

Update: Wholesale Drug Importation Program

Legislative Health and Human Services

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Before we start...

On behalf of all colleagues at the Department of Health, we humbly acknowledge we are on the unceded ancestral lands of the original peoples of the Apache, Navajo and Pueblo past and present.

With gratitude we pay our respects to the land, the people and the communities that have and continue to contribute to what today is known as the State of New Mexico.



Mission

To ensure health equity, we work with our partners to promote health and well-being, and improve health outcomes for all people in New Mexico.

Goals



We expand equitable access to services for all New Mexicans



We ensure safety in New Mexico healthcare environments



We improve health status for all New Mexicans

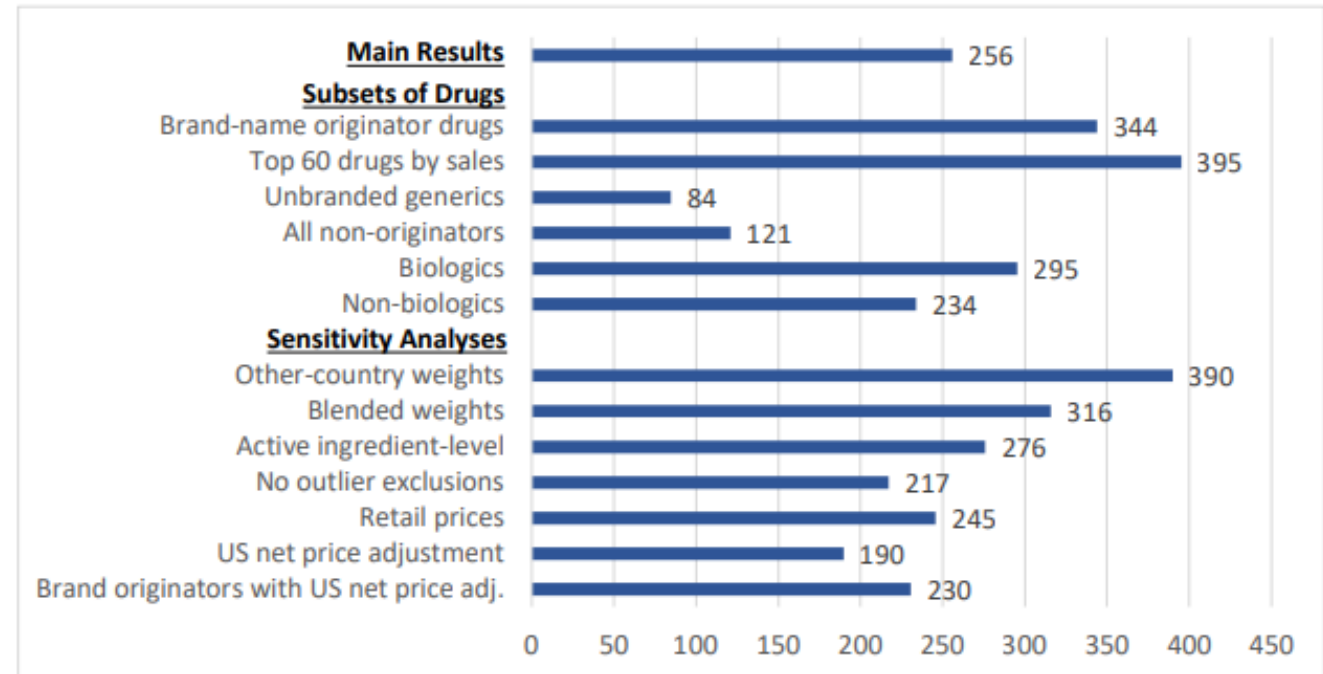


We support each other by promoting an environment of mutual respect, trust, open communication, and needed resources for staff to serve New Mexicans and to grow and reach their professional goals

INVESTMENT IN DRUG AFFORDABILITY SOLUTIONS ARE NEEDED

- Between 2014 and 2021, drug prices in the US have increased 35%, outpacing US inflation (19%).
- A US Health and Human Services Department funded study in 2018 found US drug prices are greater than other countries.
 - Overall: 256%
 - Brand drugs: 344%

Figure S.4. Summary of Selected Results: U.S. Prices as a Percentage of Other-Country Prices, 2018



SOURCE: Author analysis of IQVIA MIDAS sales and volume data for calendar year 2018 (run date October 28, 2019).
 NOTE: "Other-Country Prices" refers to all 32 OECD comparison countries combined. For "Top 60," we compared prices for the top 60 drugs by U.S. sales at the active ingredient level, excluding combination products. "Adj." is adjustment. Only some presentations sold in each country contribute to bilateral comparisons.

https://www.rand.org/pubs/research_reports/RR2956.html

Background...

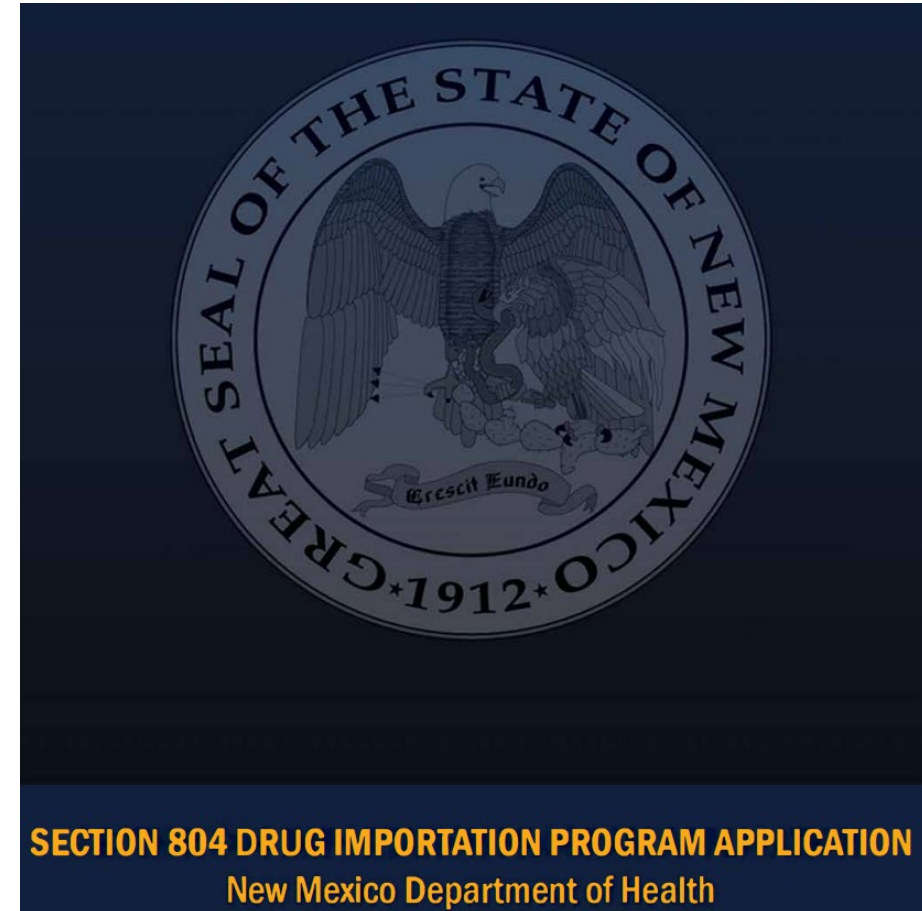
- Lowering pharmaceutical costs is a key priority of Governor and NM Legislature:
 - Interagency Pharmaceutical Purchasing Council (IPPC)
 - All Payers Claim Database (APCD),
 - New Mexico Prescription Drug Price Task Force
 - Section 804 Importation Program (passage of SB1)

Gov. Lujan Grisham establishes prescription drug price task force
Goal of group will be to decrease health care costs for New Mexicans

"This administration is committed to taking every step possible to lighten the load for New Mexico's families and seniors," said **Gov. Lujan Grisham**. "We've already taken great strides to create new pathways for affordable health care, and this task force will build upon that progress to find additional solutions that lessen the burden of prescription drug prices for New Mexicans across the state."

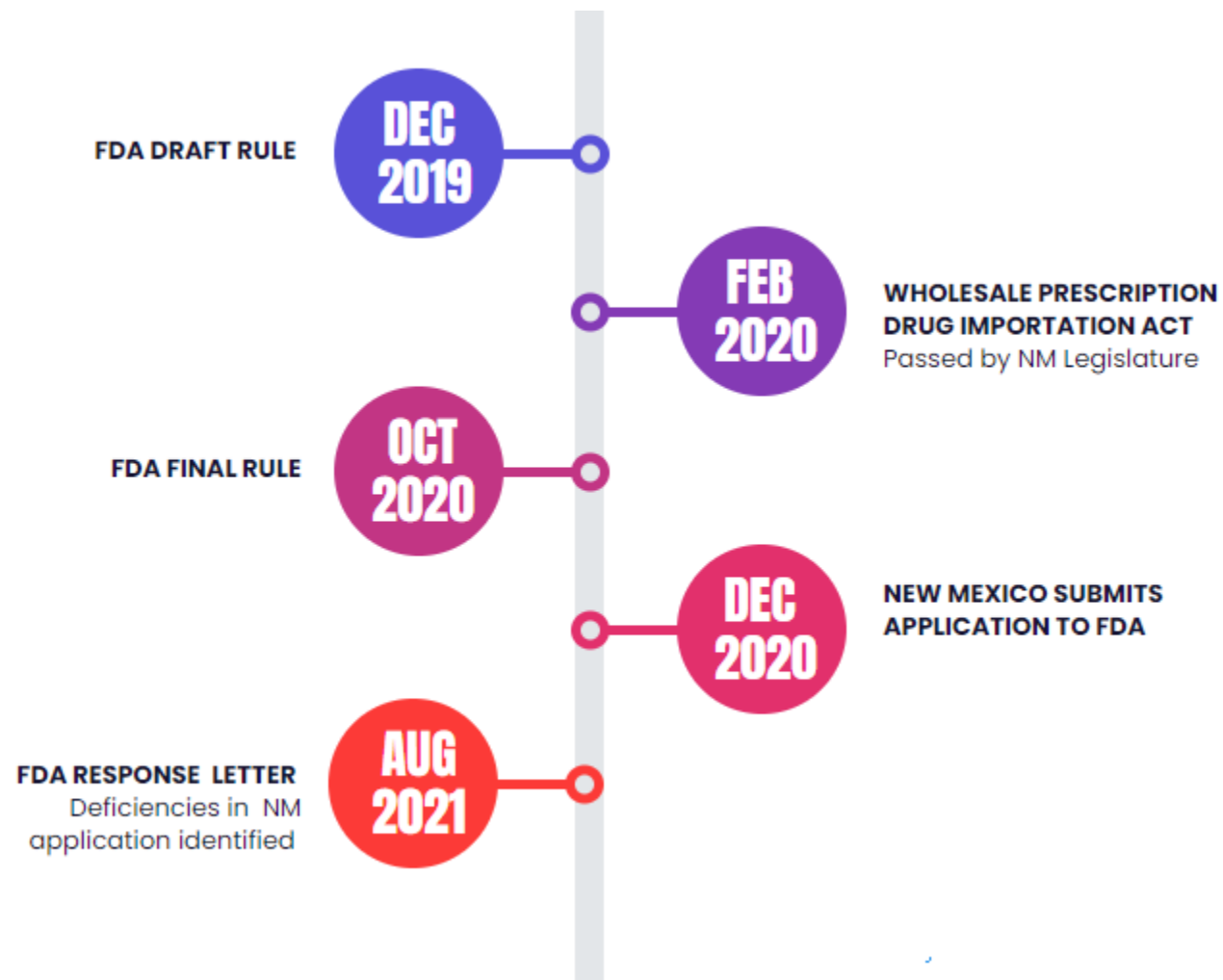
Background cont...

- In 2019, the Secretary of Health and Human Services issued the final rule to implement section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h)), which allowed state importation of certain prescription drugs from Canada.
 - The purpose of the final rule is to achieve a *significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety.*
 - NM submitted a Section 804 Drug Importation Application in Dec 2020



Section 804 Importation Program (SIP) Overview

- Drug importation offers potential consumer savings
- 6 states NM, CO, VT, MN, FL, and NH have passed legislation and submitted applications to participate.
- FDA has approved no SIPs.
 - Many states are resolving deficiencies in applications
 - Despite resolving all SIP deficiencies, CO and FL have not been granted approval



Development of the NM SIP:

- Direct support from the Governor, legislature, and other state agencies
- NM's drug importation program and drug list reflect the priorities in the State Health Improvement Plan (SHIP), which is an assessment of the critical health needs of the state.
- DOH work group sought input from stakeholders including professional groups, the Board of Pharmacy, and the Office of the Superintendent of Insurance.



Stakeholder Engagement

Stakeholders*:

- Canadian government
- Pharmaceutical manufacturers
- New Mexico Consumers for Affordable Prescriptions
- National Association of Chain Drug Stores
- The Partnership for Safe Medications
- Healthcare Distribution Alliance
- New Mexico Pharmacists Association

*not all stakeholders listed in this presentation.

- Stakeholder engagement meetings held during development of importation plan
 - Payers
 - Pharmacies
 - Consumers
- Stakeholder feedback obtained during December 2, 2020 public hearing on proposed Wholesale Drug Importation Program.
- Strong advocacy for & against implementation of a drug importation program.

NM Consumer Safety:

- NM SIP details processes ensuring patient safety and drug supply chain security:
 - DOH and NM Board of Pharmacy ensured SIP compliance with state regulations, FDA regulations, and the final rule
 - The details regarding these processes are critical for patient safety and confidence



Return on Investment/ Cost Savings

- Potential ROI dependent on FDA approval of NM's application and final drug list
- The NM All-Payer Claims Database (APCD) is in development and scheduled to be completed by fall 2023.
 - An All-Payer Claims Database will support continued iterations of a data driven medication list selection, which will provide the greatest cost savings and health impact to New Mexicans

Potential ROI in \$2.86 per \$1 invested



= \$2.86

Federal Landscape

- Ongoing PhRMA vs. HHS/ FDA Litigation:
 - PhRMA initially claimed FDA rule undermines federal role in ensuring track and trace of pharmaceuticals in addition to claiming states cannot demonstrate significant cost savings
 - PhRMA now challenging procedural integrity of the rulemaking





Investing for tomorrow, delivering today.

Questions?

Thank you!