Women Leaders in Life Sciences Law 2025 review: Evolving litigation risks in the age of policy uncertainties

The 12th Annual Summit for Women Leaders in Life Sciences Law 2025 (WILS 2025), held July 30-31 in Boston, brought together women from around the globe for forward-thinking discussion on current industry challenges and recent policy changes. Attendees and panelists unpacked recent Executive Orders (EOs) in the US legal responses, and future implications for the life sciences sector.

Several key themes emerged, including the impact of AI, the relevance of compound medications, and the impact of recent EOs on research and development, drug approval timelines, and manufacturer revenues. Given the US administration's policy agenda, companies will need to adapt and assess which elements deserve further emphasis and adjustments.

Artificial Intelligence

→ **AI utilization is increasing in both life science companies and government agencies.**

- **The FDA's use of AI.** The FDA's generative AI tool, Elsa, has encompassed reading, writing, and summarizing information with the intention of assisting FDA employees to work more efficiently. It is reported that this tool has "hallucinated" clinical studies, raising concerns about Elsa's foundation given that data submitted to the agency is not used for AI training purposes.
- **Increased litigation risks from contract disputes.** There are potential litigation risks due to manufacturer use of AI including failing to achieve contract performance representations, indemnification of third-party claims, and FTC enforcement actions for allegedly deceptive claims.
- **Compliance issues may arise from enterprise AI use.** Life Sciences companies need to provide employees with training emphasizing the acceptable use of AI at the corporate versus personal level, and update relevant policies for the type of AI being used.
- **Awareness of AI.** Panelists noted that medical devices may use AI unbeknownst to their patients and physicians (e.g., doctors may be unaware that their patient monitoring systems use AI internally) and that this could lead to product liability claims.

Compounded medications

→ **The use of compounded medications is increasing around the world. These include pharmaceuticals custom-made by licensed pharmacists due to drug shortages and/or to accommodate patients that cannot be treated with approved medications as produced.[1]**

- **New EU measures to facilitate generic/biosimilar entry.** The European Pharmacopoeia mandates that compounding should not substitute for readily available, authorized alternatives, but the recent amendments to EU pharmaceutical legislation fail to explicitly state this.
- **GLP-1 litigation surrounding the use of compounded medications.** Lawsuits are being filed against compounding pharmacies and telehealth companies for allegedly selling unauthorized compounded GLP-1 medications.

[1] See, for example, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

Pricing

→ **Several EOs have targeted pharmaceutical pricing and could lead to unintended (as well as intended) consequences. Relevant EOs include Most Favored Nation (MFN) pricing and Maximum Fair Price (MFP).**

- **MFPs and MFN pricing have the potential to lead to reduced profits for manufacturers.** In the near term, it may be hard for manufacturers to alter their research and development plans and commercial strategies to quickly adapt to forced changes in prices.
- **Reduced revenue and profits are likely to have a chilling effect on R&D and innovation.** Panelists, including CRA's Erin McDermott, noted that with less funds for manufacturers to spend on post-marketing research (research conducted after initial indication approval) there is likely to be a negative impact on indication expansion. In turn, this could lead to fewer transactions such as license agreements and acquisitions of assets.
- **Manufacturers selling drug products in the US have several potential MFN reaction strategies to consider.** These may include: (1) negotiation with benchmark countries to achieve a standardized global price; (2) the adoption of lower reference drug prices in the US; and (3) potential delay, withdrawal, or withholding of launch in some or all benchmark countries to reduce the US price depression that could be associated with MFN.

The Issuance of Complete Response Letters (CRL)

→ **On July 10, 2025, the FDA issued over 200 CRLs with the intent to provide insight on the FDA's decision-making process and to increase transparency.[2] A CRL indicates "that the review cycle for an application is complete and that the application is not ready for approval."[3]**

- **Stock price implications:** Panelists noted the issuance of CRLs can lead to significant decreases in stock prices. Anecdotal evidence included one company's stock price declining by about 75% following the issuance of a CRL.
- **Commercially Reasonable Efforts (CRE) disputes:** Concerns over CRE disputes have grown in light of recent CRLs. Panelists have noted potential increased CRE exposure stemming from personnel changes in the FDA by the new administration. One example provided by the panelists included a company that had fully complied with the prior FDA guidance and correspondence, only to receive a CRL under the new administration.
- **Trade secret concerns:** Pharmaceutical companies raised concerns regarding the potential release of previously undisclosed information within CRLs when they are made public by the FDA, raising concerns over the possibility of revealing proprietary information.

[2] https://www.fda.gov/news-events/press-announcements/fda-embraces-radical-transparency-publishing-complete-response-letters.

[3] https://www.fda.gov/drugs/laws-acts-and-rules/complete-response-letter-final-rule.

Loss of institutional knowledge

→ Unintended consequences of DOGE.

- **Reduction in Force:** Numerous sessions noted general concerns around the cumulative effect of DOGE reducing resources and the "brain drain" that follows; with many senior leadership departures, the institutional knowledge leaves with them. Issues around continuity, best practices, and seamless transitions in leadership during the regulatory process were noted. The reduction in seasoned personnel could lead to approval delays and increased sponsor costs as new personnel get up to speed.

The Use of Expert Witnesses

→ The importance and relevance of the Amended Rule 702.

- **Recent court cases:** Panelists highlighted recent court cases in which Amended Rule 702 was a factor in the court's decision including, *Sprafka v. Medical Device Bus. Servs., Inc., In re Valsartan, No 19-2875, and Eco Factor, Inc. v. Google LLC*. They noted that courts continue to have a gatekeeping role, assuring evidence admitted in a case is both relevant and reliable, and may require a more rigorous assessment by a damages expert before being put in front of a jury. One court found that when the credibility of an expert's damages calculation is properly left to a jury, "a determination of reliability under Rule 702 is an essential prerequisite."
- Key considerations for our clients and experts prior to expert report submission include:
  - Motions to exclude need to be specific to amended changes of Rule 702 given the legal standard.
  - It is beneficial to understand how the court is applying Rule 702 before the expert deposition, as opposed to waiting until the Daubert phase.
  - If testimony is excluded pre-hearing, then it would be expected to be excluded post-hearing.

We invite you to reach out to CRA consultants to share how these themes will impact your litigation strategies. If you need assistance on critical questions for your potential or ongoing litigations, please contact us.

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