

# **RIPPED FROM THE HEADLINES:**

## *LIFE SCIENCES REGULATION IN 2024*

**Kate Klaus, Esq.**  
**Zuhal Reed, Esq.**

November 20, 2024



# OTC Changes Ahead for Cold Meds

- 2005: Combat Methamphetamine Epidemic Act caused OTC cold meds containing pseudoephedrine to be sold behind the counter
- Phenylephrine introduced as a true OTC alternative to keep products on store shelves
  - E.g., Sudafed PE
- Data analysis of phenylephrine at the 10 mg dose shows that this active is not effective as a decongestant
  - Phenylephrine is not absorbed in the intestines as well as pseudoephedrine, so a much less significant amount of the active actually reaches the sinuses (~38% vs. 100%).
  - PE is effective as a short-term/acute use nasal spray because it is applied directly to the nose/sinuses.
- FDA
  - Sept. 2023: Advisory Committee recommended removal of PE from OTC monograph.
  - Nov. 2024: FDA issues proposed order re: removal of PE
    - ▶ Open for public comment through May 2025.

**The Seattle Times**  
Pharmacies are yanking cold medicines from shelves. So what are the options now?  
The Food and Drug Administration has proposed ending the use of oral phenylephrine, a common ingredient found in many cold and allergy...  
1 day ago

**The Presidential Prayer Team**  
FDA Moves to Eliminate Oral Phenylephrine from OTC Nasal Decongestants  
The U.S. Food and Drug Administration (FDA) recently proposed removing oral phenylephrine from over-the-counter (OTC) products intended for...  
3 days ago

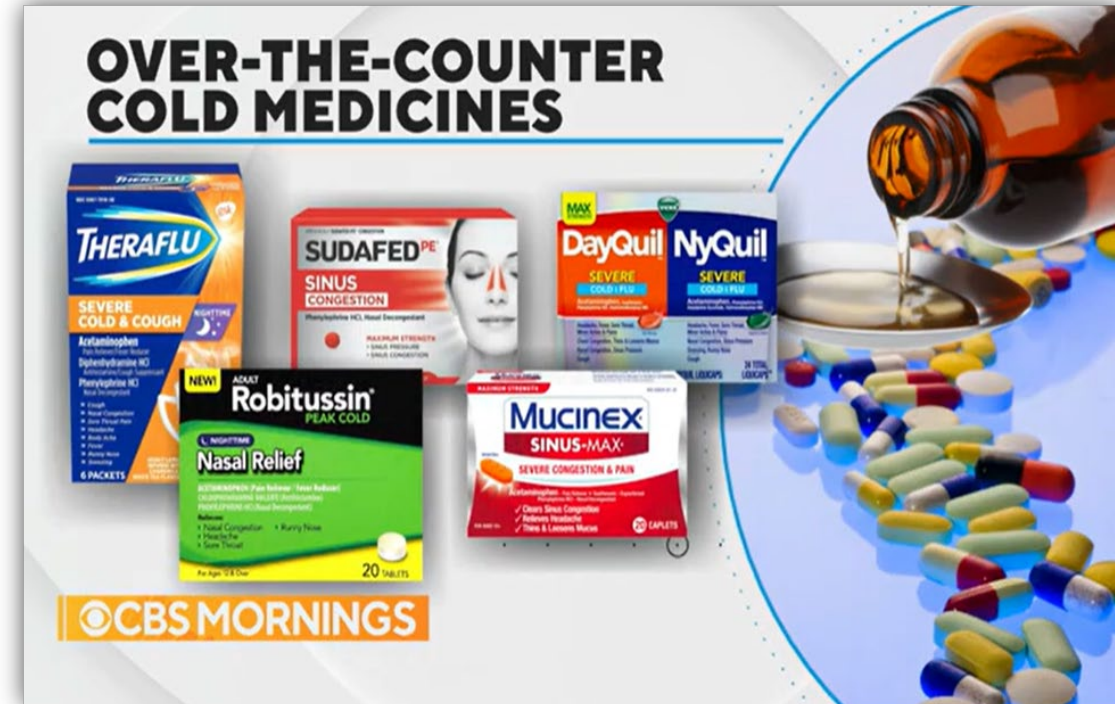
**CBS News**  
FDA to pull common but ineffective cold medicine from market  
The FDA says oral phenylephrine, used in many over-the-counter cough and cold medicines, "is not effective as a nasal decongestant."  
2 weeks ago

**CNN**  
FDA moves to pull popular decongestant from shelves amid effectiveness concerns  
The US Food and Drug Administration announced a proposal to remove oral phenylephrine – a common ingredient in many popular over-the-counter decongestants – ...  
2 weeks ago

**Lifehacker**  
The FDA Is Finally Pulling a Useless Cold Medicine From the Market  
Phenylephrine is both the most common decongestant on pharmacy shelves, and arguably the worst at its job. Last year, the FDA's advisory panel ruled it...  
1 week ago

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<https://www.cbsnews.com/news/fda-cold-medicine-phenylephrine-ineffective/>

# FDA's QS Final Rule for Medical Devices

- FDA is updating quality systems regulations to align with ISO 13485 standards.
- The current QSR framework will be modernized to harmonize U.S. requirements with global practices.
- Implications for medical device companies:
  - Streamlined regulatory compliance for manufacturers operating internationally.
  - Potential changes to internal quality systems audits.
- What can you do to prepare?

**Morgan Lewis**  
February 2, 2026 Is Quickly Approaching—Are You QMSR Ready? – Publications  
Oct 10 • By Michele Buenafe & Dennis C. Gucciardo

**MD&I**  
How Will FDA's New QMSR Affect Medical Device Companies?  
Mar 22 • By Susan Shepard

**JD Supra**  
Quality System Harmonization Is Here, But with Small Benefit to Device Industry | Mintz - Health Care Viewpoints  
Feb 16 • By Benjamin M. Zegarelli

**360Dx**  
New FDA Quality Regulations Spark Questions for IVD Developers, Clinical Labs  
Apr 16 • By Kelsy Ketchum

**Med Device Online**  
The Intersection Of ISO 13485 And ISO 14971 Under The Proposed FDA QMSR

# Direct-to-Consumer Advertising

- FDA has long regulated DTC ads on tv and radio but has failed to keep up with rapid changes in both the ads and the media landscape.
- Latest update was issued in November 2023, and the compliance deadline is effective **today**.
- Five Standards:
  1. Warnings presented in consumer-friendly, easily understandable language.
  2. Warnings must be at least as understandable as the rest of the ad.
  3. On tv, the warnings must be delivered concurrently in audio and text.
  4. On tv, the written warnings must be easily readable (e.g., text size, font, color contrast).
  5. No other audio or visual component of the ad should interfere with the ability to understand the warnings.


 Insiderradio.com

### New FDA Rules Dictating Drug Ad Disclosures Take Effect.

Today is the deadline for pharmaceutical companies to bring their radio and television advertising into compliance with new rules adopted...

3 hours ago





 Axios

### Prescription drug ads should soon start looking noticeably different

A new chapter in drug advertising begins Monday when a federal transparency rule takes effect requiring commercials to clearly spell out potential side effects.

May 20, 2024





 Bloomberg Law News

### TikToker Drug Ads Spark Demands for FDA to Clarify Its Authority

The FDA is under scrutiny by federal lawmakers and regulatory attorneys who want clarity on the agency's authority over social media influencers promoting...

Feb 16, 2024





 FiercePharma

### Senators urge FDA to fix gaping holes in oversight of DTC ads

Senators are urging the FDA to address the "alarming proliferation of dangerous and misleading content promoting prescription drugs."

Feb 20, 2024




 STAT

### The FDA and FTC need to crack down on TikTok and Instagram influencers pitching prescription drugs

In June, the Food and Drug Administration issued a warning letter about advertisements for the drug Recorlev for Cushing's syndrome – its...

Jan 22, 2024



# Direct-to-Consumer Ads in the Age of Social Media


- This is only a first step in reforming DTC ads! Next up: social media.
- Numerous ads have flooded social media in recent years
  - Celebrity endorsements (assorted Kardashians, Lady Gaga, Aly Raisman) for migraine medications
  - Word-of-mouth and microinfluencer campaigns
    - ▶ Common for cosmetics and supplements
    - ▶ Exploit audience's parasocial relationship with the influencer
- Significant concerns raised regarding presentation of warnings about drug products, especially given data about success of DTC drug advertising on sales


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# FDA's Final Rule for Laboratory Developed Tests (LDTs)

- FDA seeks to regulate LDTs as medical devices.
- How will the new rule be rolled out?
- First phase of policy implementation begins May 2025.
- Industry Impact:
  - Increased regulatory scrutiny for LDT manufacturers.
  - Transition plan needed to meet FDA requirements.
- Challenges and Considerations



# Laboratory Developed Tests (LDTs): Is that the end of the story?

- The first Trump administration enacted a policy exempting LDTs from premarket FDA review.
  - Note: This policy was implemented during the COVID-19 pandemic, but it is widely considered likely that the incoming administration will take the same position, that FDA lacks statutory authority to regulate LDTs.
- Potential HHS Secretary, Robert F. Kennedy, Jr., has stated that he wants to push the federal health agencies to focus less on infectious disease and more on preventive care.
- The issue of LDTs could be the first significant test of how the Supreme Court's 2024 *Loper Bright* decision overturning the longstanding *Chevron* doctrine will be applied to FDA.



## FDA'S LDT FINAL RULE IN JEOPARDY AFTER SUPREME COURT RULING

July 03, 2024

The future of the Food and Drug Administration's [final rule for laboratory-developed tests \(LDTs\)](#) is uncertain following a June 28 ruling by the U.S. Supreme Court in *Loper Bright Enterprises v. Raimondo*.

STAT+ | OPINION | FIRST OPINION

## Congress must act now to protect the future of diagnostic tests

Lab-developed tests will likely be removed from FDA oversight. That has to change

## Holland & Knight

IN THE HEADLINES  
JULY 30, 2024

## Could SCOTUS *Chevron* Reversal Reverse FDA's Final Rule on LDTs?

Medtech Insight, Citeline Commercial



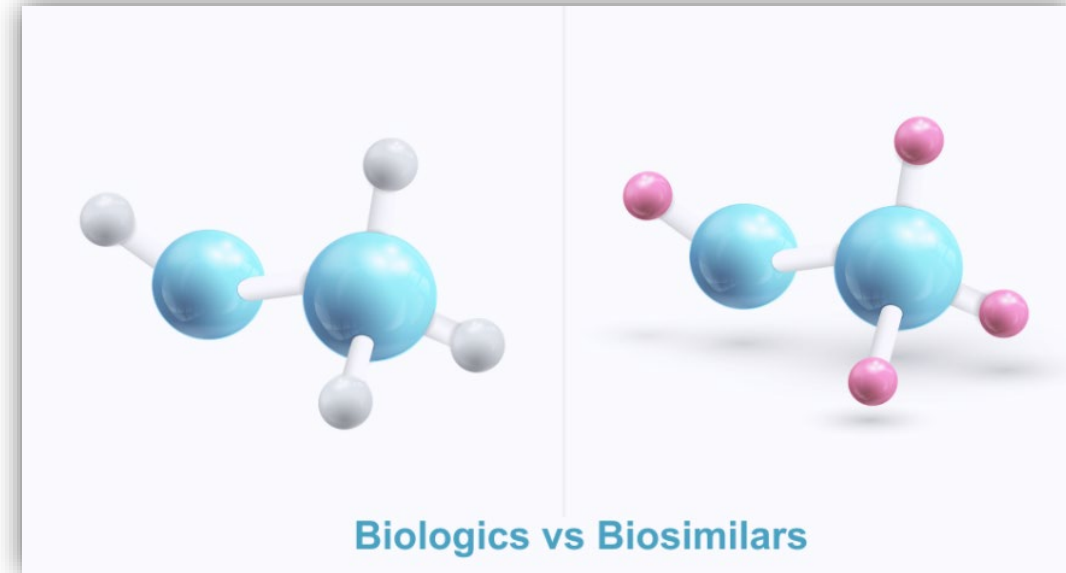
## Trump's Second Term Could Turn LDT Regulation on its Head

FDA's unpopular LDT final rule could meet its maker when the president-elect hits the oval office, but how is he most likely to upend it?



# FDA's Proposed Rule for Biosimilars

- Currently in the U.S., a biosimilar must undergo additional studies to gain “interchangeable” status.
- Proposal to eliminate switching study requirements for biosimilar approval.
  - FDA's focus will shift to ensuring robust analytical comparability and clinical data rather than requiring switching studies.
- Potential benefits for manufacturers:
  - Reduced cost and time for biosimilar development.
  - Enhanced focus on labeling, marketing strategies, and patient education.
- What does this mean for the industry?




<https://invimeds.com/updates/difference-between-biologics-and-biosimilars/>

# AI and the Impossible Task of Regulating the Hottest Tech

- FDA's device paradigm is based on static design and design validation.
  - It has adapted to technology through embracing an AI Lifecycle approach to regulating AI/ML devices.
    - ▶ But what happens when that product model is not just responding to new data, but actually **creating** it?

## I. Is it a device?


- a. Does it deploy an AI/ML model?
- b. Does it deploy a GenAI model?


 The New York Times

[From A.I. to Musk's Brain Chips, the F.D.A.'s Device Unit Faces Rapid Change](#)

The new director overseeing medical devices will confront criticisms about hasty approvals as she ushers in revolutionary technology.

2 weeks ago





 News-Medical

[FDA strengthens AI regulation to ensure patient safety and innovation in healthcare](#)

The FDA is adapting regulations to manage AI's rapid development in healthcare, focusing on patient safety and the life cycle of AI tools.

1 month ago




 FierceHealthcare

[FDA advisory committee to roll up sleeves on generative AI this week](#)

The FDA seeks advice on regulatory challenges it has identified for generative AI used in medical devices.

15 hours ago

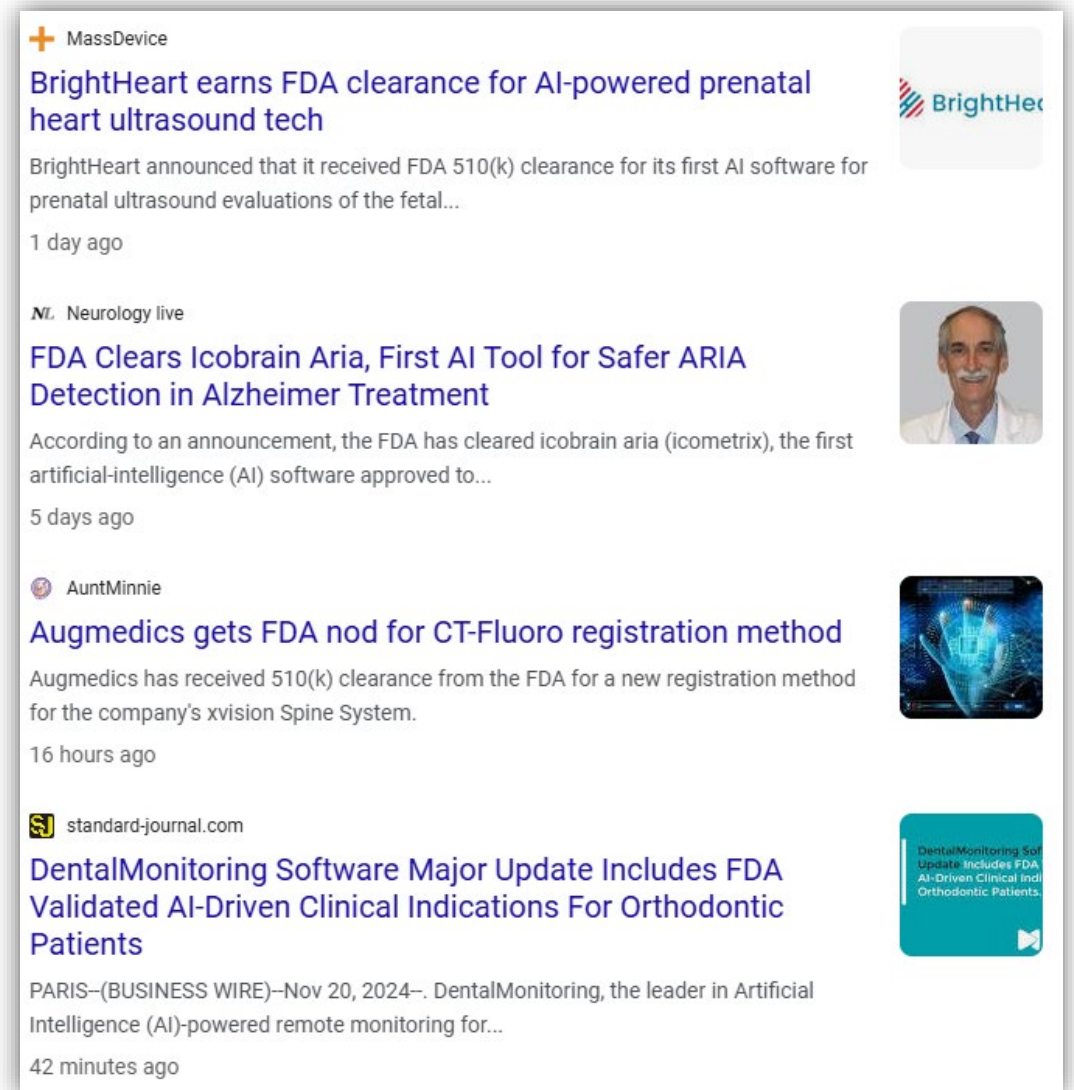


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The screenshot displays a social media feed with three news items. Each item includes a source icon, a headline, a brief description, and a timestamp. The first item is from MassDevice, the second from Neurology live, and the third from AuntMinnie. Each item also features a small image related to the news.

- MassDevice:** BrightHeart earns FDA clearance for AI-powered prenatal heart ultrasound tech. BrightHeart announced that it received FDA 510(k) clearance for its first AI software for prenatal ultrasound evaluations of the fetal... 1 day ago.
- Neurology live:** FDA Clears Icobrain Aria, First AI Tool for Safer ARIA Detection in Alzheimer Treatment. According to an announcement, the FDA has cleared icobrain aria (icometrix), the first artificial-intelligence (AI) software approved to... 5 days ago.
- AuntMinnie:** Augmedics gets FDA nod for CT-Fluoro registration method. Augmedics has received 510(k) clearance from the FDA for a new registration method for the company's xvision Spine System. 16 hours ago.
- standard-journal.com:** DentalMonitoring Software Major Update Includes FDA Validated AI-Driven Clinical Indications For Orthodontic Patients. PARIS--(BUSINESS WIRE)--Nov 20, 2024--. DentalMonitoring, the leader in Artificial Intelligence (AI)-powered remote monitoring for... 42 minutes ago.



**THANK YOU!**