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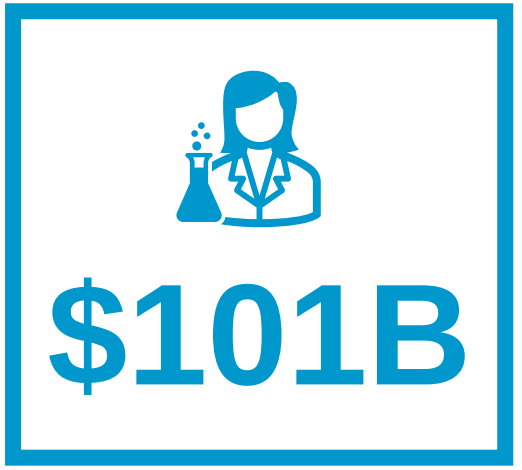
PhRMA Update

October 26, 2023

America’s Biopharmaceutical Industry Is Tireless in the Pursuit of New Treatments and Cures

New medicines approved by the FDA since 2000

Medicines in development around the globe



Invested in R&D by PhRMA member companies in 2022 alone

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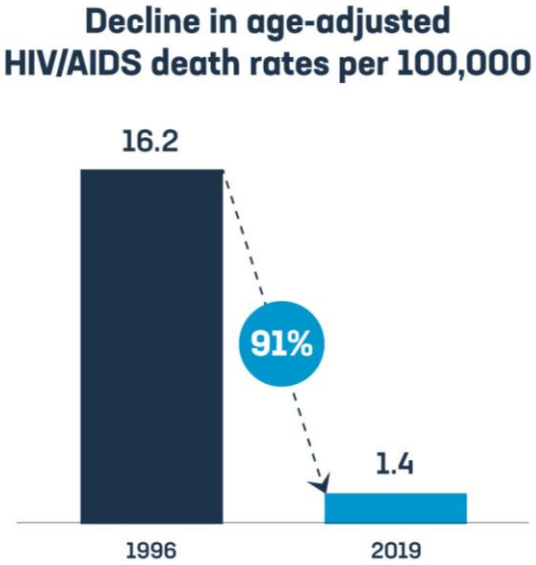
Thanks to medicines, patients all over the world are living longer, healthier and more productive lives.

FDA Approved in 2023 the first medicine specifically targeting the root cause of sickle cell disease



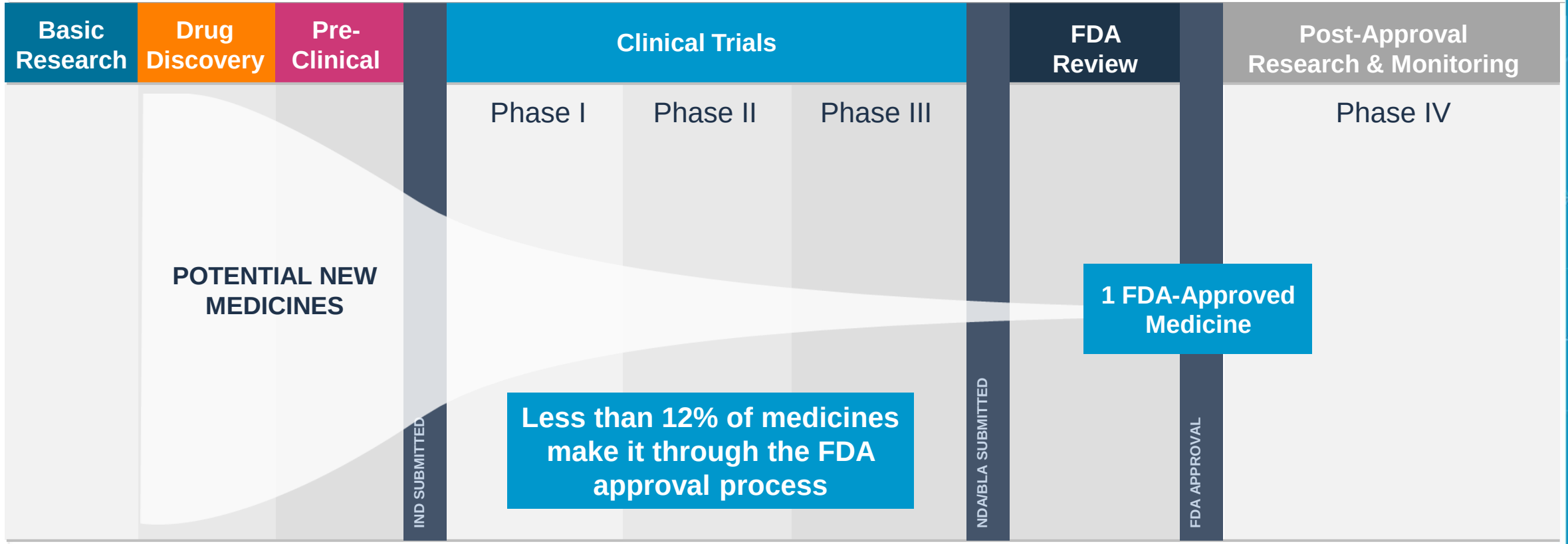
HIV/AIDS is now a chronic and manageable disease thanks to HAART.

Cancer death rates fall 33% since 1991 peak

January 12, 2023

R&D Process Overview: Lengthy, Costly and Uncertain

Developing a new medicine takes 10 to 15 years and costs an average of $2.6 billion.[1]



Key: IND= Investigational New Drug Application, NDA= New Drug Application, BLA= Biologics License Application

Sources: PhRMA adaptation of DiMasi J. et al[1], Lo A. et al[2]

Inflation Reduction Act (IRA) Will Have Unintended Consequences for Patients and Innovation

Some affordability gains …

- $2,000 annual out-of-pocket cap in Part D
- Spreading medicine costs over the course of the year in Part D

But jeopardizes access & innovation

- Jeopardizes wide-ranging choice and access in Part D
- Challenges rural and community providers' ability to offer Part B medicines
- Does not address misaligned incentives that lead to high out-of-pocket costs
- Threatens development of future treatments and cures

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IRA Threatens the New Era of Medical Innovation

- Penalizes small molecule medicines
- Discourages post-approval research
- Disincentivizes biosimilar and generic development

PhRMA's Focus: Improving Access to Medicines While Preserving Innovation

IRA	Fix the Inflation Reduction Act so patients don't lose access to medicines.
340B	Ensure the 340B program works for our nation's vulnerable patients.
PBMs	Reform the broken PBM model plagued by conflicts of interest and abusive tactics.

Current PBM Model Doesn't Work the Way it Should

Highly consolidated market plagued by conflicts of interest

3 PBMs control 80% of the market

They own or owned by big insurance

They're integrated with pharmacies and doctors' offices

Abusive tactics can drive up costs for patients, health care system

They limit access to lower-cost generics and biosimilars

They negotiate big rebates on medicines but routinely charge patients full price

They abuse market power to extract greater share of supply chain

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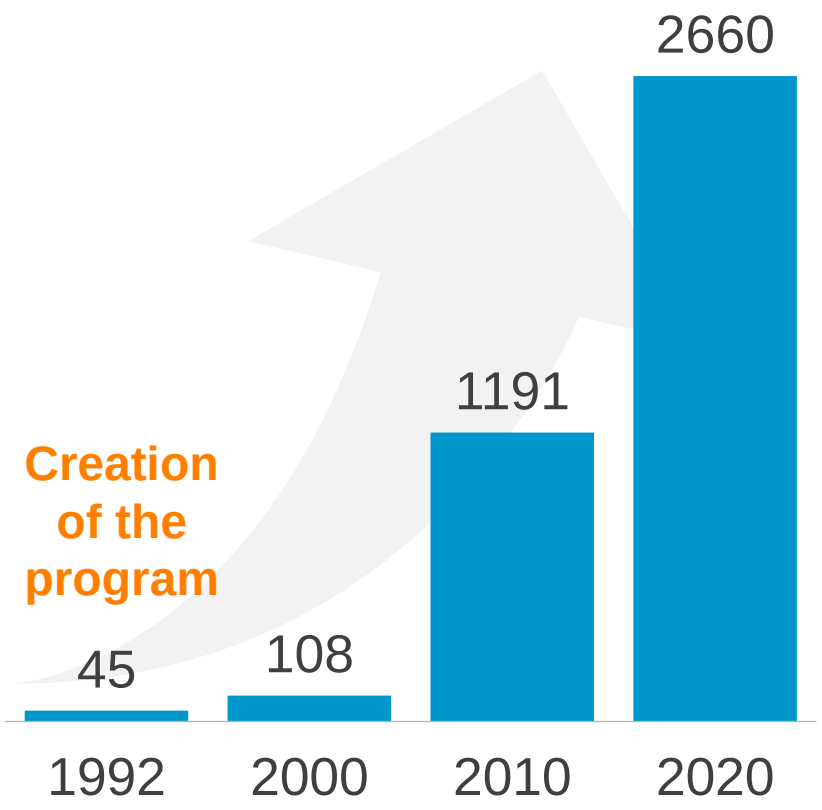
340B Has Grown Dramatically Since 1992

340B Hospital Participation



Total Sales at 340B Price: $53.7 Billion in 2022

2nd

340B is now the second largest prescription drug program administered by the federal government

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The Busy World of 340B

U.S. SENATE COMMITTEE ON
Health, Education
Labor & Pensions

Federal Investigations

Senator Cassidy is investigating two 340B hospitals, and Senator Sanders is looking into nonprofit hospital practices

State Proposals

States are wading into the debate with legislation that includes 340B pricing mandate provisions

Court Cases

Several outstanding cases related to the role of contract pharmacies in the program

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PhRMA's Ethics and Compliance Agenda

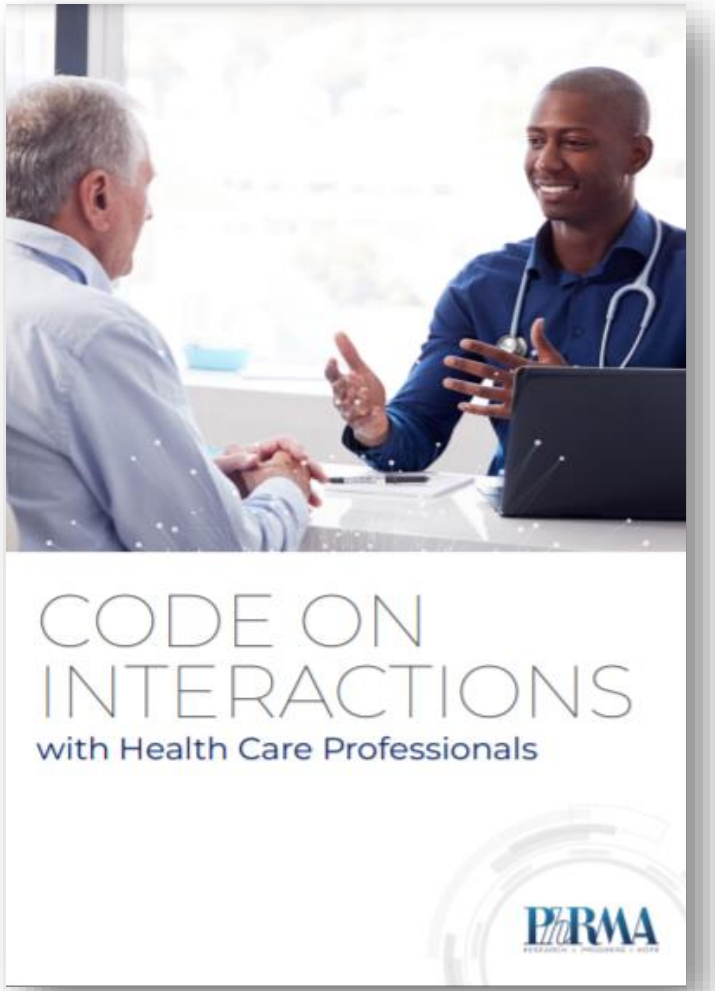
2022 PhRMA Code Update

- Latest updates effective Jan. 1, 2022
- Primarily address speaker programs and in-office and in-hospital informational presentations

https://phrma.org/About/Codes-and-guidelines

PhRMA Code on Interactions with Healthcare Professionals

- Voluntary code of conduct (but codified in some U.S. states)
- Both PhRMA members and non-members are signatories
- Applies to biopharma company interactions with **U.S. Health Care Professionals**
- Signatories certify annually to having policies and procedures in place to foster compliance with the PhRMA Code
- Signatory and certifying companies are posted publicly on PhRMA's website



Speaker Programs

The revised PhRMA Code permits speaker programs with modest, incidental meals, provided certain conditions are met.

Meals & Alcohol

- Meals are appropriate so long as modest as judged by local standards and subordinate in focus to the educational presentation.
- Companies should not pay for or provide alcohol.

Third-Party Venues

- Third-party venues, including restaurants, are permitted, so long as conducive to informational communication and not extravagant or the main attraction or perceived as such.

Physical Presence of Company Reps

- A company representative required to be physically present where a meal is provided.

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In-Office and In-Hospital Informational Presentations

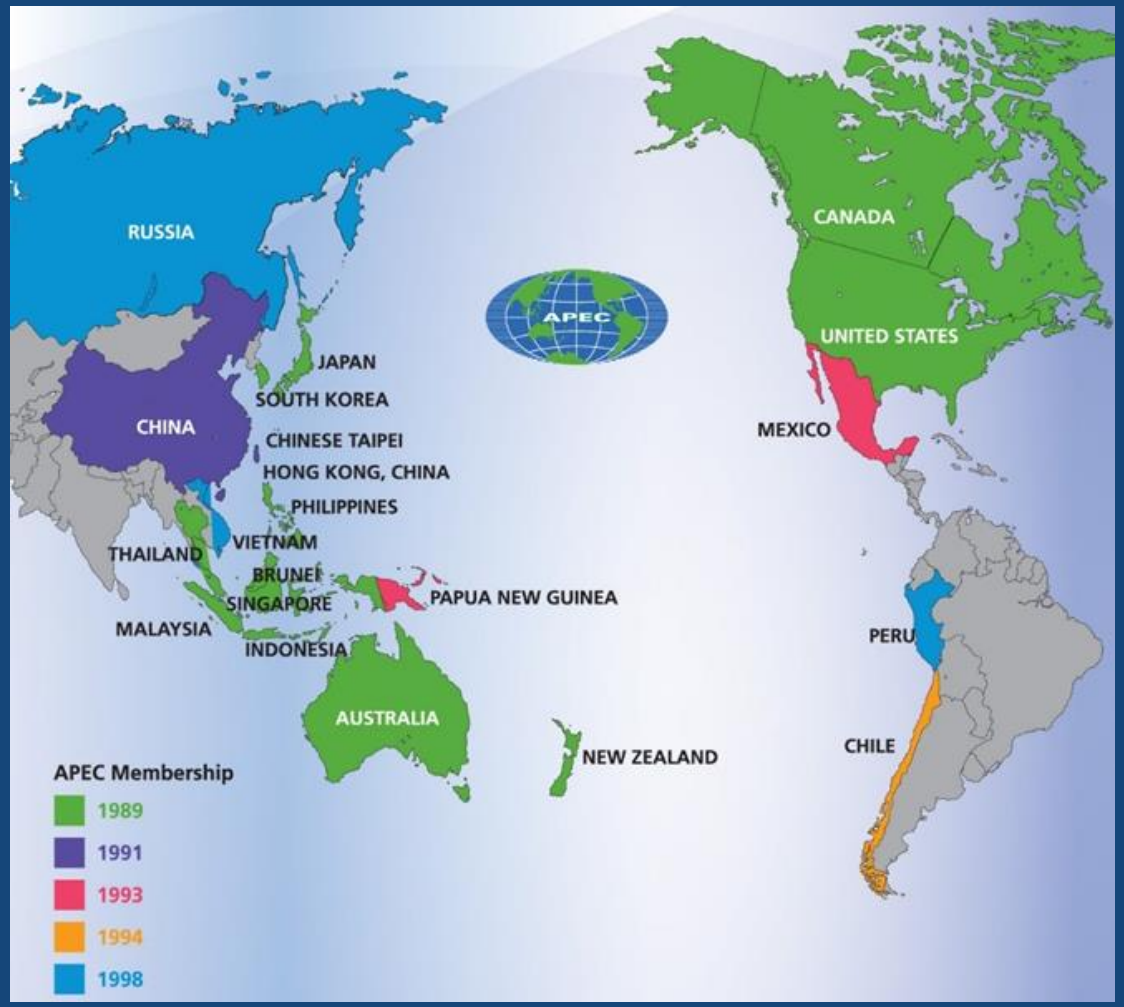
PhRMA Code Section 2

Meals should only be provided where there is a “reasonable expectation and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the company representative.”

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs Initiative

APEC 2023
UNITED STATES



APEC Overview:

- Inter-governmental
- Meets at Head of State level
- Permanent staff/secretariat
- Welcoming to multi-stakeholders
- Voluntary, consensus based
- Multi-year programming
- Diverse economies that span multiple regions

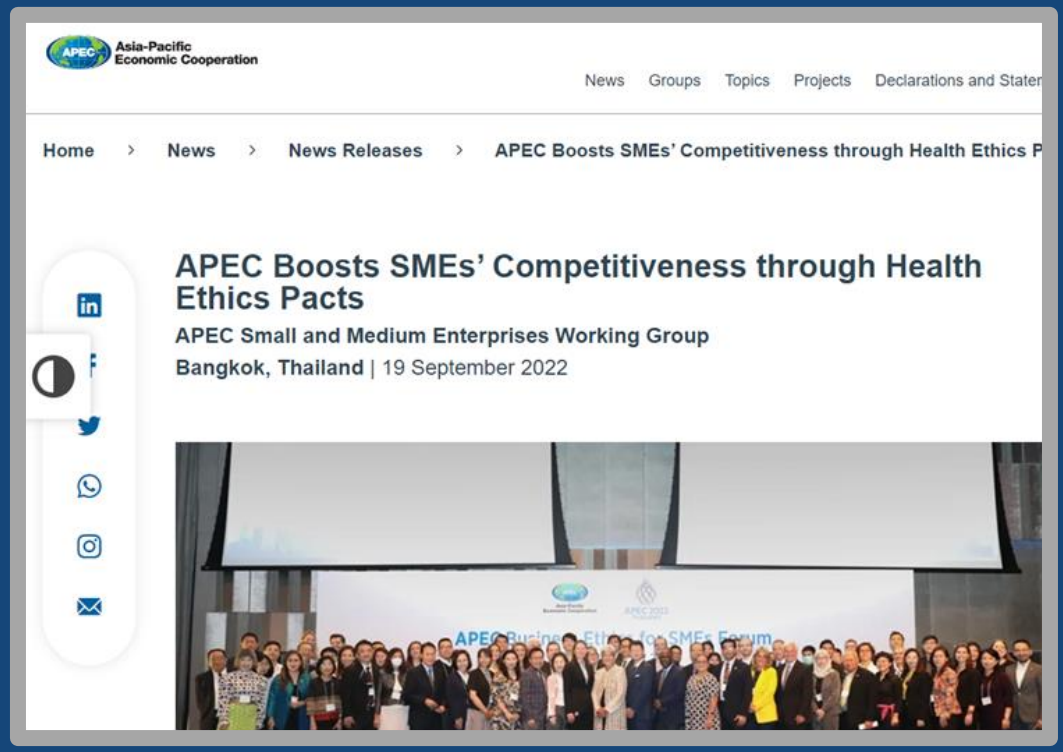
APEC 2023
UNITED STATES

Business Ethics for APEC SMEs Initiative

Focus: The role of ethical business practices to strengthen economies, businesses, health systems, and innovation

Activities: 1) set best practices, 2) build capacity, and 3) monitor & evaluate

Annual Forum: Cornerstone of the Initiative's yearly activities and serves as a space for goal setting, collective action, and multi-stakeholder engagement

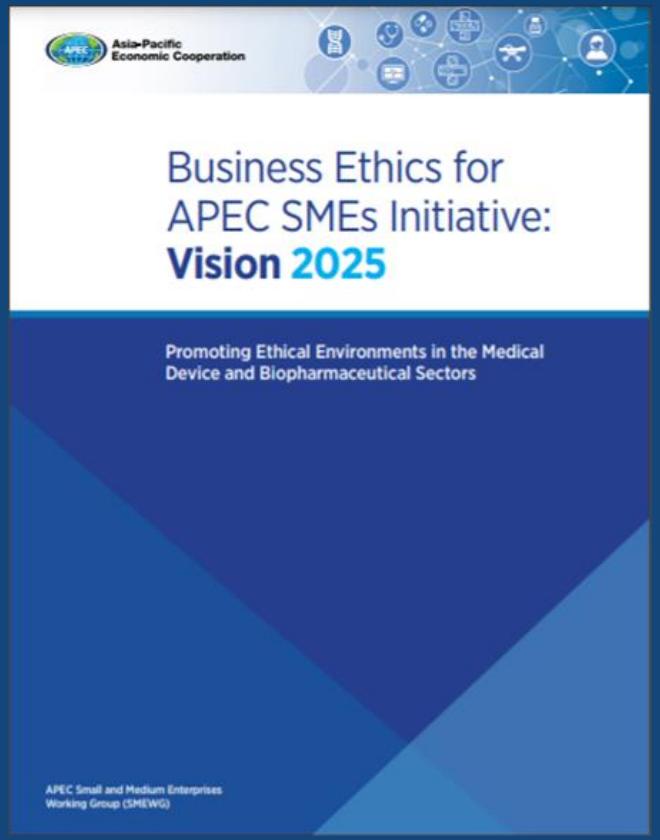


APEC 2023
UNITED STATES

Initiative Goals: Vision 2025

- Consensus framework adoption and implementation (12 established with United States in consideration)
- Code of ethics adoption and implementation (annual monitoring & evaluation and capacity building programs)
- Developing guidance and engagement with patient organizations, healthcare professionals (HCPs), and governments (via consensus frameworks and roundtables)

APEC 2023
UNITED STATES



Thank you!

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Resource Slides

Global Consensus Framework

In 2014, leading multilateral health organizations established a global Consensus Framework for ethical collaboration between patient organizations, healthcare professionals, and the pharmaceutical industry, in support of high-quality patient care.

The Consensus Framework for Ethical Collaboration is characterized by four overarching principles:

- Put Patients First;
- Support Ethical Research and Innovation;
- Ensure Independence and Ethical Conduct; and
- Promote Transparency and Accountability.

Signatories include: International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); International Pharmaceutical Federation (FIP); World Medical Association (WMA); International Alliance of Patients' Organizations (IAPO); and International Council of Nurses (ICN).

Creating a United States Consensus Framework

The U.S. has a strong regulatory environment for communications and collaboration between patients, healthcare providers, academic researchers, and biopharmaceutical and medical device companies.

A Consensus Framework would offer opportunities to meaningful convene, engage, and align on principles for ethical business conduct within the U.S. health system.

Consensus Frameworks facilitate capacity building and knowledge exchange on best practices for business ethics in healthcare, and they encourage implementation of these principles across sectors.

Potential core members of U.S. Consensus Framework include:

- National Health Council (NHC)
- National Medical Association (NMA)
- American Osteopathic Association (AOA)
- American Nursing Association (ANA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)

Potential future members:

- Advanced Medical Technology Association (AdvaMed)
- Biotechnology Innovation Association (BIO)
- American Medical Association (AMA)
- American Hospital Association (AHA)

Core members will develop the language for, launch, and operationalize a Consensus Framework for the US context.

HIV and Hepatitis Policy Institute v. HHS

Lawsuit challenging 2021 Notice of Benefit and Payment Parameters (NBPP)

- August 2022: Three patient groups challenged the 2021 NBPP, which revised 45 C.F.R. § 156.130(h) to allow health plans to choose whether to count manufacturer cost-sharing assistance toward the annual limitation on cost sharing (MOOP)
- September 2023: Court found that it was arbitrary and capricious for HHS to authorize contradictory interpretations of the definition of "cost sharing" by allowing plans to choose whether to count manufacturer cost-sharing assistance
  - 2021 NBPP vacated "to the extent it amended § 156.130(h)"
  - Remanded to HHS to issue single interpretation of the definition of "cost sharing"
- Appears to revive the 2020 NBPP final rule, which requires health plans to count manufacturer cost-sharing assistance toward the MOOP except when a medically appropriate generic equivalent is available
  - HHS has 60 days to appeal, and if not, decide what to say regarding manufacturer cost sharing and agency's interpretation of "cost sharing"
  - Tri-agencies will need to address HSA-eligible high deductible health plans