The Nucleus: Life Sciences Regulation and Enforcement Updates

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Takeaways: 'FDA Watch' Series Examines the Intersection of Regulatory Operations, M&A and Litigation and the Resulting Shifted Landscape

Executive Summary

- **What's new:** As part of the "FDA Watch" podcast series, legal and industry panelists examined how rapidly evolving FDA policy is reshaping the business and legal landscape across the life sciences and consumer products sectors.
- **Why it matters:** Regulatory uncertainty is now a central driver of valuation, disclosure, compliance strategy, litigation exposure and transaction execution for life sciences, medical devices, foods and consumer products companies.
- **What to do next:** Companies can take steps to stress-test regulatory assumptions, document substantiation and compliance efforts, evaluate disclosure controls, map privacy and cybersecurity risk, and integrate legal and business teams around a common risk framework.

Introduction – Regulatory Uncertainty Is the Driver

Across four parts of the "FDA Watch" podcast series featuring Skadden partners and counsel, legal and industry panelists convened between March and June 2026 to examine how rapidly evolving Food and Drug Administration (FDA) policy is reshaping the business and legal landscape across the life sciences and consumer products sectors. Although the issues varied by industry, a common theme emerged: Regulatory uncertainty is no longer a background concern; it is now a central driver of valuation, disclosure, compliance strategy, litigation exposure and transaction execution.

Life sciences, medical devices, foods and consumer products companies are confronting a regulatory environment marked by informal policymaking, uneven enforcement, expanding state-law activity and growing scrutiny from private litigants, investors and counterparties. In many cases, the practical challenge is not simply determining what the rules are today, but assessing how quickly they may change — and whether agencies, plaintiffs, business partners and the market will interpret those changes differently.

Set out below are key themes from the series and practical considerations for companies navigating this environment.

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Part 1 – Pharmaceuticals: Navigating Uncertainty in the New FDA Era

Skadden Participants:
Rachel Turow / Raquel Fox / Kendall Ickes

Guest: Tess Cameron, managing director on the Venture Team at RA Capital Management

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Rapidly shifting and informal policies: The discussion on pharmaceuticals focused on the challenges created by FDA's increasingly consequential policy announcements outside traditional notice-and-comment rulemaking. Panelists noted that initiatives relating to expedited approvals, priority review vouchers and single-trial approval pathways may offer the promise of faster development timelines and reduced regulatory burden. However, these policies can be difficult to rely on where they are not grounded in durable guidance or formal rulemaking and may be modified or withdrawn with little notice.

Investment and development impacts: That uncertainty is particularly significant for early-stage and single-asset biotechnology companies. From an investor perspective, the ability to value development programs depends heavily on precedent, predictability and an understood path to approval. Informal statements suggesting that a single Phase 3 study may be sufficient for approval are meaningful only if sponsors and investors also understand the evidentiary expectations that will apply in practice. If the statistical or clinical threshold is raised implicitly, the perceived efficiency gains may disappear, complicating both investment decisions and development strategy.

The effects of drug pricing initiatives on geographic commercialization strategies: The panel also considered the potential downstream effects of FDA's more expansive posture in areas such as drug pricing. Discussion of most-favored-nation-type pricing approaches underscored how U.S. policy shifts can affect launch sequencing, ex-U.S. commercial arrangements and royalty negotiations. Transactionally, these developments are already influencing how companies structure partnerships and evaluate geographic commercialization strategies.

Layered scrutiny of disclosure obligations: With Securities Exchange Commission (SEC) leadership continuing to emphasize material disclosures, public companies in the life sciences sector should expect scrutiny not only from the Division of Corporation Finance, but also from the enforcement side.Key areas of focus include:

- Risk factor drafting.
- Forward-looking statement protections.
- Careful MD&A discussion of regulatory developments.
- Coordinated review of FDA-related disclosures across legal, regulatory and investor relations functions.
- Controls around material nonpublic information.

Panelists also highlighted a developing issue for sponsors: FDA's publication of Complete Response Letters. That shift may create heightened disclosure and communications risks, particularly when companies have spoken publicly about approval timing, regulatory posture or likely outcomes. Companies therefore may want to avoid overly definitive statements and ensure that legal, disclosure and crisis communications teams are prepared to respond quickly.

Practical Takeaway

For pharmaceutical companies, cross-functional coordination is now essential. Regulatory strategy, public company disclosure, government affairs, investor communications and M&A planning can no longer operate in parallel silos where FDA policy itself is moving quickly and sometimes unpredictably.

Part 2 – Medical Devices: Gray Areas, Privacy Perils and AI's Regulatory Labyrinth

Skadden Participants:
Rachel Turow / Bill Ridgway / Michelle Gasaway

Guest: Carolyn Bruguera, vice president and general counsel at the Medical Device Manufacturers Association

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Regulated versus free-range: The medical device discussion centered on understanding the difficult line between regulated devices and products that may remain outside FDA oversight. For wellness companies in particular, the decision whether to seek 510(k) clearance is often strategic rather than purely legal. FDA clearance may improve reimbursement opportunities, bolster credibility and support commercialization. Remaining outside the regulatory framework, however, may preserve speed, product flexibility and operational simplicity.

Integrated strategy: From a financing and transaction perspective, companies should proactively anticipate complex regulatory, diligence and disclosure issues in preparing for a public offering, private financing or other transaction. Investors and counterparties want a coherent explanation of how a company's regulatory approach fits into its broader business plan and growth story, product road map and reimbursement strategy. Preparing for, and having answers to, these questions is important; uncertainty can lead to execution issues.

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Companies that have not thought through these questions in advance may find themselves disadvantaged in accessing capital markets or in other financing or transaction discussions.

Technology and privacy concerns: The conversation also highlighted the growing complexity of AI-related regulation in the device space. Manufacturers are confronting not only FDA considerations, but also HIPAA, Federal Trade Commission (FTC) oversight and an expanding patchwork of state privacy and AI laws. The practical message was clear: Companies must assess legal compliance, business model risk and go-to-market strategy together, rather than sequentially.

Cybersecurity and privacy emerged as especially significant areas of exposure. Panelists noted that the Department of Justice's (DOJ's) Civil Cyber-Fraud Initiative continues to create risk for life sciences companies that allegedly misrepresent cybersecurity capabilities or compliance. Importantly, the risk is not limited to actual breaches. Statements to the government, customers or counterparties regarding security posture may themselves become the basis for whistleblower claims, investigations, settlements and reputational harm.

Privacy compliance presents a similarly acute challenge. Companies collecting health or wellness data are increasingly expected to understand:

- What categories of data they collect.
- Where that data flows.
- What laws apply across relevant jurisdictions.
- How AI tools interact with that data.
- Whether the underlying business model remains viable under narrowing legal standards.

Panelists observed that privacy issues are increasingly surfacing as transaction-critical concerns. In diligence, outdated privacy policies, unclear data maps and uncertain legal theories around data use can materially impair deal value — and in some cases cause acquirers to walk away entirely.

Practical Takeaway

For device and digital health companies, privacy, cybersecurity and AI governance are no longer peripheral compliance issues. They are core diligence, valuation and enforcement matters to build into product design and business planning from the outset.

Part 3 – Foods: Resource Starvation, Voluntary Compliance and the Plaintiff's Bar Filling the Gaps

Skadden Participants:
Rachel Turow / Milli Hansen / Daniel Luks

Guest: Douglas Stearn, principal at Canal Row Advisors

Listen

Limited agency resources: The foods discussion highlighted the mismatch between an ambitious policy agenda and limited agency resources. Panelists described an FDA food program facing long-standing personnel and budget constraints even as it takes on new priorities, including new regulation for food dyes, registration of dietary supplement ingredients, environmental contaminants and broader nutrition-related policy initiatives. In that environment, FDA may rely more heavily on informal measures, voluntary compliance and coordination with states, rather than traditional rulemaking alone.

Missing granularity in standards: That dynamic creates meaningful uncertainty for industry. Stakeholders often receive policy signals without the scientific detail, enforcement road map or clear legal standards needed to make confident compliance decisions. Panelists noted that more transparency — including on environmental hazards such as PFAS, scientific rationale and field activity — would help companies plan more effectively.

Litigation horizon: A central theme of the discussion was that regulatory ambiguity creates litigation opportunity. Where FDA leaves gaps through enforcement discretion or policy statements that do not alter underlying statutory definitions, plaintiffs' lawyers and state attorneys general may move quickly to test new theories. FDA's evolving position on petroleum-based dyes, for example, may give companies certain practical flexibility, but it does not necessarily create a litigation safe harbor for marketing claims such as "no artificial colors."

The plaintiff's bar is also continuing to develop more sophisticated theories around ultra-processed foods and other nutrition-related claims. While causation remains a substantial hurdle in many of these cases, panelists cautioned that new public statements by regulators or policymakers could become the basis for the next wave of consumer class actions.

Expanded deal diligence regarding enforcement: From an M&A perspective, uncertainty in the food space is affecting diligence and risk allocation. Buyers are being forced to conduct earlier and more extensive diligence around regulatory exposure, state-law developments and changing enforcement priorities.

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Sellers, in turn, are well-served by performing their own presale assessment to identify areas that may affect valuation or complicate negotiations.

Practical Takeaway

Food companies should cannot assume that compliance with existing federal requirements alone will be sufficient. **In the current environment, state enforcement risk and private litigation risk may develop faster than federal rulemaking.**

Part 4 – Consumer Products: MOCRA's Self-Regulatory Reality, Class Action Sophistication and AI's Next Frontier

Skadden Participants:
Rachel Turow / Amy Van Gelder / Brett Fleisher

Guest: Katherine Armstrong, deputy director for the National Advertising Division of BBB National Programs

Listen

Overlapping regulation: The consumer products discussion emphasized that this sector often sits at the intersection of multiple regulatory regimes, even when FDA is not taking an aggressive enforcement posture. Panelists noted that cosmetics and personal care companies, for example, continue to operate in a space where the Modernization of Cosmetics Regulation Act of 2022 (MOCRA) has established important obligations, but where FDA implementation and active oversight may remain limited in the near term.

In that setting, panelists stressed the value for companies of focusing on substantiation, manufacturing controls and strong supply chain relationships. Even where FDA activity is limited, those measures can materially improve litigation defensibility and transaction readiness.

Litigation trends: Litigation exposure in the sector remains significant. Panelists identified two major trends:

- Consumer class actions targeting "natural," "clean," "gut-healthy" and similar marketing claims, as well as origin claims such as "Made in USA."
- Product liability and toxic tort claims tied to contaminants and long-term exposure allegations.

These cases are increasingly supported by independent testing and more sophisticated factual development by plaintiffs' firms. State attorneys general are also active, and state-level ingredient restrictions continue to create a fragmented compliance landscape.

Testing and documentation: A consistent theme across the conversation was the importance of documentation. Companies need to maintain robust internal procedures for testing, supply chain oversight and claim substantiation, and will want to preserve contemporaneous records supporting both product safety and marketing representations. Those materials can be critical in defending consumer claims and responding to diligence requests in a sale or financing process.

Claim substantiation: Advertising substantiation emerged as another regulatory focal point for consumer products. From the National Advertising Division's perspective, the threshold inquiry remains straightforward: What claim is being made, and what evidence supports it? Health-related claims require competent and reliable scientific evidence, while superiority, endorsement and "doctor recommended" claims must likewise be supported by appropriate substantiation.

AI-specific risk: The panel also discussed AI as an emerging area of risk. Companies increasingly use AI tools in marketing, customer engagement and product positioning, and those uses may create new exposure. AI chatbots responding to consumer questions, for example, may generate statements about products that "go beyond" approved or supportable claims. Similarly, "AI-enabled" product claims must be substantiated, and influencer marketing remains subject to the principle that influencers cannot make claims that the brand itself could not lawfully make.

Practical Takeaway

For consumer products companies, documentation, substantiation and monitoring are increasingly central to both litigation defense and enterprise value. AI-enabled marketing and consumer engagement tools need to be reviewed with the same care as traditional advertising claims.

Conclusion

The FDA and adjacent enforcement landscape continues to evolve in ways that are affecting not only compliance obligations, but also financing strategy, transaction terms, disclosure practices and litigation risk for life sciences and consumer product companies. For companies operating in regulated or consumer-facing sectors, the key challenge is no longer simply keeping pace with formal legal developments. It is building the internal discipline to respond to informal policy shifts, fragmented enforcement and increasingly sophisticated scrutiny from investors, counterparties, regulators and the plaintiffs' bar.

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In this environment, the best-positioned companies will be those that act early by stress-testing regulatory assumptions, documenting substantiation and compliance efforts, evaluating disclosure controls, mapping privacy and cybersecurity risk, and integrating legal and business teams around a common risk framework. As the "FDA Watch" series outlines, the intersection of regulatory, M&A and litigation considerations is only becoming more significant and more immediate.

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