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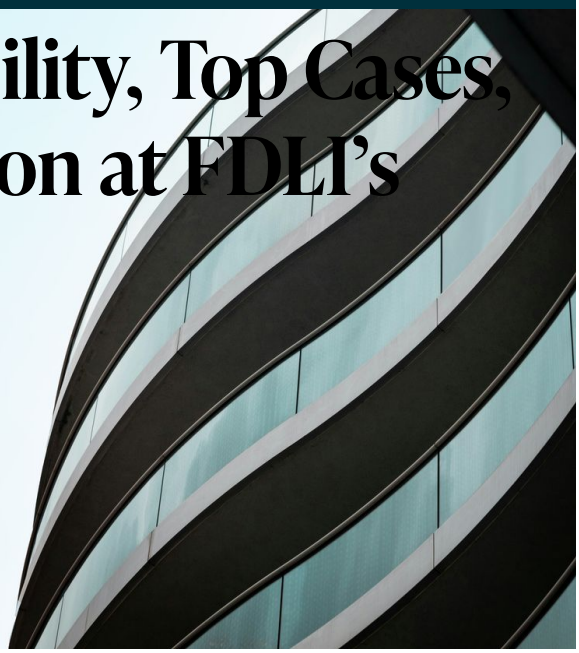
Rethinking Interchangeability, Top Cases, and Battling Misinformation at FDLI's Annual Conference



2 MIN READ

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Last week, the Food and Drug Law Institute held its Annual Conference while also celebrating its 75th anniversary. There, members of FDA and industry players gathered to discuss the latest legal, policy, and regulatory developments affecting the Agency and the industries it regulates. Here are some of the key takeaways from those discussions:

1. Rethinking interchangeability

The Director of the Center for Drug Evaluation and Research, Patrizia Cavazzoni, M.D., suggested that the interchangeability designation for biosimilars may be duplicative. Of course, the two-tiered system for licensing biosimilars in the US has been pointed to as one of the reasons for the slow uptake of biosimilars in this country compared to the European Union, which does not require that a biosimilar have an additional interchangeability designation to be automatically substituted for the reference product. Suggesting that an interchangeability designation should be easier to obtain, Cavazzoni noted that "it's time to open the door on interchangeability." The CDER head alluded to legislative proposals that would let FDA streamline interchangeability for biosimilars.

2. Health-related speech in the spotlight

FDLI's "Top Cases in Food and Drug Law" presentation had a heavy emphasis on public communications by both private parties and FDA.

The Panel's moderator analyzed the Ninth Circuit's decision in *McGinity v. The Procter & Gamble Company*, No. 22-15080 (9th Cir. 2023), where the court relied on a back-label ingredients list in determining that an "ambiguous" phrase on the front labels of shampoos and conditioners was not misleading or deceptive. *McGinity* could benefit manufacturers looking to defend against allegations of false advertising based on ambiguous labelling claims.

The panel then discussed *Horti v. Nestle*, No. 22-16932 (9th Cir. 2023), in which the court reversed the dismissal of false advertising claims related to Nestle's "Boost Glucose Control" drink. The district court initially granted a dismissal based on the label's statements indicating that the product did not treat diabetes. But upon appeal, the Ninth Circuit disagreed and cited the product's in-store placements near diabetes treatments. This case demonstrates that contextual inferences can help support false advertising claims, even where a retailer controls product placement.

Professor Erika Lietzan voiced her concerns over the precedent set by *Apter v. HHS*, No. 22-40802 (5th Cir. 2023), where the Fifth Circuit reversed the dismissal of claims against FDA based on the Agency's statements against ivermectin COVID treatments. Professor Lietzan expressed skepticism that non-binding agency statements could serve as the basis for APA claims where there was no final agency or *ultra vires* action.

3. <u>Collaboration between FDA and industry to combat misinformation</u>

In his Fireside Chat, FDA Commissioner Robert Califf, M.D., noted that combatting the increasingly prevalent medical misinformation will require FDA to have more direct communication with healthcare providers. He noted that hostility towards FDA in the wake of the COVID pandemic requires collaboration with local healthcare providers, who patients often consider to be more trustworthy than FDA. Commissioner Califf and other FDA officials stressed that FDA's capabilities were limited, noting that the Agency could not take on medical misinformation without the help of private industry and other parts of the government. Despite urging collaboration with individual providers, Califf also seemed to suggest that the industry's move towards direct-to-consumer advertising, which can lead some to request specific treatments from their providers, can sometimes walk the "fine line" between advertising and misinformation.

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