PINK SHEET
CITELINE REGULATORY

Quotable: Top Experts On Policy Hot Topics

25 Feb 2025 • By Anabel Costa-Ferreira

The Pink Sheet highlights recent comments and insights from pharma officials and executives on key issues we are covering.

• Source: Shutterstock

"It appears that the [Department of Government Efficiency (DOGE)] rampage did not e surgical cuts and were throwing the baby out with the bathwater in some nces." – A former senior US Food and Drug Administration official on the recent

recalls for staff in the Center for Devices and Radiological Health and the Office of the Chief Counsel, following a week of mass layoffs for FDA probationary employees. **Find out more:** Drug Reviewers And Legal Staff Among Those Called Back to US FDA, But Why?

"As an enabling regulator, we do not wish to keep patients waiting unnecessarily for important new medicines such as personalized immunotherapies." **–** The Medicines and Healthcare products Regulatory Agency's **June Raine** on the development of a streamlined regulatory pathway for individualized cancer mRNA immunotherapies. **Find out more:** UK MHRA Consults On The Way For Personalized mRNA Cancer Therapies

"We will continue to promote drug discovery innovation so that we can provide innovative medicines to the public, while examining the impact of the drug price reforms on pharmaceutical development." **– Takamaro Fukuoka**, of Japan's Ministry of Health, Labour and Welfare on revising the Pharmaceuticals and Medical Devices Act. **Find out more:** Japan Set To Approve Broad Revisions To PMD Act

"Going forward, all companies doing business in India including pharmaceutical companies would need to align data practices for collection of any personal information from individuals including its employees, trial data subjects, business contacts etc." **–** Nishith Desai Associates' **Milind Antani** on India's move to strengthen its data privacy programs and strengthen overall protection of digital personal data. **Find out more:** What India's Digital Personal Data Protection Norms May Mean For Clinical Trials, Big Pharma GCCs

"Practices, previously prevalent in jurisdictions with more sophisticated patent systems like the US or Europe, are now increasingly being observed in emerging markets." **–** The International Generic and Biosimilar Medicines Association's **Archana Jatkar** on patent abuse strategies. **Find out more:** IGBA Picks Apart Innovator Patent 'Gaming Systems'

"I think the communication freeze made it challenging for people to not panic because meetings within less than 24 hours got changed." **– Pamela Gavin**, of the US National Organization for Rare Disorders, on the fear felt in the scientific community following the Trump Administration's early actions aimed at freezing grants and FDA communications. **Find out more:** Rare Disease Community Stressed By US Funding Threats, Communications Freeze

"So far, no company has withdrawn its application as a direct result of a clock-stop extension being denied." **–** The European Medicines Agency on the impact of the stricter measures it has adopted to encourage companies to submit more comprehensive drug marketing applications. **Find out more:** EMA's Tougher Stance On Substandard Filings Shows Early Success

"You cannot just ignore PICOs which are not covered by a clinical trial, you have to explain why the clinical trial does not do that, or why it [doesn't include a certain] comparator." **–** Cencora's **Herbert Altmann** on the questions companies will need to address during the joint clinical assessments conducted under the EU Health Technology Assessment Regulation. **Find out more:** PICO Exercises: A Glimpse Into Future Joint Clinical Assessments Under EU HTA Regulation

"Global regulatory harmonization through joint reviews with other countries and boosting experts for new drug reviews will step up global competitiveness of the Korean pharma industry and provide faster and safer treatment options for patients at home and abroad." **–** Korea Research-based Pharma Industry Association's **Youngshin Lee** on how the country will provide an improved regulatory environment, whilst also working to become a major hub in the global pharma industry. **Find out more:** Korea 'Guide' Program To Speed Select Innovative Products To Market

"From where I sit, the prospects for bold, meaningful change has never been greater…We have a disruptor in chief in President Trump, a new HHS Secretary both committed to overturning the status quo." **–** PhRMA's **Stephen Ubl** on how large pharma companies are betting that Trump will be a win for the industry. **Find out more:** PhRMA Still All In For Trump Despite Chaos Hitting US Health Sector

"Personally, I am of the view that this might be a temporary setback. Even Trump would like to ensure savings for US consumers and patients. We will have to carry on [despite tariffs] if we want to do business, but this kind of a move cannot be sustained." **–** The Indian Drug Manufacturers' Association's **Daara Patel** on the high dependence of the US on Indian generics and concerns about incoming tariffs on pharmaceutical imports. **Find out more:** US Tariffs: With 50% Of US Generics From India, Industry Ponders If MAHA Will Trump MAGA

Additional Topics

Comp

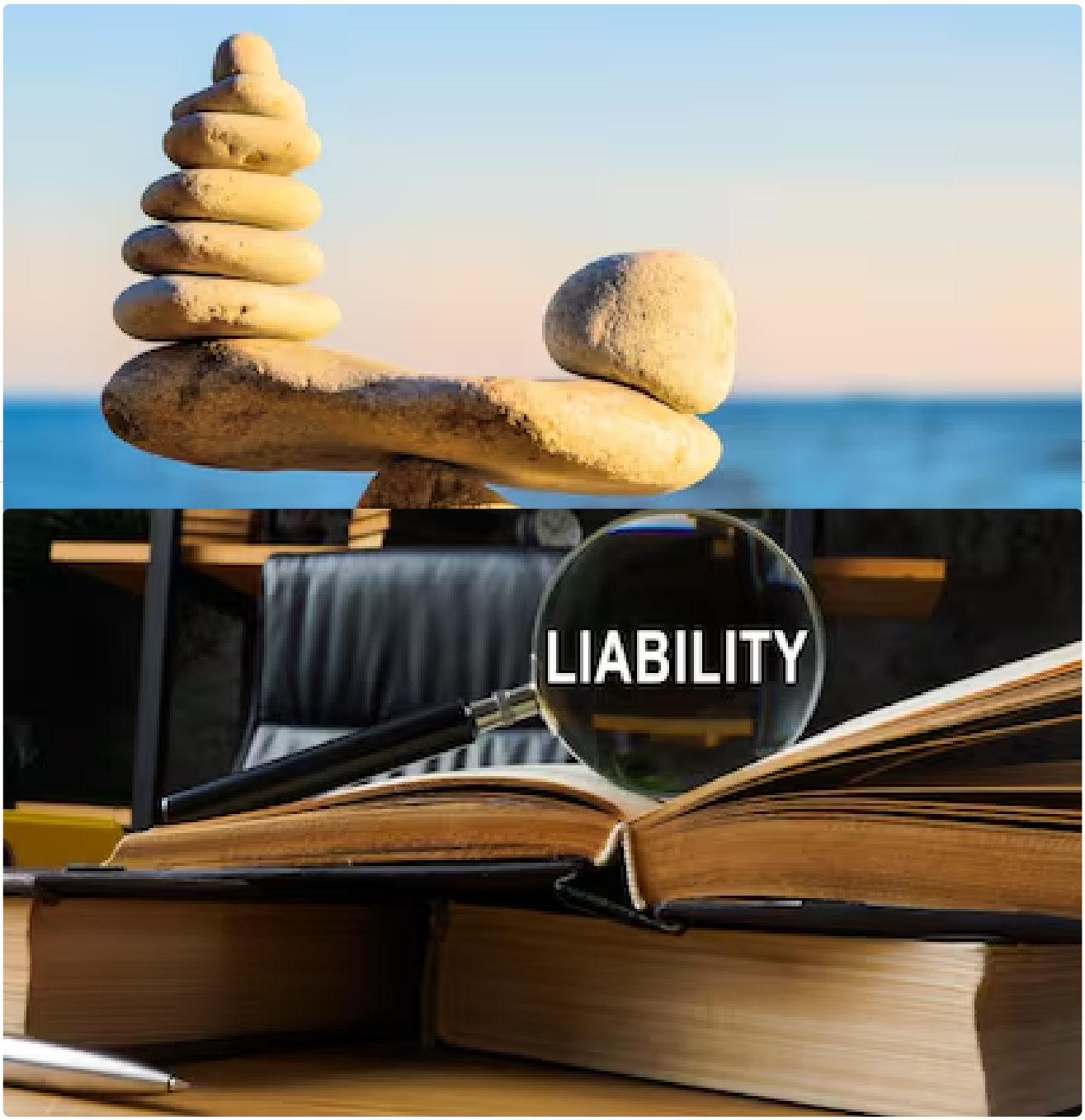
International

More from International

Global Regulators Consider Extending Pilot On Post-Approval CMC Changes After Positive Findings

26 Feb 2025 • By Eliza Slawther

Regulatory authorities from multiple regions are considering extending a pilot project related to collaborative assessments of post-approval chemistry, manufacturing and controls changes, with a focus on the supply of critical medicines.



EU Product Liability Directive Could Spell Trouble For Non-EU Pharma Firms

25 Feb 2025 • By Eliza Slawther

The EU's new Product Liability Directive will make it easier for European consumers to seek compensation relating to defective products even if manufacturers are based outside the bloc. Legal experts caution that this could have substantial implications for pharmaceutical companies.

Quotable: Top Experts On Policy Hot Topics

25 Feb 2025 • By Anabel Costa-Ferreira

The Pink Sheet highlights recent comments and insights from pharma officia executives on key issues we are covering.

See More

More from Pink Sheet

Non-Compliant Pharma Firms Face European Health Data Space Exclusion and Fines

04 Mar 2025 • By Eliza Slawther

Companies that fail to provide patient health data for secondary use when requested under the new European Health Data Space could be fined and also prevented from making access requests from other entities, a European Commission representative says.

EU CHMP Opinions And MAA Updates

04 Mar 2025 • By Neena Brizmohun

This is an update of recommendations from the European Medicines Agency's Committee for Medicinal Products for Human Use on the authorization of new medicines in the EU, and updates on EU marketing authorization changes recommended by the CHMP.

Makary Would Have Wide Leeway To Make GLP-1 Compounding Decisions As US FDA Commissioner

See More

03 Mar 2025 • By Sarah Karlin-Smith

FDA Commissioner nominee Martin Makary can comply with US ethics laws while weighing in on the contentious GLP-1 compounding debate, despite recently exiting a company that connects patients with compounded semaglutide and an ophthalmology compounding business.