The 2019 Bill T. Teague Lectureship
U.S. Blood System: Safety, Availability, and Thoughts About the Future

Jay E. Menitove, M.D.
April 23, 2019
Conflicts of Interest

• Independent contractor
  • CSL Plasma

• Independent contactor
  • Accumen
    • Patient Blood Management/Clinical Optimization
Goals

1. Review US blood utilization and collection trends

2. Assess long-term donation sustainability

3. Discuss risk tolerance vs. precautionary principles in decision making
Availability

Safety

Sustainability
Trends in RBC Collections and Transfusions, 1992-2017

Slide Adapted from J. Jones presentation at AABB 2017. NBCUS 2017 data
Population data from US Census Bureau (http://www.census.gov/popest/data/index.html)
The demand data, shared in this presentation, represents all BCA member centers, Vitalant and OneBlood. The ARC also shares their quarterly red cell and single donor platelet demand data with BCA.

The BCA/Vitalant/OneBlood data is same store sales. It is the same set of hospitals serviced by independent blood centers quarter to quarter.

If a blood center loses a hospital, its data is removed from the data set. If a blood center gains a hospital it is not added to the data set.

This data does not capture market share growth.
2014-2018Q4 Quarterly Total Platelets Equivalent Doses Demand

1SDP = 5RDPs = 1Pool RDP

<table>
<thead>
<tr>
<th>Year</th>
<th>Q4 % Change to Prior Year Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>2.65%</td>
</tr>
<tr>
<td>2016</td>
<td>-1.4%</td>
</tr>
<tr>
<td>2017</td>
<td>1.4%</td>
</tr>
<tr>
<td>2018</td>
<td>0.18%</td>
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</table>

Goel R, et al. JAMA 2018; 319: 825-7
## National Blood Collection & Utilization Survey (NBCUS)

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2011</th>
<th>2015</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC Distributed*</td>
<td>17,286</td>
<td>15,721</td>
<td>12,028</td>
<td>11,068</td>
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<tr>
<td>RBC transfused*</td>
<td>15,014</td>
<td>13,785</td>
<td>11,349</td>
<td>10,575</td>
</tr>
<tr>
<td>LR-RBC mean $$$</td>
<td>$223</td>
<td>$225</td>
<td>$217</td>
<td>$216</td>
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</table>

* in thousands
ABC Members Median Operating Margin, 2012-2017

Source: ABC Financial Ratio Survey, 2019
### Median Operating Income per FTE

<table>
<thead>
<tr>
<th>Year</th>
<th>All</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
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<tr>
<td>2013</td>
<td>$3,218</td>
<td>$3,094</td>
<td>$5,244</td>
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<td>2014</td>
<td>$1,369</td>
<td>$796</td>
<td>$1,380</td>
<td>$2,109</td>
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<tr>
<td>2015</td>
<td>-$2,023</td>
<td>-$1,874</td>
<td>-$298</td>
<td>-$2,591</td>
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<tr>
<td>2016</td>
<td>$857</td>
<td>$825</td>
<td>$1,349</td>
<td>$414</td>
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<tr>
<td>2017</td>
<td>-$1,120</td>
<td>-$1,863</td>
<td>$466</td>
<td>-$1,720</td>
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An open letter to the U.S. health care community: steps to ensure a strong national blood supply

August 2018

By Chris Hrouda, president, Biomedical Services at the American Red Cross

With fewer transfusions, blood providers have responded accordingly by reducing infrastructure and recruitment and collection activities to better contain expenses. Through less volume and controlled expenditures, the industry has shed an estimated $1.3B in expenses since 2009. Red Cross itself has eliminated more than $500M by restricting excess capacity and implementing other cost containment initiatives.

Despite the credible efforts by blood centers to control costs, these have not sufficed. Most blood products distributed in the US are supplied at a cost lower than that to produce them. The disparity between escalating costs and diminishing prices is highlighted when comparing Medical Consumer Price Index (MCPI) to average sales price. Between 2010 and 2017, the Red Cross average red cell price decreased by 11% whereas MCPI increased by 26% (as reported by the Bureau of Labor Statistics).
BLOOD & TISSUE SAFETY AND AVAILABILITY
A UNIQUE SYSTEM AND CRITICAL PRIORITY FOR PUBLIC HEALTH

• The U.S. Blood Industry is uniquely private-sector

• ~21 million components transfused annually
  ▪ 10% of all hospital procedures require the use of blood products
  ▪ 20% of all hospital procedures require safe blood be available ‘in-house’ and ready
  ▪ Safe and available blood stocks are required to respond to natural and manmade disasters

• 57% of America’s Blood Centers and 100% of American Red Cross are operating in negative margins

• Disaster donations” do not guarantee sustainability, and may be counterproductive
Blood Center/Hospital $$$
2008-2017

• 2008
  • 15,014,000 RBC units transfused

• 2017
  • 10,575,000 RBC units transfused

• 4.44 million fewer RBC units X $200 per unit = $888,000,000 in 2017
  • ~ 0.078% of US annual hospital spending
Blood Center vs. Hospital Margins

Aggregate Operating Margins
* S&P Ratings - US Not for Profit Healthcare System Median Financial Ratios - Median Operating Margin

<table>
<thead>
<tr>
<th>Year</th>
<th>ABC</th>
<th>Hospitals *</th>
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<tbody>
<tr>
<td>2013</td>
<td>1.7%</td>
<td>2.2%</td>
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<tr>
<td>2014</td>
<td>1.0%</td>
<td>2.9%</td>
</tr>
<tr>
<td>2015</td>
<td>-1.4%</td>
<td>3.6%</td>
</tr>
<tr>
<td>2016</td>
<td>0.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>2017</td>
<td>-0.9%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Source: ABC Financial Ratio Survey, 2019
Public Policy: Safety & $$$$

• Zero-risk: 1980’s strategy based on reaction to HIV crisis
  • “If anything can be done to reduce the risk of transfusion without regard to its position in the ranking among the other risk-reducing efforts society demands of medicine, it should be done. Thus, a de minimis risk stands on equal footing with major health hazards.”

  Zuck TF. Transfusion 1987;27:447-8
Precautionary Principle

Wingspread Statement, 1998

“When an activity raises threats of harm to health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”
1995 Institute of Medicine (IOM) Report

• U.S. Institute of Medicine Report, AIDS entry into the blood supply, 1995
  • Recommendation 6:
    • “Where uncertainties or countervailing public health concerns preclude completely eliminating potential risks, the FDA should encourage, or where necessary require, the blood industry to implement partial solutions that have little risk of causing harm.”

Leveton LB, Sox HC, Stoto MA. National Academy Press, 1995
RBC Service Fees vs. Safety
ABC 1985-2018

America's Blood Centers
Safety Measures and Median Red Cell Service Fees
1992 - 2018

- HCV 1.0
- HTLV-I Test
- HBc and ALT Test
- HIV-1 Ab Test
- HIV1/2 Test
- HCV 2.0 Test
- HCV Lookback
- HCV NAT (IND)
- HIV-1/HCV NAT (IND)
- HIV-1/HCV NAT
- Licensed WNV NAT
- Licensed HIV-1/HCV NAT
- TRALI Interventions
- Bacterial Detection (Single Donor Platelets)
- Chagas' Test
- WNV NAT (IND)
- HBV NAT
- ZIKA (cost of testing not included in 2018 fees)
- Leukoreduction Becomes Widespread
- Conservative Donor Hemoglobin Rules

<table>
<thead>
<tr>
<th>Year</th>
<th>RBCs</th>
<th>RBCs LR</th>
</tr>
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<tbody>
<tr>
<td>1992</td>
<td>64</td>
<td>$111</td>
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<tr>
<td>1993</td>
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<td>2017</td>
<td>205</td>
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<tr>
<td>2018</td>
<td>206</td>
<td></td>
</tr>
</tbody>
</table>

*LR = Leukoreduced*
Decisions based on Risk

- Encephalitis/coma/paralysis (WNV)
- Mad Cow Disease (vCJD)
- Cardiac death (Chagas’)
- Microcephalic babies (Zika)
  - > $100m
- ?? Teenager cognitive loss (Fe)

“When an activity raises threats of harm to health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”

Blood Products Advisory Committee (BPAC)

• March 20-21, 2019
  • Zika testing
    • 11-4 vote: continue universal testing (July 2018 Final Guidance)
    • 14-1 vote: dismissed option to eliminate testing without re-introduction of donor screening—pending another outbreak in the US

• Too many unknowns at this time

• Precaution persists
Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) and BPAC

<table>
<thead>
<tr>
<th>ACBTSA</th>
<th>BPAC</th>
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<tbody>
<tr>
<td><strong>• ACBTSA</strong></td>
<td><strong>• BPAC</strong></td>
</tr>
<tr>
<td>• Recommendations to HHS Secretary</td>
<td>• Advise FDA Commissioner</td>
</tr>
<tr>
<td>• Assistant Secretary for Health = blood safety officer</td>
<td>• CBER (regulatory)</td>
</tr>
</tbody>
</table>

- Safety
- Blood and Tissue
- Economic (product cost & supply)
- Availability
- Broad public health, ethical and legal issues

- Safety
- Blood
- Effectiveness
- Appropriate use
- Blood donor screening & testing
ACBTSA: Sustainability of US Blood System

Spring, 2015

Offeror to prepare an independent study report, “Toward a sustainable blood supply in the United States: an analysis of the current system and alternatives for the future.”

• Describe the current business model and reimbursement structure underlying the non-profit, private sector supply of blood and blood components, with particular reference to its ability to sustain technological advances and responses to safety threats and surge capacity.
The U.S. blood system under the status quo operates effectively and, in many cases, efficiently blood was always or almost always available to hospitals.

robust price competition controls blood costs.

we propose a set of narrower recommendations that HHS could consider to improve blood system sustainability.
RAND Recommendations

• Recommendation 1: Collect data on blood use and financial arrangements.
• Recommendation 2: Develop and disseminate a vision for appropriate levels of surge capacity and emergency response plans.
• Recommendation 3: Pay blood centers for maintaining surge capacity.
• Recommendation 4: Build relationships with brokers and other entities to form a blood “safety net.”
RAND Recommendations

• Recommendation 5: Build and implement a value framework for new technology.

• Recommendation 6: Pay directly for new technologies where there is no private business case for adoption.

• Recommendation 7: Implement emergency use authorization and contingency planning for key supplies and inputs.
• Whereas the Committee finds that:
  • Blood is a public good, built on the altruism of non-remunerated donors. Simple supply and demand economic principles do not fully address the societal value of this critical national resource. Consequently, there are unique considerations with respect to sustainability of the blood system.
ACBTSa: November, 2016 Recommendations

- Develop mechanisms to encourage hospitals and blood centers to participate in data collection programs; this should include collection, utilization, and cost; the Secretary should convene a panel of stakeholders to suggest appropriate data elements.
ACBTSA: November, 2016 Recommendations

- Explore the potential for direct payment to blood centers to cover the costs of the infrastructure required to maintain adequate supplies for the public good.
ACBTSA: November, 2016 Recommendations

- Examine models of **risk based decision making** to inform future public policy to include all **stakeholders in** the vein to vein process from donor to patients and their families, and including all intermediaries, (e.g., blood centers, hospitals, clinicians, medical device developers).
ACBTSA: November, 2016 Recommendations

- Reduce regulatory uncertainty with respect to innovations to encourage investment in their development and implementation.
Post-RAND Report Activities

• RAND
  • Economist viewpoint
  • Tweaks

• ACBTSA
  • “Crisis-oriented” viewpoint
  • Public good
Post-RAND Report: ACBTSA Sustainability Sub-committee Activities

• Confirm and document U.S. blood system sustainability risk
  • **Stress test (per 2008-09 banking industry crisis)**
    • More than financial crisis
      • Shrinking donor pool
      • Lack of supplies
  • Lack of central decision making
    • BARDA and FDA to assist in data collection
      • Donors
      • $$ $$ $$
Crisis in the Sustainability of the U.S. Blood System

Harvey G. Klein, M.D., J. Chris Hrouda, B.H.S., and Jay S. Epstein, M.D.
NEJM Sounding Board

• Nations Blood Supply
  • Public trust
  • Strategic resource

• US blood pipeline is now in danger of disruption

• Medical community treats blood as a commodity
  • With declining demand, the cost per unit increases
    • Additional safety testing further increases costs
    • Hospital consolidation shifted bargaining power to hospitals (fewer customers for BCs)
NEJM Sounding Board

• For in-patients
  • No direct link between hospital reimbursement to blood centers and hospitalized patients
  • Changes in DRG payments not passed through to blood collectors
• Some type of significant public or private intervention will probably be required to maintain adequate blood-system infrastructure
  • WG to develop models to access stressors and potential solutions
  • The blood system is not sustainable absent structural changes
  • A mechanism is needed that will pay full value
• A constructive intervention to stabilize the US blood system, although urgently needed, has yet to be envisioned
United States blood supply modeling
Advisory Committee on Blood and Tissue Safety and Availability

December 12, 2018
HHS / ASPR
BARDA and SIIM and in collaboration with OASH

HHS: Department of Health and Human Services
ASPR: Assistant Secretary for Preparedness and Response
BARDA: Biomedical Advanced Research and Development Authority
SIIM: Security Intelligence and Information Management
OASH: Office of the Assistant Secretary for Health
December, 2018 Conference Call

- **Blood Supply**
  - Unique donors decreased 2012-2017
  - Donor rate
    - <19 y.o. Unchanged
    - 19-50 y.o. Decreased
    - 51-60 y.o. Decreased
    - 65+ Increased
  - May leave blood system sensitive to shocks and stressors

Donor Demographic Changes through 2015

Shift towards younger and older donors accounting for 13.4% and 12.4% of the 6,812,000 individuals donating in 2015 (compared to 9,203,000 persons in 2013).

First time donors declined to 2,223,000 from 2,840,000 in 2011.

Concern about Fe depletion likely leads to reduce blood donations.

The long-term consequences of these changes raise a cautionary flag about blood supply adequacy if transfusion needs increase as the U.S. population ages.

NBCUS Sapiano MRP, et al. Transfusion 2017;57:1599-1624
Percent Contribution of RBC by Donor Age

ABC Data Warehouse, September 2018
Financial trends

December 12, 2018
HHS / ASPR
BARDA and SIIM and in collaboration with OASH

--- Expenses --- Revenue

PROPRIETARY
• Prolonged **negative margins**
  • Deplete
    • Capital equipment replacements
    • Technology enhancements
• Erode
  • Reserve $$$
  • Borrowing capacity

*Emphasis on least expensive blood drives*
$$ and (Lack of) Investment

Donor shortages

STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

- Relationship
- Winter storms
- Financial stress
- Lack of re-investment
CURRENT INTERESTS OF BOTSEC AND ACB TSA

March 2019

• Developing several “Blood System Stress Tests” similar to stress test used by the banking industry

• Contracting for the production of real-time blood industry inventory and potential pricing trend data

• ASH Interests

  ▪ Developing approaches to reach the new generation of blood donors
  ▪ Assuring the public is educated about the US blood supply system
  ▪ Outlining an innovation and public policy framework to support the future of the US blood supply and system, including novel reimbursement mechanisms

BOTSEC (de facto central decision locus)

Blood, Organ, and Tissue

Senior Executive Council
Distribution of Donor Population by Race

Trends in US minority red blood cell unit donations, *Transfusion*, 2017
Mitigation

An open letter to the U.S. health care community: steps to ensure a strong national blood supply

August 2018

By Chris Hrouda, president, Biomedical Services at the American Red Cross

Improved cost recovery for blood centers can be achieved through two primary channels: innovation and pricing. First, by modernizing operations, upgrading platforms and developing creative partnerships with hospitals and industry associates, blood centers can improve their financial position. Red Cross has dedicated resources within our Innovations Office to drive productivity and efficiency through transformation, modernization and new technologies.

The second source of cost recovery for blood centers is raising prices for products and services. As such, the American Red Cross will be increasing prices to its hospital clients, several of which have already received notification of these changes. Moving forward, pricing offered by the Red Cross will be commensurate with the value of these vital products and services and reflect the true cost to collect, produce, test and distribute blood in today’s environment. As we have done in the past, Red Cross will continue to advocate for increased reimbursement for in-patient and outpatient services from Centers for Medicare & Medicaid Services (CMS) to hospitals for the products and services we jointly provide.
Additional $$$ Mitigation

• Continuing consolidation
  • Healthcare
    • Hospital systems
    • Insurance companies
    • PHARMA manufacturers/suppliers
  • Blood Centers
    • ABC members (77 to 47)
    • ARC
  • Blood Testing Laboratories
    • CTS---~70% of US blood supply
    • NYBC lab consortium
    • Versiti
    • Atlanta consortium
Caveats

• Blood utilization decline
  • resulting blood center consolidation into fewer, but larger organizations

• ACB TSA cautioned, at its November 9-10, 2015 about
  • “adverse effects of an unconstrained competitive environment in blood collection with avoidance of potentially adverse outcomes for public health
    • monopoly or oligopoly behaviors in the absence of suitable controls”
Caveats

• Are current customer service issues facing the airlines industry a harbinger for the blood system?

• Customers benefitted for many years from fierce competition and lower prices
  • Prior to deregulation, the airline industry served simultaneously large and small markets
  • Following de-regulation, it migrated into an abusive cartel

• Patients (and donors) differ from passengers, more than pecuniary interests avail.

Kuttner R. New York Times April 17, 2017
Menitove JE. Transfusion 2017;57:1585-7
Innovation Adoption: $$ and safety risks?

Will hospitals pay for innovation?
CMS Reimbursement
Will PHARMA invest $$ if ROI uncertain?

- Pathogen reduction
- Bacterial detection (Platelet concentrates)
- Babesia testing
- Metabolomics
- Specialty products
  - Antigen matched units for SCD patients
- IT enhancements
  - Vein-to-vein
  - Blockchain, digitalization
- Hospice/palliative care, skilled nursing facilities

<table>
<thead>
<tr>
<th>Expected primary payer, %</th>
<th>2016</th>
<th>2017</th>
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<tbody>
<tr>
<td>Medicare</td>
<td>63.3</td>
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<td>Medicaid</td>
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<td>Uninsured</td>
<td>3.6</td>
<td>4.2</td>
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<tr>
<td>Other</td>
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<td>2.5</td>
</tr>
</tbody>
</table>

Prioritizing decision making

- Structured approach for defining and assessing risk
  - Zero risk---unattainable
  - Limited resources (scarcity)
Risk Assessment Principles: Risk Based Decision Making

- Transparency/full access to information that informs decisions
- Beneficence/benefit of others
- Fairness/equitable distribution
- Consultation/stakeholder involvement
- Evidence and Judgment
- Practicability and proportionality/risk: benefit ratio
- Continuous improvement
- Vigilance/post-implementation review

Leach Bennett J. Editorial. Transfusion 2015;55:2775-77
Assessing the risk of *Babesia* to the United States blood supply using a risk-based decision-making approach: Report of AABB’s Ad Hoc *Babesia* Policy Working Group (original report)

Sheila J. Ward, Susan L. Stramer, and Zbigniew M. Szczepiorkowski

Recognizing the increasing threat of transfusion-transmitted babesiosis to the US blood supply, the AABB Board of Directors tasked an Ad Hoc *Babesia* Policy Working Group (the Working Group) to use the Alliance of Blood Operators’ risk-based decision-making (RBDM) framework to assess the risks and benefits of introducing *Babesia* donation testing in the United States. The regional nature of the *Babesia microti* risk added complexity to the RBDM assessment because of the unique operational and financial considerations for

THE NEW DECISION-MAKING PARADIGM ENVISIONED FOR BLOOD SAFETY

The risk-based decision-making (RBDM) framework is an outcome of an international consensus conference sponsored by the Alliance of Blood Operators (ABO) to address the increasingly unsustainable pursuit of “zero-risk” blood products. The consensus panel concluded that risk is inherent “vein to vein,” zero risk is unattainable, and the well-being of transfusion recipients must be central to blood safety decision making.
Elimination of HBsAg testing: risk less than 1 per 4 million donations

Blood donor testing for hepatitis B virus in the United States: is there a case for continuation of hepatitis B surface antigen detection?

Roger Y. Dodd, Megan L. Nguyen, David E. Krzyztop, Edward P. Naturl, and Susan L. Stramer

Donor screening for hepatitis B: hepatitis B surface antigen—a belt, suspenders, and another belt?

The anti-HBc reagent in the third assay of the three-assay test may be unnecessary, but the three-assay test is necessary. The three-assay test is the gold standard for antihBc reactivity. The choice between a two-assay and a three-assay test is a matter of cost and convenience. The three-assay test is superior to the two-assay test in terms of specificity and sensitivity.

Louis M. Katz, Merlyn Sayers

e-mail: l Katz@americasblood.org
Blood Donor Iron Deficiency: Donor Safety

- Up to 23% of donors demonstrate donation-related iron deficiency
- Precautionary interventions to mitigate adolescent iron depletion in place > one-half US collection from 16-18 y.o.
- AABB Ad Hoc Committee on Iron Management (May 2017)
  - RBDM principles applied
- Pro/Con Commentaries Transfusion, May 2019
- Absence of proof of harm is not proof of absence of harm
  - Risk losing donor confidence
- Recommended interventions
  - No more than treating laboratory values
  - Base interventions on evidence rather than conjecture

Vassallo RR. Transfusion 2019
Others. Transfusion 2019
Lessons Learned

- Re-think “arms-length”
  - US Blood System is complex
    - Novice and myopic “expertise” does not replace long-term, intricate understanding
    - Less concern about “self-interest” bias
- Collect necessary and sufficient data
  - Representative sample
    - Determine required data set
    - Obtain sufficient data to support conclusion
- Insist on multi-disciplinary approach
  - More than an economic issue
- Present options
  - Include pragmatic and optimal solutions
  - Provide recommendations re:
    - Public Good
    - Blood Center
2019 ABC Advocacy Agenda

• Prioritize blood donation as a national imperative
  • Establish partnerships that raise awareness about the need for consistent blood donation from a diverse community of donors;
  • Address disproportionate reliance on type O donors through the implementation of utilization practices that benefit patients and promote a robust blood supply.

• Recognize the vital role of blood components in health and wellness
  • Explore pathways and reimbursement mechanisms to facilitate implementation of safety and technology measures when mandated by FDA or when market incentives otherwise do not exist.

• Reduce unnecessary and burdensome regulation
  • Evaluate the infectious disease testing burden from prespecified health economic thresholds;
  • Amend FDA regulations to maximize the gift of life. Currently, blood centers must discard an otherwise acceptable and safe blood donation if there is an error stemming from internal processes even if that error has no influence on the safety, purity, or potency of the donation.
AABB Advocacy Agenda

• **Sustainable Blood System**
  • Promote blood transfusion as essential, life-saving treatment
  • Support a sustainable blood system
  • Encourage regular blood donation
  • Support patients’ access to matched

• **Coverage and Re-imbursement for blood, blood products, transfusion medicine**
  • Protect and improve coverage and re-imbursement policies

• **Patient and donor care**
  • Support innovation
  • Review outdated/unnecessary regulation and guidance
  • **Support evidence-based policy making**
    • Validate risk-based models
    • Patient-centric approach

• **Research**
  • Biovigilance
  • Blood availability, operations, utilization
• Fall, 2019 ACBTSA meeting
  • Agenda items under discussion for recommendations to the Assistant Secretary for Health
    • Stress test findings
    • Blood donation and adequate inventory
    • Proper and timely re-imbursement for new mandates (innovation)
Conclusion

We must, indeed, all hang together, or most assuredly, we shall all hang separately.

Benjamin Franklin on signing the Declaration of Independence, 1776
THANK YOU