

Session II:

Regulatory Landscape For Household Opioid Disposal

June 26, 2023



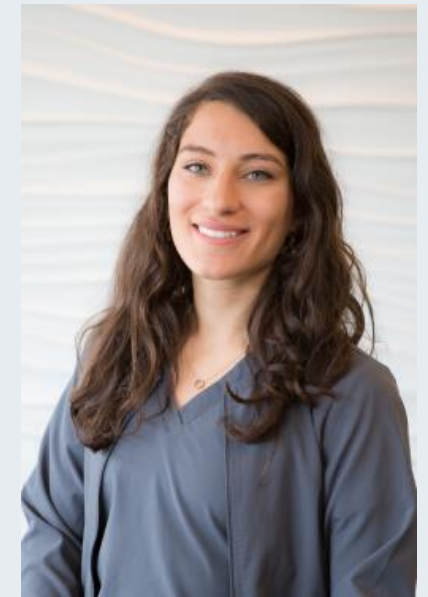
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Tufts
UNIVERSITY

School of
Medicine



Importance of Safe Pharmaceuticals Management

- Opioid Epidemic: National drug overdose deaths involving prescription opioids
- Seven out of ten people who abuse prescription drugs get them from friends or family, often out of the home medicine cabinet
- Flushing leftover medicines sends them into our rivers, streams, and waterways. In landfills, medicines leech into the water system. Wastewater treatment plants cannot remove them.
- Chemicals from medicines can end up in our drinking water, and have been shown to have harmful effects on aquatic life



**PRODUCT
STEWARDSHIP
INSTITUTE**

Two Decades of Impact



Product Categories



Batteries



Carpet



Electronics



Gas Cylinders



HHW



Junk Mail



Mercury Thermostats



Lighting



Mattresses



Medical Sharps



Mercury Auto Switches



Motor Oil



Packaging & Plastics



Paint



Pesticides



Pharmaceuticals



Phone Books



Radioactive Devices



Refrigerant-Containing Appliances



Solar Panels



Textiles

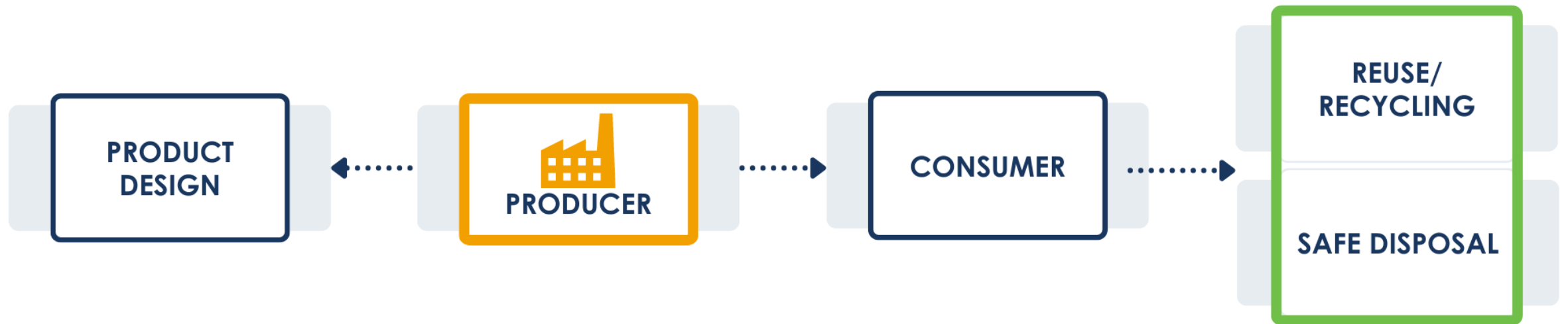


Tires

Product stewardship is the act of minimizing the health, safety, environmental, and social impacts of a product and its packaging throughout all lifecycle stages, while also maximizing economic benefits. **Stewardship can be voluntary or required by law.**



Extended Producer Responsibility (EPR)

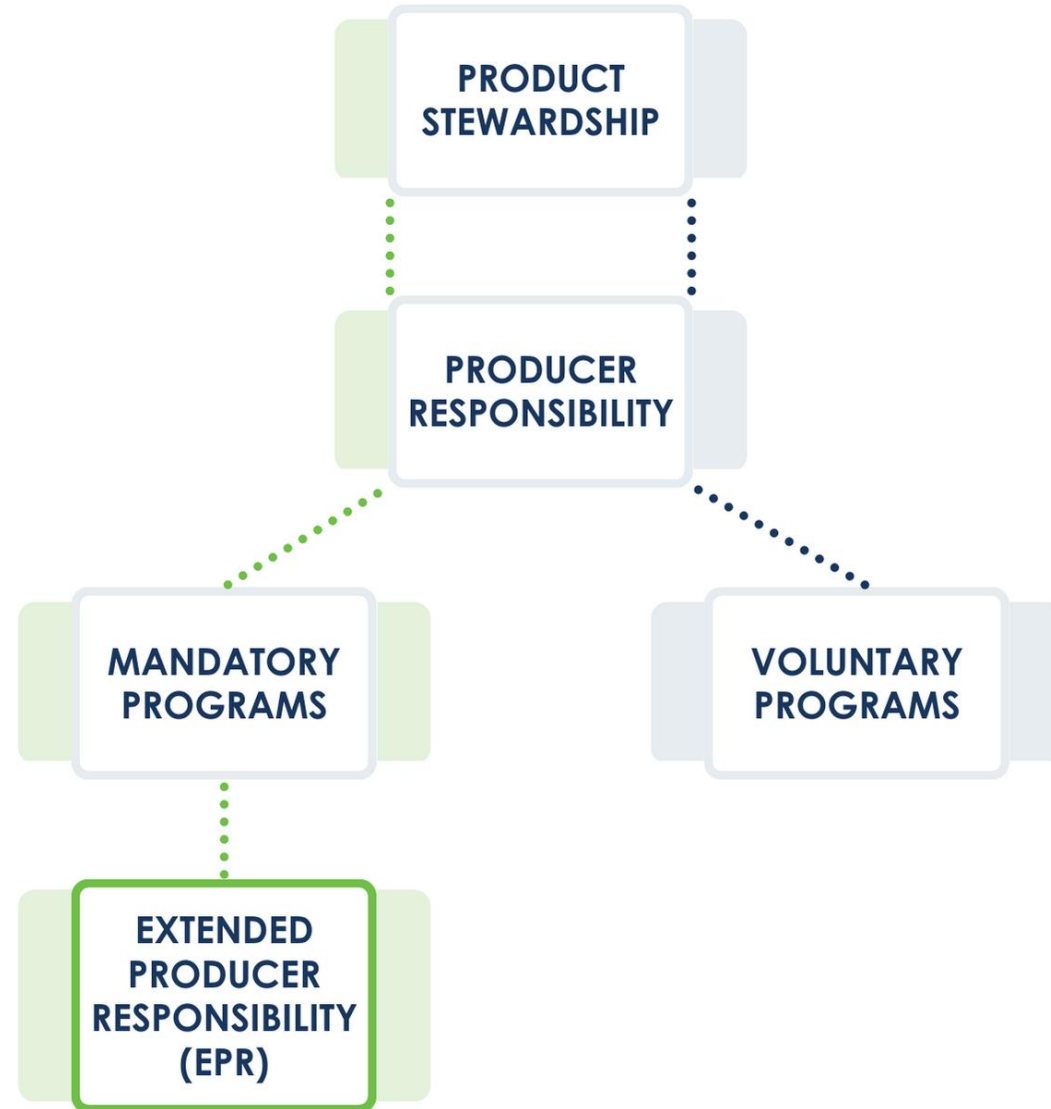


A **law** that **extends** a producer's financial and managerial **responsibility** for its products and packaging beyond the manufacturing stage — both **upstream** to product design and **downstream** to **postconsumer** reuse, recycling, or safe disposal.

Extended Producer Responsibility (EPR)

1. **Shifting** financial and management **responsibility**, with government oversight, **upstream** to the manufacturer and away from the public sector.
2. Providing **incentives** to manufacturers to incorporate **environmental** considerations into the **design** of their products and packaging.

EPR and Product Stewardship

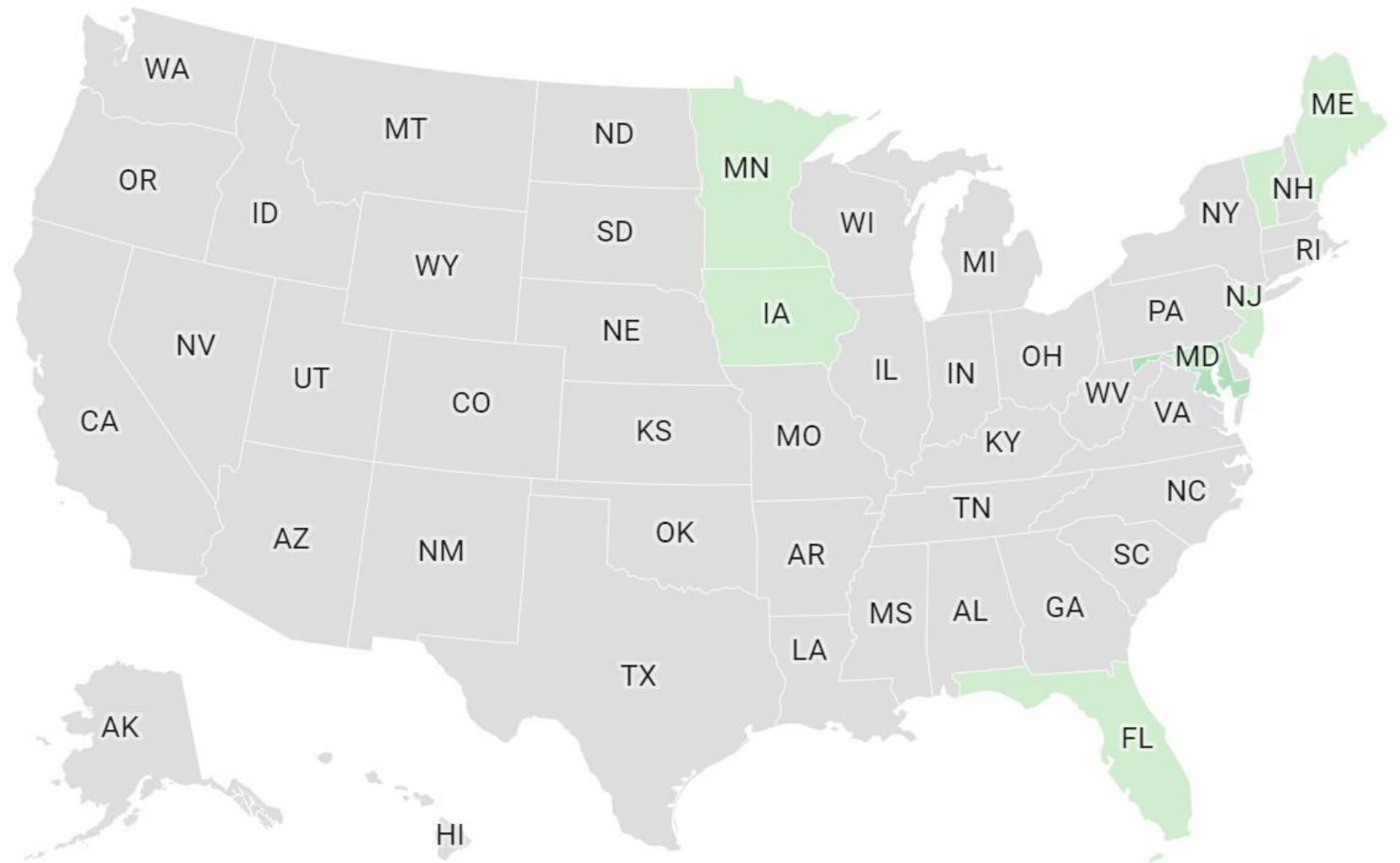


U.S. EPR Laws In 2000

8 EPR Laws

1 Product

7 States



Number of State EPR Laws in 2000

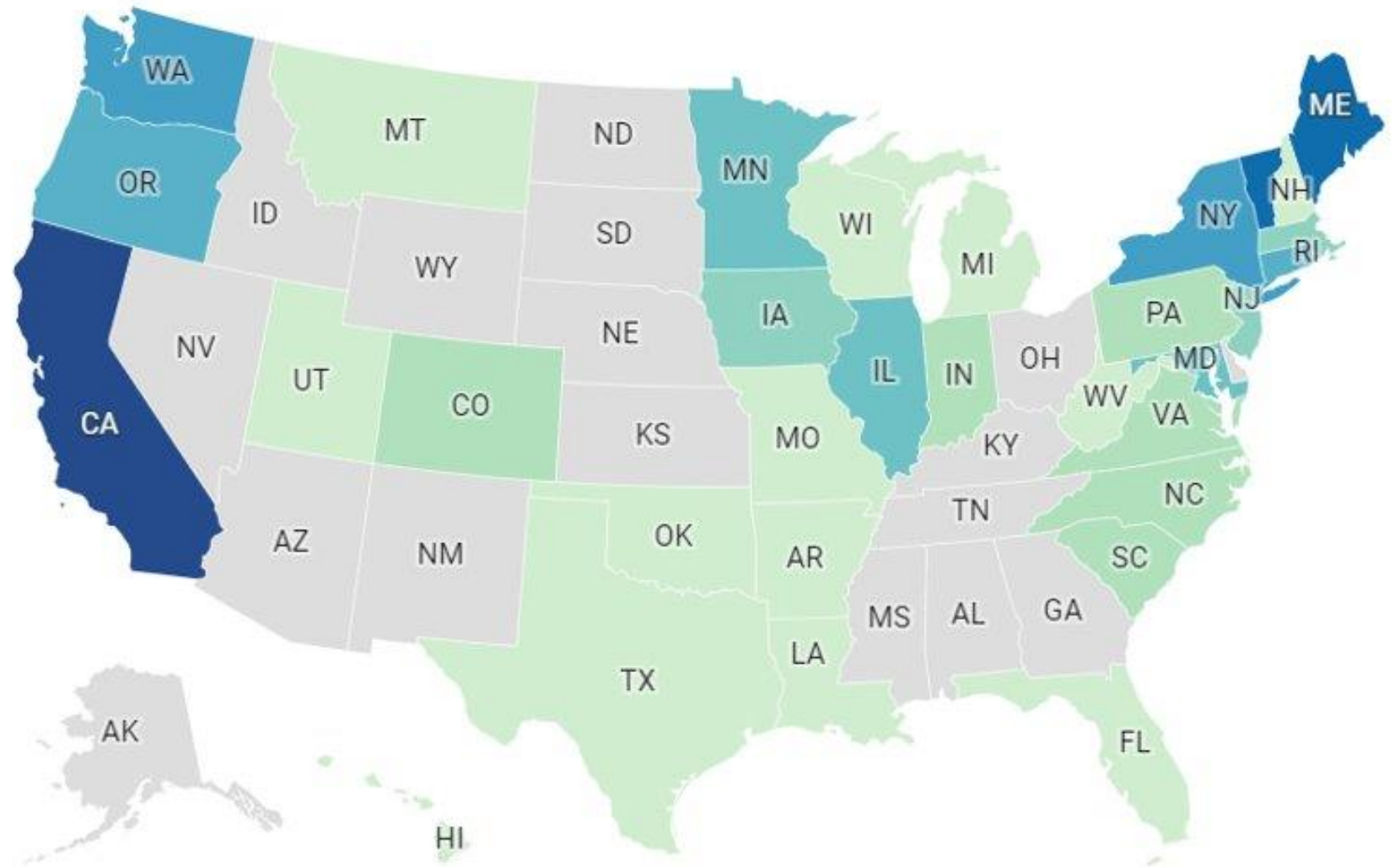
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U.S. EPR Laws

133 laws

17 products

33 states

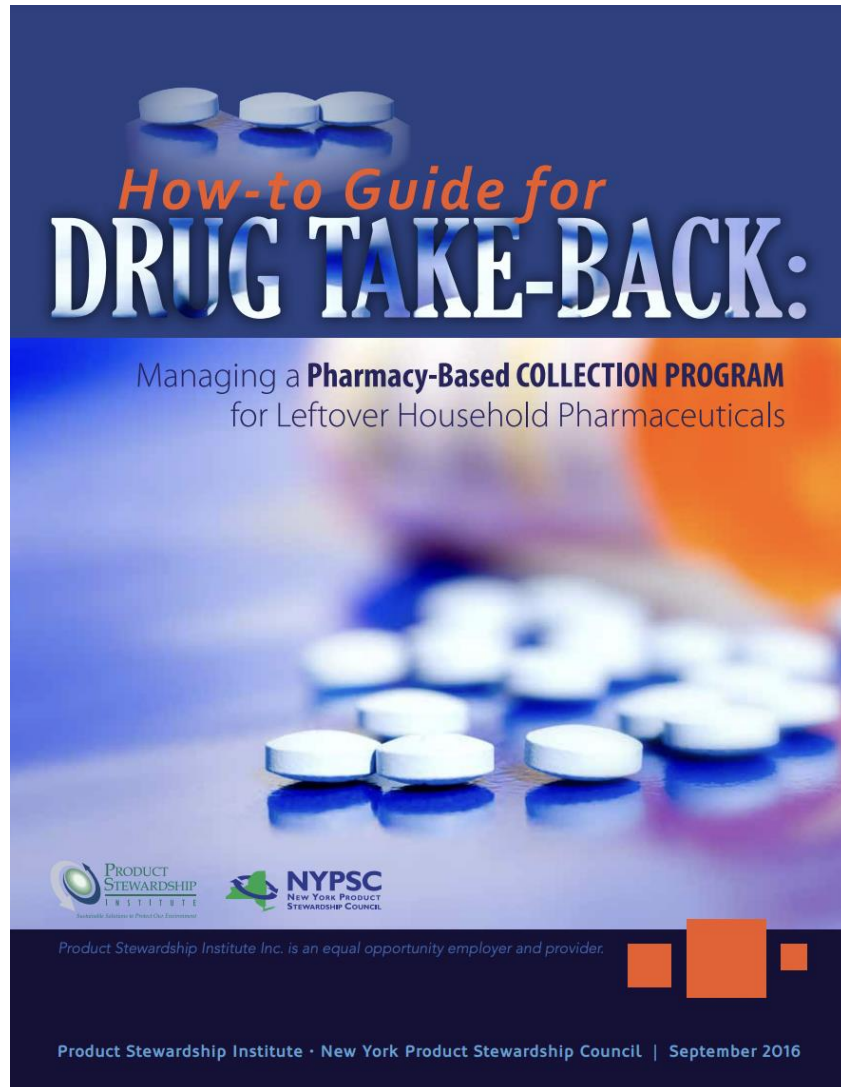


Source: Product Stewardship Institute, Inc. 2023

Timeline of U.S. Pharmaceuticals Stewardship



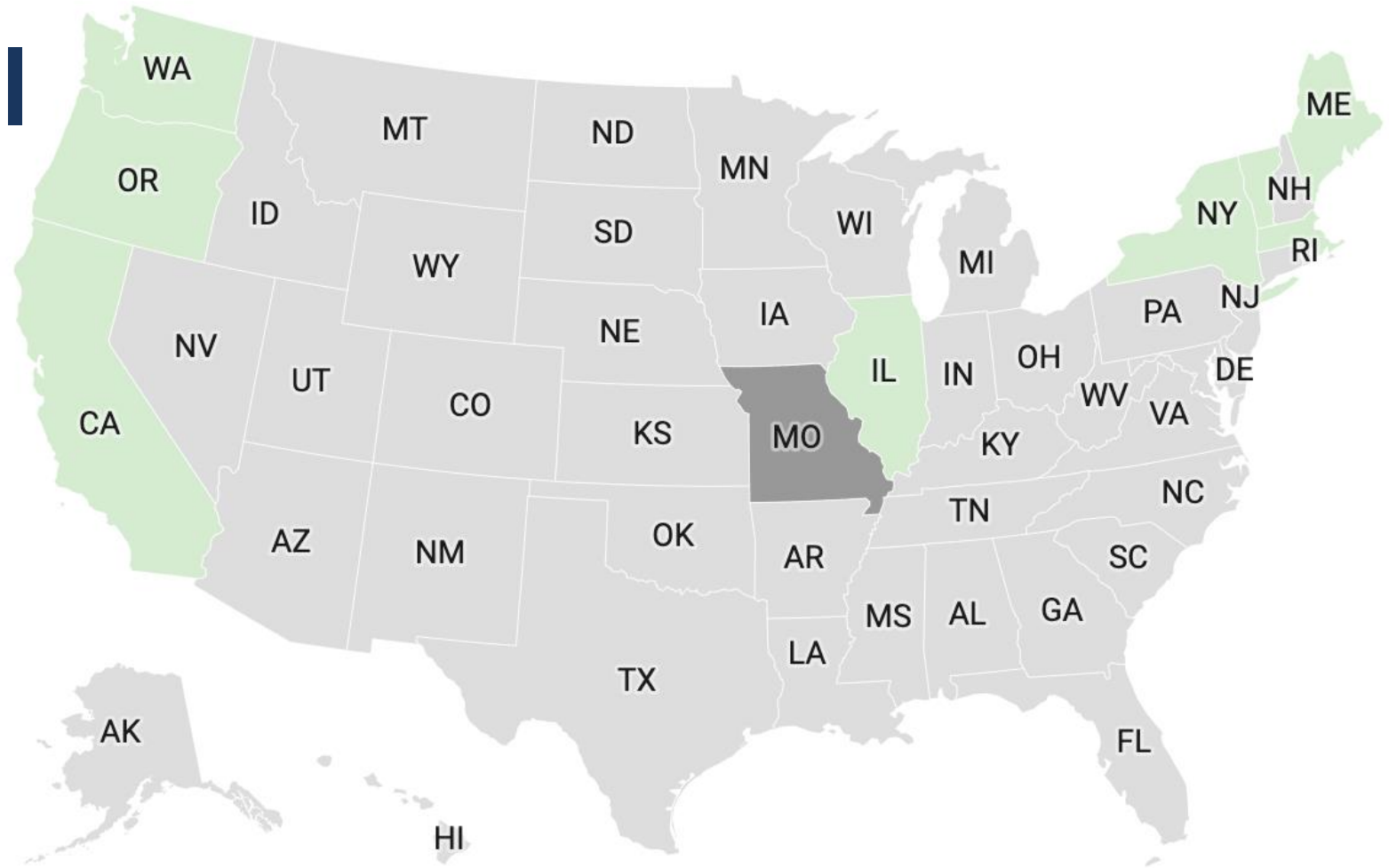
PSI Advocacy for Pharmaceutical EPR



- Research and Briefing Documents
- Pilot Demonstrations
- How-To Guide for Pharmacists
- Education, including Webinars

Pharmaceutical EPR in the U.S.

8 State EPR Laws
23 Local Laws



How has PSI worked to advance Pharmaceuticals EPR?

- Helped develop and support bills in all states that have passed legislation.
- Conducted research to support development + refinement of bills
- Held webinars to increase understanding
- Researched and developed How-To Guide and Briefing Documents

Elements of Effective U.S. EPR Laws

Covered
Materials/Products

Governance
(PRO, Advisory, Govt)

Performance
Standards

Stewardship Plan
Contents

Covered Entities

Funding Inputs

Outreach &
Education
Requirements

Annual Report
Contents

Collection &
Convenience

Funding
Allocation

Equity &
Environmental
Justice

Implementation
Timeline

Responsible Party
("Producer")

Design for
Environment

Enforcement &
Penalties for Violation

Additional
Components &
Definitions

Pharmaceuticals State Legislation

2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
NY	NY	MA	MA	CT	CA	IL	IL	IL	IL
CA		RI	NY	OR	IN	ME	ME	ME	
			VT	WA	NY	MD	NH	HI	
					WA	OR	RI	RI	

MAINE

D. A description of the collection methods to be used to ensure that only covered drugs that are household pharmaceutical waste will be collected by authorized collectors under the stewardship program and a description of how separation of those covered drugs from packaging by consumers will be encouraged to reduce transportation and disposal costs. The plan must ensure that collection methods used under the program include mail-back envelopes and collection receptacles **and do not include home disposal methods involving packets, bottles or other containers that a person may use to render nonretrievable or destroy a covered drug that is household pharmaceutical waste by means of chemical process** [PL 2021, c. 94, §2 (NEW).]



MAINE

8A (3) ...except that the department **may not approve** for use in any stewardship program under this section a **method of home disposal involving packets, bottles or other containers** that a person may use to render nonretrievable or destroy a covered drug that is household pharmaceutical waste by means of a chemical process.



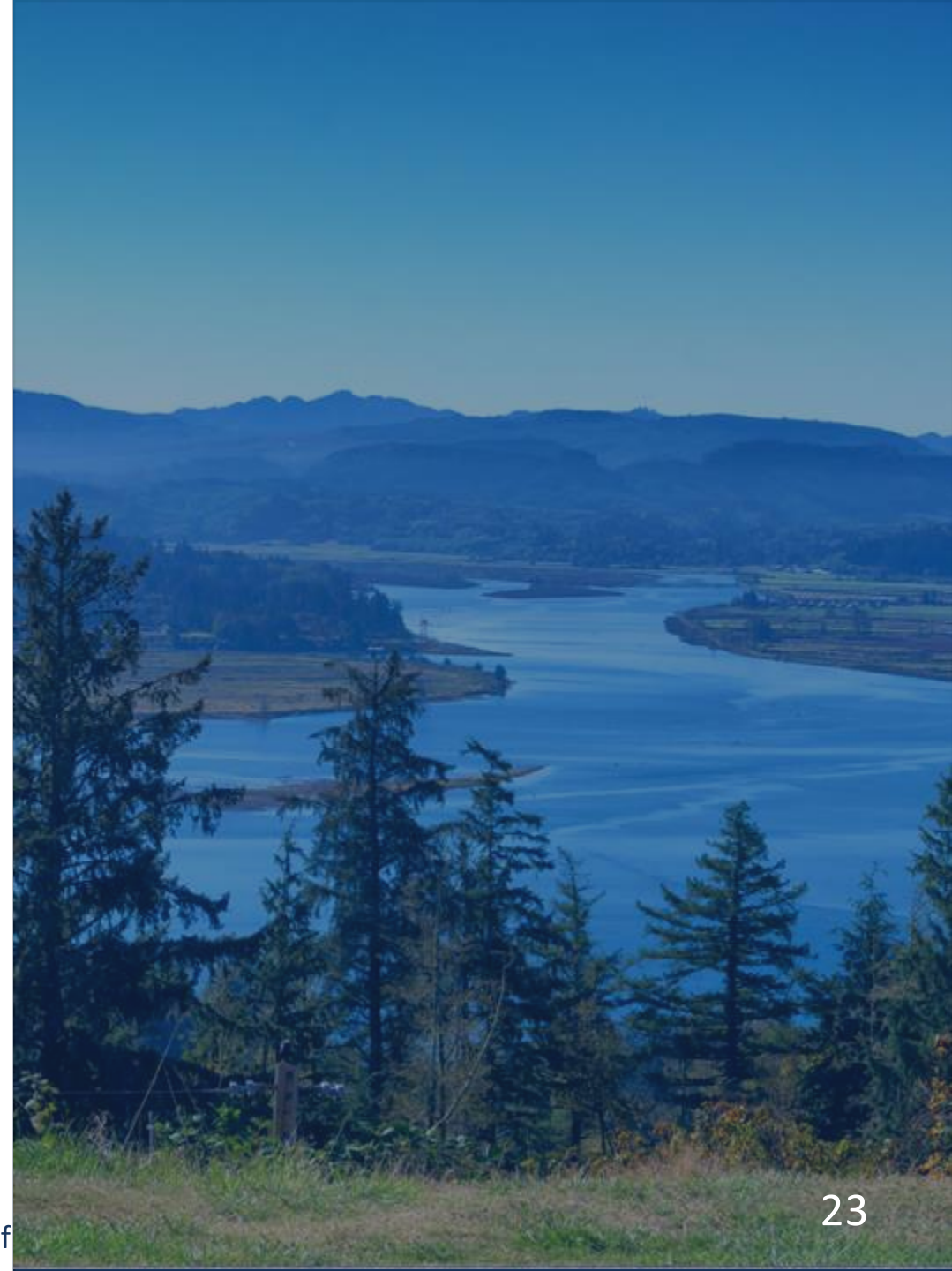
ILLINOIS

(6) Promotional materials prepared and distributed in conjunction with an approved drug take-back program under this Section may **not be used to promote in-home disposal products of any kind**, including, but not limited to, **in-home disposal products of authorized collectors participating in a drug take-back program.** Sec. 45.



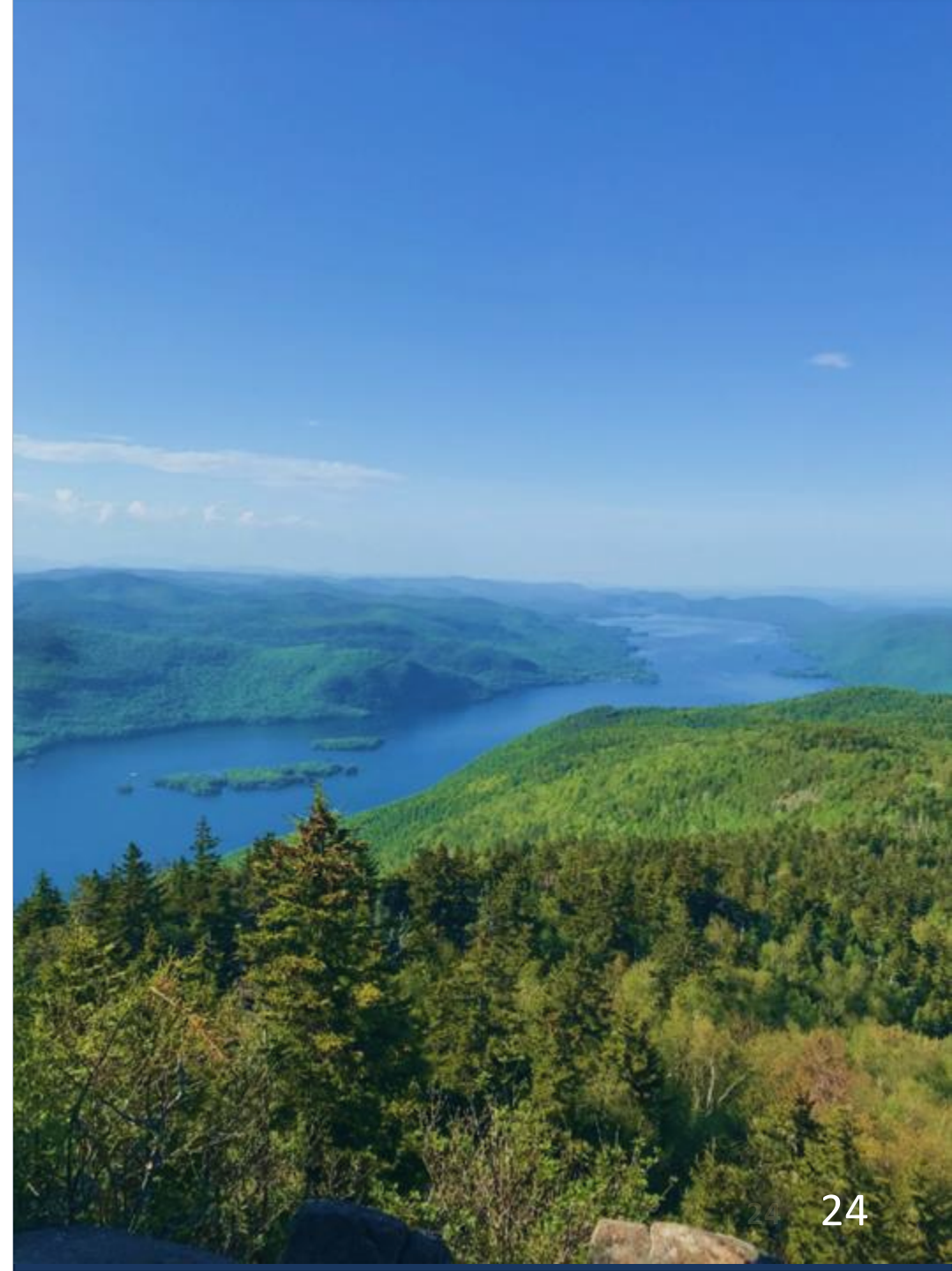
OREGON

-OR: Sec.10 (1) (c) **Discourage the disposal of covered drugs in the garbage or sewer system;**



NEW YORK

-Ny: 2. (E) explains how covered drugs will be safely and **securely tracked and handled from collection through final disposal and destruction**, policies to ensure security and compliance with all applicable laws and regulations **including disposal and destruction at a permitted waste disposal facility** meeting federal requirements;



Countries with Pharmaceutical Disposal Programs

European Union:

- EPR program for pharmaceuticals

Canada:

- EPR for pharmaceuticals:
 - Medications Return Programs (MRP) managed by Health Product Stewardship Association (HSPA) covers the costs associated with the responsible disposal of consumer health products returned by the public through collection sites. The products covered under this program are:
 - all prescription drugs,
 - over-the-counter medications, and
 - natural health products.

Comparison Of Take-back Program Models

	DROP-OFF/KIOSK	MAIL-BACK	HHW FACILITY/ COLLECTION EVENT	IN-HOME DISPOSAL (I.E. POUCH) SYSTEMS
STRENGTHS	• Highly Cost-Effective • Best for Large Volumes (Large Populations, High Usage Rates)	• Convenient, esp. for Lightly Populated Communities • Minimal Labor • Safest • Accessible (e.g., Home-Bound Individuals)	• Cost-Effective • Uses Existing Infrastructure	• Accessible
CHALLENGES	• Less Accessible for Home-Bound Individuals • Less Convenient in Lightly Populated Communities	• Less Cost-Efficient	• Less Accessible for Home-Bound Individuals • One or Few Collection Points • With Collection Events, No On-Demand Access to Take-Back	• Complex instructions • High cost • Environmental impacts • Not trackable

Importance of Outreach and Education:

2021 survey of 2000 Americans [1]:

- 53% have no idea what to do with them
- 68% would be willing to change disposal habits if they knew how

Education on responsible home medication disposal is wanted and needed.

PHARMS & SHARPS STEWARDSHIP

BUILDING CAPACITY FOR EPR

- Sarah Hanssen, VP of Sales & Marketing, UltiMed
- Elizabeth McCaskill, Environmental Program Manager, OKDEQ
- Rachel Ofir, Business Development Manager, Covanta
- Angie Snyder, Planner, Ozarks Headwaters Recycling & Materials Management District
- Justin D. Wilcox, Choctaw Nation of Oklahoma



Moderated by Hanz Atia, PSI

Hosted by the Product Stewardship Institute

FREE WEBINAR

JUNE 29, 2023

11:00 - 12:30 EST



2023 U.S. PRODUCT STEWARDSHIP FORUM

**To register or sponsor, visit
www.productstewardship.us**



September 11-14



Portland, Oregon

Thank you!



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