

Building a Movement for Quality Medicines

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Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods



Standard Setting



We develop public, scientific quality standards that help protect people's health

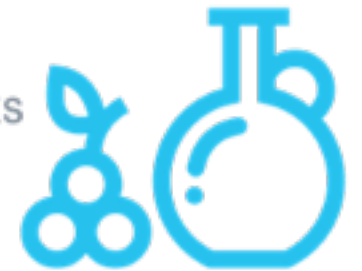


Pharmaceuticals

Nearly 200 years of ensuring trust and confidence among patients and providers

Food ingredients

Globalization means food supplies today face greater risks



Healthcare quality

Ongoing transformation in health delivery reveals additional needs for standards setting



Dietary supplements & herbal medicines

Explosive industry growth demands a focus on quality to ensure consumer confidence and safety



Global public health

Combating substandard and counterfeit medicines in under-resourced countries around the globe





2 billion people

around the world have access to quality medicines, dietary supplements and food as a result of our standards, advocacy and education

Global & Regional platforms



Official Relations
Framework for
Engagement of Non-State
Actors (FENSA)



**NGO Consultative
Status**
United Nations
Economic & Social
Council



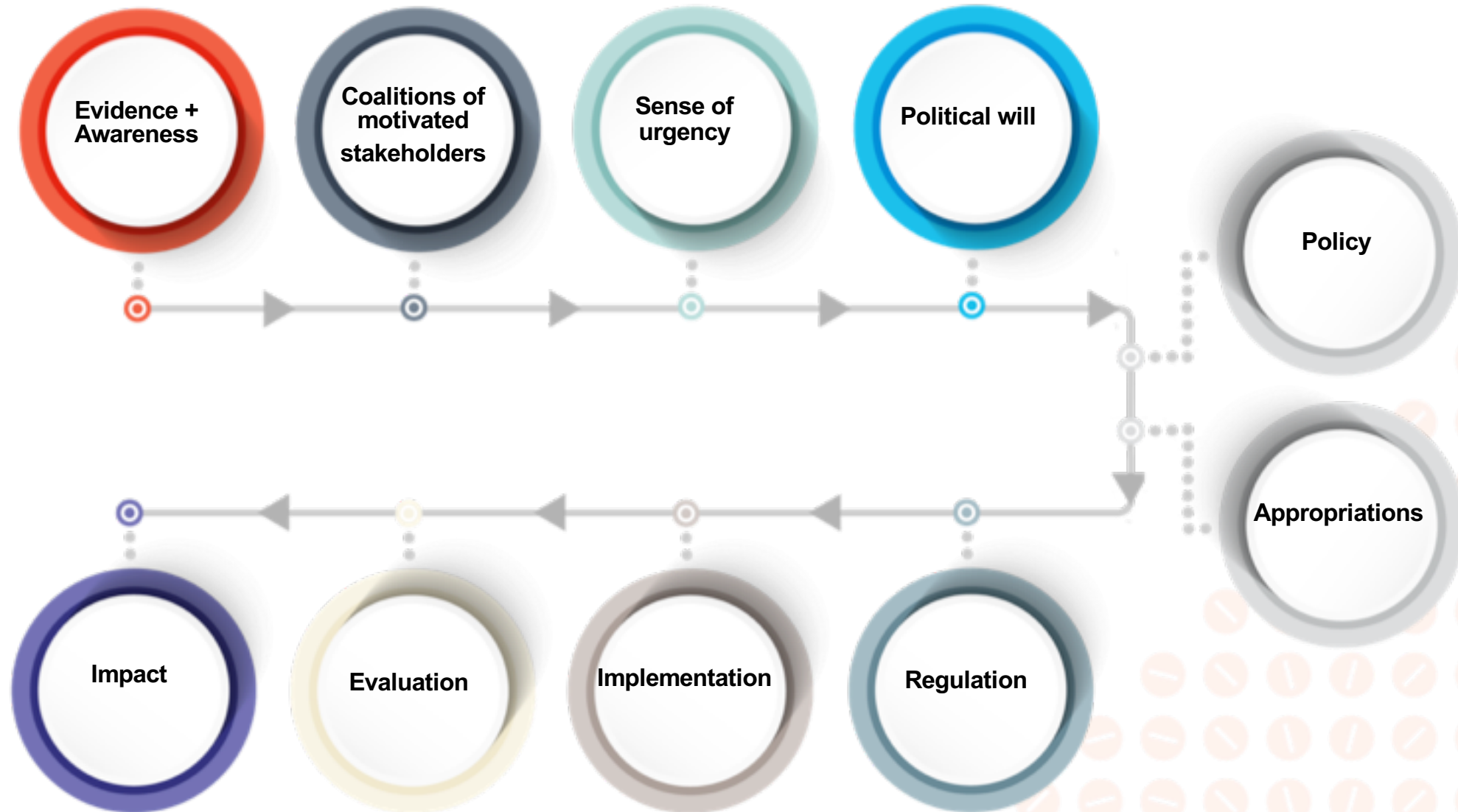
Official Observer Status
Non-State Actor



Official Board Member
APEC LSIF
Center of Regulatory
Excellence

Advocate for medicines quality issues in global policies
Consultations at different levels of governments

Lifecycle of change



USP's contribution to combatting SSF meds



Standards for Quality

- ▶ Nearly 4000 USP quality standards
 - Identity, strength, purity
 - Industry uses standards before releasing product
 - Regulators use these to test against a medicine in the field
- ▶ USP standards established by unbiased experts who volunteer their expertise



USP's contribution to combatting SSF meds



Quality systems strengthening

- ▶ Regulator capacity building around the world
- ▶ Accrediting drug control labs to test medicines for quality
- ▶ Working with drug makers to help them improve quality to increase availability of essential medicines (WHO PQ)
- ▶ APEC – *Center of Excellence for Supply Chain Integrity*



USP's contribution to combatting SSF meds



Advocacy

- ▶ Generating evidence on link between poor quality and public health priorities (eg. AMR)
- ▶ Convening regulators and patient, disease and others groups around the issue
- ▶ Building a movement for medicine quality



Sub-standard antimicrobials



- ▶ Overuse in animals and humans
- ▶ Inappropriate prescribing of the wrong antibiotic
- ▶ Use in animals, fish and agriculture for growth
- ▶ Pathogen exposure to sub-therapeutic levels of active pharmaceutical ingredient
 - Low patient adherence to treatment regimens
 - **Substandard human medicines – medicines that are low quality**
 - Substandard animal medicines driving resistance passed to humans through food

WHO data show antimicrobials compose largest proportion of reported instances of substandard and falsified medicines

FIG. 3: COUNTRIES IN WHICH SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS HAVE BEEN DISCOVERED AND REPORTED TO THE WHO GSMS, 2013–2017



Substandard and falsified (S&F) medicines are seen in countries from all income brackets

Approximately
1 in 10 medicines
are substandard or falsified



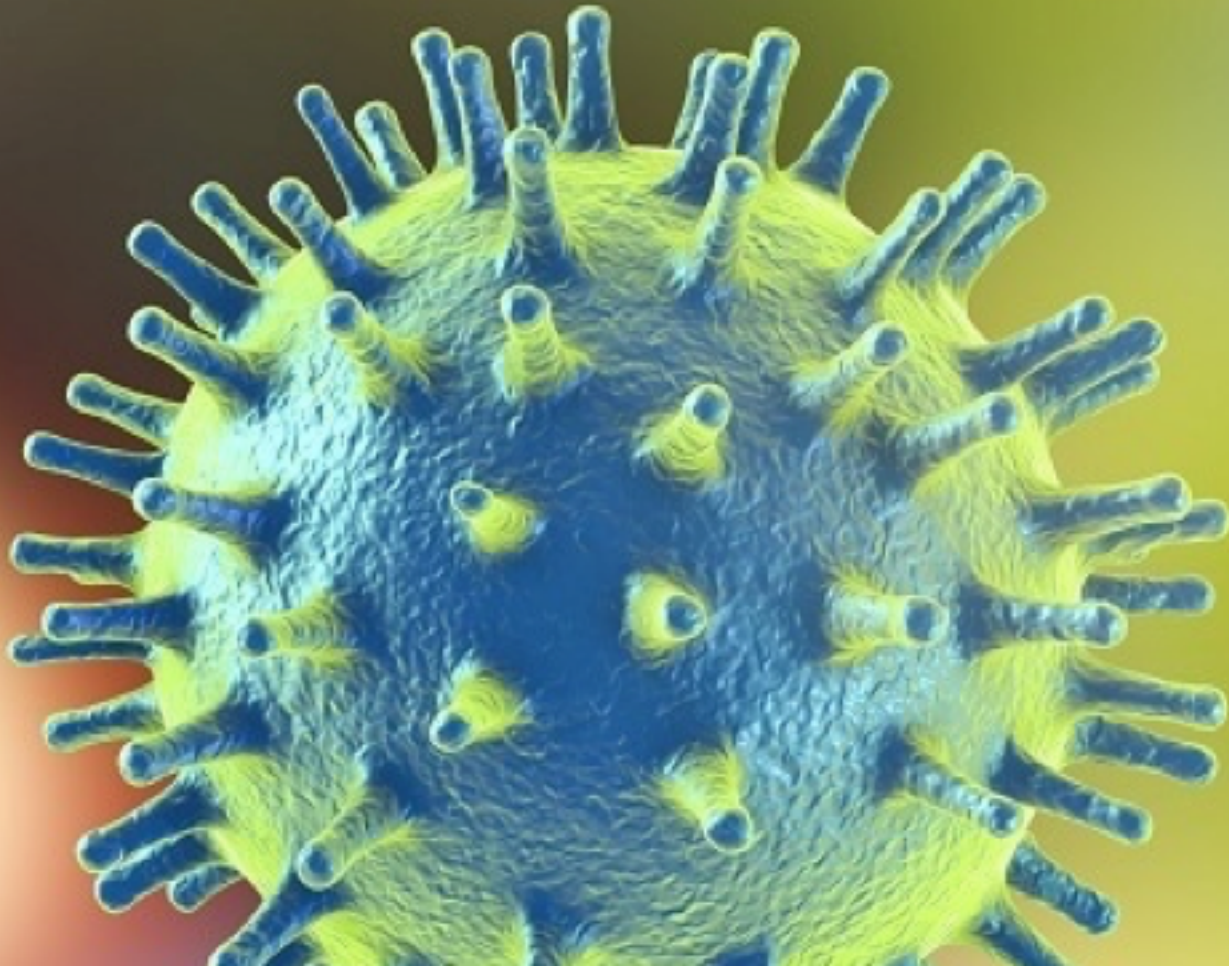
Nearly 40%
of poor-quality medicines
are antimicrobials



- Global data suggest 1 in 10 medicines circulating in lower/lower-middle income countries are substandard or falsified
- Antibiotics and antimalarials are two large sub-groups of antimicrobials
- Antibiotics make up 17% of substandard/falsified products reported to WHO; some antibiotics are also used as antimalarials

Pathogens travel

Drug resistant pathogens in the US



Clostridium Difficile (CDIFF)

Carbapenem-Resistant Enterobacteriaceae (CRE)

Neisseria gonorrhoeae

Multidrug-Resistant Acinetobacter

Drug-Resistant Campylobacter

Fluconazole-Resistant Candida

Extended Spectrum Enterobacteriaceae (ESBL)

Vancomycin-Resistant Enterococcus (VRE)

Multidrug-Resistant Pseudomonas Aeruginosa

Drug-Resistant Non-Typhoidal Salmonella

Drug-Resistant Salmonella Serotype Typhi

Drug-Resistant Shigella

Methicillin-Resistant Staphylococcus Aureus (MRSA)

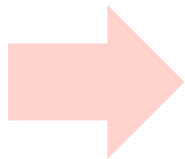
Drug-Resistant Streptococcus Pneumoniae

Drug-Resistant Tuberculosis

USP's AMR advocacy



USP Quality Institute develops evidence and dialogue to support



Poor quality medicines contribute to AMR

There are **proven systems** to ensure medicine quality

If countries **prioritize and resource quality-assurance systems**, the quality of antimicrobials will improve

One factor contributing to AMR can be mitigated

In the process, **the quality of all medicines will be enhanced** by investing in QA infrastructure

Better health and economic outcomes

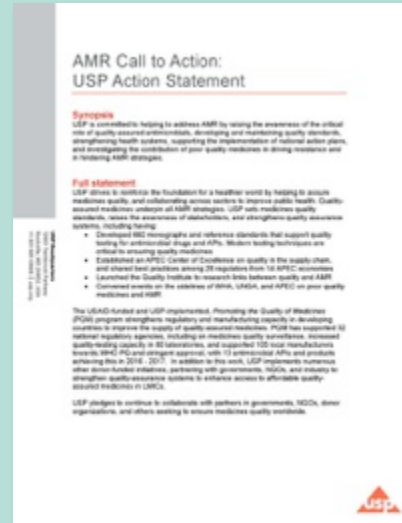
Coalition, Consensus, Commitment, Collaboration, Coordination



- ▶ Building a coalition
- ▶ World Health Assembly
- ▶ May 2017



- ▶ Thought leader consensus
- ▶ UN General Assembly
- ▶ Sept 2017



- ▶ Commitment to Action
- ▶ WHO IACG Oct 2017



- ▶ Collaboration on the Framework
- ▶ WHO Member State Consultation
- ▶ November 2017



- ▶ Coordination on National Action and Quality Assurance Systems
- ▶ Prince Mahidol Awards Conference
- ▶ Co-hosted by USP, USAID and Thailand FDA
- ▶ Jan 2018

Seven reasons to prioritize medicine quality



Poor quality medicines:

- 1 are a **wasteful use of healthcare resources**
- 2 are **dangerous to patients** (poor outcomes, toxic)
- 3 are **dangerous to public health** (drug resistance)
- 4 **undercut trust** in healthcare systems and governments
- 5 **undermine progress** across many global health priorities
- 6 **kill people and destroy families**
- 7 there are **effective solutions** to improve quality

The Challenge

Poor-quality medicines are a threat to families, countries & global health progress.

Why hasn't it been a priority?

1

Supporters mostly talking to each other

2

Perceived lack of urgency

3

No shared platform

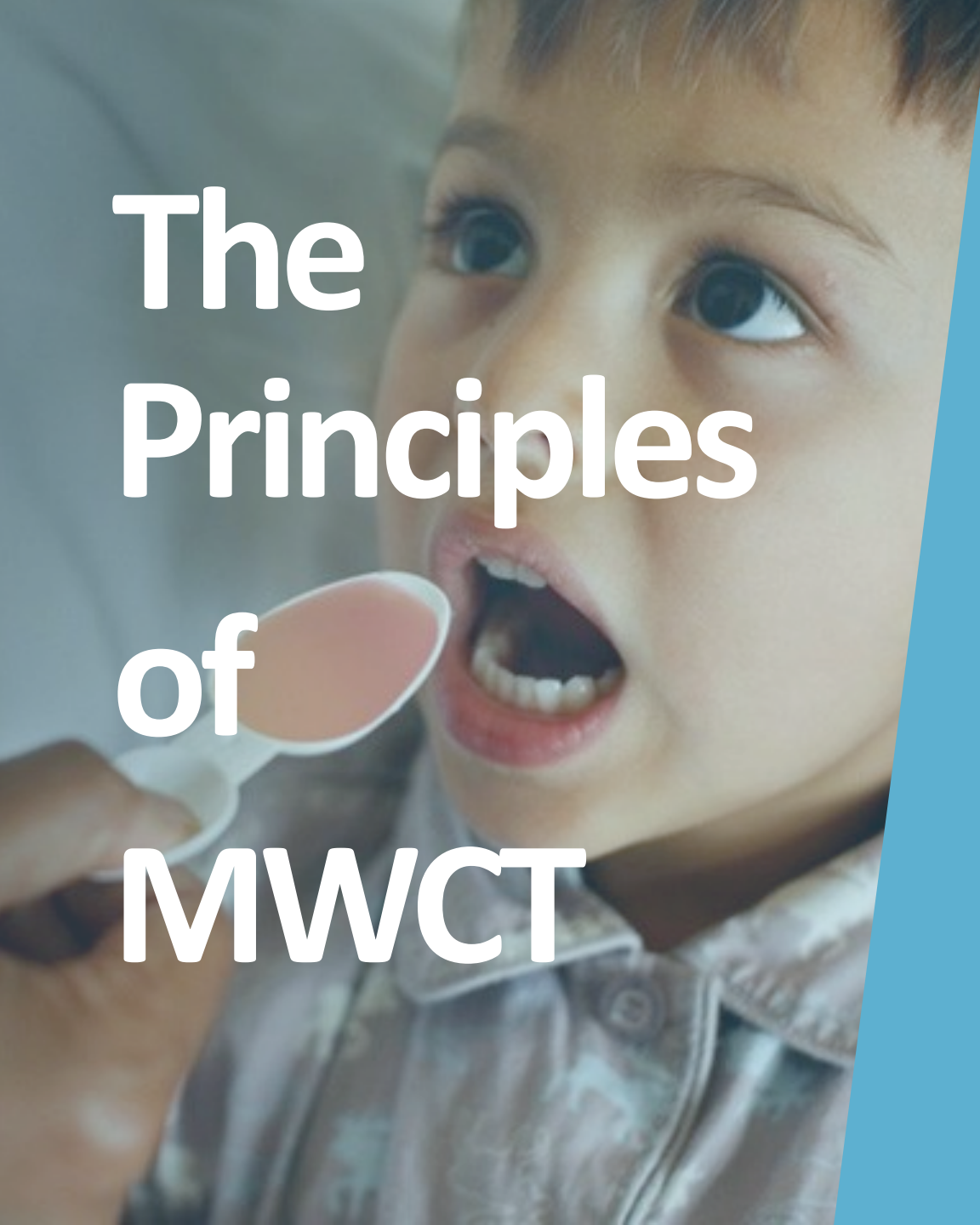
Medicines We Can Trust

The Opportunity

A global campaign on the right to safe, quality medicines can:

- ✓ **Focus on the impact on people**
- ✓ **Engage patient, consumer and disease advocacy groups**
- ✓ **Raise awareness & urgency**
- ✓ **Inspire collective action**





The Principles of MWCT

We Believe

Everyone should have access to **medicines they can trust** – as a right, not a privilege.

High Stakes

Global health progress depends on **safe, quality** medicines in every country, to prevent and to treat every condition.

Call to Action

We **can and must** reach all people with medicines they need and deserve.

Medicines We Can Trust: A Call to Safeguard Quality

Alongside #WHA71, join a high-level discussion on **why poor-quality medicines matter** and a preview of a **new campaign** on the right to safe, quality medicines.

Confirmed speakers include:

- **Fiona Adshead**, Deputy CEO & Director of Strategy and Partnerships, NCD Alliance
- **Sally Davies**, Chief Medical Officer, England & Chief Medical Advisor, UK
- **Michael Deats**, Group Lead, Substandard and Falsified Medical Products, WHO
- **Tom Frieden**, President & CEO, Resolve to Save Lives, an initiative of Vital Strategies
- **Githinji Gitahi**, CEO, Amref Health Africa
- **Jayasree Iyer**, Executive Director, Access to Medicine Foundation
- **Ashish Jha**, Director, Harvard Global Health Institute
- **Sicily Kariuki**, Cabinet Secretary, Ministry of Health, Kenya
- **Anthony Lakavage**, Senior Vice President, Global External Affairs, USP
- **Ron Piervincenzi**, CEO, USP
- **Julio Sánchez y Tépoz**, Federal Commissioner, COFEPRIS Mexico
- **Brenda Waning**, Chief of the Global Drug Facility, Stop TB Partnership

RSVP at www.cvent.com/d/hgq053

TIME Wednesday, 23 May
8:00-10:00 AM CEST

LOCATION Restaurant Vieux-Bois
Avenue de la Paix 12

LIVESTREAM www.facebook.com/USPharmacoepia/



The Next Year

1

Co-creating the call to action with partners

2

Engaging media

3

Building online hub

4

Formal Launch

5

Bring the Campaign to Major Health Policy Events



To learn more about the campaign, please visit

medswecantrust.org

MedsWeCanTrust.org



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