

INSIGHTS

Senate HELP
Committee
Hearing on
Dr. Overton to be
FDA Commissioner

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On September 24, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a [hearing](#) on the nomination of Dr. Heidi Overton to be Commissioner of the Food and Drug Administration (FDA). Much of the questioning focused on whether Dr. Overton would keep FDA product decisions independent from the White House, particularly after President Trump's recent comments calling the Measles, Mumps, and Rubella (MMR) vaccine lethal. Dr. Overton said repeatedly that every vaccine on the U.S. market is safe and effective and that she would follow the statutory standards for safety and efficacy in reviewing individual products. Senators also pressed her on recent flavored vape authorizations, the ongoing mifepristone safety review, expedited approvals for rare disease treatments, oversight of clinical trials in China, and resources for FDA's Human Foods Program.

OPENING STATEMENTS

- [Committee Chair Bill Cassidy \(R-LA\)](#)
- [Committee Ranking Member Bernie Sanders \(I-VT\)](#)

WITNESS TESTIMONY

- [Dr. Heidi Overton, MD, PhD, Nominee for Commissioner of Food and Drugs](#)

MEMBER DISCUSSION

Vaccines and FDA Independence

Members expressed concerns regarding Dr. Overton's history of supporting President Trump's vaccine statements and questioned her ability to make informed decisions regardless of his input. Chair Bill Cassidy (R-LA), Sen. Maggie Hassan (D-NH), and Sen. Ed Markey (D-MA) asked Dr. Overton about President Trump's claim that the MMR vaccine is lethal. She said the vaccine is safe, 97% effective, and the best tool currently available to combat MMR. She also expressed confidence in the safety of every vaccine on the U.S. market given the FDA's oversight of each product. Chair Cassidy, Ranking Member Bernie Sanders (I-VT) pressed her on what she would do if the president's directions conflicted with FDA science or the law. She said she would follow the law and the statutory standards for safety and efficacy, and that while the president sets policy priorities, individual product reviews belong to FDA experts. Sen. Lisa Blunt Rochester (D-DE) and Sen. Markey asked about her role in the executive order on childhood vaccines and the proposal to split the MMR vaccine into three shots. Dr. Overton said she

simply coordinated agency input and presented options to the president. She also confirmed that no separate MMR vaccines are currently available in the U.S. and said any new application would be reviewed against the same standards. Sen. Hassan also asked about the President's claims that Tylenol causes autism, and Dr. Overton said she has not seen causal evidence linking the two.

Drug Development and Clinical Trials

Members focused on ways to improve drug development and clinical trial timelines in the U.S. Sen. Susan Collins (R-ME) asked how FDA could speed approval of safe, promising treatments for rare diseases where large trials are not feasible. Dr. Overton called it a key priority, pointed to the plausible mechanism pathway, and said FDA's flexible, risk-based approach should be formalized into policy. Sen. Jim Banks (R-IN) asked about inspections of clinical trials in China and other countries. She said progress has been made, but more is needed to ensure data meets good clinical practice standards, and that her goal is to make it easier to develop and manufacture products in America. Sen. Chris Murphy (D-CT) asked her to restore disbanded advisory committees. She called them a critical part of FDA's work and said she would review each one to ensure they are all fulfilling their purpose.

Tobacco and Vaping

There was bipartisan concern regarding the FDA's recent flavored vape authorizations. Sen. Tommy Tuberville (R-AL) and Sen. Tammy Baldwin (D-WI) raised that the changes have allowed flavored vapes to continue to be marketed to children. Dr. Overton said protecting kids comes first, that the flavored vape decision reflected adult use under current law, and that the administration has asked Congress for more authority to fight illicit products. Sen. Ashley Moody (R-FL) asked Dr. Overton about current guidance allowing companies awaiting application approval to continue to sell their products on the market. She said the application backlog has fallen from about 300,000 in May to about 100,000, with 48 products approved, and committed to revisiting current guidance that lets products stay on the market while applications are pending. Sen. Murphy, Sen. Angela Alsobrooks (D-MD), and Sen. Tim Kaine (D-VA) questioned the timing of the policy change after a major tobacco company donated to and met with President Trump. Dr. Overton rejected the framing, said career officials made the recommendation, and said she has not been involved since her nomination.

Mifepristone and Reproductive Health

Sen. Patty Murray (D-WA), Sen. Baldwin, Sen. Banks, and Sen. Josh Hawley (R-MO) questioned Dr. Overton on mifepristone from opposing directions. She said the drug was approved as meeting FDA's safety and efficacy standard under its current Risk Evaluation and Mitigation Strategies (REMS), but that an internal safety review of the changes to the REMS is ongoing and she could not prejudge whether the label should change. Sen. Hawley noted that FDA has said in court it will not stand behind the REMS adopted under

the Biden administration. Sen. Banks asked her to accelerate the review, and she said it would be on her desk immediately, noting an FDA update due to a Louisiana court filing deadline on October 7.

Food Safety and Nutrition

Members also sought clarity on Dr. Overton's plans to manage food safety and labeling, especially after the large number of recalls this summer. Sen. Murray, Sen. Banks, and Sen. Murkowski asked about resources for the Human Foods Program and state and local inspection partnerships. Dr. Overton said the program would need more resources and that FDA, which has 17,000 employees, is hiring. She did not know the program's current staffing and, when asked which office monitors foodborne illness outbreaks, named the Food Safety and Inspection Center before Sen. Murray corrected her with the Coordinated Outbreak Response and Evaluation (CORE) Network. Sen. Baldwin and Sen. Murkowski asked about labeling for dairy names and genetically engineered foods, and Dr. Overton called accurate labeling a top priority. Ranking Member Sanders asked about legislation banning over-processed food ads targeted at kids, and she said she supports addressing childhood obesity and improving food quality.

Other Topics

In response to a question on drug prices, she told Ranking Member Sanders that prices have dropped under Most Favored Nation (MFN) policies.

We trust you found this summary useful. Please reach out to [us](#) with any questions.

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