



WEBINAR

# TOP TAKEAWAYS

## REGULATORY DISPUTES WITH HHS: WHEN TO NEGOTIATE AND WHEN TO LITIGATE

For healthcare and life sciences companies, regulatory disputes with the US Department of Health and Human Services (HHS) and its operating divisions can present significant economic and reputational risks. Efficient resolution of such disputes is always preferable and requires a thorough grasp of both the law and the institutional relationships among the relevant HHS operating divisions, other parts of the Executive Branch, and agency personnel. When a company cannot reach an efficient resolution through negotiation and litigation is the only option, the company must vindicate its rights in a principled way that mitigates reputation risks.

In this webinar, McDermott partners Brian R. Stimson and Brian J. Malkin draw on their backgrounds with HHS and the US Food and Drug Administration, respectively, to help in-house healthcare and life sciences lawyers successfully navigate regulatory disputes with HHS and its operating divisions. Read on for select highlights from this insightful discussion.

1

The Administrative Procedure Act (APA) sets out the operating principles around which HHS is organized and gives litigators a lens through which they can assess agency efforts to implement policy. Among other things, the APA defines the parameters and procedures for bringing an action against the agency.

2

Stakeholders generally have the best chance of successfully litigating under the APA when they can challenge an agency action as contrary to the law. “Once you veer into the agency’s deference in interpreting the law, or the agency’s deference in administering a statute, it becomes very difficult under the APA to prevail, because the agency is deemed to have expertise and is deemed to act in good faith,” Stimson said.

3

Industry stakeholders should take every available opportunity to comment on proposed agency rulemaking. Doing so helps build a robust administrative record that can support a future challenge. “Whenever you can, put in your argument, your case, your position,” Malkin said. “You want to do that to preserve those arguments for what becomes the administrative record.”

4

When considering whether to advocate in an administrative or judicial forum, stakeholders should take into account several factors. For example, a judicial forum typically has a high level of transparency, whereas transparency across agencies can vary significantly. Pursuing a judicial action may also be viewed as more adversarial than working within an administrative process. “What’s going to be the impact for your engagement with that agency over time?” Malkin said. “What’s the institutional relationship that you have?”

5

Policy changes are a normal part of any incoming presidential administration and often result in lawsuits from parties that object to the changes. “We’re in an environment where we’re going to see a lot of policy changes at HHS, and many of them will involve reversing the prior administration’s policies, some of which were deregulatory in nature,” Stimson said. “This is a setting that’s conducive to a lot of APA litigation for that reason, and I think it’s something to keep an eye on.” Additional areas of stakeholder interest this year may include COVID-19 product-related challenges, product exclusivity challenges, food labeling and traceability issues, cannabis and tobacco.

VISIT [MWE.COM/HEALTH](https://www.mwe.com/health)

©4/12/2021 McDermott Will & Emery. McDermott Will & Emery conducts its practice through separate legal entities in each of the countries where it has offices. For a complete list visit [mwe.com/legalnotices](https://www.mwe.com/legalnotices).

**McDermott  
Will & Emery**