



Biotechnology
Innovation Organization

What to Know and Do as FDA Advertising Scrutiny Increases for Life Sciences

Thursday, November 20, 2026, 2:00 PM (ET)

Moderator:

- Ilyssa Levins-Pimienta, Inventor/Founder of SecureCHEK AI and Center for Communication Compliance

Speakers:

- Robert Dean, Head of Global Labeling Strategy & Ad/Promo, EMD Serono, Inc.
- Howard Dorfman, Founder, H.L. Dorfman Pharmaceutical Consulting, LLC

Predicting the Future in 2023



Panelists said: U.S. Department of Justice (DOJ) statistics suggest that enforcement will be a top government priority in the coming years



FDA NEWS RELEASE

FDA Launches Crackdown on Deceptive Drug Advertising

[More Press Announcements](#)

For Immediate Release: September 09, 2025

The U.S. Department of Health and Human Services and the Food and Drug Administration today announced sweeping reforms to rein in misleading direct-to-consumer pharmaceutical advertisements. Today, the FDA is sending thousands of [letters](#) warning pharmaceutical companies to remove misleading ads and issuing approximately 100 cease-and-desist letters to companies with deceptive ads.

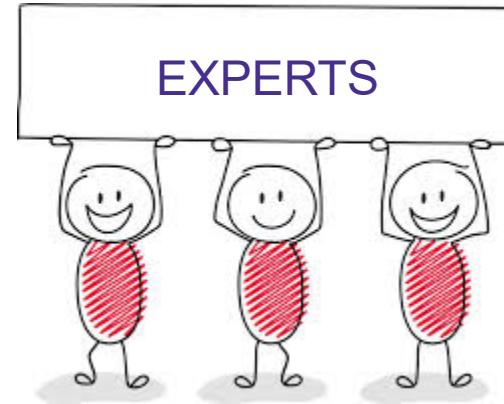
In addition to enforcing existing law, the FDA is initiating rulemaking to close the “adequate provision” loophole created in 1997, which drug companies have used to conceal critical safety risks in broadcast and digital ads, fueling inappropriate drug use and eroding public trust.

This Webinar Will Cover the Following:

- **FDA'S OPENING SALVO** Reinforces Regulations That Have Always Been in Place
- Principles For **RESPONSIBLE PROMOTION** Within Approved Labeling
- Pre-commercial Conversations **WITHOUT CROSSING THE LINE**
- Avoiding **UNBRANDED TRAPS** When Disease-awareness Draws Scrutiny
- Before Another Shoe Drops, Get Your **HOUSE IN ORDER**



How Panel Discussion Will Unfold



Test Question #1: Fair Balance

Which of the following statements is true about the FDA's "fair balance" requirement for promotion: (select the best answer)

- A. Include adverse events only if the incidence is over 10 percent
- B. Tone and emotional cues that inadvertently amplify benefits can be construed as an FDA violation
- C. The fair balance must be always be identified with the words: "Important Fair Balance Information"

ANSWER

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Panel Discussion:

FDA'S OPENING SALVO
Reinforces Regulations That
Have Always Been in Place

Test Question #2: Spokespeople

Which statement is true when companies work with healthcare providers who are third-party spokespeople speaking promotionally and publicly on their behalf: (select the best answer)

- A. Paid third-party spokespeople are subject to the same regulatory rules as company employees
- B. Third-party spokespeople should discuss their own clinical experience with the product even if their statements are inconsistent with the approved labeling.

ANSWER

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Panel Discussion:

Principles For
RESPONSIBLE PROMOTION
Within Approved Labeling

Pre-commercial Conversations
**WITHOUT CROSSING
THE LINE**

Test Question #3: Disease State Awareness

Which of the characteristics below could turn a company-sponsored disease state website, with no product mention, into what FDA would consider to be product promotion and therefore subject to regulations: (select the best answer)

- A. The company is the only one that makes a product for the disease being discussed
- B. The disease awareness site has a very similar "look and feel" to the company's product-specific site
- C. The disease awareness site references articles in the medical literature that mention of product name
- D. All of the above

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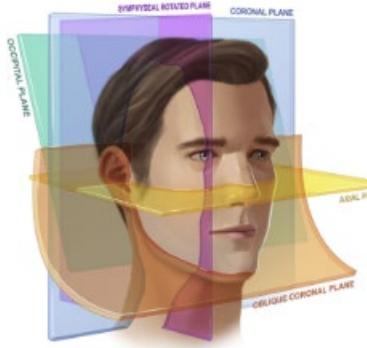


Panel Discussion:

Avoiding
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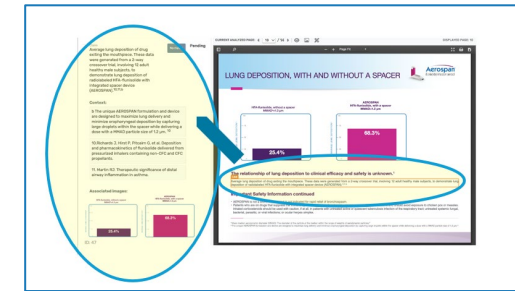
What is a medical legal review process?



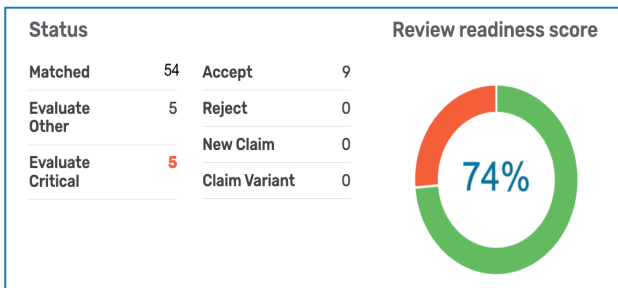
Define and communicate risk tolerance



Automate always current libraries



Automate content prechecks



Train and test your staff and agencies



Ask your compliance experts for help



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