Advancing Transfusion and Cellular Therapies Worldwide

AABB Advocacy Agenda 2018

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Overview

- Definition of advocacy
- Legislative and regulatory environment
- 2018 Advocacy Agenda

Definition of Advocacy

Advocacy

- "The application of information and resources to effect systemic changes…."

- "A set of skills used to create a shift in public opinion and public policy, and to mobilize the necessary resources and forces to support an issue, policy, or constituency."

Hearne, S. Practice-Based Teaching for Health Policy Action and Advocacy, Public Health Reports, Volume 123, Supp. 2; 2008, pp. 65-70.

Advocacy Framework

- **Information**
  - Activities involved in identifying, describing and quantifying a problem
- **Strategy**
  - Activities involved in using the available information to identify what needs to change
- **Action**
  - Activities involved in implementing specific strategies

Christoffel, K. Public Health Advocacy: Process and Product, American Journal of Public Health, Volume 90, No. 5; 2000, pp. 722-726.

Legislative and Regulatory Environment

Key Legislation

- FY 2018 appropriations
- FY 2019 appropriations
- Pandemic and All-Hazards Preparedness Act Reauthorization
- Protect Access to Cellular Transplant Act (H.R. 4215)
- Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act (H.R. 2410)

Administration

- **Secretary of HHS**: Alex Azar, J.D.
- **Assistant Secretary for Health**: Brett Giroir, M.D.
- **Commissioner of FDA**: Scott Gottlieb, M.D.
- **Acting Director of CDC**: Anne Schuchat, M.D. (RADM, USPHS)
- **Director of NIH**: Francis S. Collins, M.D., Ph.D.

Regulatory Update

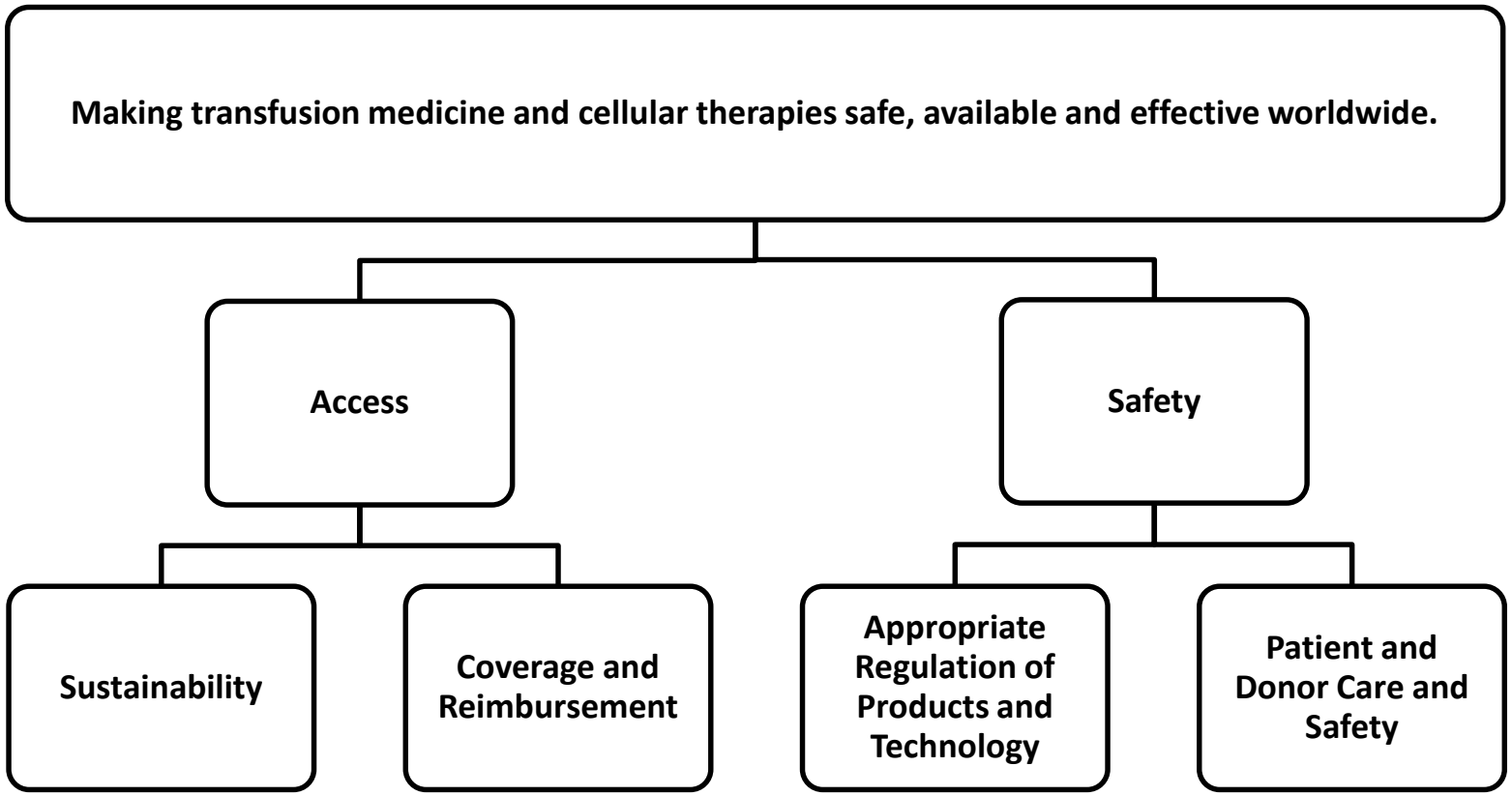
- **Continued focus on deregulation across agencies**
- **Centers for Medicare & Medicaid Services**
  - Anticipate deregulatory proposals in 2019 payment rules
    - FY 2019 hospital inpatient payment rule will be released by April 1.
- **National Institutes of Health**
  - NHLBI celebrates 70th anniversary in 2018

Regulatory Update

- **Food and Drug Administration**
  - 2018 Strategic Policy Roadmap
    - **Priority: Leverage innovation and competition to improve healthcare, broaden access, and advance public health goals.**
      - Launch a new policy roadmap for the introduction of innovations in blood products and blood product testing
      - Advance a comprehensive framework to facilitate the efficient development of safe and effective gene therapy products
      - Advance FDA's new framework for expediting the development and approval of safe and effective cell-based regenerative medicine products
      - Expand FDA's oversight and enforcement with respect to cell-based regenerative medicine products, taking new steps to address products that are putting patients at risk and making false health claims
      - Advance a new program to foster more efficient development of products intended for use in austere environments that can provide benefit to military personnel in deployed settings

2018 AABB Advocacy Agenda

2018 Advocacy Agenda



Advocacy Objectives

- Vision: Making transfusion medicine and cellular therapies safe, available and effective worldwide.
  - **Access:** AABB advocates for policies that ensure that patients and healthcare providers have adequate, appropriate access to safe transfusion medicine and cellular therapies.
  - **Safety:** AABB advocates for policies that enhance patient and donor care and safety in transfusion medicine and cellular therapies.

Access: Promote a sustainable U.S. blood system as a critical component of the healthcare system and emergency preparedness.

- AABB advocates for policies that:
  - Support a stable blood supply that has sufficient capacity to respond to emerging infectious diseases, disasters and emergencies.
  - Encourage research related to transfusion medicine and blood availability.
  - Promote the collection, analysis and public reporting of data related to the blood system.

Access: Promote access to cellular therapies.

- AABB advocates for policies that:
  - Support patients' access to safe, novel cellular therapies.
  - Foster research related to cellular therapies.
  - Advance a sustainable U.S. supply of high quality cord blood products.

Access: Promote adequate coverage and payment policies for transfusion medicine and cellular therapies.

- AABB advocates for policies that protect and improve Medicare coverage and reimbursement policies related to blood, blood products, transfusion medicine and cellular therapies.

Safety: Promote policies that support the appropriate regulation and timely introduction of new products and safety technologies for transfusion medicine and cellular therapies.

- AABB advocates for:
  - The use of evidence-based policymaking, which includes but is not limited to risk assessment.
  - Revising regulations and guidances that:
    (1) do not result in increased safety,
    (2) are duplicative, outdated, unnecessary or overly burdensome;
    (3) unnecessarily restrict access to products and technologies; and
    (4) stifle innovation.

Safety: Promote policies that advance patient and donor care and safety in transfusion medicine and cellular therapies.

- AABB advocates for policies that:
  - Promote enhanced patient and donor care and safety, such as patient and donor hemovigilance programs.
  - Encourage the use of patient blood management as a means of improving the quality of patient care and potentially reducing healthcare costs.
  - Encourage research related to patient and donor care and safety.

Questions?

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