

Top 10 Healthcare and Life Sciences Issues to Watch in 2024

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Introduction

Throughout 2023, life sciences and healthcare industry stakeholders contended with growing economic and financial uncertainties, heightened state and federal enforcement efforts and an increasingly complex regulatory environment. These challenges are likely to continue in 2024, and stakeholders that proactively address these challenges will be best positioned to manage risk in an uncertain environment. We summarize below some of the most notable developments expected to impact healthcare and life sciences in the coming year.

Growing Number of States Enact Healthcare Transaction Oversight Laws

State lawmakers are expanding their healthcare transaction review and approval authorities, creating an increasingly complex and potentially restrictive regulatory environment. Intended to address competition, access and cost in the healthcare industry, a growing number of states—including California, Connecticut, Illinois, Massachusetts, Minnesota, Nevada, New Hampshire, New York, Oregon, Rhode Island and Washington—have enacted laws and regulations requiring certain healthcare entities to provide written notice (which can include detailed descriptions of the transaction and transacting parties) to the relevant state authority for comprehensive review, and potentially approval, prior to closing.

Emblematic of this trend is California’s recently enacted California Health Care Quality and Affordability Act, which will require transacting parties to provide notice to the newly-formed Office of Health Care Affordability (“OHCA”), which could then (i) collect and report data that are informative to the legislature and the public regarding healthcare expenditures and cost trends and (ii) develop data-informed policies and enforceable cost targets. Beginning on January 1, 2024, a “health care entity”—which includes payers, providers, healthcare delivery systems, pharmacy benefit managers and

other entities that “perform the functions” of such entities—must provide OHCA with written notice of any “material change” that will occur on or after April 1, 2024. Adding to the regulatory complexity, state statutes vary widely as to which entities and transactions are subject to oversight and the timelines for review/approval, and whether they require notice or affirmative consent from state regulators. Regardless, such state reviews/approvals can be incredibly costly and time-consuming for transacting parties given the vast scope of information that must typically be submitted with the notice. Further, sufficiently large transactions are likely to trigger review in multiple states and at the federal level; the ability in certain states to toll the review period during concurrent review by other reviewing entities can result in significantly delayed closing dates.

As states expand their regulatory authority over healthcare transactions, healthcare entities must be aware of the numerous notice requirements that may be triggered, plan for lengthier transaction timelines and consider the types of sensitive information they may be required to disclose under new state review laws.¹

Revised Federal Regulatory Guidance Creates Uncertainty for Healthcare Mergers

In his remarks at the Capitol Forum Health Care Competition Conference in October 2023, Deputy Assistant Attorney General Andrew Forman noted, “there is little doubt that key aspects of competition in the healthcare industry are broken . . . [c]ompanies inking healthcare deals with potential antitrust issues should continue to expect close scrutiny.” Mr. Forman noted that important issues for healthcare competition-related enforcement include questions about provider/payer consolidation, roll-ups, data accumulation and a trend toward a more concentrated market structure.

These remarks came toward the close of a year during which the Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) (collectively, the “agencies”) took several measures to translate the Biden administration’s tough antitrust rhetoric into policies with significant impact on consolidation within the healthcare industry. In February, the DOJ’s Antitrust Division (the “Division”) announced its withdrawal of three “outdated” antitrust policy statements (issued jointly with the FTC) related to enforcement in health care markets. Among other things, the policy statements addressed the provision of “safety zones” for hospitals involved in mergers, joint ventures and purchasing arrangements and exchanges of price and cost information.

¹ For prior Debevoise Updates on state healthcare transaction oversight laws, *see* Debevoise Update: California Regulators Publish Draft Regulations on Health Care Pre-Transaction Notice Requirements (Aug. 29, 2023), available [here](#); Debevoise Update: New York Seeks Review and Approval Authority Over Certain Healthcare Transactions (March 7, 2023), available [here](#).

The Division concluded that as a result of a changing health care landscape, the statements provided “overly permissive” guidance on certain subjects, such as information sharing, that would be better addressed with a case-by-case enforcement approach. The FTC followed suit in July, withdrawing two of the three policy statements and noting that it will evaluate mergers and conduct in health care markets on a case-by-case basis.

Over the summer, the agencies announced important changes to the merger review process. In June, the agencies released a proposed rule to significantly broaden the range of documents that parties to a merger must submit to the government in a Hart-Scott-Rodino (“HSR”) filing. In July, the agencies jointly released updated draft merger guidelines, which for the first time address private equity roll-up strategies, transactions involving multi-side platforms and the protection of labor. The new guidelines, which lower the bar for when horizontal mergers will be presumptively illegal, allow the agencies significantly increased flexibility in objecting to a transaction as anticompetitive. The final versions of the merger guidelines—mostly unchanged from the draft guidelines—were issued on December 18, 2023.

Collectively, these policies create uncertainty for healthcare companies, including in the M&A context. The removal of safety zones in healthcare mergers eliminates a source of predictability and suggests potential scrutiny of transactions previously within the safety zones. More restrictive merger guidelines, including between vertically related parties, may make it more difficult for large insurers and hospitals to complete acquisitions of physician groups, specialized medical chains and home health and hospice providers. Similarly, roll-up strategies, even involving acquisitions below the HSR threshold, are subject to increased scrutiny under the new merger guidelines’ emphasis on preventing a “pattern or strategy of multiple acquisitions in the same or related business lines.” The guidelines’ focus on labor protection indicates that regulators may analyze the effects of a healthcare transaction on wages and bargaining power for doctors, nurses and other healthcare professionals. Agency guidelines provide the industry a glimpse into how the agencies evaluate proposed transactions, but lack the force of law. We anticipate that as the agencies’ enforcement policies are tested in court, some clarity is likely to emerge in what has become an increasingly uncertain antitrust landscape.

Increased Enforcement Ahead as the Federal Trade Commission Targets Health Information

The digitization of healthcare has spurred exponential growth of direct-to-consumer health technologies that collect large quantities of personal health data. In response to

the proliferation of mobile health apps, the FTC issued a 2021 policy statement² affirming that health apps or connected devices that collect consumer health information (e.g., fertility, fitness, glucose levels and other health data) that are not regulated by the Health Insurance Portability and Accountability Act (“HIPAA”) are considered vendors of personal health records (“PHRs”) for purposes of the Health Breach Notification Rule (“HBNR”). HBNR requires PHR vendors and PHR-related entities to notify affected consumers, the FTC and, in certain scenarios, the media, when consumers’ identifying health information is disclosed without consent.³ Companies that fail to comply with HBNR could be subject to penalties of up to \$50,120 per violation; the FTC may also seek to impose a blanket prohibition on future data sharing.

Further to its statement that enforcement of HBNR is a top priority for the FTC, in May 2023, the agency issued a Notice of Proposed Rulemaking and a parallel Request for Comment on proposed changes to HBNR that would clarify both its application and the circumstances that constitute a breach of security (the “Proposed Rule”).⁴ The Proposed Rule, among other things, defines health data broadly: the FTC notes that its new definition “covers traditional health information (such as diagnoses or medications), health information derived from consumers’ interactions with apps and other online services (such as health information generated from tracking technologies employed on websites or mobile applications or from customized records of website or mobile application interactions), as well as emergent health data (such as health information inferred from non-health-related data points, such as location and recent purchases).”⁵

The Proposed Rule follows several high-profile HBNR enforcement actions,⁶ signaling the agency’s intent to use HBNR—long considered a dormant tool—to protect non-HIPAA regulated health data and shape health technology data practices. Given the FTC’s increasingly aggressive approach, companies and other stakeholders should carefully evaluate their exposure under HBNR, determine what health information is being shared with third parties and whether proper consents are being collected, and emphasize a compliance-focused approach to health data collection and sharing.

² Statement of the Commission On Breaches by Health Apps and Other Connected Devices (Sept. 15, 2021) (available [here](#)).

³ Health Breach Notification Rule: The Basics for Business (Jan. 2022) (available [here](#)).

⁴ FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule (May 18, 2023) (available [here](#)).

⁵ Text of the Proposed Rule, (June 9, 2023) (available [here](#)).

⁶ An overview of 2023 enforcement actions is available [here](#).

Continued Growth in the Use of Contingent Value Rights in Life Sciences M&A to Bridge the Valuation Gap

Event-driven contingent value rights (“CVRs”) have grown in popularity as a key method of bridging valuation gaps between buyers and sellers. CVRs provide additional potential value to selling stockholders if certain future events occur. Within the life sciences sector, triggering events often include achieving pre-set sales or regulatory milestones (e.g., approval of a premarket approval application, receiving clinical recommendations) by a specified date. The use of CVRs in public biopharma M&A transactions has significantly increased in recent years. Of the 43 such transactions announced in 2023, 47% included a CVR, more than double the 21% rate at which CVRs were utilized in deals in 2022 and more than triple the 13% CVR use in 2021; over the five-year period prior to 2021, only 19% of public biopharma deals included a CVR. The instrument has been even more prevalent in smaller transactions. More than half of biopharma acquisitions announced over the past five years in which the target had an enterprise value of less than \$1 billion included a CVR, compared to less than 10% for transactions above that threshold.⁷

While CVRs help bridge valuation gaps, they may also elevate the risk of litigation and increase the complexity of negotiations. For example, in 2019, Sanofi spent \$315 million to settle a lawsuit brought by former Genzyme stockholders over allegations that Sanofi held back its efforts to secure approval of Genzyme’s Lemtrada in order to avoid a CVR payment.⁸ More recently, Bristol Myers Squibb (“BMS”) faced, and ultimately prevailed in dismissing a \$6.4 billion lawsuit that alleged BMS intentionally failed to obtain approval of Celgene’s Breyanzi prior to the CVR milestone date.⁹ Parties may try to mitigate the risk of litigation arising from CVR use by clearly defining revenue milestones. Further, in certain situations tying a CVR issuer’s “effort” to a quantitative measure like amount of capital or number of employees dedicated to the project may help reduce uncertainty compared to using even a carefully-worded definition of “commercially reasonable effort” or “diligent efforts” that evaluates the CVR issuer’s conduct by a less objective standard of a theoretical peer company. In light of potential litigation risk, companies may even try to explicitly disclaim an efforts obligation, although of the 15 biopharma transactions announced since the start of 2019 in which a CVR agreement was made public, only one included such an explicit disclaimer. As CVRs continue to proliferate in biopharma transactions, potential buyers should proactively address the risks that come with the use of the instrument.

⁷ DEALPOINT DATA, <https://www.dealpointdata.com/> (last visited January 2, 2024).

⁸ SANOFI, *Sanofi Announces Settlement Agreement Related to Contingent Value Rights (CVRs) Litigation* (Oct. 31, 2019), <https://www.sanofi.com/en/media-room/press-releases/2019/2019-10-31-03-30-00-1938440>.

⁹ Jonathan Stempel, *Bristol Myers Wins Dismissal of a \$6.4 Billion Lawsuit over Cancer Drug Delay*, REUTERS (Mar. 1, 2023, 6:13 PM) <https://www.reuters.com/legal/bristol-myers-wins-dismissal-lawsuit-over-celgene-drugs-2023-03-01/>.

Strong Biopharma Deal Volume Likely to Fuel M&A Activity in 2024

Despite lower overall deal volume across the healthcare and life sciences sector, biopharma M&A activity continued to drive higher deal volume and value throughout 2023. While overall transaction volume is unlikely to significantly accelerate absent greater availability and lower cost of capital, relatively strong deal volume is likely to continue into 2024 due to two main factors. First, the sector is closing in on a “patent cliff,” the point at which patents for drugs that account for a significant share of firm sales are set to expire; as a result, companies are likely to tap into the M&A market to help refill their pipelines of later-stage drugs. Second, many early-stage biotech companies may continue to struggle to access financing on attractive terms, making them more willing sellers to better-capitalized acquirors.

Many large cap pharma companies are open to small to mid-size acquisitions, whether through joint ventures, R&D collaborations, licensing or full acquisitions, and these smaller transactions are likely to account for a larger share of inorganic growth. Potential acquirors may pursue a barbell strategy, focusing on early stage high-potential innovative products, or on largely de-risked late stage assets that would be able to almost immediately add accretive growth. As the Biden administration’s antitrust policies continue to be implemented, industry participants must account for various risks along the continuum. In addition to renewed scrutiny over large pharmaceutical mergers, the FTC’s focus on protecting “potential entrants” to a market indicates that even small acquisitions may be subject to scrutiny. Regardless of what acquisition strategy biopharma companies pursue, given the current administration’s aggressive stance on lowering prescription drug costs, potential acquirors should remain mindful of regulatory hurdles.

IRA’s Drug Price Negotiation Provisions Face Looming Litigation Uncertainty in 2024

2024 is likely to be a pivotal year for the drug price negotiation provisions of the Inflation Reduction Act (“IRA”), which was enacted by President Biden in 2022.

As we discuss [here](#), the IRA gives the Centers for Medicare and Medicaid Services (“CMS”) the ability to coerce significant price reductions of certain drugs. This past August, CMS announced the first 10 drugs selected for Part D price negotiations in 2026. If all goes as planned, CMS is set to submit initial offers to manufacturers by February 1, 2024. CMS’s initial offers start the clock for negotiations, which are supposed to conclude by August 1, 2024. At that point, a manufacturer that fails to reach an agreement with CMS on the maximum fair price may be subject to a punitive excise tax.

The IRA's drug negotiation provisions may be stayed—and ultimately invalidated—depending on the outcome of 10 separate challenges to these provisions filed by innovator drug manufacturers and others. These lawsuits, which were filed over the course of 2023, have contended that the IRA's drug price negotiation provisions are unconstitutional because, among other things, they constitute a deprivation of property rights, violate free speech and/or violate, through their implementation by CMS, the Administrative Procedures Act. These challenges have raised credible arguments that are likely to receive careful consideration by the courts. Should any of these courts issue an injunction, the negotiation process could be halted and the negotiations invalidated. At minimum, there is likely to be uncertainty until the appellate courts—and possibly the U.S. Supreme Court—rule on the permissibility of these provisions.

Rapidly Evolving Regulatory Oversight of Artificial Intelligence in Healthcare and Life Sciences

As artificial intelligence (“AI”) becomes increasingly prevalent in the healthcare and life sciences industries, regulators like the Food and Drug Administration (“FDA”) and FTC are rapidly evolving their regulatory frameworks.

The FDA has been focused on building a framework for regulating the use of AI in medical devices, drug development and manufacturing. The agency's traditional medical device regulatory framework is based on the approval of static, unchanging devices. Modifications to certain aspects of the FDA medical device regulatory regime are, therefore, required to adapt to AI devices, which benefit from their ability to learn dynamically and adapt based on new data. Even in the absence of an established framework for AI medical devices, over 150 AI-enabled medical devices were added to the FDA's public registry between August of 2022 and July of 2023 alone. The FDA issued draft guidance in March of 2023, which promoted the use of “predetermined change control plans” (“PCCPs”) to ensure flexibility without sacrificing safety and efficacy; PCCPs would be included with premarket submissions and describe anticipated modifications to AI-enabled medical devices and methods for implementation, allowing for subsequent modifications without the need for additional submissions to the FDA for approval.¹⁰ The United States is not alone in the use of PCCPs: the FDA recently

¹⁰ Debevoise In Depth: Artificial Intelligence and the Life Sciences Industry: FDA and FTC Regulatory Update (May 16, 2023), available [here](#); Debevoise In Depth: Artificial Intelligence in Healthcare: Balancing Risks and Rewards (July 31, 2023), available [here](#).

joined with Canadian and UK regulators to identify five guiding principles for PCCPs that focus on monitoring AI performance and managing associated risks.¹¹

In drug discovery, pharmaceutical companies are increasingly relying on AI for a variety of applications, including study participant recruitment, real-time safety monitoring and data collection. Efficiencies introduced by leveraging AI in the clinical trial process have the potential to significantly shorten drug development time, ultimately reducing costs. In May of 2023, the FDA released a discussion paper¹² on the use of AI in drug discovery that, while supportive of these emerging uses of AI, highlighted the FDA's concern with AI's lack of explainability and the myriad data issues the technology may present (e.g., privacy, amplification of pre-existing biases, cyberattacks). Likewise, AI has the potential to optimize pharmaceutical manufacturing by monitoring processes and product quality, detecting faults and examining deviation reports to identify priority areas for improvement. The FDA issued a separate discussion paper regarding AI use in drug manufacturing in March of 2023, which highlighted similar issues of explainability and data safety and security.¹³

The FTC is also monitoring advertisements for AI-enabled medical devices, most recently opining that the federal government cannot rely on AI companies to self-regulate and affirming the FTC's intent to challenge deceptive representations of AI-enabled technology.¹⁴ In particular, the agency has identified the following areas of focus for enforcement: (i) exaggerations regarding what AI products can do; (ii) promises that AI-enabled products outperform non-AI products; (iii) the identification of foreseeable risks; and (iv) whether products actually use AI at all.¹⁵ In light of the rapid development and implementation of AI, we expect the agency to ramp up its scrutiny and enforcement of AI marketing.

Building on the regulatory concerns surrounding AI use in healthcare and life sciences, President Biden recently issued an Executive Order on AI with ramifications for the healthcare and life sciences industries.¹⁶ The Department of Health and Human Services ("HHS") has been tasked with crafting a strategy to maintain an appropriate level of security and quality for AI-enabled tech and establishing an AI safety program designed to regulate AI throughout the different phases of the drug development process. Given

¹¹ FDA's five guiding principles draw on overarching principles from its 2021 statement on Good Machine Learning Practice for Medical Device Development. The five guiding principles are available [here](#).

¹² FDA's discussion paper is available [here](#).

¹³ FDA's discussion paper is available [here](#).

¹⁴ *See A Progress Report on Key Priorities, and a Warning on AI Self-Regulation*, available [here](#).

¹⁵ FTC Business Blog, *Keep Your AI Claims in Check* (Feb. 27, 2023), available [here](#); Debevoise Update: *Risks of Overselling Your AI: The FTC is Watching* (Mar. 6, 2023), available [here](#).

¹⁶ The executive order is available [here](#).

the quick timeline to comply with its directives¹⁷ and the intent of the current administration to increase regulatory oversight of AI under its existing authority, the AI regulatory landscape for healthcare and life sciences companies could dramatically change in the coming year. Companies and investors using AI should be carefully monitor these developments and actively engage with regulators to ensure compliance with this complex regulatory environment.

Federal Regulators Will Continue Enhanced Scrutiny of Medicare Advantage

With the number of eligible beneficiaries enrolled in Medicare Advantage plans skyrocketing (from 19% in 2007 to 51% in 2023), both CMS and the DOJ have focused their attention on the operation of such plans.

CMS has indicated it is likely to focus on particular areas of concern in 2024, such as:

- Competition: CMS has expressed concern that a significant percentage of Medicare Advantage beneficiaries are enrolled in plans operated by a small number of Medicare Advantage Organizations (“MAOs”). CMS is focused on perks that certain MAOs are providing to agents, which may lead them to drive beneficiaries to particular plans.
- Prior Authorization: MAOs, like all managed care providers, use prior authorization as a tool to avoid spending on medically unnecessary services. CMS is concerned that some MAOs are using prior authorization to improperly avoid paying for medically *necessary* services, particularly in disadvantaged communities.
- Behavioral Health: Consistent with a focus by state and federal regulators on mental health needs, CMS wants to ensure that Medicare Advantage beneficiaries have appropriate access to behavioral health providers.
- Advertisements: Certain MAOs have been criticized for running high-profile advertisements that are allegedly misleading. CMS recently put rules into effect that are aimed at ensuring truthful advertising.

The DOJ is likely to continue addressing allegations of fraud committed by MAOs through the False Claims Act. As illustrated by a recent nine-figure settlement involving an MAO, the DOJ is particularly focused on alleged schemes aimed at increasing risk adjustment payments from CMS via the use of inaccurate diagnostic codes (i.e.,

¹⁷ The executive order gives HHS 180 days to develop its security and quality strategy and one year to establish its AI safety program.

reporting that members are sicker than they actually are in an effort to receive additional payments). MAOs should review their existing procedures in light of the heightened scrutiny.

The Food and Drug Administration Changes Course and Asserts Regulatory Authority over Laboratory Developed Tests

On October 3, 2023, the FDA issued a proposed rule that, if finalized, would significantly increase the agency's regulatory oversight over laboratory developed tests ("LDTs").¹⁸

LDTs are a subset of *in vitro* diagnostic products that are designed, manufactured and used within a single clinical laboratory for a variety of clinical purposes, including measuring or detecting substances, providing information about patients' health and diagnosing disease. For decades, the FDA has exercised enforcement discretion and, as a general rule, has not required LDTs to comply with medical device regulatory requirements, despite the agency's assertion (at various points in time) that it has jurisdiction over LDTs.

In response to the rapid growth of the industry (currently valued at over \$10 billion) and pervasive use of LDTs in medical care, the FDA has become increasingly concerned with the accuracy of LDTs in the absence of more rigorous oversight and testing, citing several studies in the proposed rule that call into question the efficacy of such tests.

In the wake of failed efforts by Congress to enact statutory requirements governing the FDA's regulation of LDTs,¹⁹ the FDA's proposed rule seeks to fill the regulatory gap by: (i) regulating LDTs as medical devices under its existing authority, regardless of where they are manufactured and (ii) phasing out the agency's historic enforcement discretion policy. If finalized, the proposed rule would require manufacturers of certain types of LDTs to comply with the myriad regulations applicable to medical devices (e.g., premarket review, quality system regulation, medical device reporting, corrections or removals reporting, establishment registration and product listing, product labeling requirements). The public comment period closed on December 4, 2023, and the FDA received over 2,000 submissions from various stakeholders.

¹⁸ 88 Fed. Reg. 68006 (Oct. 3, 2023), available [here](#).

¹⁹ Congress failed to pass the Verifying Accurate Leading-edge IVCT Development ("VALID") Act as part of the 2023 Consolidated Appropriations Act. The VALID Act would have created a modern regulatory framework designed specifically for diagnostic tests and allowed FDA to oversee the development and validation process, rather than just regulating the tests themselves.

While some parties believe additional oversight would enhance patient protection, clinical labs argue that the proposed rule is premature and would hinder clinical decision-making, leading to worse health outcomes for patients. Further, clinical labs contend FDA lacks statutory authority to regulate LDTs under its medical device authority, arguing, among other things, that LDTs are already regulated by CMS under the Clinical Laboratory Improvement Amendments; given the unique level of risk and complexity associated with LDTs, there is support for a new regulatory paradigm specific to LDTs, much like the FDA's distinction between over-the-counter and prescription drugs.

FDA has indicated it expects to finalize the proposed rule in 2024 and, pending any legal challenges, clinical labs, investors and industry stakeholders should ensure that compliance programs are adequately equipped to handle the regulatory transition.

SCOTUS to Hear Chevron Doctrine Challenge

In 2024, the Supreme Court will hear two cases challenging traditional judicial deference to federal agencies—*Loper Bright Enterprises v. Raimondo* and *Relentless Inc. v. Department of Commerce*. The current Court has not hesitated to overturn longstanding precedent in recent years, and there is a distinct possibility that it may do so here. Under the *Chevron* doctrine—named for *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, decided by the Supreme Court in 1984—courts must defer to a federal agency's interpretation of the statute that authorizes its actions when a statute is ambiguous, so long as the agency's interpretation is reasonable. The *Chevron* doctrine makes it challenging for plaintiffs to prevail in lawsuits in which courts have to second-guess agency determinations on technical issues.

Loper Bright Enterprises challenges the authority of the National Marine Fisheries Service to establish a mandate requiring fisheries to carry and pay for federal monitors aboard their vessels. This regulation, which passes the cost of the federal monitors onto the fisheries, was upheld by a lower court relying on *Chevron*. *Relentless*, which will be decided at the same time as *Loper Bright Enterprises*, asks the same fundamental legal question: should the Court “overrule *Chevron* or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency[?]”

If, in deciding these cases, the Court establishes new precedent that would have courts grant less deference to agency decision-making, it could create substantial uncertainty for healthcare and life sciences companies. Agencies like the FDA have historically been granted deference by the courts based on the agency's scientific and technical expertise.

With *Chevron* deference, stakeholders in many instances relied on agency determinations knowing that they were likely to be respected by the courts. If *Chevron* deference is abolished, the risk of litigation challenges to agency determinations would increase, potentially providing less stability for federally regulated entities. That said, in some instances, regulated entities may find that abolition of the *Chevron* doctrine facilitates their ability to challenge regulations that they believe are unlawful. Accordingly, if the Supreme Court revises or abolishes the deference traditionally accorded to agency decision making, businesses in the healthcare sector should carefully consider whether and how their litigation and regulatory strategies should be revised.

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