Ripped from the Headlines:

Life Sciences Regulation in 2024

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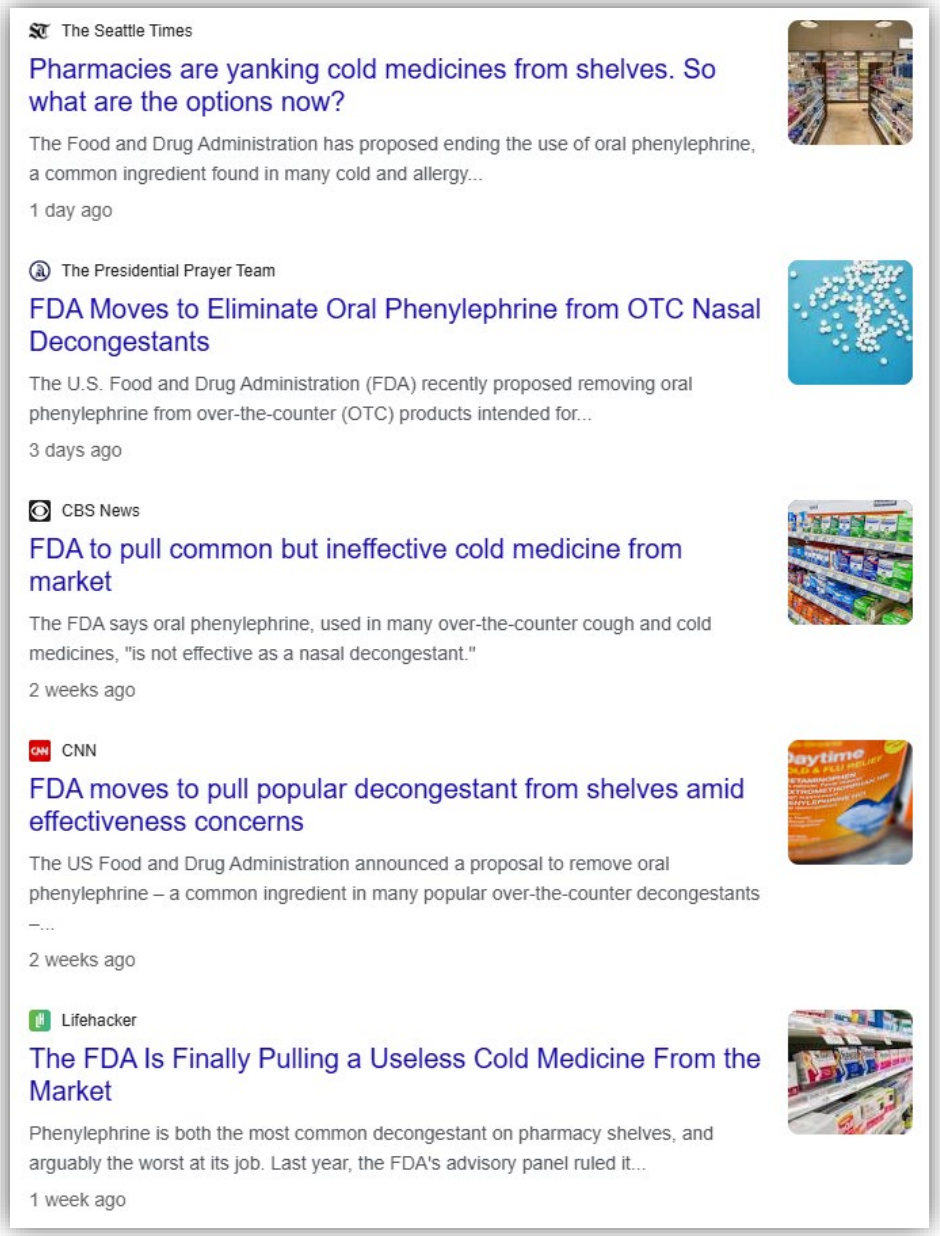
November 20, 2024

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.



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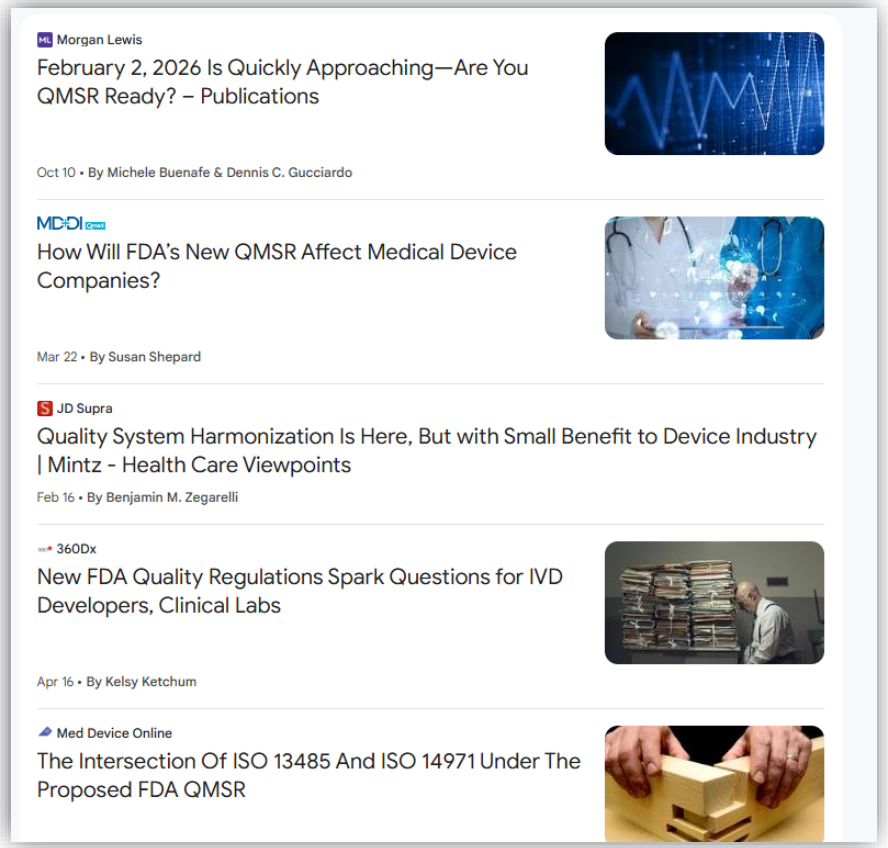
https://www.cbsnews.com/news/fda-cold-medicine-phenylephrine-ineffective/

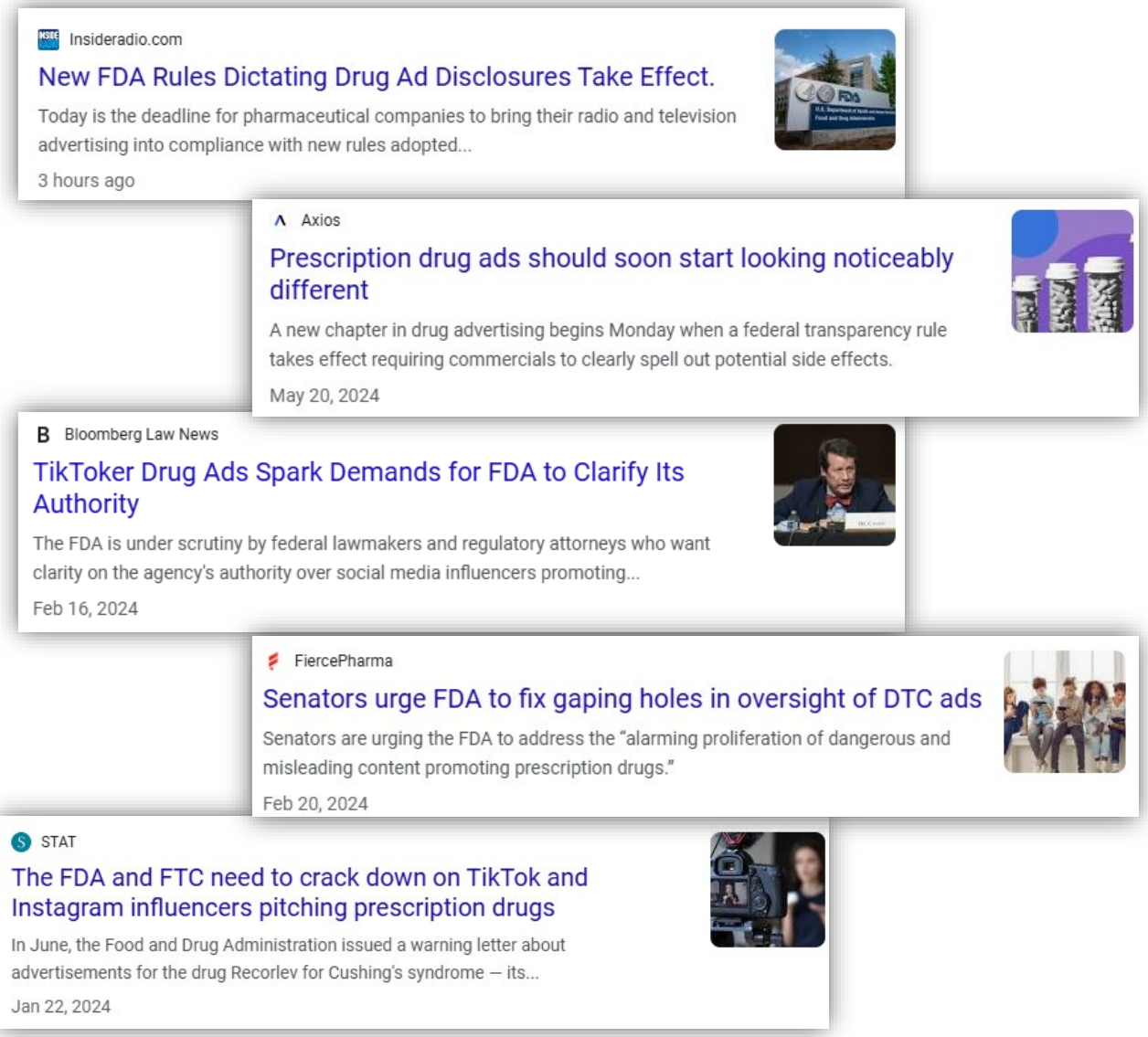
FDA's QS Final Rule for Medical Devices

- 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?



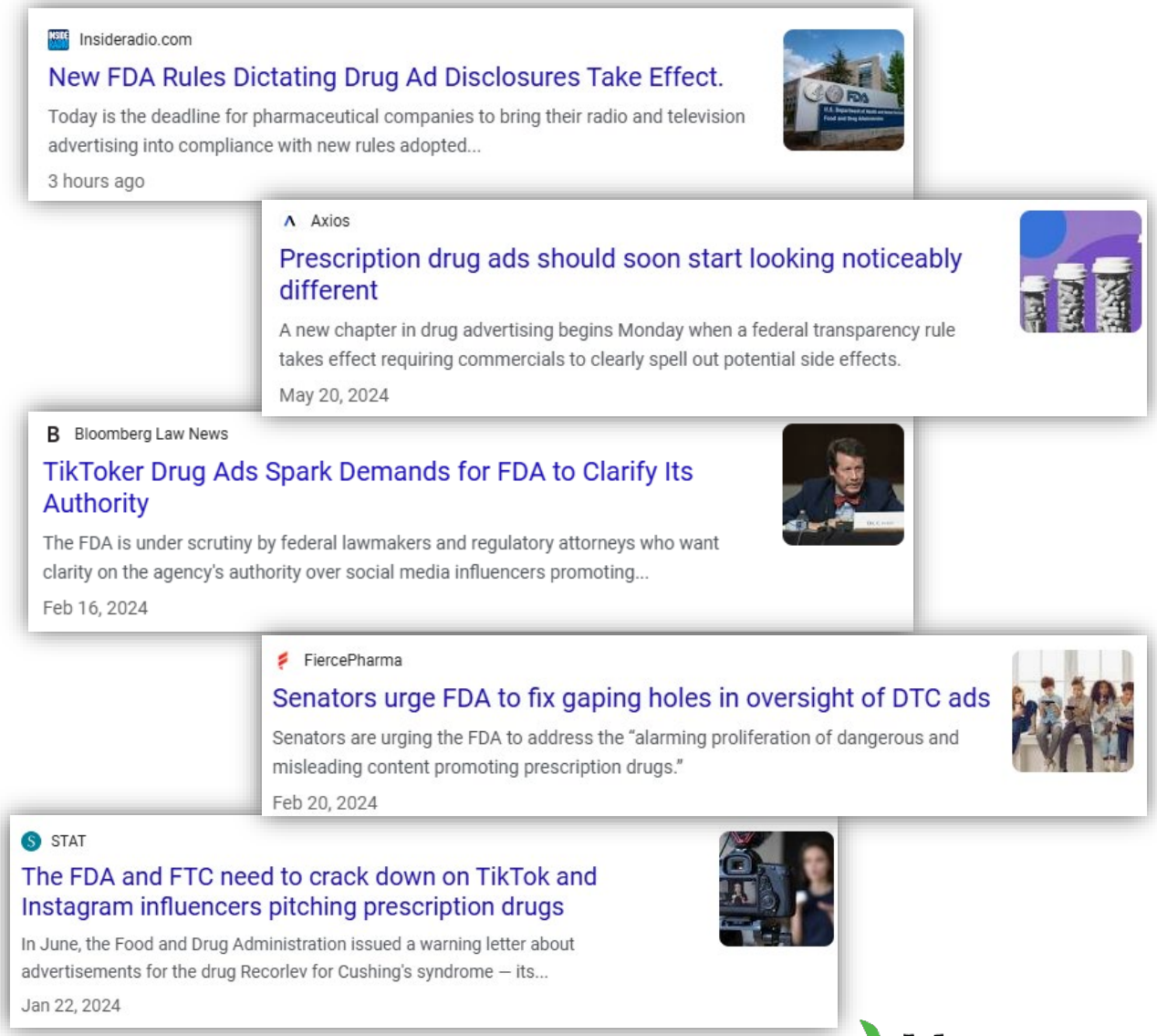
Direct-to-Consumer Advertising

- 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.



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

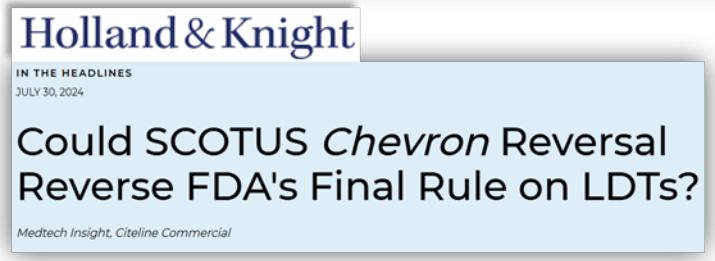


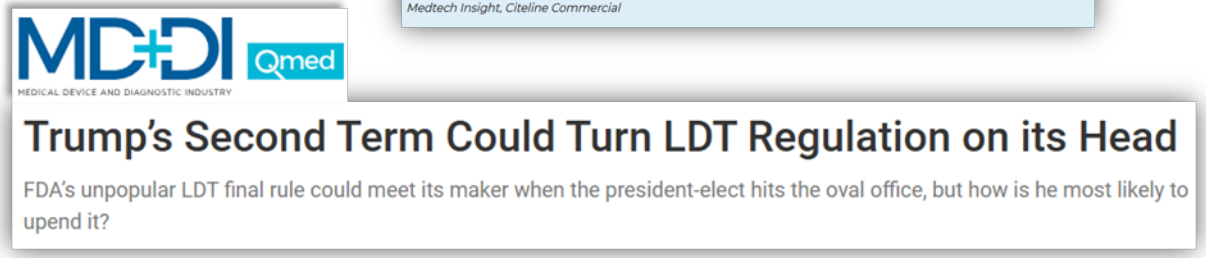
FDA's Final Rule for Laboratory Developed Tests (LDTs)

- 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?

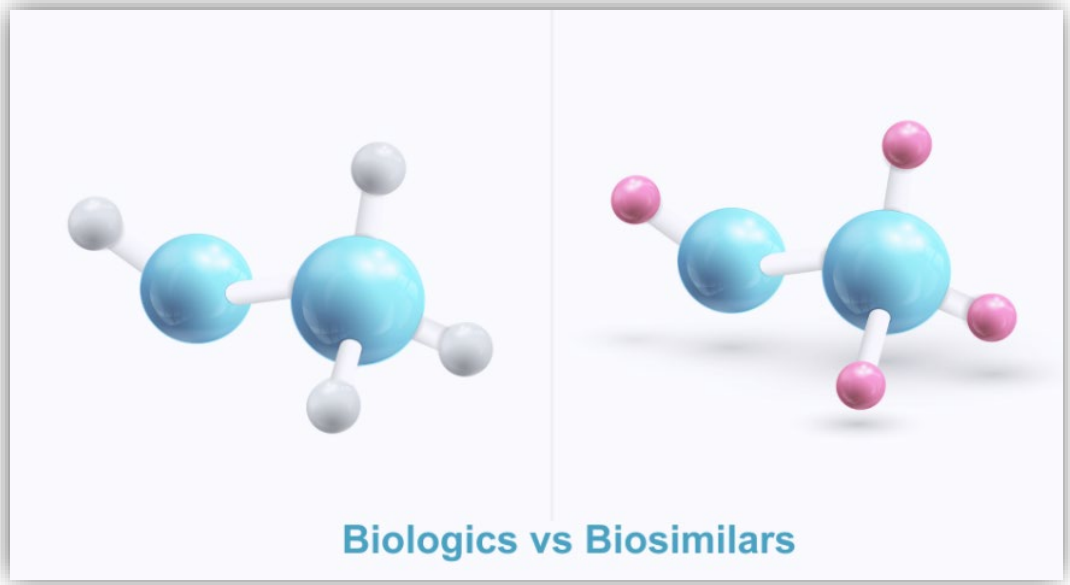
- The first Trump administration enacted a policy exempting LDTs from premarket FDA review.
  - Note: This policy was implemented during the COVID-19 pandemic, but it is widely considered likely that the incoming administration will take the same position, that FDA lacks statutory authority to regulate 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 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?

1. 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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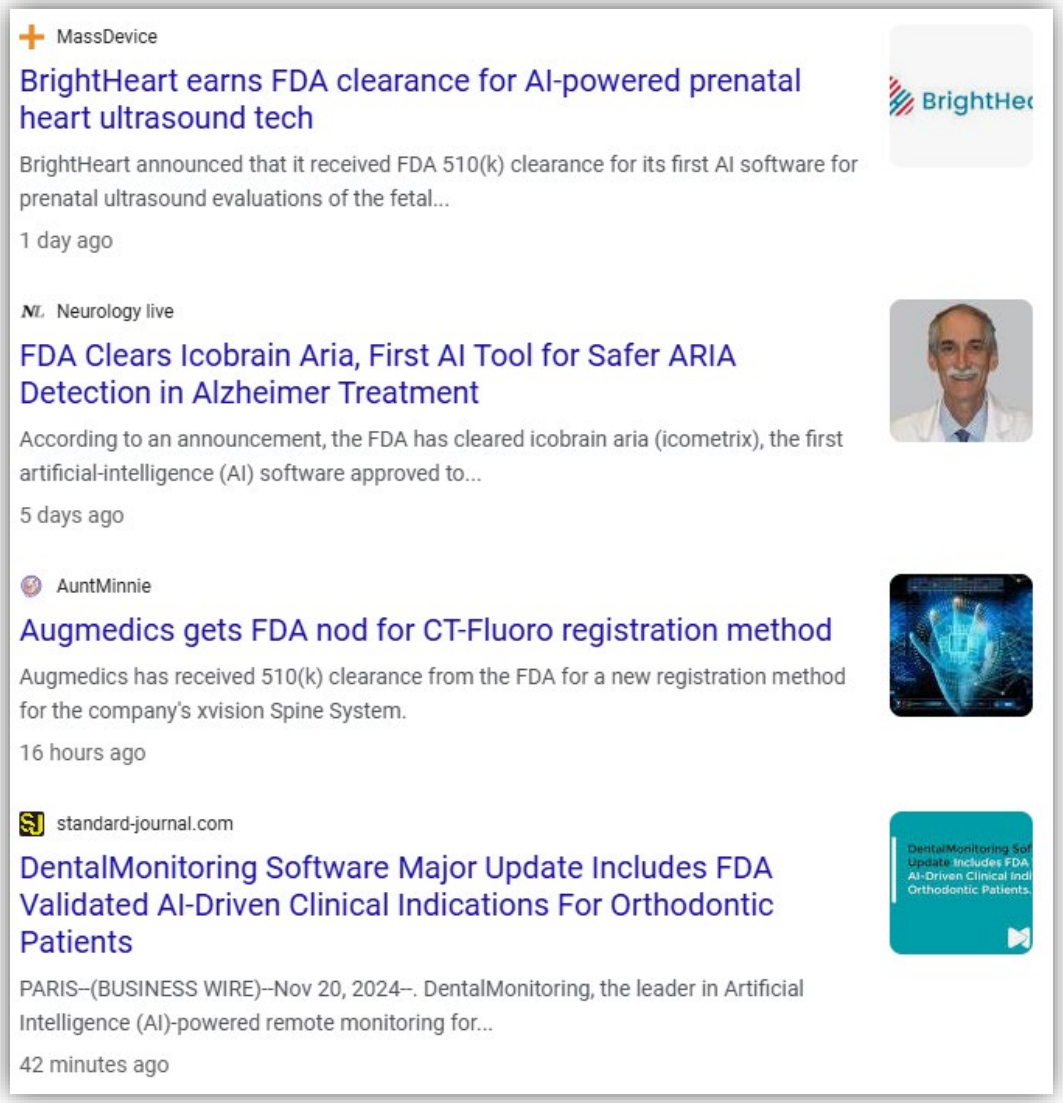

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