# TOBACCO INDUSTRY USER FEES IN THE UNITED STATES

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# REGULATORY/LITIGATION HISTORY

- FDA's initial effort
  - 2+ year investigation of the industry and role of nicotine
  - Assertion of jurisdiction over tobacco products in 1996
  - Tobacco industry immediately sued
  - Industry litigation resulted in Supreme Court ruling in 2000
- Supreme Court decision in the *Brown & Williamson* case
  - FDA assertion of jurisdiction overturned
  - Bottom line…only Congress had the power to determine whether FDA should regulate tobacco products
- Nine years later Congress finally acted

# FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT (2009)

- Passed with overwhelming bipartisan support in both chambers
- Lengthy/complex legislation gave FDA broad authority to regulate all aspects of manufacturing, sale and distribution of regulated products
- Gave FDA initial regulatory jurisdiction over cigarettes and smokeless tobacco products; gained jurisdiction over e-cigarettes in 2016
- Entire program funded under the user fee provision (Section 919)
- Thanks to user fees, the unfinished business we started in the 1990s was fully operationalized while I was Center Director from 2013 to 2022.

# RATIONALE FOR SECTION 919

- Bipartisan support for making the tobacco industry pay to be regulated rather than out of taxpayer dollars or by raising federal taxes
- Avoid making FDA's tobacco regulatory budget subject to the annual appropriations process in Congress
  - One-year budget cycle where Congress decides each year how much money each agency gets and what it should be spent on
  - Can be extremely political
  - Congress often fails to pass new appropriations bills and reverts to "continuing resolutions"
- But leave all decision-making on how money is to be used to FDA and its Center for Tobacco Products

# UNIQUE FEATURES OF SECTION 919

- Annual budget amounts fixed by law with guaranteed increases each year from 2009 to 2019
  - Started at $85 million in 2009
  - Capped at $712 million in 2019
  - Remains at $712 million each year
- Unspent dollars (the "carryover") remain in the budget and are in addition to the next year's allocation

# HOW USER FEES ARE ASSESSED

- Tied to whether a category of regulated products is subject to federal excise taxes
- Only 6 such categories
  - Cigarettes
  - Snuff
  - Chewing tobacco
  - Roll-your-own tobacco
  - Cigars
  - Pipe tobacco

# HOW USER FEES ARE ASSESSED

- Each category is assessed its proportionate share of whatever the annual budget is based on its share of overall annual excise taxes paid
  - *Example, Part A:* If budget is $500 million and cigarettes paid 80% of all excise taxes, then the cigarette category share of that year's budget is $400 million
- Within each category, each company pays its share based on its market share of the category (based upon a review of actual share volume from federal tax data)
  - *Example, Part B:* For the $400 million that cigarette category must pay, Company A with a 50% market share volume would pay $200 million that the category owes; Company X with a 1% market share volume would pay $4 million
  - Fees are assessed and collected on a quarterly basis

# HOW USER FEES ARE USED

- Can only be expended on tobacco product regulation activities
  - Cannot be spent on programs like cessation services and other elements of comprehensive tobacco control
- Five major programmatic areas of investment as determined by FDA
  - Scientific research and review of marketing applications
  - Compliance and enforcement
  - Public education
  - Other communications
  - Leadership and management oversight
- Plus
  - Overhead

# CONCLUDING THOUGHTS FROM A U.S. PERSPECTIVE

- U.S. user fee system is proof of principle
  - Mandates to raise money from the tobacco industry can work
- The U.K. 'polluter pays' proposal adds value by going further
- Capping tobacco manufacturers' profits will:
  - Support delivery of the U.K. "ultimatum for industry to make smoked tobacco obsolete" (2019 green paper)
  - Provide needed funding to deliver on the ambitious Smokefree 2030 goals