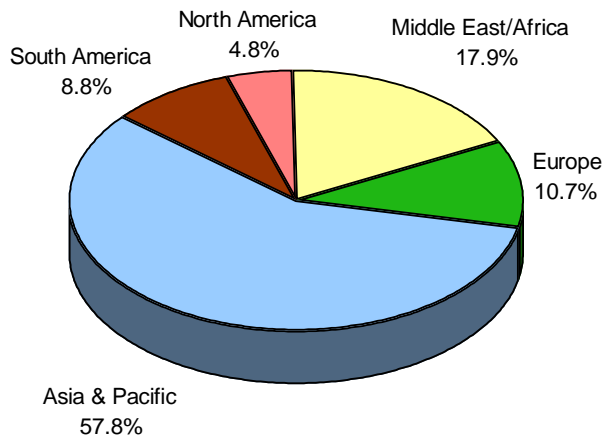
THE WORLDWIDE PLASMA PROTEINS MARKET BY REGION - 2014

WITHOUT RECOMBINANT FACTORS

Total Market \$18,514.0 Million



World Population by Region - 2013



North America holds 44% of the global market but has only 5% of the world population while Africa and the Middle East together hold 5% of the market with 18% of the world population

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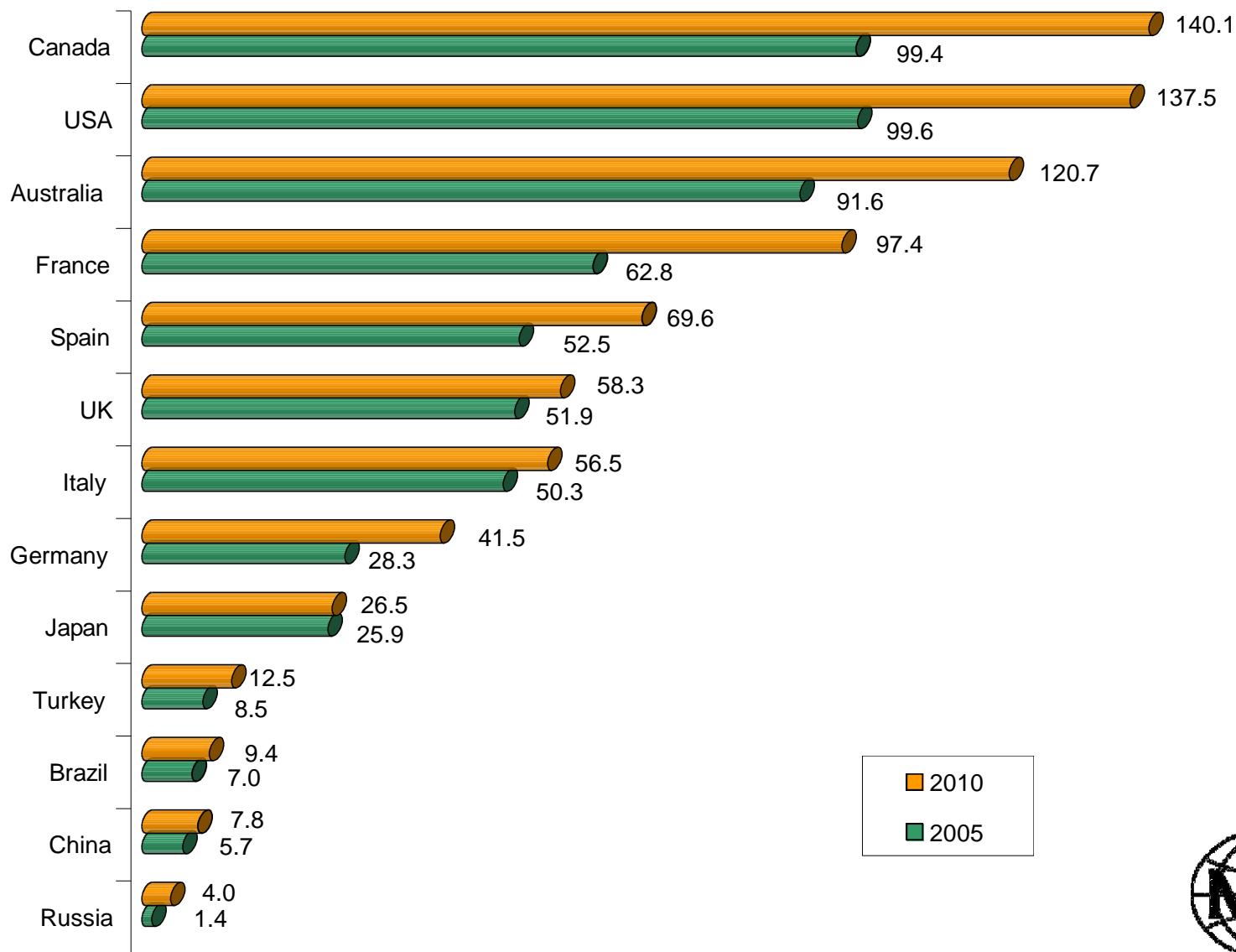


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IVIG/SCIG CONSUMPTION PER CAPITA IN SELECTED COUNTRIES 2010 AND 2005 (Grams per thousand Inhabitants)



International differences in per capita consumption of IVIG/SCIG can be explained by:

- **Market penetration of IVIG therapy, physicians' awareness and training, diagnosis**
- **Use for chronic diseases treatment vs. acute conditions**
- **Competitive therapies and pharmaceutical drugs**
- **Absence of restrictions for and reimbursement of off-label IVIG use**
- **Product promotion, brand competition**
- **Influence of patients advocacy groups**
- **And, above all, funding!**

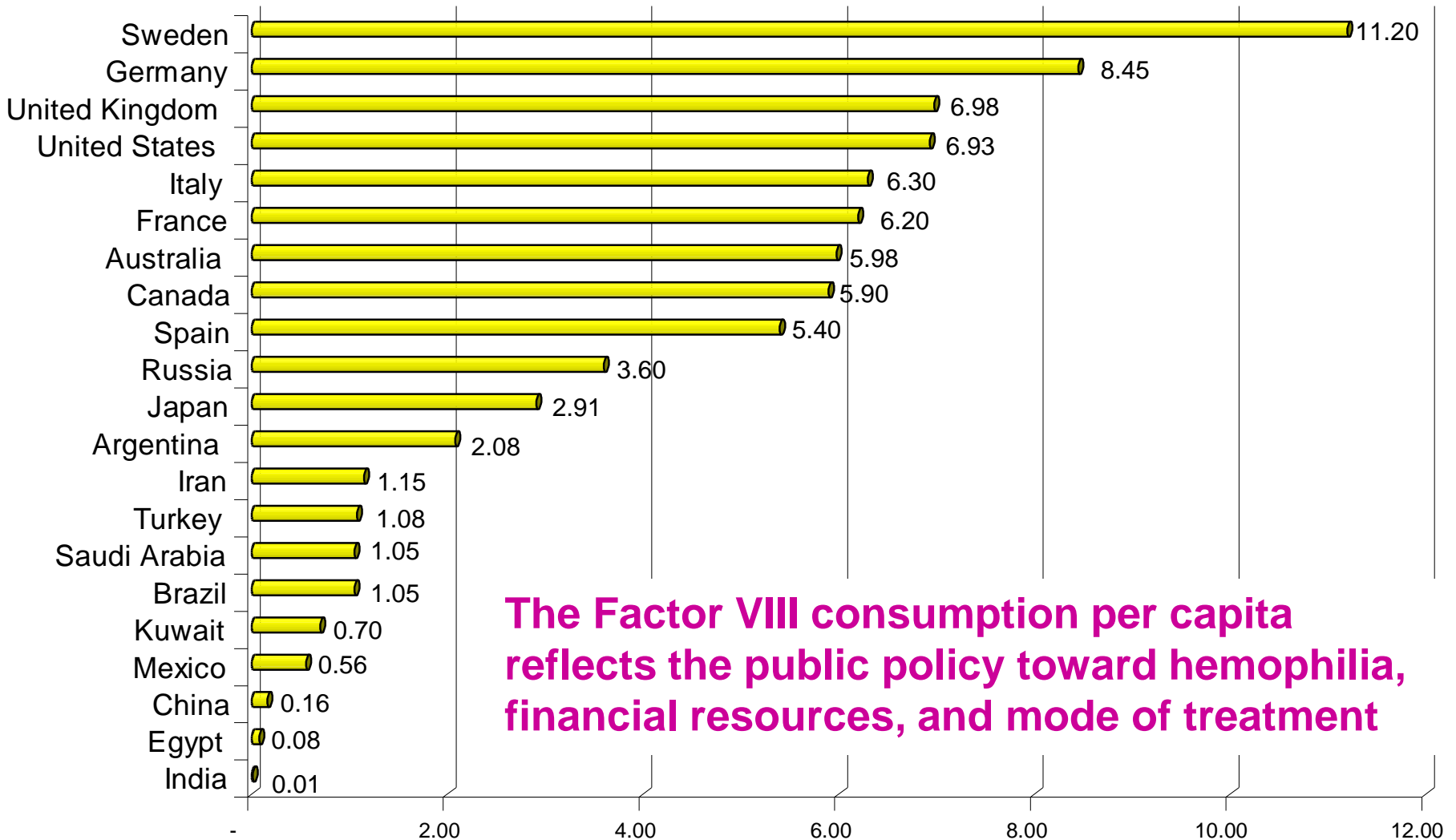
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Consumption of Plasma Products by Country

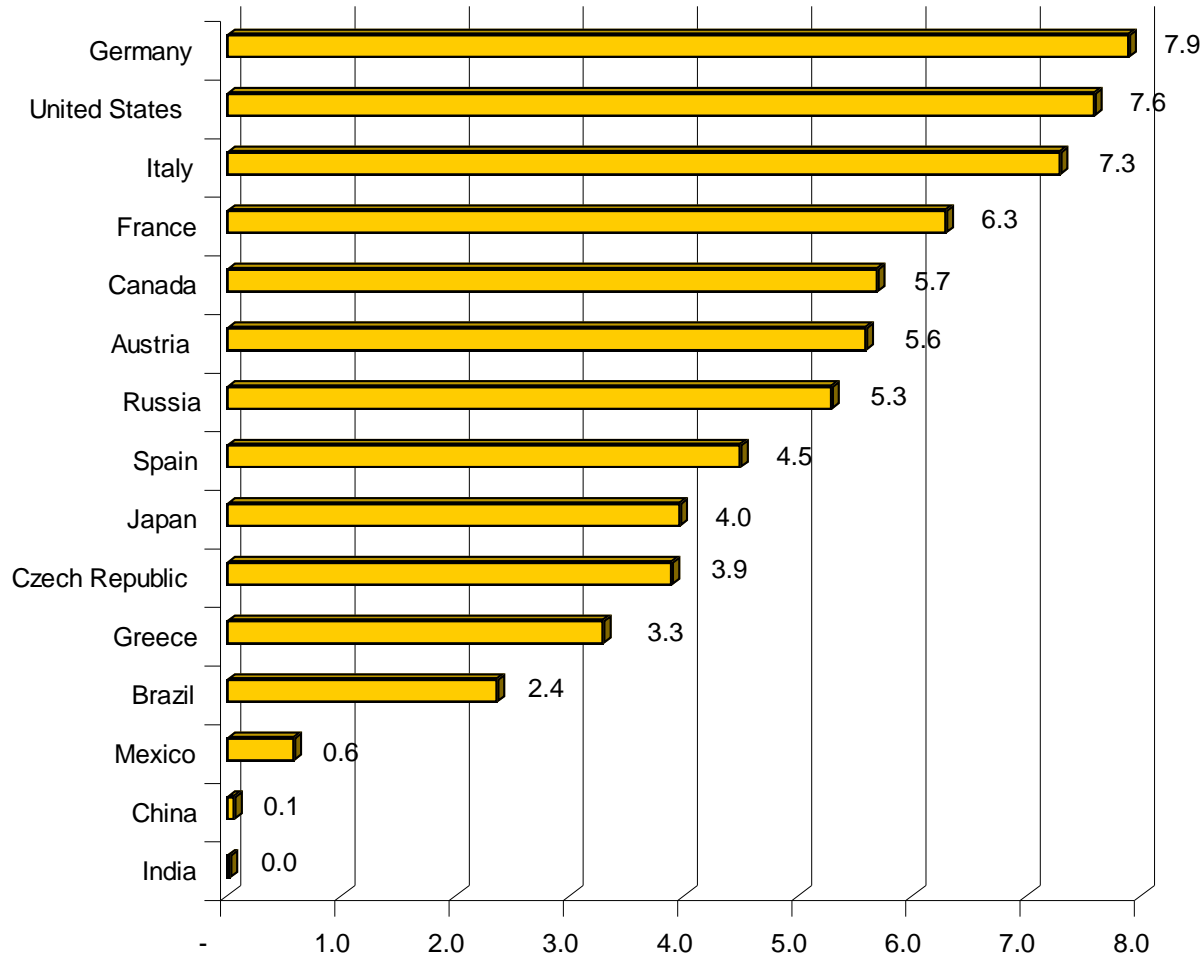
FACTOR VIII CONSUMPTION PER CAPITA IN SELECTED COUNTRIES
RECOMBINANT & PLASMA-DERIVED 2007-2009
(International Units per Inhabitant)



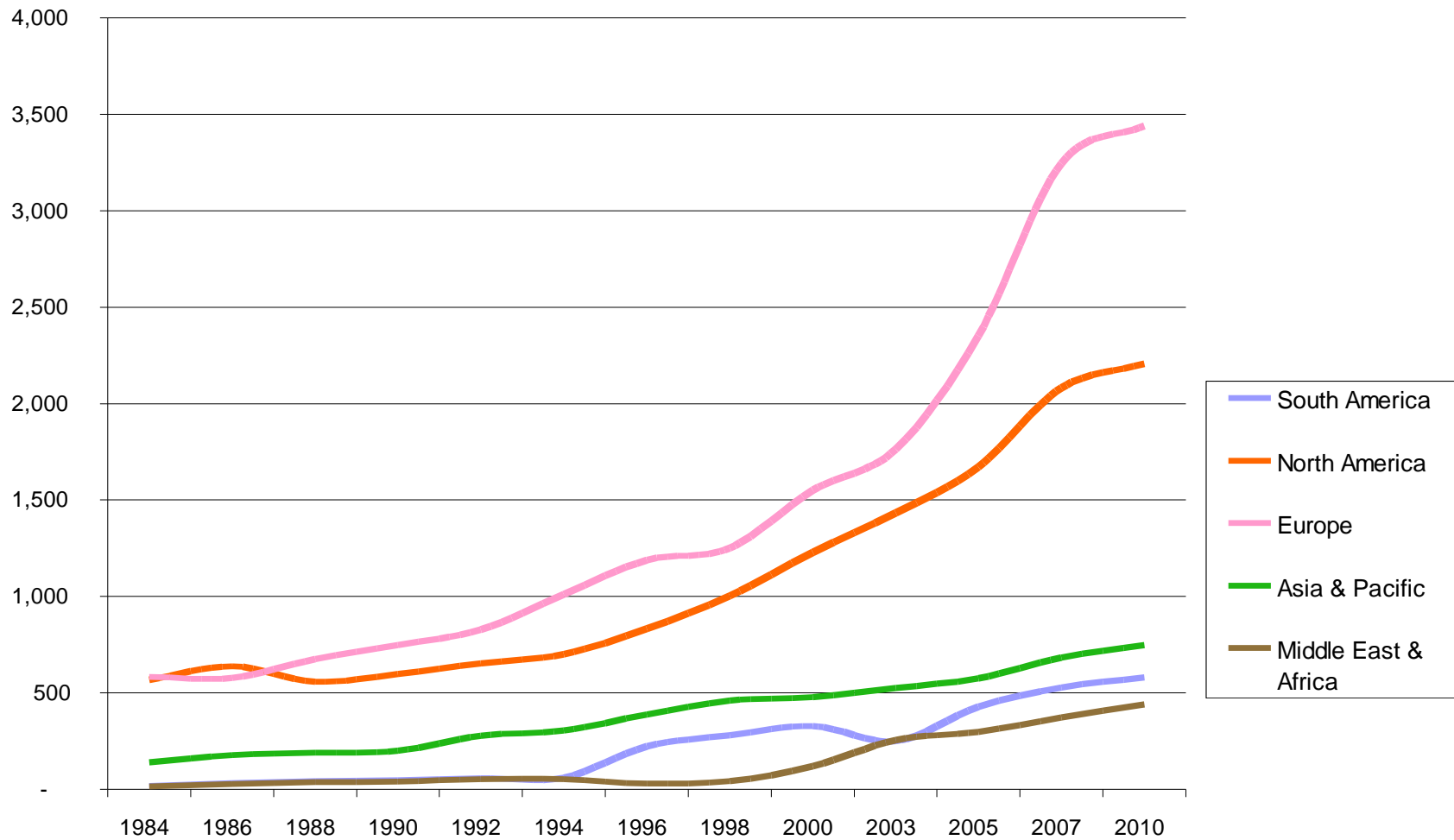
The Factor VIII consumption per capita reflects the public policy toward hemophilia, financial resources, and mode of treatment

**AVERAGE FACTOR VIII CONSUMPTION BY COUNTRY
2010/2012**
**Recombinant & Plasma-derived
(International Units per Capita)**

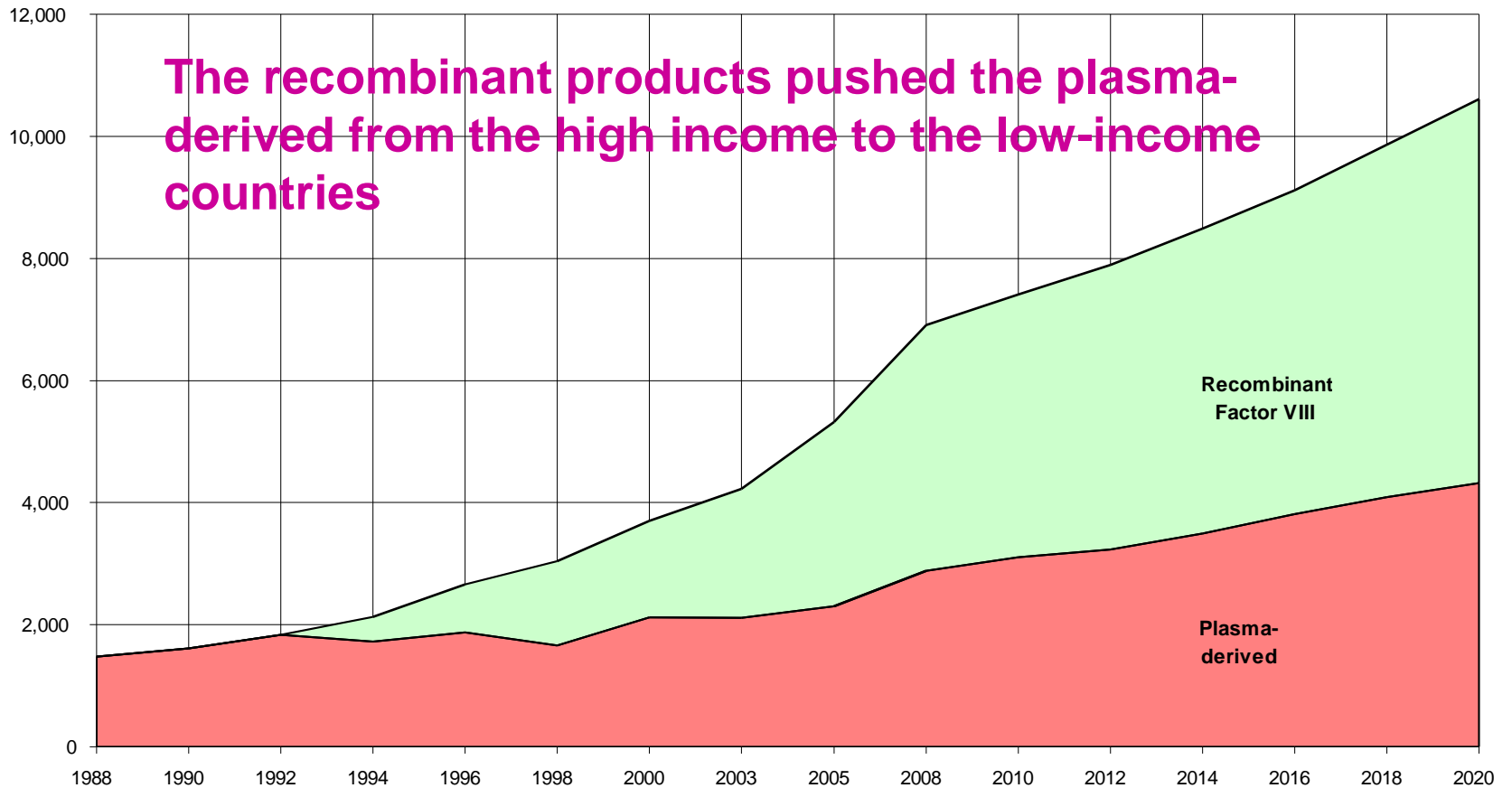
There is a huge gap between the industrialized and emerging countries



GLOBAL FACTOR VIII CONSUMPTION BY REGION FROM 1984 TO 2010
PLASMA-DERIVED AND RECOMBINANT
(International Units x 1,000)



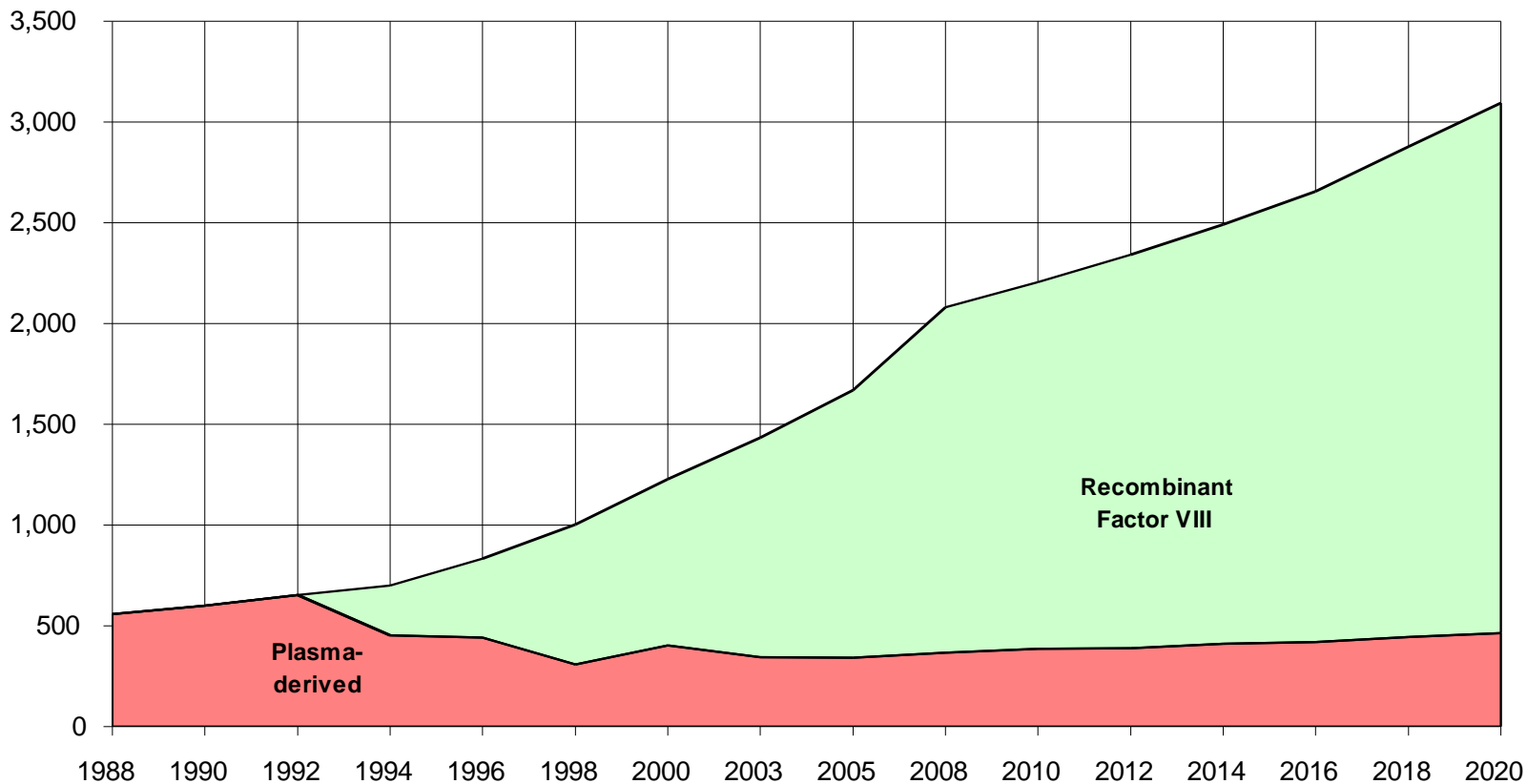
**THE WORLDWIDE FACTOR VIII MARKET
FROM 1988 TO 2020 (Est.)
(International Units x Million)**



The recombinant products pushed the plasma-derived from the high income to the low-income countries

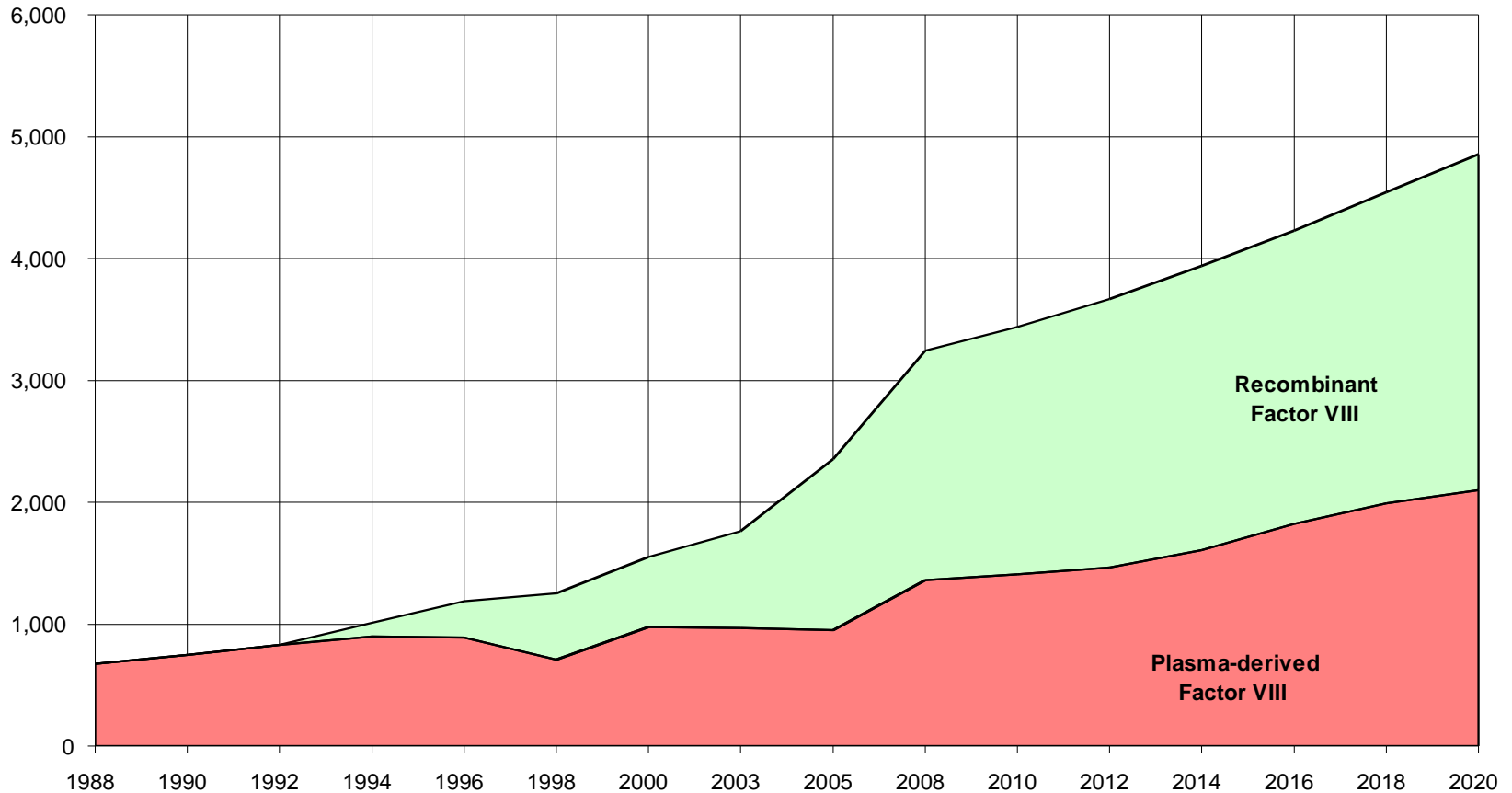
Market penetration of recombinant factor VIII in 30 years in units.

**THE FACTOR VIII MARKET IN NORTH AMERICA
FROM 1988 TO 2020 (Est.)
(International Units x Million)**



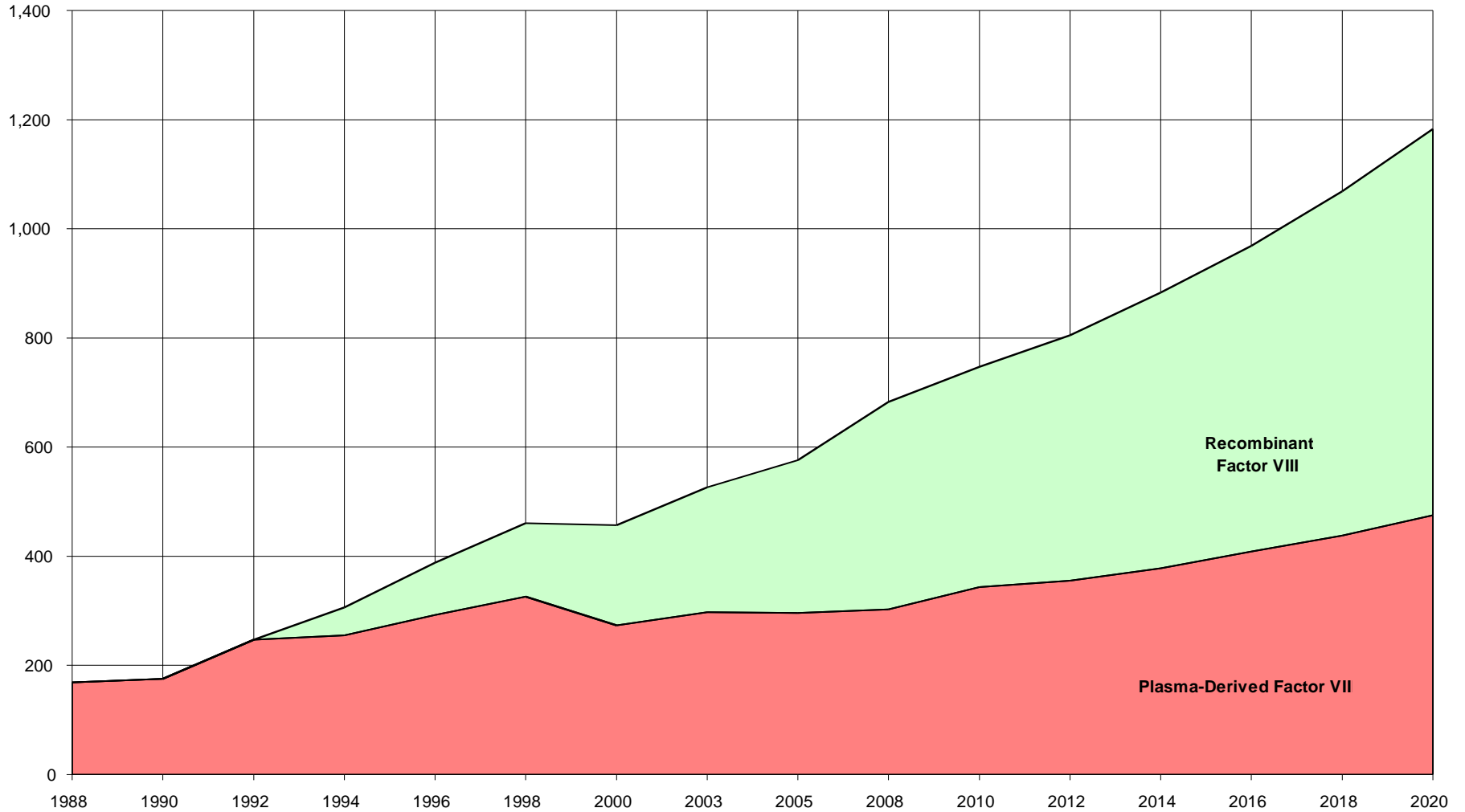
The units growth rate will decline as the extended half-life recombinant products gain market share, due to the lower consumption per patient

**THE FACTOR VIII MARKET IN EUROPE
FROM 1988 TO 2020 (Est.)
(International Units x Million)**



In Europe, recombinant products faced some initial resistance in some countries (France, Germany, Italy, etc)

**THE FACTOR VIII MARKET IN ASIA & PACIFIC (including Australia & New Zealand)
FROM 1988 TO 2020 (Est.)
(International Units x Million)**



**THE FACTOR VIII MARKET IN SOUTH AMERICA & THE MIDDLE EAST
FROM 1988 TO 2020 (Est.)
(International Units x Million)**

**Hemophilia care policy and funding
have resulted in a low penetration of
recombinant factor products in low
income countries**

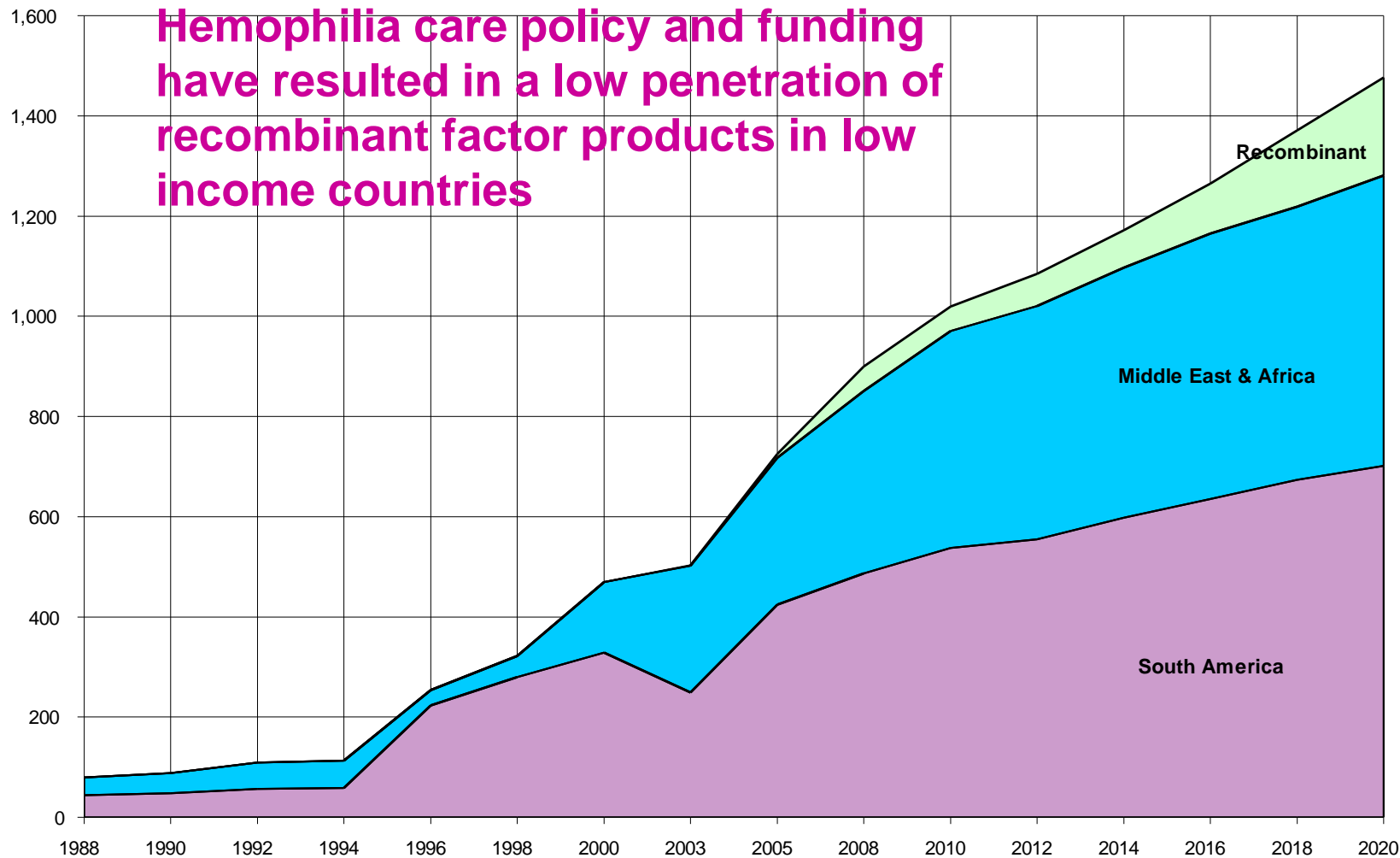


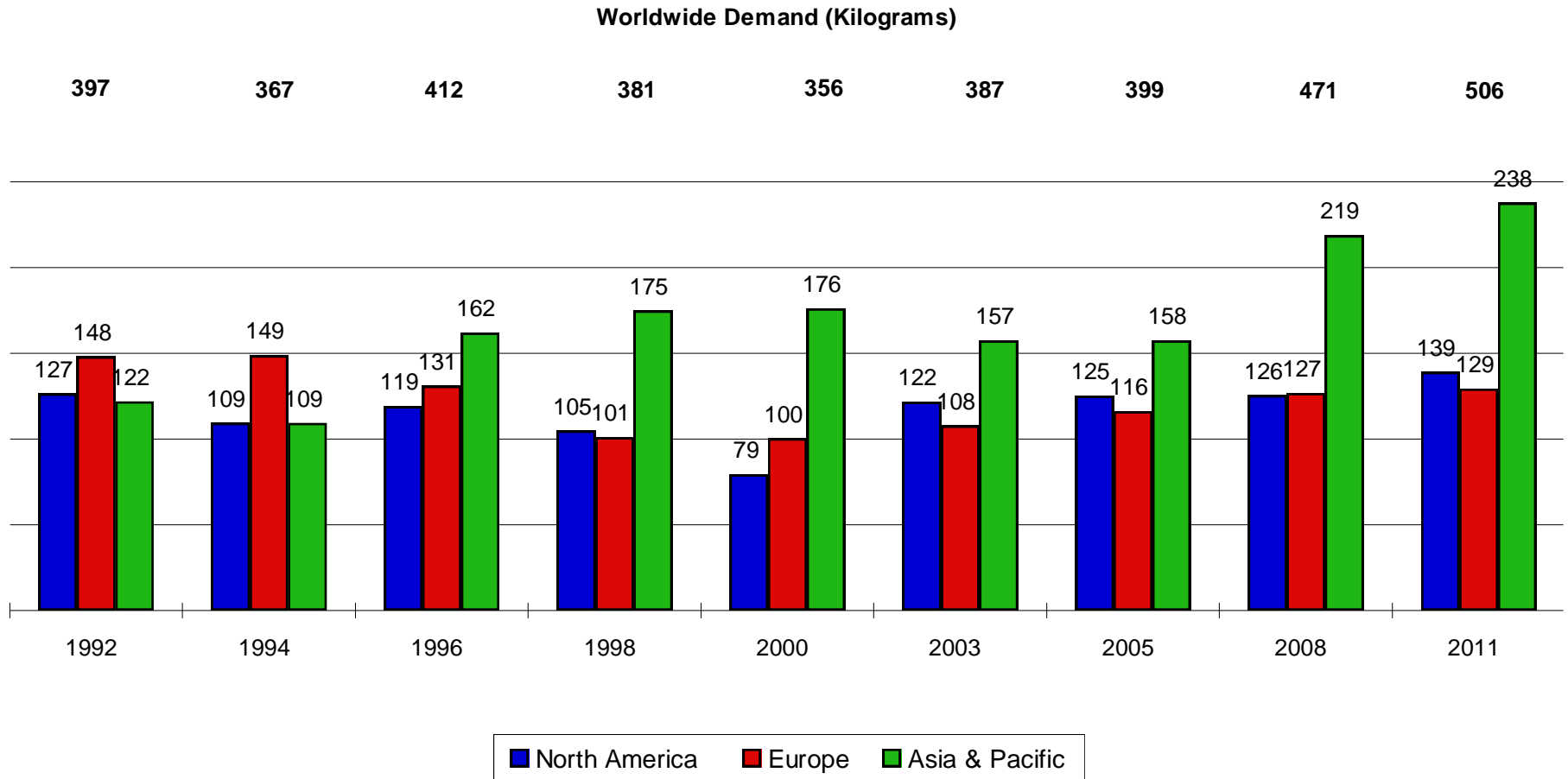
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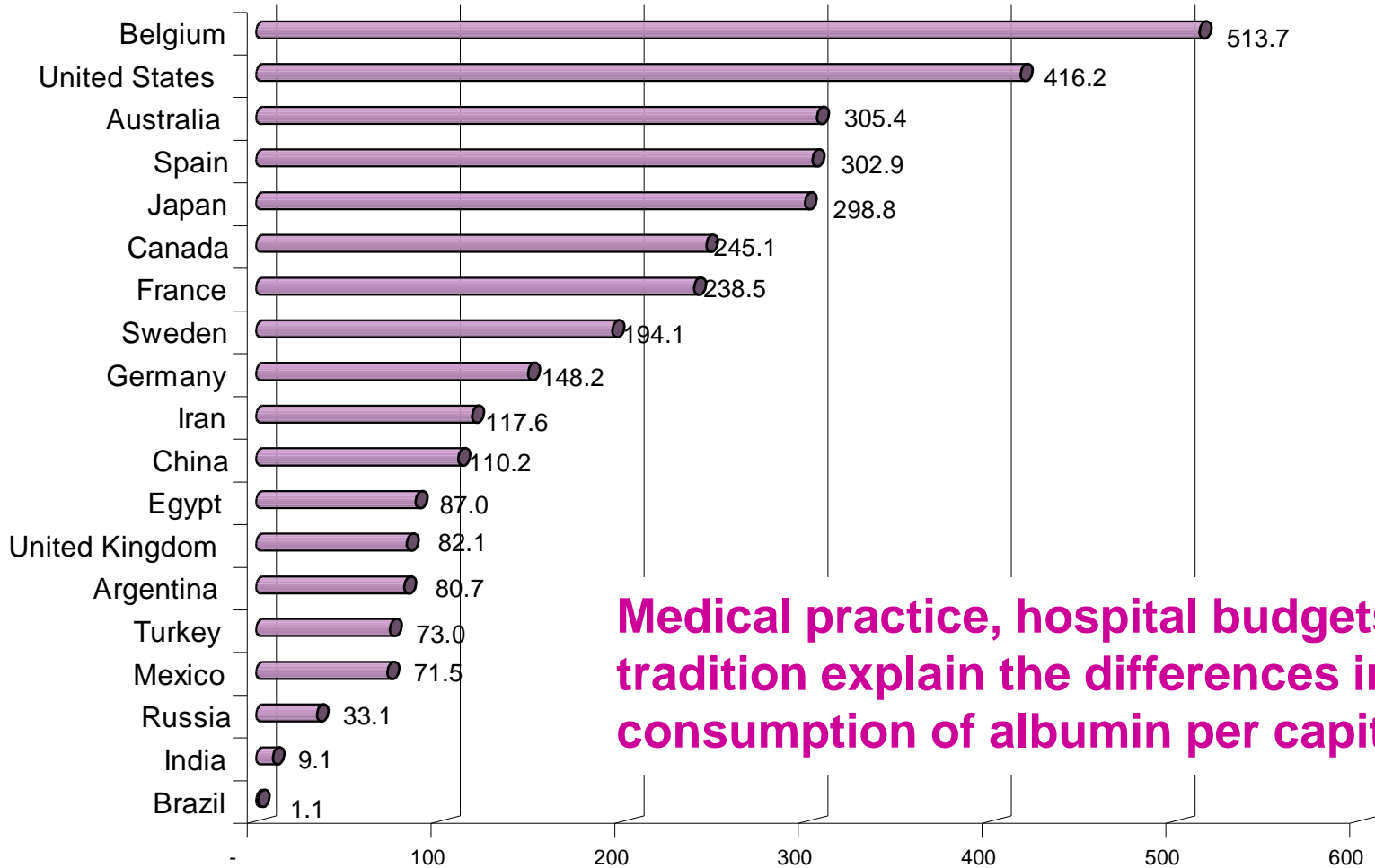
Over the years, the importance of albumin in Asia has increased

WORLDWIDE ALBUMIN DEMAND 1992 - 2011 (METRIC TONS)



Consumption of Plasma Products by Country

ALBUMIN CONSUMPTION PER CAPITA IN SELECTED COUNTRIES
2008-2010
(Kilograms per Inhabitant)



Medical practice, hospital budgets and tradition explain the differences in the consumption of albumin per capita

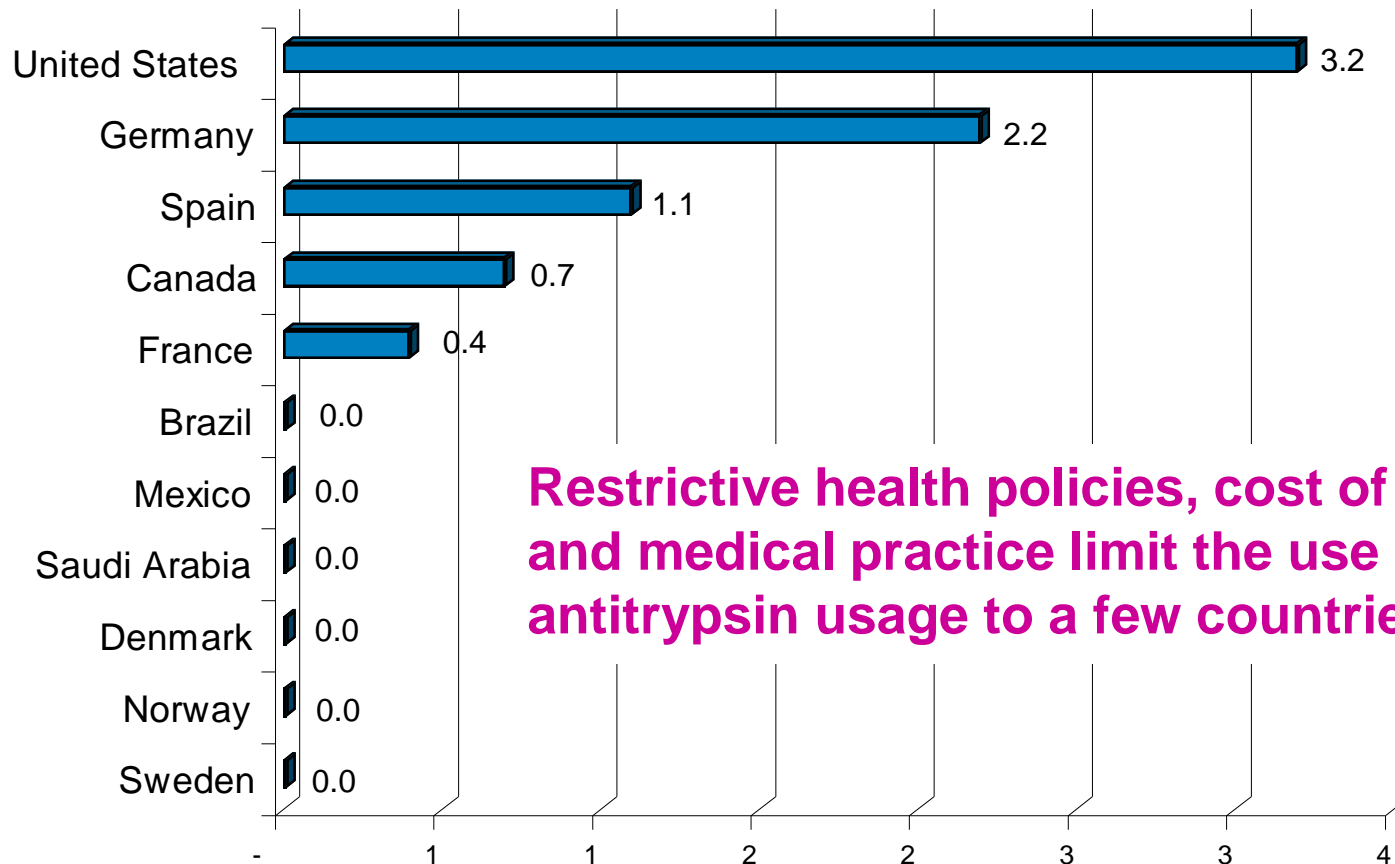
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Consumption of Plasma Products by Country

**ALPHA-1 ANTITRYPSIN CONSUMPTION PER CAPITA IN SELECTED COUNTRIES
2008-2011
(Kilograms per million Inhabitants)**



Restrictive health policies, cost of therapy and medical practice limit the use of alpha-1 antitrypsin usage to a few countries



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The Market Drivers

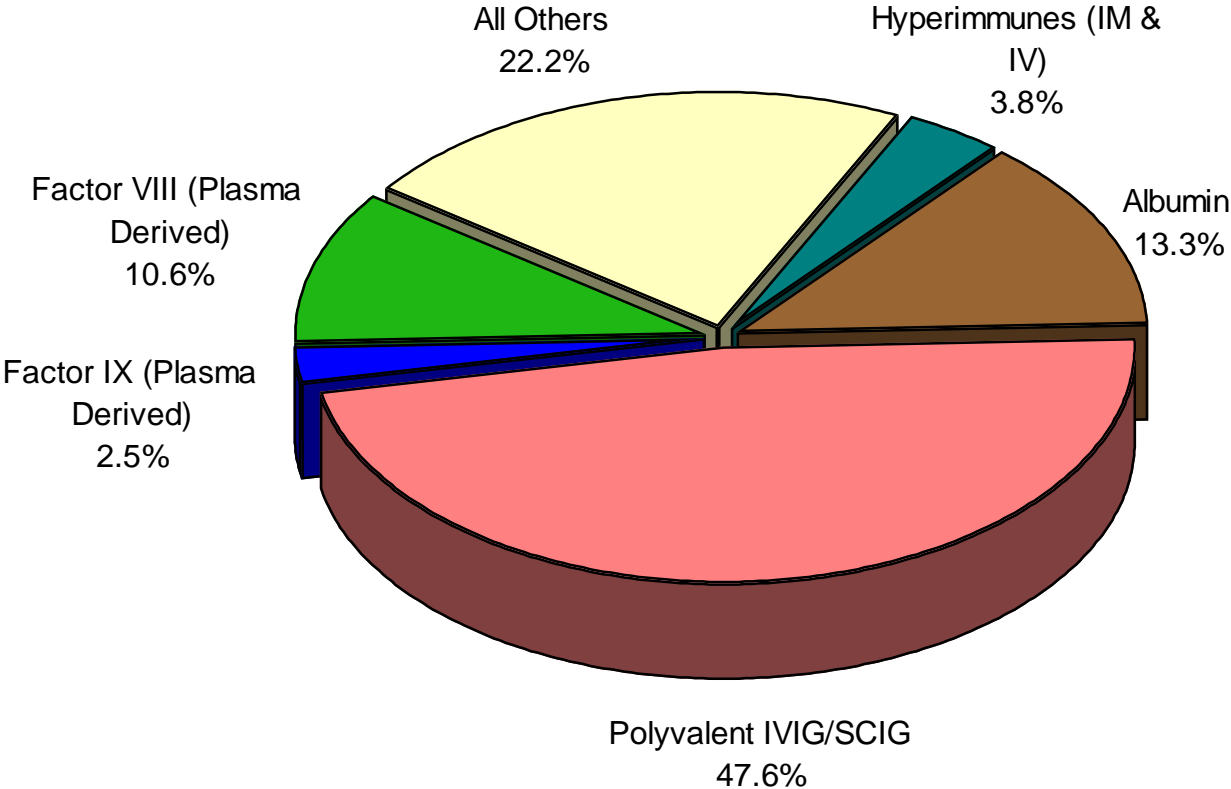
- Plasma Supply



THE WORLDWIDE PLASMA PROTEINS MARKET BY PRODUCT - 2012

WITHOUT RECOMBINANT FACTORS

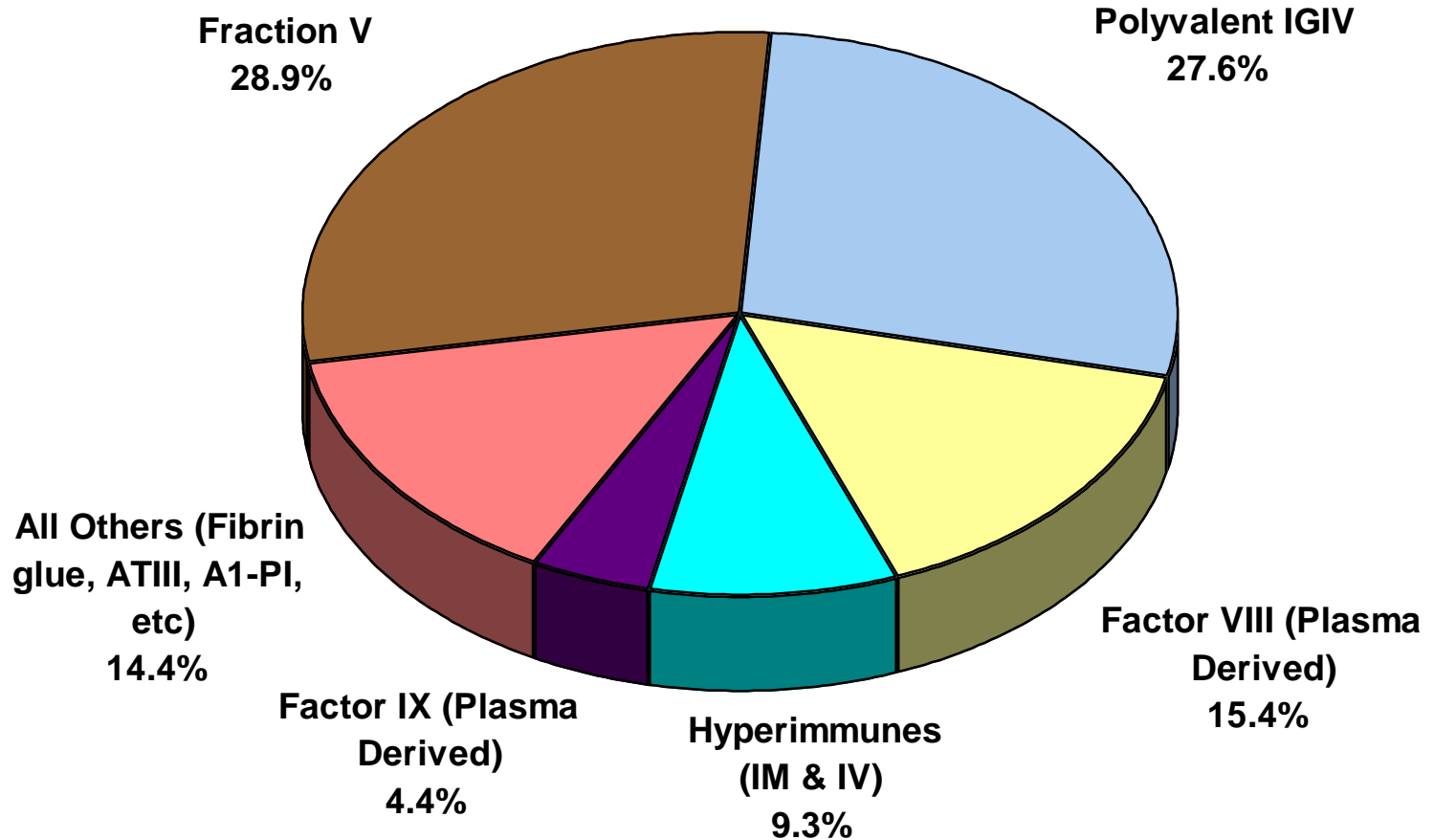
Total Market \$15,222 Million



THE WORLDWIDE PLASMA FRACTIONS MARKET BY PRODUCT - 2000

WITHOUT rFVIII

Total Market \$5,100.6 (MM)

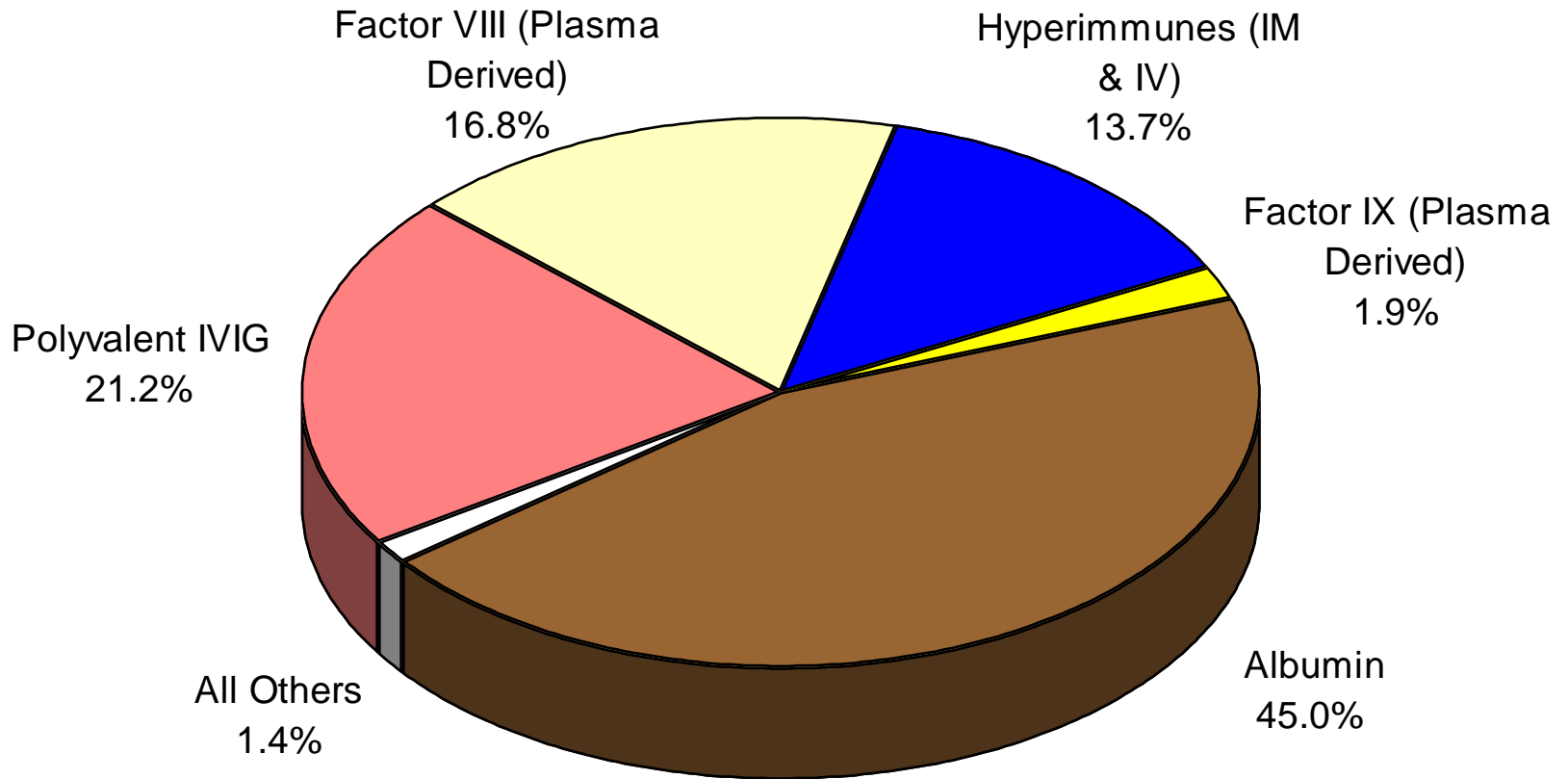


IVIG = 28% of total market, albumin 29%, factor VIII 15%

**THE WORLDWIDE PLASMA FRACTIONS MARKET
BY PRODUCT - 1986**

(Without recombinant Factors)

Total Market \$1,853.7 (MM)

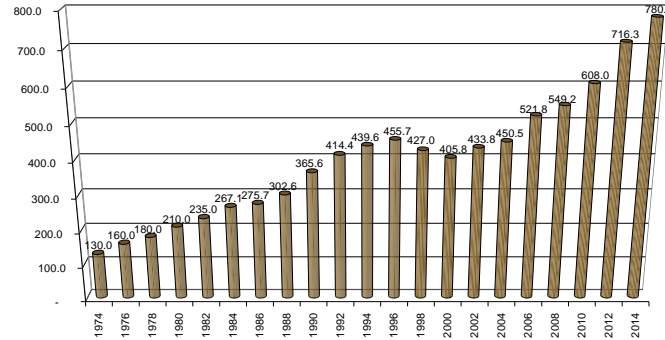


IVIG = 21% of total market, albumin 45%, factor VIII 17%

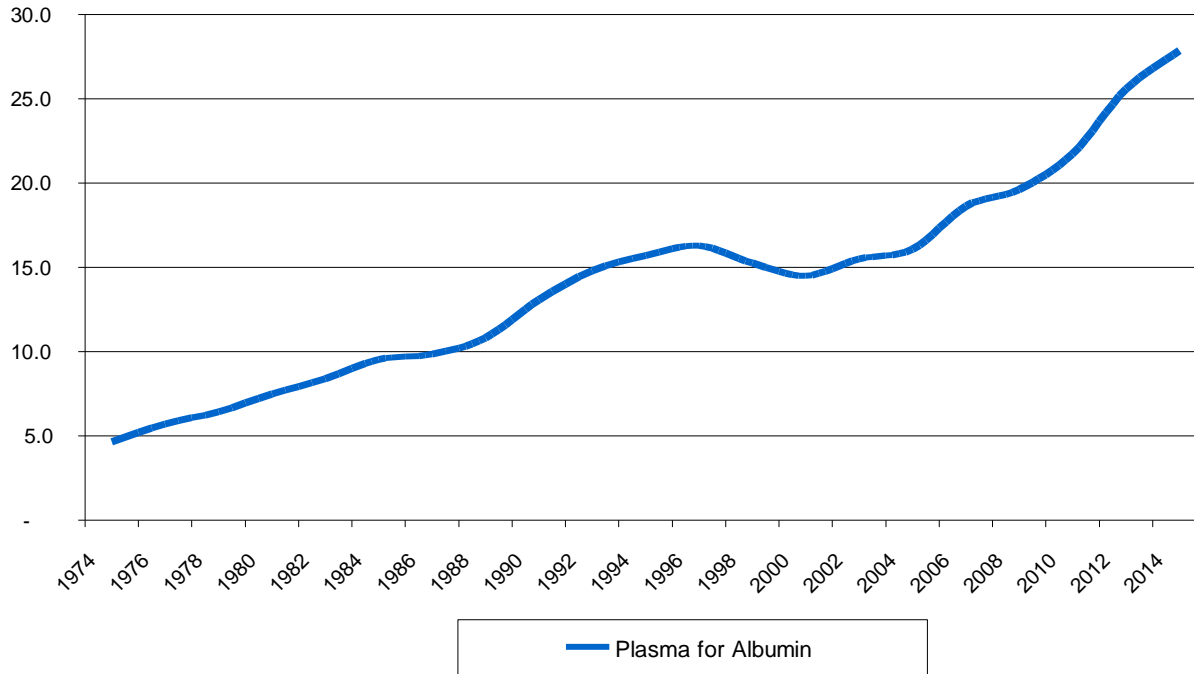
Market Drivers

- From 1974 to 1980, albumin drove the plasma market because neither factor VIII nor IVIG were available in large quantities. One liter of plasma generated approximately 28 grams of albumin.
- In 1980, plasma-derived factor VIII became the market driver: its global needs determined the quantity of plasma to fractionate. Its production yield was 150-180 international units per liter of plasma.
- IVIG took over as the market driver in 2000, and will keep this role in the foreseeable future. Its production yield ranges from 3 to 5 grams per liter of plasma.

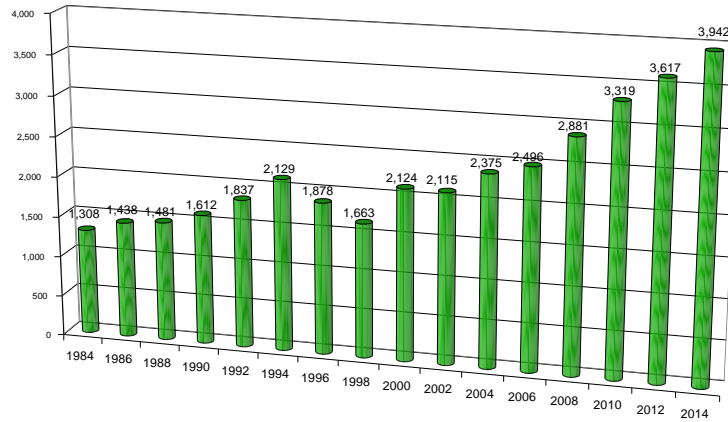
WORLDWIDE ALBUMIN DEMAND 1974 - 2014
Metric Tons



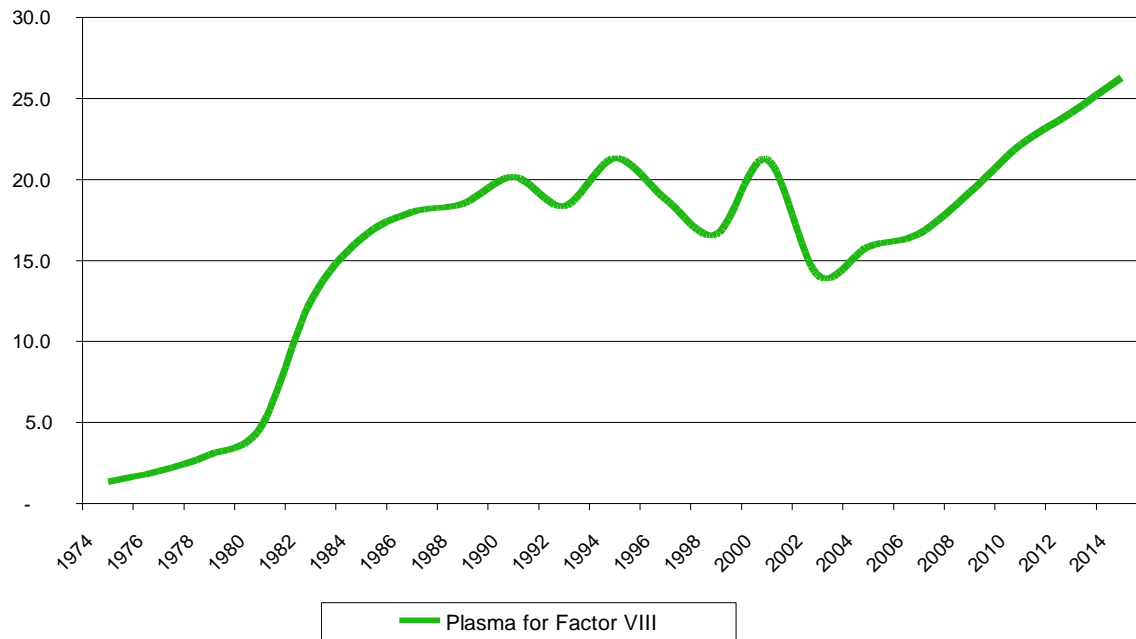
PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
1974 - 2014 - Million Liters



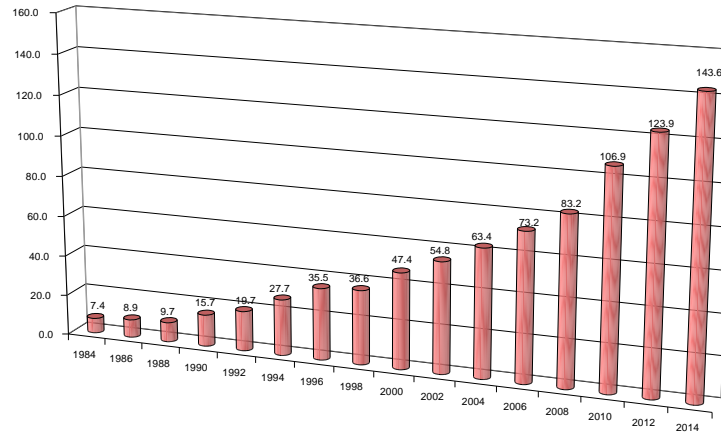
WORLDWIDE DEMAND FOR FACTOR VIII 1984 - 2014
Plasma-derived, Million International Units



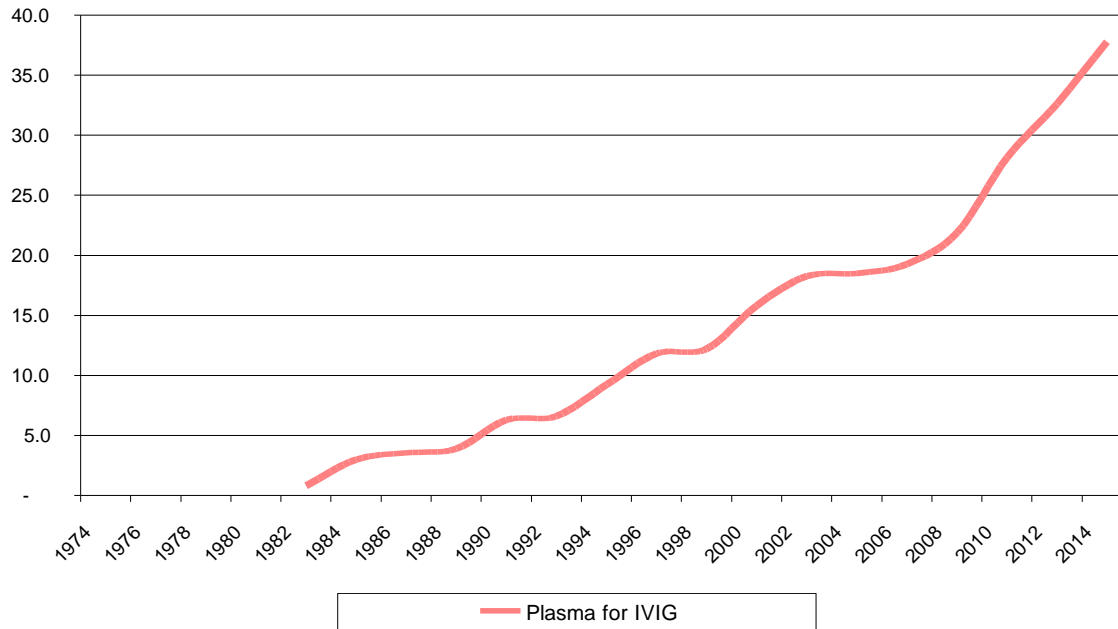
PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
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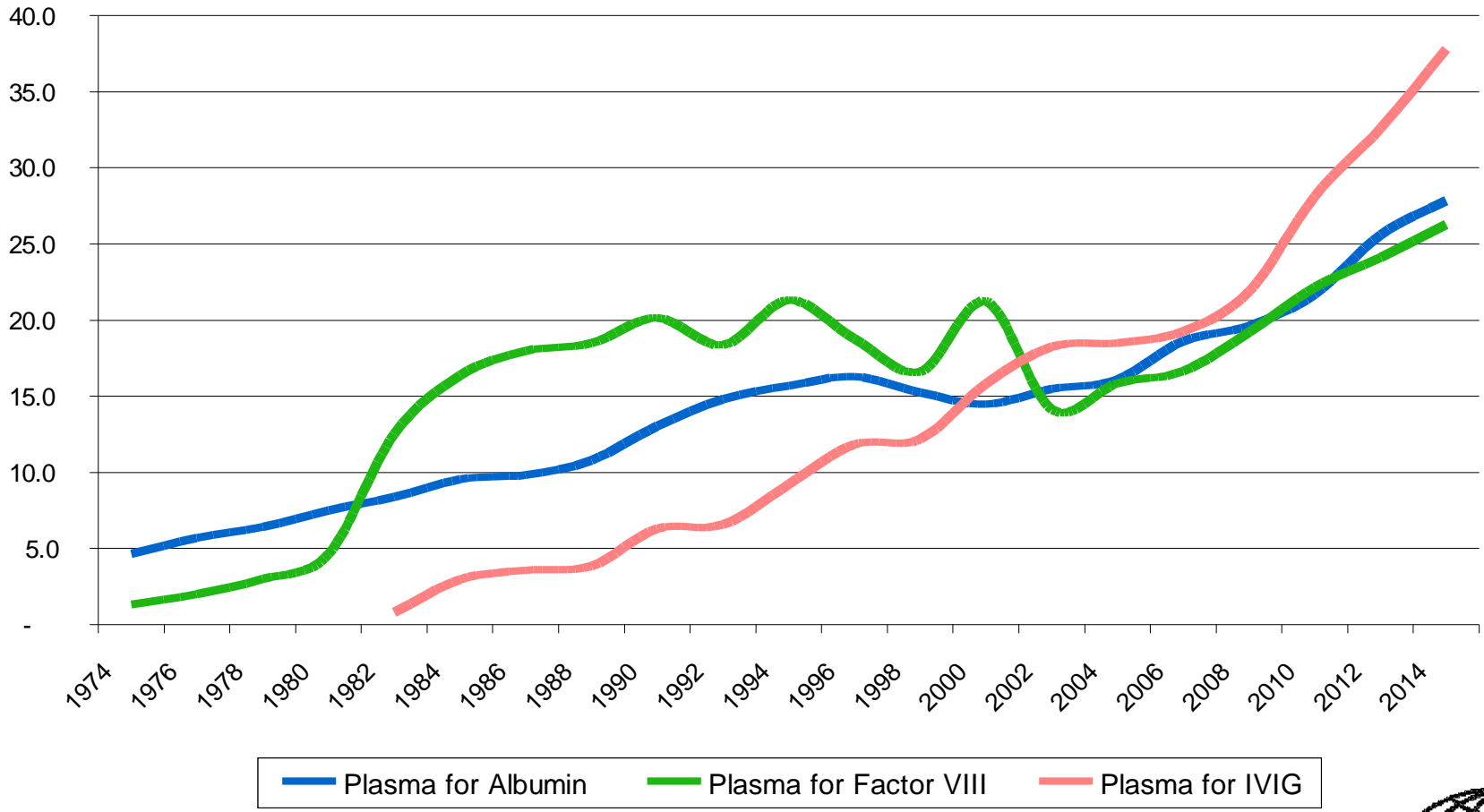
**WORLDWIDE DEMAND FOR INTRAVENOUS & SUBCUTANEOUS IMMUNE GLOBULIN (IVIG/SCIG)
1984 - 2014
Metric Tons**



**PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG
1974 - 2014 - Million Liters**



PLASMA REQUIREMENTS FOR ALBUMIN, FACTOR & IVIG 1974 - 2014 - Million Liters



Market Drivers

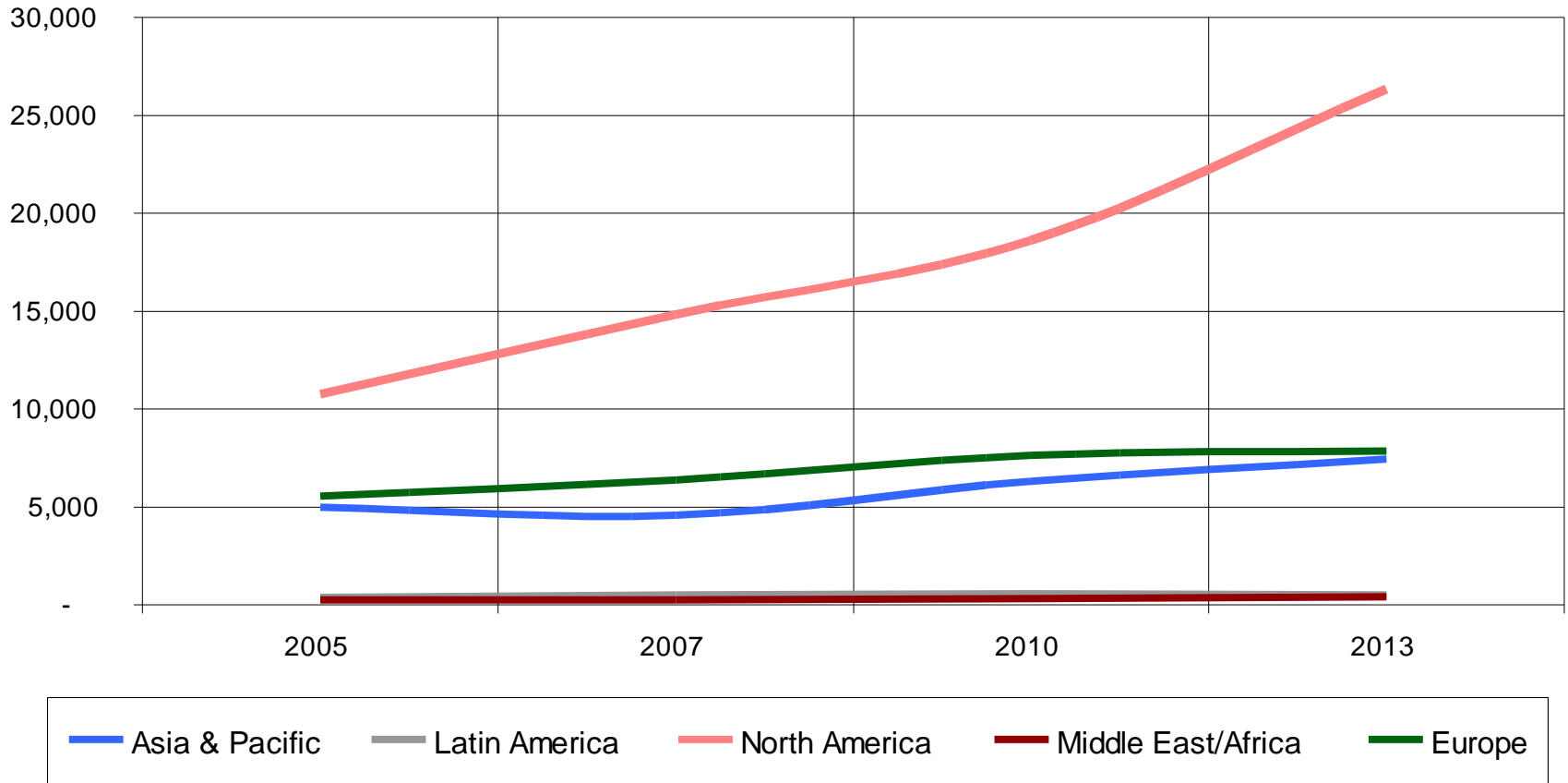
- IVIG drives the North American market because of history, funding of non-approved indications, ample supply, role of patient organizations, company promotion, etc.
- Albumin drives the Asian market because IVIG is not yet widely accepted and albumin is prescribed more liberally than in the west.
- Increased sales of recombinant factor VIII have reduced the demand for plasma-derived of factor VIII, resulting in donations of the latter product to low-income countries by Canada, Denmark, Italy, etc.

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- Historical Development
- Plasma Fractionation
- Worldwide Plasma Products Demand
- **Plasma Supply**



Plasma for Fractionation by Region 2005 to 2013 (1000 x liters, recovered & apheresis)



Source (apheresis) plasma collections grow the fastest, particularly in the United States

CONCLUSIONS

- **The use of most plasma products continues to grow because of their safety and efficacy, and in spite of financial barriers,**
- **The growing demand will require that large quantities of plasma be collected and fractionated,**
- **The commercial and non-profit fractionators have the technical and logistical ability to meet future demand.**

THANK YOU FOR YOUR ATTENTION

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