PPTA
Plasma Protein Therapeutics Association

# *"IVIG Supply and Reimbursement"*

## Advisory Committee on Blood Safety and Availability

## Bethesda, MD

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**Julie A. Birkofer**

**Executive Director, PPTA North America**

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# Main Messages

- Supply is linked to capacity, production and demand
  - Manufacturers are committed to producing life-saving therapies
  - Industry has demonstrated its commitment to invest in the IVIG community
  - Plasma fractionation results in the production of multiple proteins
  - Patient demand for IVIG has increased
- Access is linked to reimbursement
  - Methodologies applied unilaterally fail to recognize the unique nature of plasma protein therapies
  - ASP plus 6% as implemented does not reflect market dynamics
  - Providers and consumer organizations report that changes in reimbursement methodology are negatively impacting access to IVIG

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# IVIG Supply

- Goal is to manufacture lifesaving therapies in a manner that assures the long-term viability of the industry
- Work with Stakeholders to support access to the therapies
- March 2005 data (yellow) do not support shortage scenario
- As demand shifts over time companies respond by increasing supply to meet demand
- IVIG production increases must be in balance with the market demand for other therapies
  - Production levels are not directly linked to reimbursement
- Possible issues impacting supply and demand balance:
  - New entrants to U.S. market
  - Increased use
  - Yield improving technologies
  - Scheduled maintenance shutdowns
  - Order Assessment

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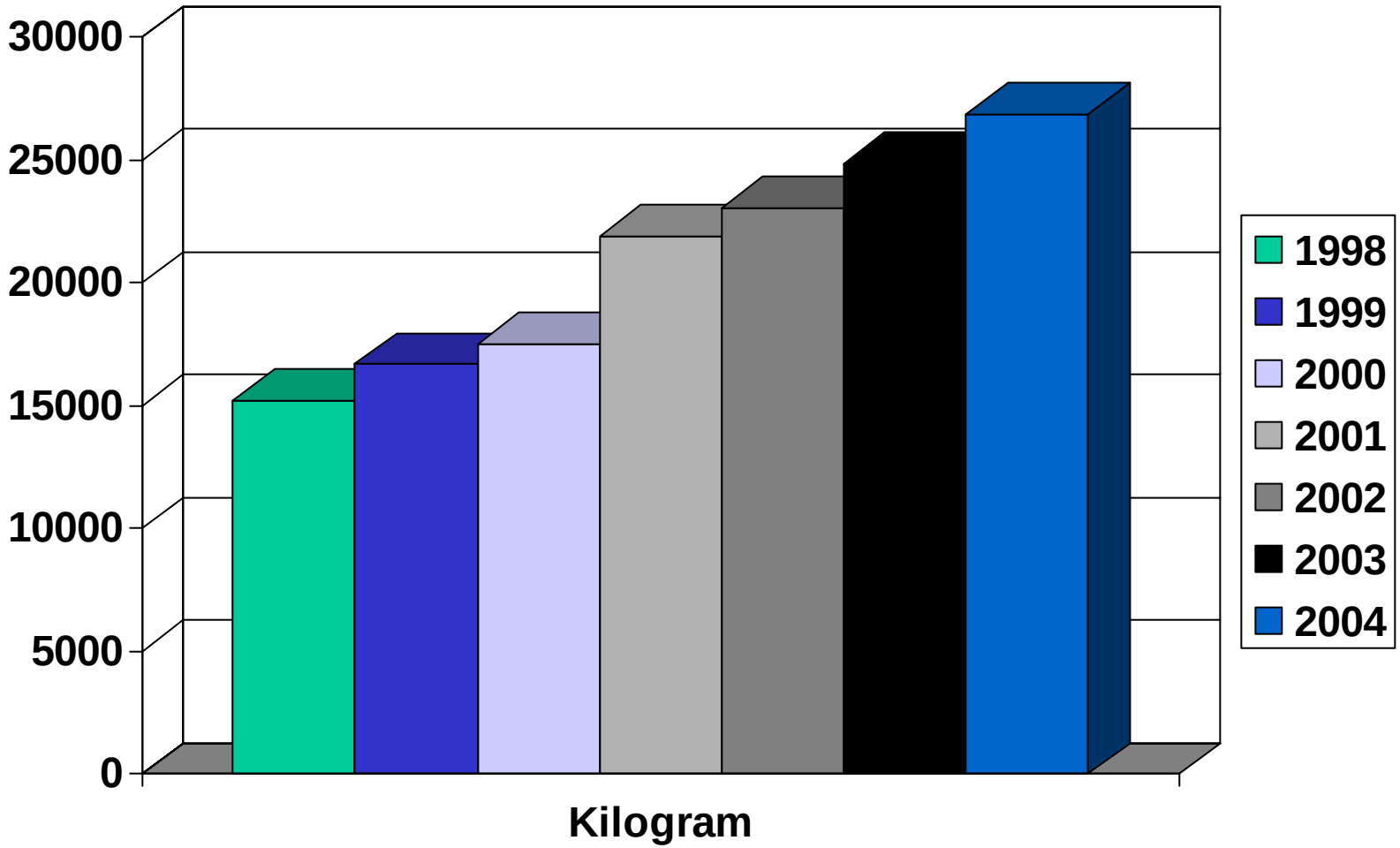
# US IVIG Supply



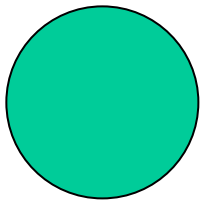
# Data Gathering Program

- Keeping our commitment to Stakeholders
  - Since 1998
- PPTA voluntarily reports industry-aggregated data to stakeholders
  - a useful system for approximating available IVIG

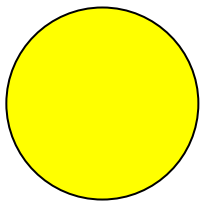
  - Companies report data monthly
  - Letters to stakeholders when system indicates yellow or red
  - Web-based traffic light style system

# Traffic Light System

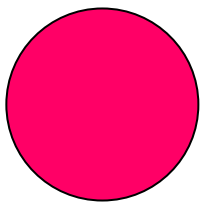
## Available on PPTA website



More than 5 weeks of supply are available and supply is adequate.



Inventory levels are between 2 – 5 weeks and supply is still adequate.
*Monthly inventory and average 12 month distribution data will be displayed by clicking on the yellow light.*



Inventory levels are up to 2 weeks.
*Monthly inventory and average 12 month distribution data will be displayed by clicking on the red light.*

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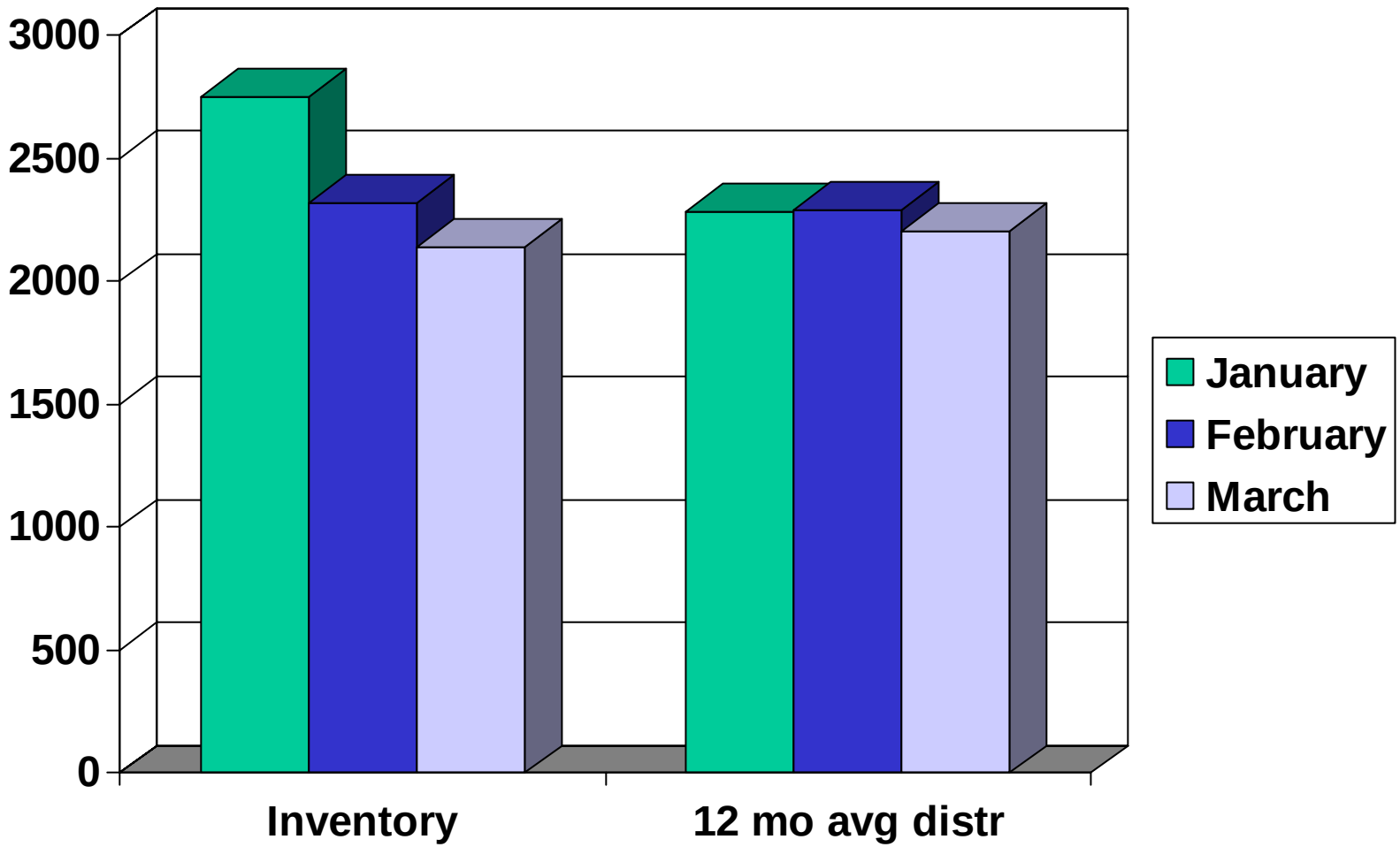
# IVIG "Yellow" Light



# Responsible Industry Action

- May 7 1998 congressional hearing finding
  - "stockpiling and price gauging" in the distribution chain
- Order Assessment - Manufacturers have begun assessing IVIG distribution
- The decision to assess distribution is based on an individual company's production planning and inventory status

- **Order assessment should not be confused with shortage, consistent with yellow light**
- **IVIG is available; but access is impaired**

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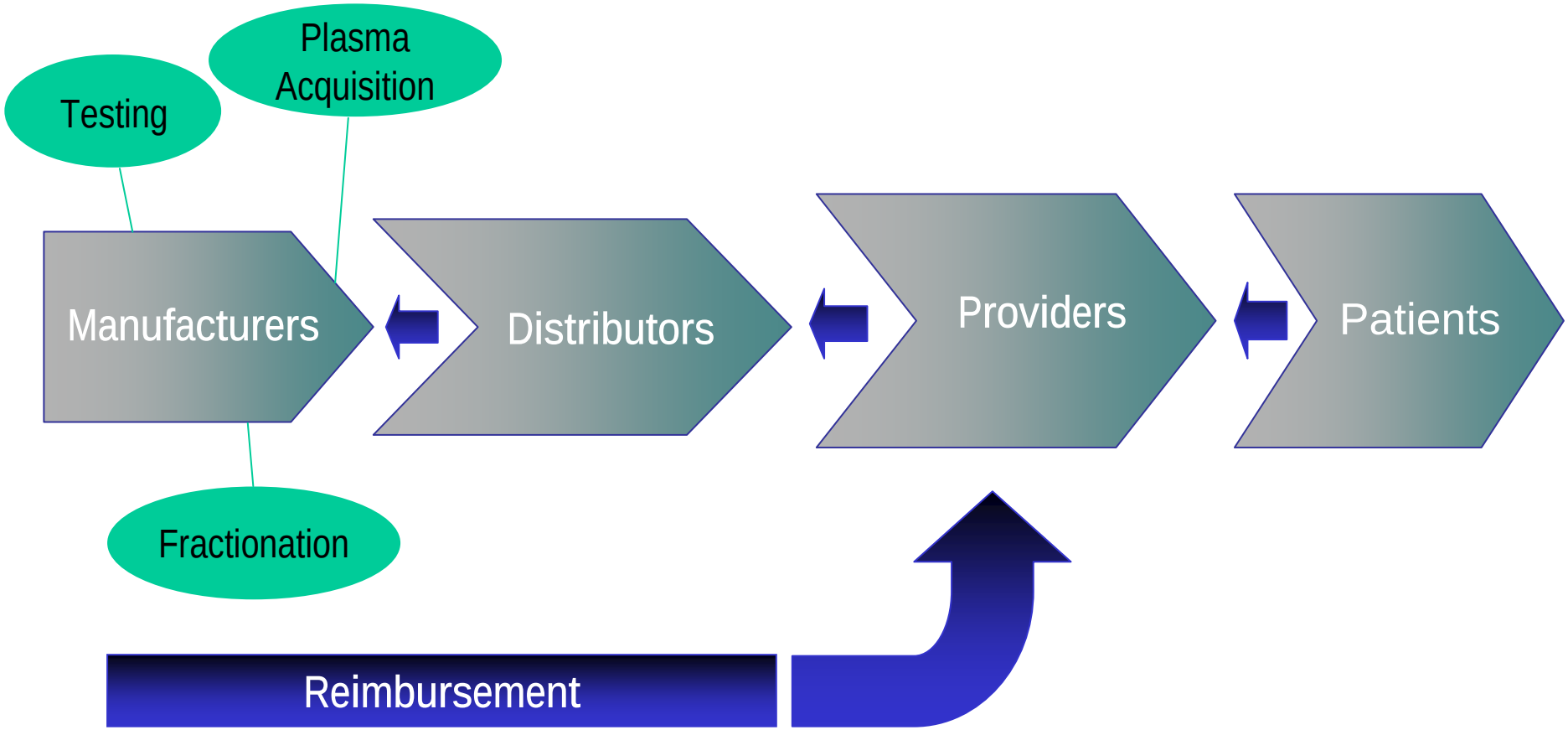
# Supply / **Access**



# MMA's Impact on Access

- Legislated major change in reimbursement methodology
  - Switch from AWP to ASP

Major unknown: Can/Will ASP+ 6 sustain access?

- *PPTA Part B Comments to CMS, January 3, 2005*

*"…we believe that the transition to a new payment system for these therapies has the potential to create access problems…"*

# Administrative Remedies

Proposals from interested parties:

- Increase provider reimbursement for administration of IVIG by **classifying IVIG as a biologic response modifier** to reflect the true resource level
- **De-bundle** the HCPCS codes and provide for an **add-on payment** to cover the cost of services and supplies
- Classify **IVIG as a blood product** and reimburse accordingly (Stakeholder Recommendation)
- Conduct an IVIG demonstration (survey) similar to that for chemotherapy infusions, additional payment per encounter is paid to participating providers

# ASP Methodology

- **Rate based on sales in all sites of service including hospitals**
  - except PHS, DoD and VA pricing

  – Hospitals generally use larger amounts of IVIG than Part B providers and are able to negotiate lower prices
  – Reimbursement rate applies only to physician office and other Part B providers

Result: ASP rates brought down by sales to hospitals

# ASP Limitations

- Six month lag time
  - Does NOT recognize the dynamic market
  - Individual company price fluctuations can and do occur within six month period
  - A CMS calculated ASP may not reflect actual ASPs by the time a payment rate is published
- Lack of verification by a CMS funded third-party auditor

# Impact of ASP+6% on Access

## Negative Impact

- Restricts physician/patient freedom of choice
- Providers reporting ASP+6 is not a sustainable business model
- Reported disruptions in site of service

  - IDF 2002 Survey – 67% of patients receive IVIG under physician payment system

# CMS Response

**April 1, 2005** **Separation of liquid versus lyophilized forms of IVIG**

- This is NOT a complete solution
- The long-term solution is to debundle entirely
- Arbitrary split fails to recognize individual therapeutic values
  - Result: access problems still exist
    - Therapies still bundled
    - Same reported inadequacy issues with ASP +6

# CMS Action

**CMS must take appropriate action**

- Failure to do so may result in continued patient access to care problems for IVIG
- Patients may be forced to receive treatment in the hospitals
  - Change in site of service could expose immune compromised patients to increased risk
  - Increases costs to the Medicare system

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# Conclusion

- We encourage CMS to help establish a long-term strategy on reimbursement for plasma protein therapies
- 8/2003, ACBSA - … “the Committee recommends that CMS be directed to utilize validated cost data available from product manufacturers and distributors.”
- Plasma protein therapies (IVIG) are unique and a one size fits all reimbursement formula does not work
- Companies are in the business of producing lifesaving therapies
- PPTA has long demonstrated a commitment to patient access and will continue to work with CMS, Congress, ACBSA and all policymakers to assure patient access