A&O SHEARMAN

Life sciences and healthcare insights

Introduction

Welcome to our inaugural Life sciences and healthcare insights report, where our global team share their insights on the most important commercial, legal, and regulatory issues facing life sciences and healthcare companies around the world.

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SUMMARY

In this edition we examine how current market volatility and a looming patent cliff are affecting corporate development activity. Our team explores some of the creative deal structures that are emerging to better share risk, support continued innovation and allow the sector's leading players to access enabling technologies such as CRISPR-based gene editing and antibody-drug conjugate linkers.

Next, we analyze how President Trump's policy agenda—and the approach of U.S. health secretary Robert F. Kennedy Jr.—are influencing federal regulation and the broader work of the U.S. Food and Drug Administration.

We then take stock of legal and regulatory developments in Europe and explain the consequences of a shift in approach to merger reviews, closer FDI scrutiny at member state level, and recent antitrust rulings by the European Court of Justice.

Our fourth article examines what the future holds for pharma companies and their divested consumer healthcare divisions following a string of separation deals.

Next we look at the sector's use of artificial intelligence and ask how life sciences professionals, policymakers, software companies and lawyers can devise frameworks that deliver the greatest health improvements while addressing AI's complex legal and ethical challenges.

In our sixth article we clarify the complex and evolving U.S. regulatory framework around medical devices and wearables. We also explore their associated privacy and cyber risks—and explain the responsibilities of developers and end-users.

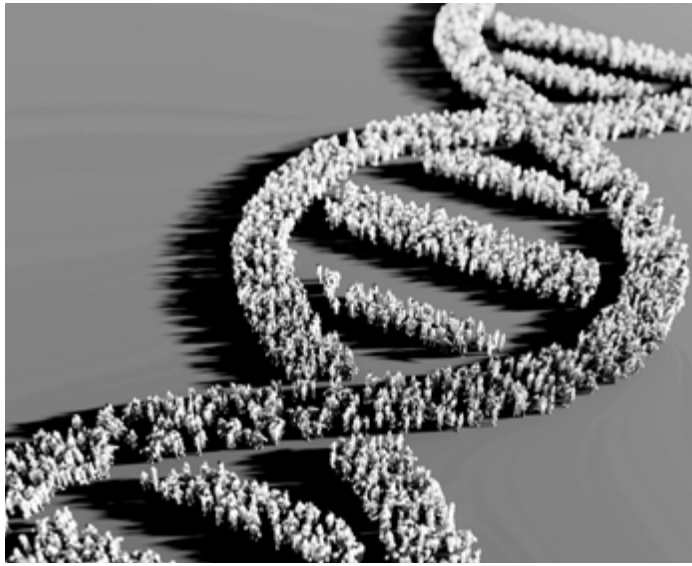
And in our final piece we look at a landmark recent decision from the EU's UPC Court of Appeal, which has for the first time in the pharma sector granted a provisional injunction for imminent patent infringement.

This document contains elements that are interactive.

CONTENTS

Creative deal structures help life sciences innovators weather the macro storm

Pharma innovators have long pursued a variety of deal structures to navigate the risks associated with the drug development process. Here we explore the legal and regulatory dynamics of these creative transactions, which are helping industry players navigate current market volatility.



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Globally, market volatility has eroded confidence and subdued M&A activity. A "wait and see" approach is the prevailing sentiment for many market participants; it is difficult to convince boards to advance deals while valuations are unpredictable and there remain persistent geopolitical tensions, inflationary pressures, fluctuating interest rates, and uncertainties surrounding tariffs. All these factors add complexity to negotiations and long-term planning.

In the life sciences and healthcare sector in particular, deal value dropped sharply during the last full-year period, with total M&A including contingent payments falling 36% year-on-year in 2024 to USD137.3 billion.

In biopharma the decline was even steeper, with M&A value falling 60% year-on-year to USD62.3bn with contingent payments included. However, more recently the market has stabilized; in H1 2025, activity was broadly flat at USD88.6bn including contingent payments, compared with USD88.9bn in H1 2024.

At the same time, there are factors specific to the industry that continue to drive transactional activity, including that the sector is willing to deploy its accumulated cash in return for access to promising assets. In H1 2025, 50 M&A transactions were announced between biopharma therapeutics and platform companies totalling USD55.9bn with contingent payments. This represents a 35% increase in deal value compared to the same period in 2024.

PATENT CLIFF CREATES MOMENTUM TO PURSUE INNOVATIVE ASSETS

In the U.S., large-cap pharmaceutical companies are confronting a patent cliff that is expected to put more than USD300bn of sales at risk over the next five years, representing 3–4% of the overall market. This dynamic is compelling acquirors to pursue innovative assets—particularly in oncology, immunology, gene therapy, and rare diseases—within start-ups and mid-cap biotech targets.

At the same time, the shift toward precision medicine and platform-based R&D has amplified demand for data analytics systems, AI-enabled drug-discovery technologies, and integrated diagnostic capabilities, and in doing so broadened the definition of a "life-sciences" target to include digital health companies, genomic-sequencing firms, and specialty contract research organisations.

On the sell-side, capital markets dislocation—exacerbated by elevated interest rates, a tepid IPO window, and venture investors' prioritization of portfolio triage—has compelled many early-stage biotechs to contemplate strategic alternatives at valuations that are lower than during the market's 2021 zenith and are therefore attractive to cash-rich strategic buyers.

PRIVATE CAPITAL INVESTORS INCREASE EXPOSURE TO SECTOR

Concurrently, private equity sponsors and sovereign wealth funds have increased their exposure to the sector, often via consortium structures that pair their capital with R&D-oriented operating partners. These hybrid arrangements typically accommodate the extended investment horizons inherent in clinical development while addressing acquirors' desire for downside risk-sharing, milestone-based earnouts, and royalty streams.

While significant acquisitions have been less frequent in the life sciences industry in recent years, the sector has a long-standing reliance on traditional M&A as an engine for growth, portfolio realignment, and pipeline replenishment. With that said, unorthodox structures such as the hybrid arrangements noted above are another key driver for expansion and innovation.

STRATEGIC ALLIANCES FEATURE AS LOWER-RISK PRECURSORS TO OUTRIGHT ACQUISITIONS

Looking ahead, we remain optimistic about a gradual reopening of the U.S. biotech IPO market in the remainder of the year. Nevertheless, the patent-expiry super-cycle and the urgency of therapeutic differentiation are expected to preserve M&A as the sector's dominant strategic lever. Transaction structures are likely to retain contingent components, while strategic alliances—licensing partnerships, co-development and joint research agreements, joint ventures, and option-to-acquire deals—will continue to feature prominently as lower-risk precursors to outright acquisitions.

Creative deal structures and transactions have always been a staple of the life sciences industry. The frenetic pace of scientific discovery, the huge cost of clinical trials, and the inherent uncertainty of the regulatory approval process have driven companies to adopt an array of collaborative and innovative approaches that differ markedly from the conventional, full-company "sign-and-close" acquisition model more common in other industries. The global nature of the sector also drives diversity in dealmaking.

For example, Merck & Co's partnership with Daiichi Sankyo in 2023 exemplified a multi-asset collaboration with the companies co-promoting and sharing profits and expenses. Such structures are designed to allocate risk, optimize capital deployment, preserve optionality, facilitate access to specialized capabilities, and accelerate time to market without incurring the balance-sheet and integration burdens that accompany outright acquisitions.

FLEXIBLE STRATEGIES PROVE RESILIENT IN CHALLENGING M&A MARKETS

These flexible strategies have proven especially resilient in challenging M&A markets, as they allow parties to tailor deal terms to evolving macro conditions, defer major capital commitments, and pursue incremental value creation even when traditional dealmaking slows due to macroeconomic uncertainty or constrained financing environments.

While each transaction is highly bespoke, they frequently share certain legal features: complex intellectual property allocation mechanisms, tiered economic waterfalls, unilateral or mutual termination and control-transfer triggers, and governance frameworks that resemble miniature joint venture constitutions.

At the earliest stages of research, parties often enter discovery collaborations or target-identification alliances via which a large pharmaceutical company will fund basic research in exchange for an exclusive option—exercisable upon the achievement of preclinical or early clinical milestones—to license or acquire the resulting intellectual property.

A good example is the 2024 collaboration between GSK and Flagship Pioneering, which aims to discover and develop ten transformational medicines and vaccines in a deal worth up to USD870 million. The transaction gave GSK an exclusive option to license the candidates for further clinical development. Meanwhile, Novartis announced at the end of last year a multi-year, multi-target alliance with Schrödinger to apply the latter's computational predictive modelling technology and enterprise informatics platform to identify and advance therapeutics.

OPTION STRUCTURE PROVIDES ORIGINATOR WITH NONDILUTIVE CAPITAL AND VALIDATION

The option structure provides the originator with nondilutive capital and a validation halo, while permitting the larger party to defer major consideration until meaningful de-risking has occurred. Option considerations are invariably tiered: an upfront technology fee, periodic research funding tranches, an exercise price calibrated to the stage of development at exercise, and downstream milestone and royalty payments. The accompanying legal architecture must address ownership of background IP, the extent of the license during the option term, publication restrictions, exclusivity commitments, and termination rights keyed around safety signals or any failure to reach agreed research goals.

As the asset matures, co-development and co-commercialization arrangements emerge, typically involving a sharing of global clinical development costs and a geographic or field-based allocation of commercialization rights.

Economic participation is usually expressed through either cost-sharing and profit-split formulas or royalties. Here, the governance terms resemble those found in joint ventures: joint steering committees, escalation paths, deadlock-resolution provisions, tie-breaker voting rights for the party bearing greater financial risk, alliance managers, and dispute-escalation ladders.

STAGED BUYOUTS INCREASE IN POPULARITY

An increasingly popular variant is the staged buyout: the commercial lead receives an option to purchase the partner's retained co-commercialization stake after regulatory approval, with a pre-agreed multiplier on net sales or fair-market-value floor to compensate the minority partner for early-stage risk-sharing.

Regional or territory-specific license transactions continue to proliferate as companies seek rapid entry into markets such as China, Japan, and Latin America, where legacy incumbents possess established regulatory, manufacturing, and distribution infrastructure. For example, in 2024 Bayer acquired the rights to Cytokinetics' heart drug in Japan to strengthen its cardiovascular business.

These deals address antitrust and national security concerns by channeling rights through local subsidiaries and incorporating CFIUS- (or analogous regime-) compliant information-sharing protocols. Increasingly, parties negotiate step-in provisions that enable the global licensor to re-assume rights upon the occurrence of predefined performance shortfalls, thereby providing a synthetic "call option" to re-aggregate global rights without the complexity of a traditional acquisition.

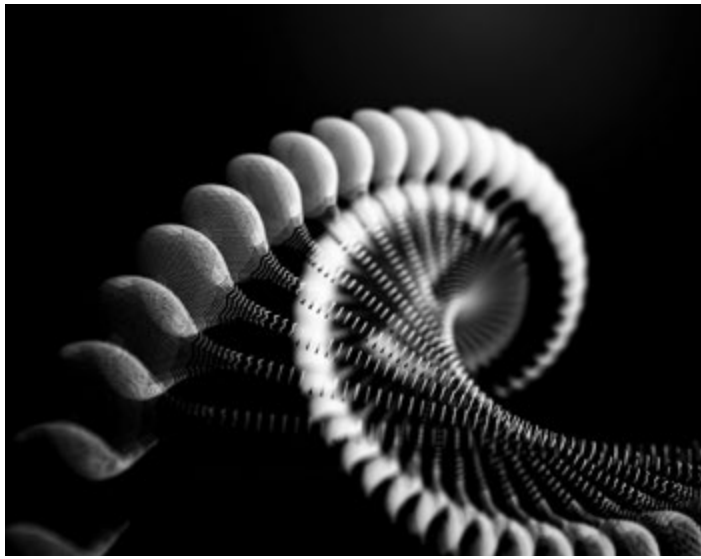
PLATFORM COLLABORATIONS WHERE DISCOVERY-STAGE COMPANY POSSESSES ENABLING TECHNOLOGY

Then there are platform collaborations, which are serviceable when a discovery-stage company possesses an enabling technology—such as mRNA, CRISPR-based gene editing, or antibody-drug conjugate linkers—that can spawn multiple product candidates across disparate therapeutic areas.

The largest collaborative R&D alliance in 2024 saw Bristol Myers Squibb pay USD55m to collaborate with Prime Medicine to develop reagents for ex-vivo T-cell therapies. Under the terms of the agreement, Prime will design optimized editor reagents for a select number of targets, including reagents that leverage its Prime Assisted Site-Specific Integrase Gene Editing (PASSIGE) technology.

Here, rather than buying the platform outright, a larger counterparty will license access to a limited number of "collaboration targets" while typically receiving an equity stake to align incentives. Each target is governed by its own development plan and set of milestones. Because the platform owner is concurrently developing its own pipeline assets, the definitive agreements must define "fields", background and foreground IP, and improvements with exceptional granularity to mitigate freedom-to-operate conflicts. Oversight of publication rights and competitive programs, especially when the platform may be foundational across multiple alliances, is a perennial negotiation flashpoint.

Manufacturing and supply partnerships often function as quasi-joint ventures, particularly for biologics that require specialized cell-culture or gene-therapy vector capacity. For instance, the 2020 partnership between Lonza and Moderna to manufacture mRNA-1273, Moderna's COVID-19 vaccine, involved long-term capacity commitments and technology transfers. More recently, Regeneron has agreed a ten-year manufacturing and supply agreement worth USD3bn with Fujifilm Diosynth Biotechnologies, which will make large bulk drug products for the biotech at a new site in North Carolina. This deal nearly doubles Regeneron's U.S. manufacturing capacity amid ongoing tariff concerns in the U.S.



CHANGE-OF-CONTROL PROVISIONS UNDER SPOTLIGHT IN MANUFACTURING PARTNERSHIPS

Under these deals, the innovator retains product ownership but commits to long-term minimum purchase obligations, frequently backed by capacity reservation fees and take-or-pay terms. Change-of-control provisions receive heightened scrutiny because any acquirer of either party could find itself contractually bound to an unwanted long-term supply arrangement or forced to share proprietary manufacturing know-how with a competitor.

Asset purchases coupled with contingent milestone or royalty consideration have replaced whole-company acquisitions where the seller is a single-asset entity. For instance, in 2024 AstraZeneca acquired Amolyt Pharma for USD800m with a potential contingent payment of USD250m and BioNTech's acquisition of Biotheus with potential USD150m contingent payment.

These assignments may be structured through the sale of patents, investigational new drug applications (INDs), and/or manufacturing know-how, sometimes consolidated in an IP-holding subsidiary that is spun off to the buyer. In these arrangements the earn-out component is of outsized importance and often extends across commercial sales, label expansions, and even patent-term-extension events. Deal agreements must address audit rights, information-sharing, change-of-control acceleration, and buyer obligation to use "diligent" or "commercially reasonable" efforts, with each calibrated to bind the buyer to sustain development. In the U.S., the Delaware court has traditionally been reluctant to enforce vague best-efforts covenants.

SYNTHETIC SECURITIZATIONS ALLOW MATURE REVENUE STREAMS TO BE MONETIZED

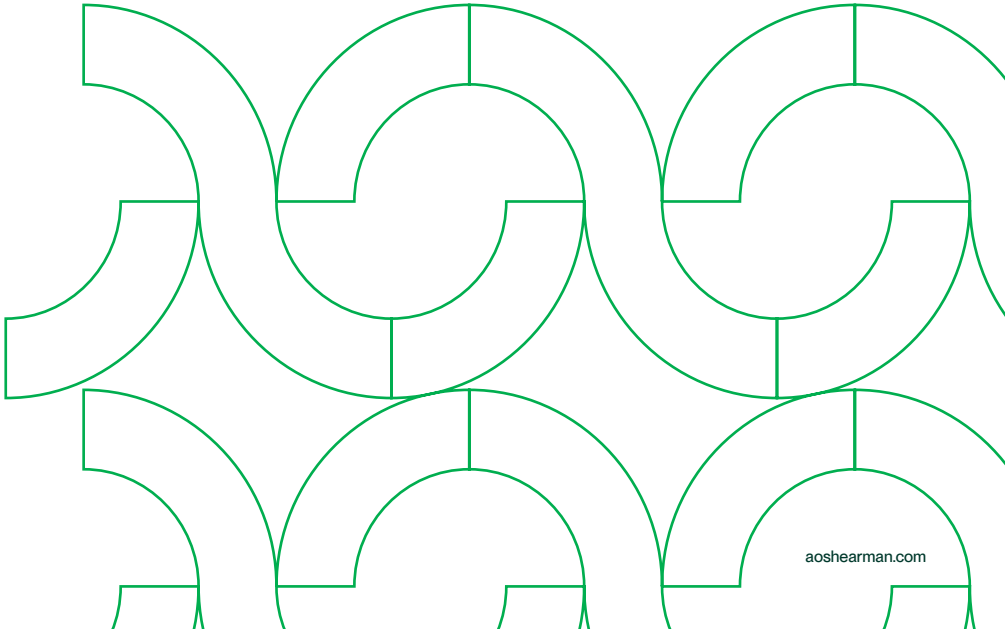
Royalty-interest divestitures, sometimes styled as synthetic securitizations, enable innovators to monetize mature revenue streams while retaining product ownership. A recent example is Royalty Pharma's 2024 purchase of royalties and milestones on autoimmune disease drug frexalimab from ImmuNext for USD525m.

Structured spin-outs—where an originator contributes a non-core therapeutic program into a newly capitalized subsidiary funded by venture investors and retains an option or right of first refusal to reacquire the program post-proof-of-concept—allow large pharma companies to offload near-term R&D expense while preserving future strategic control. The parent's option is usually exercisable at predetermined multiples of invested capital or fair value, often combined with an automatic conversion of the venture investors' preferred shares into a royalty or milestone entitlement to align economics upon re-acquisition.

ASSET SWAPS GAIN TRACTION AS COMPANIES REFOCUS

Finally, asset swaps and therapeutic-area carve-outs have gained traction as companies refocus their pipelines.

In these transactions two parties exchange late-stage or commercial portfolios in disparate therapeutic areas, obviating cash consideration, accelerating strategic fit, and sidestepping antitrust concerns that might arise from concentration within a single modality. Because valuation mismatches are inevitable, balancing payments or contingent-value rights are integrated to equalize post-closing economics, and transitional-services agreements govern supply chain, pharmacovigilance, and quality-assurance obligations until full operational separation is achieved.



DEAL CONSIDERATIONS

When structured carefully, these alliances and novel transactional forms provide life science companies with the flexibility to access capital, capabilities, and markets while minimizing the binary risk profile that has historically typified blockbuster drug development.

Across all of these collaborative and non-traditional M&A structures, practitioners confront recurring commercial and contractual considerations:

- Scrupulous delineation of background versus foreground intellectual property and improvements.
- Sophisticated milestone-based economics that align risk and reward while safeguarding accounting treatment under frameworks such as U.S. Accounting Standards Codification 606.
- Governance provisions that provide for joint oversight while sidestepping antitrust or fiduciary duty constraints.
- Rigorous change-of-control and assignment clauses calibrated to the high acquisition churn in the sector.
- Data-privacy, pharmacovigilance, and regulatory compliance frameworks to manage the global exchange of clinical data.
- Dispute-resolution mechanisms that often combine expedited arbitration for scientific disagreements with traditional court procedures for monetary claims.

Hybrid arrangements also often present novel tax considerations compared to more vanilla M&A structures. Parties will need to consider tax consequences early in negotiations and seek alignment on structure, intended tax treatment, and risk allocation.

For example, structures that incorporate research funding payments and back-end options to acquire target assets or equity may raise questions about the tax treatment of the payments vis-à-vis the funder, the target and the target's equity holders.

The deductibility or capitalization of the funder's payments versus the current or deferred taxation of those payments at the target or equity-holder level depends on the terms of the deal and the tax laws of the relevant jurisdiction(s). Here, beneficial tax regimes in the target's jurisdiction (e.g., R&D tax credits or full expensing of certain R&D costs, the latter of which is currently included in U.S. tax legislative proposals) may play a role.

Similarly, deals that include contingent or optional asset or equity sales—with or without earnout payments—may raise notable tax differences, including the potential for two levels of tax in an asset sale versus a possible tax exemption in an equity sale.

Moreover, hybrid arrangements that anticipate royalty streams or other current returns on investment may give rise to withholding taxes that would materially alter economics absent local or double tax treaty relief, requiring early consideration of withholding taxes and risk allocation. If an actual or quasi joint venture is planned, key considerations will include whether the JV constitutes a separate entity for local tax purposes and/or whether any flows are subject to "arm's length" pricing requirements.

These examples are just a few of the tax considerations that may arise in a hybrid arrangement. Given the panoply of options parties may consider to achieve their commercial and strategic objectives, a particular structure could give rise to any number of tax considerations. making tax a key component across the full life cycle of the deal.

Drug and medical device regulation under the Trump administration

Many of President Trump's executive orders (EOs) and legislative measures have been designed to curtail federal regulation, reduce the size of the administrative state, and withdraw the U.S. from multilateral institutions. Here we examine how the President's policy agenda—along with the approach of U.S. health secretary Robert F. Kennedy Jr.—is impacting the U.S. Food and Drug Administration

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The Trump administration's policy agenda, the approach of U.S. health secretary Robert F. Kennedy Jr., and the work of the Department of Government Efficiency (DOGE), are upending the way pharmaceutical products, medical devices and healthcare innovations are evaluated and approved in the United States.

Several of President Trump's more than 150 executive orders (EOs) signed during his early months in office have a direct impact on the U.S. Food and Drug Administration (FDA), and by extension the life sciences industry.

These include specific EOs designed to lower drug prices by accelerating the approval of "generics, biosimilars, combination products and second-in-class brand name medications", and to reshore domestic pharmaceutical manufacturing (including of active ingredients) by streamlining reviews of domestic products while increasing costs and reporting requirements for foreign drug-makers. The FDA is also under pressure from further executive orders designed to facilitate the Trump administration's deregulatory agenda.

At the same time, Secretary Kennedy is spearheading the development of a new public health strategy which aims to tackle the prevalence of cancer, autism spectrum disorders, autoimmune disease, allergies and asthma—particularly among children.

"Americans of all ages are becoming sicker, beset by illnesses that our medical system is not addressing effectively," says the EO establishing the Trump administration's Make America Healthy Again Commission. "These trends harm us, our economy, and our security."

For supporters, these moves represent a long-overdue disruption of the status quo. But within the life sciences sector there has also been disquiet at the speed at which health policy is changing—and fears that the scientific rigor of the U.S. regulatory process is being diluted by the administration's measures and approach.

The FDA has lost a number of career scientists from senior positions since the Trump administration took office, with Secretary Kennedy reportedly planning substantial reductions to the number of FDA staff. Major cuts are also planned to federal funding for scientific research, while the impact of the EO entitled "Unleashing prosperity through deregulation"—which aims to reduce the volume of regulation by requiring new measures to be accompanied by the removal of ten existing rules—has caused concern within the industry.

Meanwhile, the withdrawal of the U.S. from the World Health Organization has raised questions over U.S. participation in, and alignment with, global regulatory standards.

This, coupled with the threat of increased tariffs on pharmaceutical imports, has created uncertainty for U.S. life sciences companies that sell their products globally and that have complex cross-border supply chains.

NEW LEADERSHIP AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FDA

Robert F. Kennedy Jr. was sworn in as Health and Human Services (HHS) Secretary in February. Secretary Kennedy initially ran for the Democratic presidential nomination before standing as an independent and eventually supporting the candidacy of President Trump.

Secretary Kennedy's Make America Healthy Again (MAHA) campaign championed "health freedom" and promised to prioritize "liberty and environmental integrity as cornerstones of a thriving nation".

In September, the MAHA Commission launched a 128-initiative strategy that includes policy recommendations aimed at examining and addressing the root causes of childhood chronic disease. These include developing a new vaccine framework and addressing vaccine injuries, limiting food dyes, enacting stricter rules on pharmaceutical advertising, defining ultra-processed foods, and closing generally recognized as safe (GRAS) food ingredient loopholes.

Secretary Kennedy was a controversial choice for the role of America's top health official given his repeated unsubstantiated claims about corruption within the FDA and the broader pharmaceutical industry and his views on vaccine efficacy and water fluoridation, among other things.

While MAHA supporters have welcomed his focus on exercise, natural foods and supplements over prescription drugs, Secretary Kennedy has been accused by his critics of cherry-picking study findings and promoting therapies that are not supported by scientific research. His comments that parents of newborns should "do their own research" before vaccinating their children have been criticized for going against decades of public health advice.

On June 9, Jim O'Neill was sworn in as deputy health secretary. Having previously held senior roles at HHS between 2002 and 2008, he has since then worked at an investment fund, the Thiel Foundation, and a health research group seeking regenerative medical solutions for age-related diseases.

Welcoming Mr O'Neill, Secretary Kennedy said he would "help us harness cutting-edge AI, telemedicine, and other breakthrough technologies" and "promote outcome-centric medical care, champion radical transparency, uphold gold-standard science, and empower Americans to take charge of their own health."

NEW ADMINISTRATION PROMPTS LEADERSHIP AND STAFF CHANGES

In March, a bipartisan vote in the Senate confirmed Marty Makary, a British-American surgeon, as the new head of the FDA. Welcoming the appointment, Secretary Kennedy praised Dr. Makary's "extensive research, clinical experience, and national leadership".

While Dr. Makary has promised to "ensure that the FDA holds to the gold standard of trusted science, transparency, and common sense", since the Trump administration took office, the agency has lost a number of long-serving senior doctors, scientists and policymakers across multiple divisions.

Among those to resign their posts have been Dr. Peter Marks, who had been head of the Center for Biologics Evaluation and Research (CBER) since 2016; Dr. Patrizia Cavazzoni, director of the Center for Drug Evaluation and Research (CDER) since 2021; and Jim Jones, head of Human Foods since 2023.

The Center for Devices and Radiological Health (CDHR), meanwhile, has lost its Digital Health Center of Excellence director.

Senior officials put on administrative leave include Julie Tierney, acting director at the CBER; Dr. Peter Stein, director of the Office of New Drugs; and Dr. Hilary Marston, chief medical officer.

"These deep cuts and the loss of experienced leadership at virtually all the major centers that regulate the safety of food, drugs, devices is quite high risk," said Dr. Jesse Goodman, former chief scientist at the FDA and director of Georgetown University's Center on Medical Product Access, Safety and Stewardship.

Following the exit of Dr. Marks, who oversaw the government's vaccine program, John Crowley, president and CEO of biotech industry association BIO, voiced his concern that the loss of experienced leadership at the FDA would "erode scientific standards and broadly [affect] the development of new, transformative therapies".

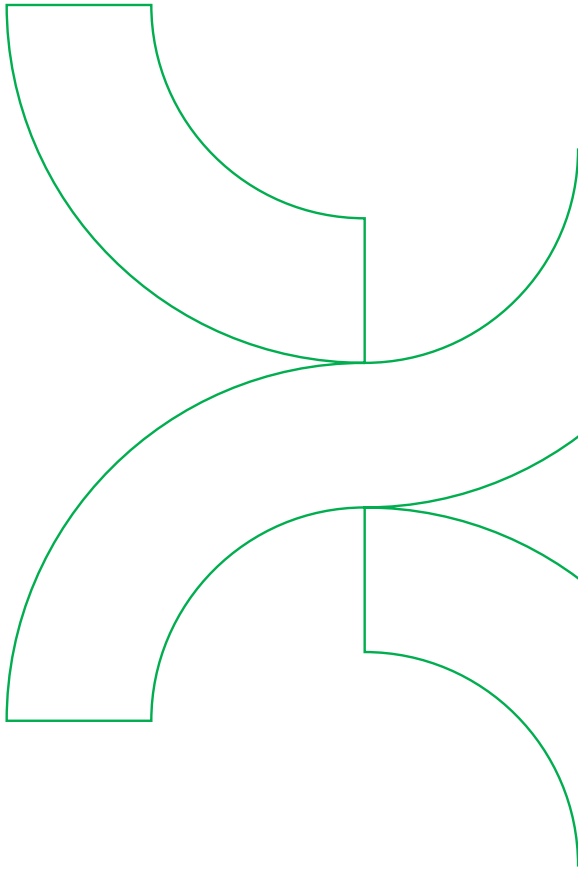
Dr. Vinay Prasad, a critic of U.S. government Covid policies on school closures, mask mandates and booster shots, took over the CBER in May. One of his first moves was to end Covid boosters for healthy people under the age of 65 unless manufacturers can demonstrate efficacy for that group using randomized, controlled trial data to evaluate clinical outcomes. (The latter point is in line with FDA Commissioner Makary's views on the benefits of such trials, outlined in his recent book, *Blind Spots*).

Dr. Prasad stepped down from the agency in July, following a conservative backlash against his decision to pause the use of a drug linked to two patient deaths. However he was reinstated a few weeks later.

Meanwhile, Kyle Diamantas, a corporate lawyer and policymaker who is reportedly close to the Trump family, has been appointed as deputy commissioner for human foods, where he oversees the agency's activities relating to nutrition and food safety.

The changes in leadership come against a backdrop of significant reductions in FDA staff. In early April around 3,500 jobs were cut, although some scientists and inspection staff were subsequently reinstated after the layoffs interrupted the agency's oversight of drug and food safety.

Overall, the FDA will reportedly lose close to a quarter of its staff through a combination of layoffs, early retirements and voluntary redundancies through President Trump's second term.



FAST-TRACKING AND DEREGULATION: BENEFIT OR RISK FOR CONSUMERS?

On May 16, Grace Graham, the FDA's deputy commissioner for policy, legislation and international affairs, gave a speech outlining the FDA's strategy under Secretary Kennedy's leadership. Appointed to her role in March, she has held policymaking positions under Democrat and Republican presidencies.

Deputy commissioner Graham stated the agency's objective to reduce the time it takes to develop new medicines, especially those targeting rare diseases. She also highlighted plans to use technology to streamline drug development, phase out animal testing, and accelerate development of generics and biosimilars (complex medicines made from living organisms such as cells, bacteria, or yeast). These moves, she said, would cut drug costs and increase accessibility.

Her speech confirmed that the FDA would follow the administration's ten-for-1 rule, which requires federal agencies to cut ten pieces of regulation or guidance for every additional piece introduced. While Ms. Graham said the policy would not "hamstring us from issuing the necessary regulatory documents" to ensure safe, effective access to high-quality drugs, others have expressed doubts over applying the ten-for-1 rule to the work of the FDA.

According to analysis from Politico, there are more than 170 life sciences-related guidance documents under development or in the pipeline at the agency. If the EO were followed to the letter, to publish them all, the FDA would need to remove more than half of the guidance documents currently in circulation.

Secretary Kennedy and President Trump have both expressed their support for eliminating the FDA's user fee programs, seeing such payments from industry participants as a threat to the regulator's independence. Such a move, which would have to be approved with a congressional act, would leave taxpayers to cover the funding gap. Ms. Graham suggested in her speech that these fees could be "restructured and simplified" at their next reauthorization in 2027.

There are concerns over the administration's deregulatory agenda, which has targeted pre-market approval requirements for medical products, labeling and advertising disclosures for dietary supplements and processed foods, and limits the FDA's post-market surveillance and recall authority. Critics argue that this scaling back benefits industry players at the expense of safety.

Speaking on a podcast in June, Secretary Kennedy stated that alternative treatments such as stem cells, vitamins, peptides, and chelation therapy should be less regulated.

He acknowledged however that "of course you're going to get a lot of charlatans, and you're going to get people who have bad results. Ultimately, you can't prevent that either way. Leaving the whole thing in the hands of pharma is not working for us."

Industry sources say the administration has either proposed or implemented significant cuts to the FDA and United States Department of Agriculture (USDA)'s operating budgets including via job cuts among inspectors, lab technicians, and scientific reviewers; reductions in the infrastructure supporting foodborne illness surveillance, drug shortage tracking and enforcement databases; and delayed modernization of regulatory systems (e.g., for electronic submissions, data transparency, and AI-driven oversight tools).

DRUG DEVELOPMENT, APPROVALS AND PRICING

Job cuts at the FDA are reportedly already slowing the drug approval process and causing the agency to miss deadlines. There are fears that staff reductions could result in less engagement between drug developers and the FDA.

While big pharma companies have large scientific and legal teams and are well-versed with the FDA process, this dynamic could disproportionately impact smaller innovators, which typically engage intensively with the agency through the development cycle.

Secretary Kennedy has been vocal about his concerns regarding the FDA's use of emergency use authorizations (EUAs) and accelerated approval pathways, particularly in the context of vaccine development. He has expressed a preference for more rigorous testing, including potentially requiring new vaccines to be tested against placebos, which is a controversial stance among public health experts.

There are concerns that any deprioritizing of post-market safety systems could lead to delays or underreporting of adverse event data; inadequate tracking of drug interactions and long-term outcomes; and increased public health risks from recalls of compounded drugs, biologics, or combination products accelerated for approval as part of the administration's plan to lower drug prices. (We explore some of the antitrust implications of these moves here.)

At the same time, the U.S. Department of Commerce has initiated a Section 232 national security investigation into imports of pharmaceuticals and pharmaceutical ingredients. The probe—which will conclude at the end of this year—will cover finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients (APIs), key starting materials, and derivative products.

Similar investigations into aluminum, steel, cars, and car parts have resulted in significant tariff increases.

STANCE ON VACCINES PROMPTS CONTINUED CONTROVERSY

On June 9, Secretary Kennedy wrote an opinion piece in the Wall Street Journal explaining his decision to remove all 19 members of the Advisory Committee for Immunization Practices (ACIP), eight of whom had been appointed during the final weeks of the previous administration. He said the move would put "the restoration of public trust above any pro- or antivaccine agenda" and "ensure the American people receive the safest vaccines possible".

The ACIP evaluates the safety, efficacy and clinical need for vaccines and passes its findings on to the Centers for Disease Control and Prevention (CDC). Secretary Kennedy said the committee was "plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine".

At the time, public health experts and former officials voiced concerns that the action would "exacerbate mistrust in vaccines", and cause challenges for doctors, nurses and pharmacists.

However, Secretary Kennedy swiftly appointed eight new members to the committee, describing them as "highly credentialed scientists, leading public-health experts, and some of America's most accomplished physicians".

Groups such as the American College of Physicians said the new members had been selected too quickly and without transparency, causing "confusion and uncertainty".

In May, Secretary Kennedy and Commissioner Makary announced that the CDC would remove Covid-19 booster shots from its recommended immunization schedule for healthy children and pregnant women.

The CDC, however, said it would retain Covid vaccines for healthy children age six months to 17 years old, as long as there is "shared decision-making" between families and their doctors.

This followed a new requirement by the FDA that drug manufacturers conduct more studies as a condition for approving updated Covid vaccines for healthy adults under age 65. It will likely still be possible for doctors and pharmacies to recommend and administer the vaccine off-label, but insurance may stop covering the cost for that demographic.

In August, the administration fired CDC director Susan Monarez after just a month, saying she was "not aligned with the president's agenda", replacing her with deputy health secretary Jim O'Neill. Chief medical officer Debra Houry is among senior officials to have resigned in recent months, warning of a "rise of misinformation" about vaccines.

MEDICAL DEVICES BENEFIT FROM INNOVATION, BUT REQUIRE MORE SURVEILLANCE

Under Secretary Kennedy, the FDA would like to see more citizens take responsibility for their own health. As deputy commissioner Graham said in her recent speech: "Medical devices can help Americans better track their own health needs before they get sick and creating conditions for more of these products and information to be available without a prescription can maybe help some avoid more severe disease." At the same time, the administration is also pursuing an aggressive deregulatory agenda designed to prioritize speed to market.

To accelerate access to novel medical devices, the government could expand the 510(k) pathway under which companies make a pre-market submission to the FDA to demonstrate that their product is as safe and effective as another device that is already on the market.

It is also thought to be under pressure to accept real-world evidence and to go further with the "least burdensome" approach introduced in 2019. Industry sources are concerned that such a move could reduce oversight and clinical evidence requirements for many devices.

Another risk is that staffing cuts at the FDA's Center for Devices and Radiological Health (CDRH) could delay public notices related to medical device recalls and safety alerts, slow device reviews and curtail post-market reviews.

Resource constraints are also creating bottlenecks for complex applications and weakening FDA enforcement capacity. Key programs like inspections, compliance follow-ups, and data modernization programs are similarly being delayed.

Cuts are likely to exacerbate existing flaws in the system, including in relation to the FDA's surveillance infrastructure. Here, manufacturers do not consistently inform the agency about adverse events involving medical devices using MAUDE, a searchable database of medical device reports (MDRs). A study in the British Medical Journal (BMJ) found that nearly a third (over 1.2 million) of initial manufacturer reports were not submitted on time between September 2019 and December 2022.

Withholding safety information may "cause avoidable patient harm", which could be prevented if the FDA "systematically and prospectively collected" post-market monitoring data rather than relying on self-reporting, said report author Alexander Everhart.

Efforts by the FDA to increase active surveillance using electronic medical records and insurance claims have been hampered by devices frequently lacking unique device identifiers (UDIs), despite bipartisan calls to make them mandatory.

Late death reports in particular were disproportionately more common if they were associated with breakthrough devices, which benefit from speedier development, assessment, and review for premarket approval. The fact that the agency has scaled back its active post-market monitoring work raises the risk that dangerous or defective devices remain in circulation.

In July 2024, the Government Accountability Office (GAO) said that more than 1.7 million injuries and 83,000 deaths had been potentially linked to faulty medical devices over a ten-year period. The FDA, it continued, had begun building a surveillance system to look for potential safety issues in devices from surgical masks to implantable pacemakers. Obstacles to setting up the system—identified as a priority since 2009—included funding and identifying the patients using the devices.

Another area where the FDA (and other agencies) is playing catch-up is in response to the rapid proliferation of AI in medical devices. It has proposed draft guidance for adaptive algorithms, and will require funding, political backing, and internal consensus to finalize and enforce robust rules. CDHR has furthermore been subject to layoffs of recently hired specialists in artificial intelligence and machine learning.

Technology-enabled products such as digital therapeutics, and software-based tools often fall between regulatory jurisdictions, creating ambiguity in classification, review, and enforcement. A digital device for example, might be regulated by the Federal Communications Commission (FCC) and FDA, with additional oversight from the Consumer Product Safety Commission (CPSC) and Federal Trade Commission (FTC)—while being subject to certain privacy and security laws.

Overcoming this—while enabling innovation in a way that is safe for patients—will require more coordination among FDA units, as well as inter-agency harmonization.

In her May 16 speech, Grace Graham said the FDA was concerned about the number (and standard) of clinical trials taking place abroad. She added that addressing this would require new infrastructure in the U.S., and the "streamlining and modernizing" of regulations such as Good Laboratory Practices, which was last adapted in the 1970s.

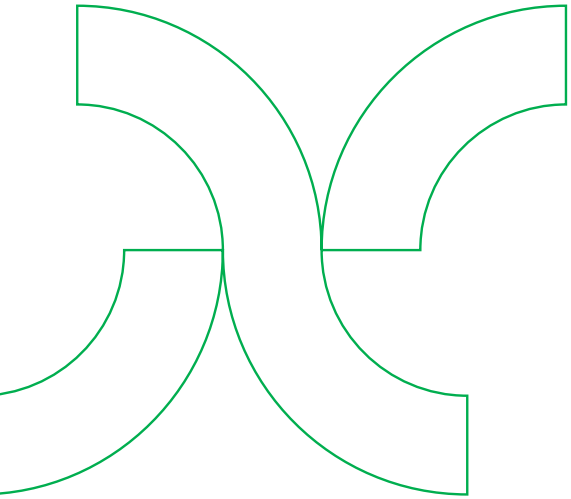
However exactly what this process would entail remains to be seen.

LEGAL CHALLENGES TO THE FDA'S AUTHORITY

In the meantime, legal and judicial challenges are increasingly aimed at constraining the FDA's rulemaking and enforcement powers.

Courts are also leveraging nondelegation arguments that challenge the constitutionality of federal agency discretion. These efforts are supported by the Supreme Court's decision to end the "Chevron deference" (which gave federal agencies broad powers to interpret ambiguous laws and statutes). They may also curtail the FDA's ability to regulate emerging technologies or impose new obligations on innovators. Industry-aligned litigants are also challenging new FDA guidance as improper rulemaking, seeking to weaken the agency's ability to adapt without new legislation.

Looking ahead, it's possible that these shifts could increase the risk of judicially imposed paralysis in emerging areas of regulation, such as AI-driven diagnostics or genetically modified organisms.



ISOLATION, IMMIGRATION AND TRADE

A rejection of multilateralism reduces U.S. influence in shaping global norms and could ultimately lead to U.S. products being isolated from international markets if they don't maintain compliance with stricter regulatory standards overseas.

The Trump administration has ordered an immediate halt to engagement of all kinds with the WHO (although the U.S. cannot officially leave until 2026), and the FDA is likely to diverge from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards by replacing or reducing in vivo toxicology testing for certain drugs.

The U.S. withdrawal from the WHO has locked it out of the Codex Alimentarius (food standards) body. Meanwhile the Trump administration has also paused further funding for the World Trade Organization (WTO), threatening its influence over WTO trade and safety standards discussions.

This, plus the fact that the FDA is now less active in global bodies such as the International Medical Device Regulators Forum (IMDRF), will likely weaken U.S. influence over the development of new regulatory frameworks. At the same time, escalating trade tensions could lead to further misalignment with foreign regulatory systems, creating uncertainty for U.S. exporters and importers.

We are already starting to see major U.S. pharma companies seeking initial regulatory approvals in Europe rather than at home in order to preserve their ability to sell their products globally. They may also consider expanding their R&D, testing and production capabilities outside the U.S. in jurisdictions with access to skilled talent.

At home, the administration has launched measures to tackle illegal immigration, which is set to significantly reduce the labor force in agriculture and meatpacking. Trade disputes meanwhile will likely slow inspections at ports of entry due to resource strain in the FDA, and at U.S. Customs and Border Protection.

Dwindling domestic production of ingredients for drugs could increase reliance on imports from countries with weaker regulatory regimes, without proportional inspection capacity. Likewise, bottlenecks in the global pharmaceutical supply chain could cause shortages of active pharmaceutical ingredients (APIs), among other challenges.

When highlighting the administration's desire to reshore pharmaceutical manufacturing, FDA deputy commissioner Grace Graham noted that 73% of all FDA-registered manufacturing facilities of active pharmaceutical ingredients and 52% of all FDA-registered finished drug manufacturing facilities are currently located outside the U.S., with China as a leading global supplier. The Trump administration is bidding to reduce the current five to ten years it takes to build the relevant domestic facilities.

At the same time, the FDA would like to "reverse the trend" of innovative drugs being first developed overseas. Deputy commissioner Graham noted that some global studies "may not be representative of the U.S. population." FDA regulations require that, to use foreign data as the sole basis for marketing approval, it must be "appliable to the U.S. population", so it is possible that Graham was implying such considerations could be leveraged in future to limit imports of certain products.

TARIFFS COULD PUSH OVERSEAS PRODUCTION TO THE U.S.

In early August, President Trump announced plans to place an initial "small tariff" on pharmaceutical imports into the U.S.

"In one year, one and a half years maximum, it's going to go to 150% and then it's going to go to 250% because we want pharmaceuticals made in our country," he said in an interview.

Following the announcement, the UK's AstraZeneca said it would invest USD50bn by 2030 to expand production and research in the U.S. That company declined comment on rumors that it had considered moving its primary stock listing across the Atlantic.

Ursula von der Leyen, president of the European Commission, meanwhile agreed to a trade deal capping tariffs on sectors including pharmaceuticals at 15%.

Switzerland is seeking to reduce the 39% tariff set on its exports to the U.S. Potential compromises could involve industry leaders such as Novartis and Roche reducing the prices they charge American customers, or increasing investments in the U.S.

BUSINESSES CAN TAKE STEPS TO BECOME MORE RESILIENT

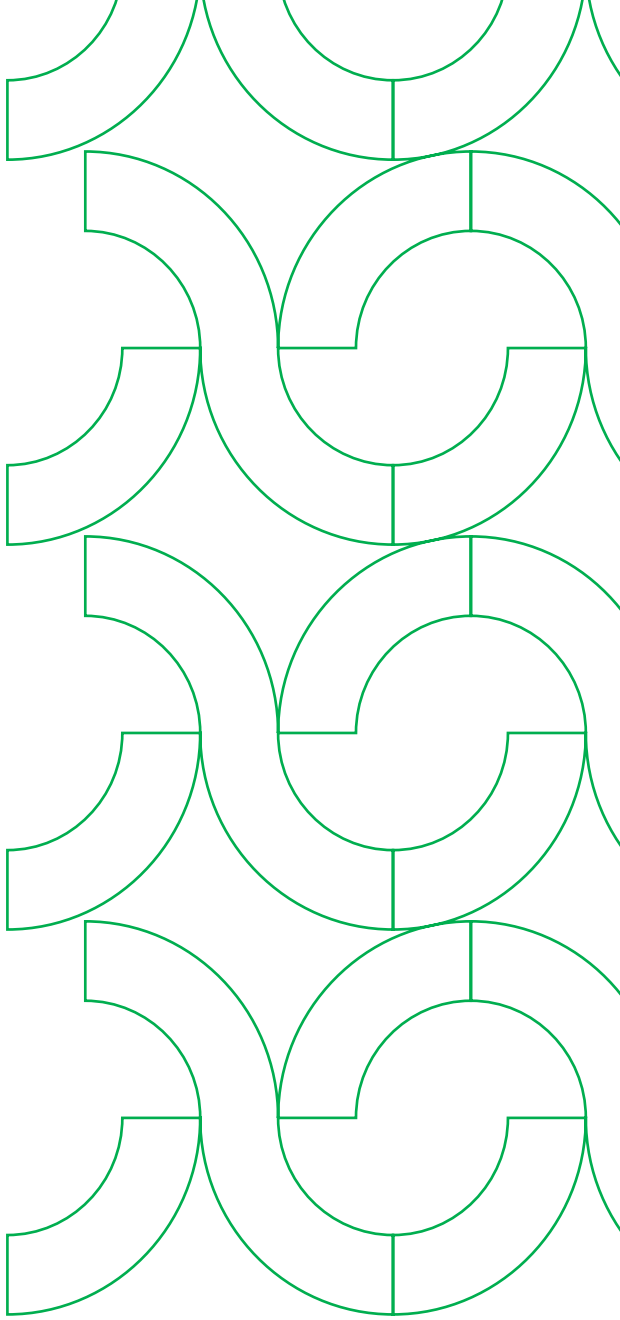
Whether they are already under way or on the horizon, regulatory shifts at the FDA have led to increased uncertainty and risk for businesses. The resulting challenges are numerous and require careful strategic recalibration.

Businesses face a less predictable FDA and will likely seek more clarity on the speed and level of oversight, approval pathways, and post-market surveillance they can expect.

Given fears about the erosion of scientific standards at the FDA, we have started to see major U.S. pharma companies seeking initial regulatory approvals in Europe rather than at home in order to preserve their ability to sell their products globally. They may also consider expanding their R&D and production capabilities outside the U.S. in jurisdictions with access to skilled talent.

In the meantime, companies can prepare for potentially higher litigation risk by enhancing their product liability insurance and post-market monitoring protocols.

Smaller innovators with less extensive in-house quality assurance, auditing, and regulatory capabilities must ensure they can access robust advice, while staying abreast of legal and policy developments, judicial rulings, and executive actions.



Antitrust in life sciences—key European developments for pharma companies

From shifts in merger review to significant abuse of dominance fines from the European Commission, we round up the most important recent events in the antitrust space that life sciences companies should be aware of.

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MERGERS: EU CALL-IN POWERS AND FDI REMAIN HIGH ON THE AGENDA

For years, companies in innovative industries have paid close attention to the power of antitrust authorities to "call in" mergers that fall below mandatory filing thresholds, including to catch the acquisition of pre-revenue or low-revenue targets.

When the European Court of Justice (ECJ) confirmed in Illumina/GRAIL in September 2024 that the European Commission (EC) could only call in transactions that a member state (or states) had jurisdiction to review under its national merger control regime, it prompted cautious optimism that EU call-in risk would become a less pressing concern. However, at the time we noted that this should be tempered by (i) the increasing breadth of EU member states' powers to review transactions that do not require mandatory notification; and (ii) national merger control regimes that are not based solely on turnover thresholds (see our analysis here).

A year on from Illumina/GRAIL, mitigating call-in risk continues to require careful consideration for life sciences transactions, although the focus of the analysis has shifted somewhat, with dealmakers now focusing on member state-level risk before looking at the Europe-wide picture. This often requires an assessment of mandatory notification thresholds in Germany (where there is a deal value test) and call-in risk in Italy (as well as a number of other member states that have the ability to review acquisitions of small or pre-revenue targets). It can be expected that, where transactions are reviewable at national level, member states may confer and, ultimately, agree with the EC to refer up any suitable cases, as occurred with the acquisition of Run:ai Labs Ltd by NVIDIA at the end of 2024.

Foreign direct investment (FDI) filing processes also remain important to deal-making—and particularly deal timing—in the sector. Often, life sciences and healthcare transactions trigger FDI filings in jurisdictions where the timeline for review of even straightforward deals can be substantially longer than the equivalent reviews under merger control regimes. This means that FDI (in Europe and internationally) is increasingly a key hurdle for life sciences and healthcare deals and can drive transaction timings even for deals that receive unconditional clearance.

ANTITRUST: DOMINANCE, DISPARAGEMENT AND PATENT STRATEGIES ARE A KEY FOCUS GIVEN RECENT DECISIONS

Among many important decisions over the past year (including the ECJ's ruling in Servier and the settlement decisions entered into by the EC and the UK Competition and Markets Authority (CMA) with Vifor), the EC's EUR462.6m abuse of dominance fine on Teva stands out due to the wide-ranging implications it may have for the life sciences sector.

We first published key insights on the Teva decision when it was announced in October 2024. Some months later, in April 2025, the EC published the full decision and gave the industry more detail to consider. Three key themes have attracted particular attention.

DOMINANCE: MORE LIKELY TO ARISE SHORTLY BEFORE OR AFTER GENERIC (OR GENERIC-LIKE) PRODUCTS ENTER THE MARKET IF THEY INTRODUCE A DEGREE OF NEW PRICE COMPETITION

Following similar approaches in previous cases (including last year's ECJ ruling in Servier), the EC's Teva decision found that market definition can evolve over the product lifecycle. The EC emphasized its view that the first step in analyzing market definition for a pharmaceutical product is to establish which treatments are therapeutically substitutable. The second step is to establish which of these therapeutically substitutable treatments actually exerts an effective competitive constraint on the product.

In Teva, the EC found that, shortly before the generic-like entry of a product based on the same active pharmaceutical ingredient, Teva's Copaxone product faced price competition for the first time. This had consequential effects on Copaxone's prices, volumes and profits. The (anticipated) entry of this generic-like product, therefore, transformed and narrowed the market in which Copaxone competed to the molecule level, excluding other therapeutic substitutes based on other active pharmaceutical ingredients. This may not have been a novel finding in the same vein as the decision's findings on disparagement and patent strategies. But, together with the Servier judgement, it serves as another example of a narrow pharmaceutical market definition, with an emphasis on price over non-price competition.

DISPARAGEMENT: COMPLEX ANALYSIS IN EU'S FIRST INFRINGEMENT DECISION UNDERSCORES NEED FOR CARE AROUND CLAIMS ABOUT COMPETITORS

Following the EC's settlement with Vifor and a number of other EU member state cases, the Teva decision was the first in which the EC found an infringement of the prohibition on abuse of dominance for disseminating misleading and disparaging claims about a competitor product. The claims focused on the competitor product's safety, efficacy and therapeutic equivalence with Teva's Copaxone product.

The EC's decision included lengthy and complex analysis of whether Teva's claims were (i) objectively misleading; (ii) capable of "producing exclusionary effects" by making it more difficult for competitors to enter or remain on the market; and (iii) not objectively justified. Several internal documents authored or circulated by Teva's in-house legal team were used as evidence of the company's disparagement strategy, with the EC reiterating that communications reflecting advice emanating from in-house lawyers are not covered by EU legal professional privilege (nor are any strategic business communications).

The main takeaway for pharmaceutical and healthcare companies who may enjoy a dominant position: any communications strategy that draws a comparison to, or makes statements about, competitor products needs to be designed carefully with input from (external) antitrust experts and supported by objective evidence.

PATENT "GAMING": EC TEVA DECISION LEAVES COMPANIES WITH QUESTIONS BUT SHOWS THE IMPORTANCE OF INTERNAL COMMUNICATIONS TO ITS VIEW ON WHETHER A PATENT STRATEGY IS "ARTIFICIALLY PROLONGING" LEGAL UNCERTAINTY AROUND PATENT PROTECTION

The EC's decision describes, in detail, a "divisionals game" by Teva comprised of two "legs". The first leg comprised the staggered filings of divisional patents on process or dosage before the European Patent Office that largely overlapped in content (with shared essential features and, in the EC's view, related legal weaknesses). The second leg consisted of the obstruction of effective legal review of challenged patents through the strategic withdrawal of patents before competent appeal courts could adopt a decision about them.

The EC's decision draws heavily on internal documents that were redacted in the published text. According to the EC, these documents indicated that Teva was aware of inherent weaknesses in its patents and intended, through its patent strategy, to artificially prolong legal uncertainty around its patent protection.

The EC's detailed analysis in its decision is somewhat helpful, but it highlights several case-specific factors, some of which may have been more decisive than others. The most obvious practical takeaway for companies is that internal documents and correspondence matter to the analysis of whether a strategy "artificially prolongs" legal uncertainty and amounts to an abuse of dominance.

ANOTHER EMERGING TOPIC OF ANTITRUST INTEREST: THE U.S. MFN EXECUTIVE ORDER

On May 12, 2025, the Trump administration issued an Executive Order announcing that it would issue "most favored nation" pricing targets for pharmaceutical manufacturers to "bring prices for American patients in line with comparably developed nations". We explore the impact of U.S. policy developments on the U.S. regulatory environment here.

This is attracting close attention for a number of important reasons. From an antitrust perspective, any development that might affect (and in particular could have the effect of increasing) prices, or supply, in Europe will always require careful consideration to avoid any unintended increase in risk exposure. This will be particularly true for any company that may hold a dominant position in any product. As companies come to design their response to any requirements imposed on them because of this order, antitrust risk will be one factor they will need to keep firmly in mind.

Life after separation: what the future holds for pharma companies and their separated consumer health divisions

In recent years, many of the world's biggest pharmaceutical companies have carved out and spun off their consumer health divisions in an effort to refocus on core strategic areas and free up cash for investment. Here, we examine what's next for both pharma companies and the new standalone consumer health divisions.

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WHAT DOES THE FUTURE HOLD FOR PURE-PLAY PHARMA COMPANIES?

Over the last decade, pharmaceutical giants such as Novartis, Merck, GSK, Bristol Myers Squibb, Pfizer, Johnson & Johnson and Sanofi have separated their consumer health divisions—refining their portfolios to focus solely on pharma/Rx products. Two key exceptions are Bayer, which owns key OTC brands such as Aspirin and Claritin, and AbbVie, which owns aesthetic treatments such as BOTOX as a result of its 2020 acquisition of Allergan Aesthetics.

Post separation, "pure-play" pharma companies are more reliant on patent protection and regulatory exclusivity to protect their revenue streams without the stable income from their consumer health divisions—and cannot afford to be complacent about the looming patent cliff facing the industry, which will see drugs worth some USD300 billion in sales face competition from generics over the next five years.

As a result, we are seeing these companies under greater pressure from shareholders and investors to fill pipeline gaps through acquisitions and in-licensing using their capital, including that released from the sale or separation of their consumer health units. They face the critical (and, at times, unenviable) choice of where best to deploy that capital—for which assets, in which therapeutic areas, and in which territories.

STRATEGIC FOCUS: THERAPEUTIC AREA PRIORITIZATION AND REDUCING RELIANCE ON INTERNAL R&D

With pharma companies moving away from a historic reliance on internally generated R&D leads, this year has seen a steady stream of transactions targeting oncology and immunology in particular—structured both as M&A and licensing transactions. In January, GSK entered into a collaboration with Oxford University to establish the GSK-Oxford Cancer Immuno-Prevention Programme.

In February, GSK completed its acquisition of oncology drug developer IDRx for up to USD1.15bn in cash, and Lilly signed a partnership and license agreement with Magnet Biomedicine to develop and commercialize oncology molecular glue therapeutics. In March, Lilly completed its acquisition of Scorpion Therapeutics, a developer of precision oncology therapies, for up to USD2.5bn in cash. In April, Johnson & Johnson completed its acquisition of neuroscience drugmaker Intra-Cellular Therapies for USD14.6bn, while three months later, Merck KGaA paid USD3.9bn for biopharmaceutical rare cancer specialist SpringWorks.

Notably, licensing deals relating to obesity, diabetes and other metabolic disorders reached record levels in the first half of 2025, with announced transactions providing for aggregate payments of up to USD18.2bn, more than double the total for the whole of 2024. A key example was Roche and Zealand Pharma's partnership to advance Zealand's mid-stage obesity candidate petrelintide, which provides for payments of up to USD5.3bn.

We expect these therapeutic areas to continue to be a priority target for dealmakers—in particular, given the increasing prevalence of cancers and metabolic disorders in aging populations in key territories.

Going forward, it will also be key for pharma companies to keep a critical eye on R&D prioritization in order to quickly discontinue investment into pipeline assets that are not meeting established evidence criteria (ideally before reaching the more expensive trial phases). To avoid overdependence on a single blockbuster drug, we expect pharma companies to seek to maintain a diverse pipeline by ensuring both R&D investment and deal spend is spread across multiple core therapeutic areas, as well as different modalities and mechanisms of action within each.

Given pure-play pharma companies are typically valued on their R&D success, pipelines and current portfolios (as well as related patent protection and regulatory exclusivity), expert shareholder engagement will also be imperative.

NAVIGATING GEOPOLITICAL HEADWINDS AND EVOLVING REGULATORY LANDSCAPES

Chinese-domiciled biopharma continues to be a popular target for acquisitions and in-licensing transactions by global pharma companies, especially in respect of oncology and ADC technology. In the first half of 2025, 38% of large-cap biopharma's major transactions originated from Chinese biopharma. In particular, according to Morgan Stanley, Chinese biotech partnerships are attractive from a financial standpoint, with in-licensing offering a 76% discount in net value as compared to an acquisition.

However, geopolitical challenges, resulting supply chain issues (interruptions, increasing costs, etc.) and rapidly-changing regulatory landscapes (including the implications of the proposed U.S. BIOSECURE Act), are a particular challenge for pure-play pharma companies.

This is because pharmaceutical manufacturing and distribution are more specialized and complex than consumer health supply chains (which are more like those in the fast moving consumer goods (FMCG) sector), and because all aspects of the pharmaceutical product lifecycle are much more highly regulated.

Supply chain flexibility and regulatory horizon scanning can help to mitigate these exposures, while pharma companies must also be particularly careful when navigating the integration of Chinese biopharma assets into their wider businesses.

WHAT DOES LIFE LOOK LIKE FOR STANDALONE CONSUMER HEALTH COMPANIES?

Standalone consumer health companies face a different set of issues, not least because they have lost the ability to leverage their parent's scientific reputation. They must navigate shifting consumer sentiment, as well as their heavy exposure to fluctuations in brand reputation and spending preferences, especially in respect of their more discretionary products.

Consumer health companies typically have lower margins and are more cash generative (given their reduced R&D spend) than pharma companies—with many in the post-separation period enjoying the greater returns that come from having standalone financials. Consumer health businesses will be focused on leveraging this to maintain momentum while doubling down on cost discipline and supply chain efficiency.

There is a fine line to tread between reinvesting in innovation, marketing or bolt-on transactions to boost portfolios, and returning cash to shareholders who have been supportive through the company's journey to a standalone entity. Analysts describe most standalone consumer health businesses as having "steady growth"—falling short of this expectation can rapidly impact market credibility and share price.

These companies will need to decide whether to maintain a broad offering across OTC categories or focus on specific high-growth segments. Without protection from patents or regulatory exclusivity, consumer health companies must find new ways to innovate; for example, by investing in Rx-to-OTC switches or expanding into wellness and digital health markets.

1. Rx-to-OTC switches

In recent years, the U.S. Food and Drug Administration (FDA), the UK Medicines and Healthcare Products Regulatory Agency (MHRA), as well as national regulators in Canada, Australia and New Zealand, have made it easier for companies to make drugs available over-the-counter. This trend allows consumer health companies to sell a wider range of products; according to IQVIA, the global OTC market increased from USD150bn in 2020 to USD193bn in 2024.

As a result, consumer health businesses are prioritizing investment in these switch assets. This is largely done by in-licensing from a pharma company that commercializes the Rx version of the product. For example, Opella gained FDA approval to market an OTC version of erectile dysfunction drug rights for Cialis, in a January 2025 agreement that preceded the company's spin-off from Sanofi.

2. Wellness

At the same time, consumers globally are spending more on products and services that promote better health, creating a wellness market worth USD1.8 trillion that is on track to grow by 5% to 10% per year. Standalone consumer health businesses already have robust product offerings in this space, so are well-positioned to benefit from this trend. Furthermore, they are likely to consider bolt-on acquisitions of the most promising new players coming into the market. Now competing head-to-head with FMCG giants, consumer health businesses must leverage their scientific origins to build consumer confidence in their wellness products. However, whether this will be enough to set themselves apart from their FMCG competitors remains to be seen.

3. Digital health

As individuals take increasing interest in, and control over, their own health, digital solutions such as smartphones and wearable technologies present another valuable source of growth for the consumer health industry. One study predicts that the global market for wearable healthcare devices could reach USD70bn by 2028, with annual growth of more than 11%.

The potential in this sub-segment of the market is evident from recent financing rounds. In December 2024, fitness tracking ring maker Oura raised USD200 million in Series D funding that valued the business at USD5.2bn. In May 2025, MindSpire, which develops AI-powered wearable devices for stress regulation and cognitive enhancement, raised USD850,000 in pre-seed funding.

As previously mentioned, independent consumer health businesses have been investing in Rx-to-OTC switches. However, they have not yet made significant moves to acquire wellness or digital health assets, although we expect to see this changing over the next few years as independent consumer health businesses seek to build new revenue streams and valuable datasets. In doing so, they will need to move away from their historic working practices and master FMCG-style agility and customer centricity, while still remaining conscious of the traps of consumer regulations and product liability risk.

AI in healthcare: legal and ethical considerations at the new frontier

AI is already transforming drug discovery and diagnosis—and has the potential to do likewise across other elements of the healthcare industry. But to get there will require robust regulatory frameworks to address safety, privacy, and bias concerns—as well as scenario-based assessments to ensure AI's safe and ethical deployment.

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Can human beings cure all diseases in our lifetime? For centuries, humanity has strived to cure diseases. With the advent of Artificial Intelligence (AI), the dream of a disease-free world seems more attainable than ever before. AI holds immense potential to revolutionize healthcare, promising enhanced care quality, expedited drug development, and reduced costs. Some experts predict that "AI will be as common in healthcare as the stethoscope."[1]

However, the rapid advancement of AI also potentially heightens certain risks, such as safety concerns, privacy issues, and bias. It is therefore essential to establish robust regulatory and ethical frameworks to manage them effectively.

01_K. Savchuk. "AI Will Be as Common in Healthcare as the Stethoscope." May 15, 2024. gsb.stanford.edu/insights/ai-will-be-common-healthcare-stethoscope.

AI'S ROLES IN HEALTHCARE

AI is revolutionizing healthcare by enhancing various aspects such as drug development, disease diagnosis, treatment, patient monitoring, and administrative tasks. Notable examples include Google's Med-PaLM, Stanford's CheXNet, and NVIDIA's partnership with Hippocratic AI. In addition to the advancements by the private sector, the World Health Organization (WHO) launched S.A.R.A.H. (Smart AI Resource Assistant for Health) in April 2024. This digital health promoter prototype, powered by generative AI, features enhanced empathetic responses in eight languages.

Looking ahead, we can expect a growing trend of collaboration among healthcare companies, technology firms, and research institutions. This synergy will drive further innovations and improvements in healthcare delivery and patient outcomes.

LEGAL FRAMEWORKS GOVERNING AI IN HEALTHCARE

Regulating AI in healthcare is an intricate task that involves striking a balance between fostering scientific innovation and protecting human rights and safety. Different countries may adopt various approaches to AI regulation, reflecting their unique values and priorities. For instance, jurisdictions such as the European Union (EU), Japan, South Korea, and China have AI-specific laws, while others, including the UK, US, and Australia, are applying existing technology-neutral laws to AI.[2] These diverging regulatory approaches result in significant compliance burdens for companies deploying and building AI.

We believe that effective regulation of AI in health requires international collaboration. By working together, countries can create a cohesive framework that enhances human welfare on a global scale. This collaborative effort can help ensure that AI technologies are used safely and ethically, while also promoting innovation and protecting human rights.

02_ In the U.S., there is no comprehensive federal legislation that regulates the development of AI to date. The White House recently released the U.S. AI Action Plan, which directs various U.S. agencies to take steps to invest in and enable vastly greater AI infrastructure in the U.S., foster AI innovation, and export U.S. AI innovation internationally while protecting U.S. trade secrets. The federal government is also seeking to quell AI regulation at U.S. State level, however there are many hundreds of AI-focused regulations that have been enacted or proposed across U.S. states, resulting in a fragmented landscape.

OVERVIEW OF AI LEGAL FRAMEWORKS

CURRENT AI LEGAL FRAMEWORKS

International organizations and governments are actively engaging with stakeholders to develop regulations and industry standards. Currently, most of these guidelines are principle-based, focusing on the fair and equitable use of AI.

- The WHO, for instance, has published various guidelines on AI in healthcare, emphasizing ethical considerations and best practices. These guidelines stress the importance of designing and using AI systems in ways that respect patient privacy, promote equity, and mitigate biases.
- In 2024, the Organization for Economic Cooperation and Development (OECD) updated its AI Principles, marking the first intergovernmental standard on AI. These principles aim to balance innovation, human rights, and democratic values.

From the perspective of legislation by sovereign states, the legal landscape for AI in healthcare is still in its infancy and continues to evolve. Many countries are currently relying on existing technology-neutral laws, such as data protection and equality laws, as well as industry standards, to address AI-related matters. Additionally, some nations are taking proactive steps to develop approaches to address issues arising from AI technologies.

- In the U.S., the Food and Drug Administration (FDA) has recently issued several discussion papers on AI drug development and manufacturing medical devices and guidance on decentralized clinical trials.[3] FDA generally supports the use of AI in healthcare development and has already reviewed and authorized over 1200 AI/Machine Learning (ML)-enabled medical devices.[4] In addition, the Center for Drug Evaluation and Research (CDER) of the FDA has established the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative to support the adoption of advanced manufacturing technologies that could bring benefits to patients.
- In the EU, the AI Act is recognized as the world's first comprehensive AI law. Although most of its requirements will only come into effect from August 1, 2026, and pure research and development AI is excluded much of its scope, the Act imposes regulatory requirements on AI systems based on four risk categories: (1) prohibited AI, (2) high risk AI, (3) AI triggering transparency requirements, and (4) general-purpose AI. In the context of healthcare, the middle two categories—"high risk AI" and "AI triggering transparency requirements"—are likely to be the most relevant. These categories will impose specific regulatory obligations to ensure the safe and ethical use of AI in healthcare applications.
- We are also increasingly seeing healthcare companies using general purpose AI models (GPAIM) for many hundreds of different use cases, across R&D and corporate functions. This is typically by way of customizing large language models using proprietary data. As such, the industry has been calling out for clarification regarding the extent to which such bespoke deployment of GPAIM will engage the specific EU AI Act obligations (applying from August 2, 2025). Whilst the EU Commission's guidelines[5], published in July 2025, offer some insight as to the compute threshold at which downstream modification constitutes the creation of a new model (with that downstream modifier then becoming a "provider" of the GPAIM and therefore subject to extensive compliance requirements), simple numerical thresholds do not necessarily tell the whole story. There are many different techniques for customizing general purpose AI models, and a simple compute threshold will not capture some customization techniques that are likely to have a more significant impact on model behavior, such as system prompts. Careful case-by-case consideration of the modification in practice will be necessary.

Organizations at risk of falling within scope of the EU AI Act GPAI requirements should consider the relevance of the General Purpose AI Code of Practice (the GPAI Code)6. The GPAI Code, while non-binding, has been developed collaboratively under the leadership of the European AI Office and is intended to be a practical tool to support organizations in complying with the AI Act for GPAI models, addressing transparency, copyright and safety and security in particular. The drafting process sparked significant debate among stakeholders: some arguing that the GPAI Code is overly restrictive with calls for greater flexibility, particularly regarding the training of LLMs. However, the European Commission asserts that signatories will benefit from a "simple and transparent way to demonstrate compliance with the AI Act", with enforcement expected to be focused on monitoring their adherence to the GPAI Code. It remains to be seen how organizations manage that adherence, particularly, for example, in the face of technical challenges (such as output filtering) and legal complexities (not least due to the interplay with ongoing court action) and the allocation of liability between provider and deployer.

03_The U.S. FDA. "Conducting Clinical Trials Decentralized Elements Guidance for Industry, Investigators, and Other Interested Parties." September 2024. https://www.fda.gov/media/167696/download.
04_The U.S. FDA. "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices." July 10, 2025. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.
05_General Purpose AI Guidelines, July 18, 2025. https://digital-strategy.ec.europa.eu/en/library/guidelines-scope-obligations-providers-general-purpose-ai-models-under-ai-act.
06_General Purpose AI Code of Practice, July 10, 2025 https://digital-strategy.ec.europa.eu/en/policies/contents-code-gpai.

- Unlike the EU, the UK has, to date, chosen not to pass any AI-specific laws. Instead, it encourages regulators to first determine how existing technology-neutral legislation, such as the Medical Device Regulations, the UK GDPR, and the Data Protection Act, can be applied to AI uses. For example, the Medicines and Healthcare products Regulatory Agency (MHRA) is actively working to extend existing software regulations to encompass "AI as a Medical Device" (or AIaMD). The MHRA's new program focuses on ensuring both explainability and interpretability of AI systems as well as managing the retraining of AI models to maintain their effectiveness and safety over time.
- In China, the National Health Commission and the National Medical Products Administration recently published several guidelines on the registration of AI-driven medical devices and the permissible use cases of applying AI in diagnosis, treatment, public health, medical education, and administration. The guidelines all emphasize AI's assisting roles in drug and medical device development and monitoring under human supervision.

Leading AI developers are also setting up in-house AI ethics policies and processes, including independent ethics board and review committee, to ensure safe and ethical AI research. These frameworks are crucial while the international landscape of legally binding regulations continues to mature.

RECOMMENDATIONS: SCENARIO-BASED ASSESSMENTS FOR AI TOOLS

Healthcare companies face a delicate balancing act. On one hand, their license to operate depends on maintaining the trust of patients, which requires prioritizing safety above all else. Ensuring that patients feel secure is non-negotiable in a sector where lives are at stake. On the other hand, being overly risk-averse can stifle the very innovations that have the potential to transform lives and deliver better outcomes for patients and society as a whole. Striking this balance is critical: rigorous testing and review processes must coexist with a commitment to fostering innovation, ensuring progress without compromising safety.

In this regard, a risk-based framework is recommended for regulating AI in healthcare. This approach involves varying the approval processes based on the risk level of each application. Essentially, the higher the risks associated with the AI tools, the more controls and safeguards should be required by authorities. For instance, AI tools that conduct medical training, promote disease awareness, and perform medical automation should generally be considered low risk. Conversely, AI tools that perform autonomous surgery and critical monitoring may be regarded as higher risk and require greater transparency and scrutiny. By tailoring the regulatory requirements to the specific risks, we can foster innovation while ensuring that safety is adequately protected.

Moreover, teams reviewing AI systems should consist of stakeholders representing a broad range of expertise and disciplines to ensure comprehensive oversight. For example, this may include professionals with backgrounds in healthcare, medical technology, legal and compliance, cybersecurity, ethics and other relevant fields as well as patient interest groups. By bringing together diverse perspectives, the complexities and ethical considerations of AI in healthcare can be better addressed, fostering trust and accountability.

DATA PROTECTION AND PRIVACY

Data privacy requirements are a key consideration when using AI in healthcare contexts, especially given that many jurisdictions' laws broadly define "personal data", potentially capturing a wide range of data. Further, privacy regulators have been the forerunners in bringing AI-related enforcement actions. For example, AI tools such as OpenAI's ChatGPT have encountered extensive regulatory scrutiny at EU level through the European Data Protection Board (EDPB) taskforce and NOYB (None of your Business)/the European Center for Digital Rights, the data privacy campaign group founded by Max Schrems, the well-known privacy activist, has initiated a complaint against the company in Austria, alleging GDPR breach. DeepSeek has also attracted immediate attention from EU and other international regulators, with investigations initiated and the EDPB taskforce extended to cover its offerings.

PRIVACY CONSIDERATIONS IN AI

There are several privacy considerations to navigate when using AI. This can raise challenges as, often U.S.-based, developers look to navigate highly regulated jurisdictions such as those in the EU, where regulators are scrutinizing approaches taken to data protection compliance. This includes the issue of identifying a lawful basis for the processing activity. Many jurisdictions' data privacy laws contain a legitimate interests basis or similar provisions which, when applicable, permit the data controller to process personal data without first requiring individuals' explicit consent. However, there are diverging views on whether this basis can be used for AI-related processing.

The European Data Protection Board (EDPB) issued an Opinion 28/2024[7] in December 2024, which provides detailed guidance on the use of legitimate interest as a legal basis for processing personal data in the development and deployment of AI models, including LLMs (the EDPB AI Opinion). The EDPB AI Opinion, although indicating that legitimate interest may be a possible legal basis, highlights the three-step test that should be applied when assessing the use of legitimate interest as a legal basis, i.e. (1) identify the legitimate interest pursued by the controller or a third party; (2) analyse the necessity of the processing for the purposes of the legitimate interest pursued (the "necessity test"); and (3) assess that the legitimate interest is not overridden by the interests or fundamental rights and freedoms of the data subjects (the "balancing test"). It also highlights the need for robust safeguards to protect data subjects' rights. The examples where legitimate interests could be a suitable lawful basis in the EDPB AI Opinion are relatively limited, including examples such as a conversational agent, fraud detection and threat analysis in an information system."

An EDPB Opinion adopted a few months earlier, in October 2024, which addresses the legitimate interests basis for processing of personal data more generally (the EDPB LI Opinion), while helpful in referencing scientific research as a potential legitimate interest, is cautious about establishing a legitimate interest on the basis of societal benefit, emphasizing that the legitimate interest should tie to the interest of the controller or third party and that processing should be "strictly" necessary to achieve the legitimate interest (i.e., there is no other reasonable and equally effective method which is less privacy intrusive). The EDPB AI Opinion clarifies that the unlawful processing of personal data during the development phase may not automatically render subsequent processing in the deployment phase unlawful, but controllers must be able to demonstrate compliance and accountability throughout the lifecycle of the AI system.

07_EDPB Opinion 28/2024 on certain data protection aspects related to the processing of personal data in the context of AI models. https://www.edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-282024-certain-data-protection-aspects_en.

INDIVIDUAL CONSENT

As an alternative, businesses may need to obtain individual consent for AI-related processing activities. While this can be a difficult basis to use given the high bar for valid consent, it can be particularly challenging in an AI healthcare context given the heightened compliance obligations that apply to special category data (which includes health data), raising the requirement for consent to "explicit consent" combined with the potential for public distrust and misunderstanding around AI technologies. Further, in some jurisdictions it is common for individuals to place stringent conditions, including time restrictions, on what their personal data can be used for. This could prevent their personal data being used in connection with AI, given it is not always possible to delete or amend personal data once it has been ingested into an AI system.

PROFESSIONAL ACCOUNTABILITY

Determining fault when an AI system makes an error is a particularly complex issue, especially given the number of parties that may be involved throughout the value chain. The challenge is heightened by the fact that different regulations may apply at different stages, and the legal landscape is still developing in response to these new technologies.

In the case of fully autonomous AI decision-making, one possible approach is that liability could fall on the AI developer, as it may be difficult to hold a human user responsible for outcomes they do not control. However, the allocation of responsibility could vary depending on the specific circumstances and regulatory frameworks in place.

Where AI systems operate with human involvement, another potential approach is for regulators to introduce a strict liability standard for consequences arising from the use of AI tools. While this could offer greater protection for patients, it may also have implications for the pace of technological innovation. Alternatively, some have suggested that requiring AI developers and commercial users to carry insurance against product liability claims could help address these risks. The WHO, for example, has recommended the establishment of no-fault, no-liability compensation funds as a way to ensure that patients are compensated for harm without the need to prove fault.[8]

In July 2025, a study, commissioned by the European Parliament's Policy Department for Justice, Civil Liberties and Institutional Affairs, was published[9]. Its aim was to critically analyze the EU's evolving approach to regulating civil liability for AI systems, four policy proposals are discussed and the report advocated for a strict liability regime targeting high-risk AI systems. Ultimately, the question of legal responsibility for AI in healthcare remains unsettled and is likely to require ongoing adaptation as technology and regulation evolve. Accountability will be a particular challenge given the complexity of the value chain and the interplay of different regulatory regimes. It will be important for all stakeholders to engage in continued dialogue to ensure that legal frameworks keep pace with technological developments and that patient safety remains a central focus.

08_WHO. "Ethics and governance of artificial intelligence for health: Guidance on large multi-modal models." 2024.
09_European Parliament. "State of Play of Academic Freedom in the EU Member States." Study, Directorate-General for Internal Policies, Policy Department for Citizens' Rights and Constitutional Affairs, 2025. https://www.europarl.europa.eu/RegData/etudes/STUD/2025/776426/IUST_STU(2025)776426_EN.pdf.

ETHICAL CONCERNS

There are multiple ethical considerations that developers and deployers may need to address when using AI systems in healthcare. Three prominent examples are explored below.

BIAS CAUSING UNJUST DISCRIMINATION

Bias in AI systems can lead to unjustified discriminatory treatment of certain protected groups. There are two primary types of bias that may arise in healthcare:

- Disparate impact risk: This occurs when people are treated differently when they should be treated the same. For example, a study[10] found that Black patients in the U.S. health care system were assigned significantly lower "risk scores" than White patients with similar medical conditions. This discrepancy arose because the algorithm used each patient's annual cost of care as a proxy for determining the complexity of their medical condition(s). However, less money is spent on Black patients due to various factors including systemic racism, lower rates of insurance, and poorer access to care.[11] Consequently, using care costs created unjustified discrepancies for Black patients.
- Improper treatment risk: Bias in AI systems can arise when training data fails to account for the diversity of patient populations, leading to suboptimal or harmful outcomes. For example, one study[12] demonstrated that facial recognition algorithms often exhibit higher error rates when identifying individuals with darker skin tones.[13] While this study focused on facial recognition, the same principle applies in healthcare, where AI systems used for dermatological diagnoses have been found to perform less accurately on patients with darker skin. This occurs because the datasets used to train these systems often contain a disproportionate number of images from lighter-skinned individuals. Such biases can lead to misdiagnoses or delays in treatment, illustrating the critical need for diverse and representative training data in healthcare AI applications.

TRANSPARENCY AND EXPLAINABILITY

Providing individuals with information about how healthcare decisions are made, the process used to reach that decision, and the factors considered is crucial for maintaining trust between medical professionals and their patients. Understanding the reasoning behind certain decisions is not only important for ensuring high-quality healthcare and patient safety, but also helps facilitate patients' medical and bodily autonomy over their treatment. However, explainability can be particularly challenging for AI systems, especially generative AI, as their "black box" nature means deployers may not always be able to identify exactly how an AI system produced its output. It is hoped that technological advances, including recent work on neural network interpretability,[14] will assist with practical solutions to this challenge.

HUMAN REVIEW

To facilitate fair, high-quality outcomes, it is important for end-users—often healthcare professionals—to understand the AI system's intended role in their clinical workflow and whether the AI system is intended to replace user decision-making or augment it. However, it may not always be appropriate for the human to override the AI system's output; their involvement in the workflow will likely vary depending on what the AI tool is being used for.

For example, if an AI system has been trained to detect potentially cancerous cells in skin cell samples, and the AI system flags the sample as being potentially cancerous but the healthcare professional disagrees, it may be more appropriate to escalate the test to a second-level review than to permit the healthcare professional to simply override the AI system's decision. A false positive here is likely to be less risky than a false negative. It is therefore important to take a considered, nuanced approach when determining how any human-in-the-loop process flow should operate.

CONCLUSION

AI offers significant benefits in healthcare but also presents legal and ethical challenges that must be navigated. Collaborative efforts among policymakers, healthcare professionals, AI developers, and legal experts are essential to establish robust frameworks that safeguard patient rights and promote equitable access to advanced healthcare technologies.

10_Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. "Dissecting racial bias in an algorithm used to manage the health of populations." Science, 366(6464), 447-453 (2019). https://www.science.org/doi/10.1126/science.aax2342.
11_Hoffman, K.M., Trawalter, S., Axt, J.R., & Oliver, M.N. "Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites." Proceedings of the National Academy of Sciences, 113(16), 4296-4301 (2016). pmc.ncbi.nlm.nih.gov/articles/PMC4638275 and www.pnas.org/doi/10.1073/pnas.1516047113.
12_Buolamwini, J., & Gebru, T., "Gender shades: Intersectional accuracy disparities in commercial gender classification", Proceedings of Machine Learning Research, 81, 1–15 (2018). https://www.media.mit.edu/publications/gender-shades-intersectional-accuracy-disparities-in-commercial-gender-classification/.
13_Melanoma Research Alliance. "Making AI Work for People of Color: Diagnosing Melanoma and Other Skin Cancers.: Melanoma Research Alliance. 2022. https://www.curemelanoma.org/blog/article/making-ai-work-for-people-of-color-diagnosing-melanoma-and-other-skin-cancers.
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Medical wearables under the microscope: U.S. regulatory, data privacy and cybersecurity perspectives

Wearable tech is everywhere: smart rings that track our every move, medical devices that can time and dose meds, luxury smartwatches... But as we obsess over our step counts and sleep scores, bigger questions arise. Are unseen eyes—doctors, developers, data brokers—also watching? Who's protecting our data, and what boundaries—if any—exist at this rapidly expanding digital frontier?

Here, we clarify the complex and evolving U.S. regulatory framework around medical devices and wearables. We also explore their associated privacy and cyber risks—and explain the responsibilities of developers and end-users.

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The default assumption in the U.S. is that all health data is regulated by the Health Insurance Portability and Accountability Act (HIPAA). However, in reality, health data privacy is regulated by a patchwork of federal laws, agency rules, and a maze of state regulations. HIPAA is just one piece of a much bigger, messier puzzle.

Nonetheless, when considering the privacy of health data, HIPAA is a good place to begin. HIPAA applies to three kinds of "covered entities"—healthcare providers, health plans, and healthcare clearing houses (effectively middlemen that help collect payments and check claims from healthcare providers for errors before forwarding them to health plans for processing). It also picks up third parties and vendors who access protected health information (PHI) as part of the services they provide to covered entities, also known as "business associates". Organizations that exist outside of those categories (i.e., covered entity or business associate) are not subject to HIPAA.

WHY MUCH OF THE LIFE SCIENCES AND WELLNESS INDUSTRY IS BEYOND HIPAA'S REACH

This leaves a broad swath of the life sciences and health and wellness space beyond HIPAA's reach: pharmaceutical companies, health tracking apps, and certain providers that exist outside of the insurance market. In fact, it's often more accurate to think of HIPAA as regulating participants in the U.S. health insurance system, rather than the entire healthcare ecosystem. As a result, despite consumer expectations, HIPAA may not apply to the wearable, device, or the company that develops it—even if it does apply to the entity using it.

Moreover, the U.S. Department of Health and Human Services (HHS) has clarified this point. In a 2005 FAQ, HHS states that "a medical device company is not providing 'health care' if it simply sells its appropriately labeled products to another entity for that entity to use or dispense to individuals." It also notes that in those cases, the device manufacturer is governed by the Food and Drug Administration (FDA). This means that a healthcare provider may be subject to HIPAA but the manufacturer of the device or wearable may be wholly exempt.

For example, a doctor may be able to access device-level data from a continuous glucose monitoring system or a direct-to-consumer sleep tracker. The healthcare provider then feeds that data into an individual's health record and treatment plan, thus creating PHI. However, the device manufacturer may never access that data or provide treatment advice.

Assuming it does access that data, it still does so outside of the scope of HIPAA. There is no covered entity or business associate relationship, it is simply the maker. And the user is just that—a consumer, not a patient. However, this does not mean the device maker is off the hook as far as health data privacy is concerned. For the purposes of that activity, the device manufacturer is subject to the FDA's jurisdiction, while the loss of any personal data may be covered by other healthcare privacy laws, like the Federal Trade Commission's (FTC) health breach notification rule and state breach notification laws.

At the same time, there remain circumstances where a device manufacturer may be subject to HIPAA. More often than not, this relates to how the device or a connected app is serviced. For example, in the above scenario, if the device manufacturer creates a connected app for its glucose monitor and that app is designed to allow a healthcare provider to directly access the app and manage patient care, the manufacturer and app are now within HIPAA's scope because the app is in the care chain.

FDA RELATIVELY QUIET ON PRIVACY AND CYBER—UNTIL NOW

While the FDA is the primary regulator of medical devices, it has been less prolific when it comes to privacy and cybersecurity rules. This is despite the agency repeatedly stating that cyber is a top concern.

That may be starting to change. The Consolidated Appropriations Act of 2023 established mandatory cybersecurity requirements applicable to the marketing of new "cyber devices" (i.e., medical devices). The act empowered the FDA to enforce compliance with these requirements through warning letters, mandatory recall and remediation, withdrawal or denial of market approval, civil penalties, and in certain cases, criminal sanctions.

In June 2025, the FDA published guidance with cybersecurity recommendations for premarket approval of medical devices, including use of a Secure Product Development Framework (SPDF), a set of processes to identify and reduce vulnerabilities through the device lifecycle (design, development, release, support, and decommissioning). The guidance also sets forth special requirements for developers and manufacturers of "cyber devices" with software, internet connectivity, and technology features that could be vulnerable to cybersecurity threats. Cyber device developers and manufacturers must include the following information with their premarket submissions:

- a cybersecurity management plan;
- documentation of processes and procedures to ensure reasonable assurance of cybersecurity (e.g., implementation and documentation of security controls and cybersecurity testing); and
- a software bill of materials (SBOM) that identifies all proprietary, commercial, open-source, and off-the-shelf software components along with their support status and end-of-support dates.

Enforcement, however, has been spotty. Since 2023, the FDA has issued several warnings in relation to medical devices where cybersecurity vulnerabilities would either cause the device to malfunction, enable remote access, and/or allow the alteration of sensitive data. In July 2023, it also issued a mandatory recall of DNA sequencing systems for remediation of a known vulnerability. In that case, the manufacturer's compliance with the FDA's conditions was not the end of the story.

The DOJ brought claims alleging the manufacturer violated the False Claims Act by knowingly selling the systems to federal agencies without an adequate cybersecurity program to sufficiently identify and address such vulnerabilities. In 2025, the manufacturer entered into a settlement of USD9.8 million with the DOJ to resolve the allegations.

To avoid the risk of FDA and other agency enforcement, developers and manufacturers should consider (and are) voluntarily recalling their cyber devices or pushing out patches for identified or potential weaknesses.

FTC IS PRIMARY REGULATOR FOR CONSUMER HEALTHTECH COMPANIES BEYOND SCOPE OF HIPAA

The FTC has become the primary regulator for the rapidly growing sector of consumer-facing health technology companies that fall outside the scope of HIPAA.

As of early 2010, the FTC Health Breach Notification Rule (HBNR) covered businesses that offer products and services (e.g., online services, mobile apps, and connected devices) directly or indirectly related to personal health records (PHR).

Initially, PHR referred to electronic individually identifiable health information collected from multiple sources and managed by or for individuals. However, since 2021, the FTC has clarified that the HBNR applies to PHR regardless of whether it is collected from multiple sources, broadening the landscape of companies that must comply with the HBNR's breach notification obligations.

Notably, a failure to comply constitutes an unfair and deceptive trade practice under Section 5 of the Federal Trade Commission Act. Here, the FTC has been successful in obtaining significant monetary and structural remedies against businesses with consumer-facing health apps, wearables, telehealth platforms, and ancillary services.

WHEN DOES A HEALTHCARE OR WELLNESS APP, OR WEARABLE, BECOME A MEDICAL DEVICE?

Is the mobile app that sends you wellness tips or the smart watch that tracks your heart rate considered an FDA-regulated medical device? The answer is that it depends on its intended use and the functions it performs.

A healthcare app or wearable becomes an FDA-regulated medical device when (i) it performs (or transforms a device to perform) functions that are intended to diagnose, cure, mitigate, treat, or prevent disease or otherwise affect the structure or function of the body; or (ii) is marketed with claims that it may perform such functions.

The FDA also regulates apps that are accessories to regulated medical devices. For example, a healthcare app that provides insulin dose calculations based on user-entered glucose readings would be considered an FDA-regulated medical device because it performs diagnostic functions and provides treatment recommendations for a specific disease and/or person. Conversely, an app or wearable that merely collects, stores, and transmits health information without interpreting it, like a running watch or calorie intake tracker intended to encourage a healthy lifestyle, is not considered an FDA-regulated medical device. However, such apps and devices remain subject to other federal and state consumer protection and privacy regulators and laws. And the line between the two can be blurry for developers and consumers.

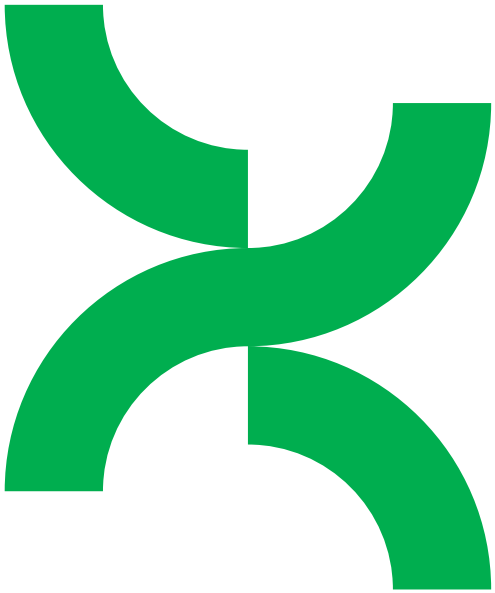
UNIQUE RISKS TO WEARABLES AND MEDICAL DEVICES

Medical devices and the systems that support them are susceptible to the same cyber attacks as other technologies. These include ransomware strikes, distributed denial of service (DDoS) attacks, which are intended to disrupt the availability of an app or device, and even surveillance operations that use devices or wearables to collect sensitive data.

However, as a piece of operational technology, there are some specific risks worth addressing in relation to medical devices. The first is jailbreaking.

Jailbreaking is the unauthorized modification of a device's software or firmware to bypass manufacturer settings and restrictions, usually to enable features or functions not added by the manufacturer. Jailbreaking is not necessarily malicious, and indeed is often done by users or patients. For example, medical devices from different manufacturers often cannot directly communicate with each other, meaning that hardware such as glucose monitors and insulin pumps may be controlled by separate apps. However, it may be possible for a configuration modification to enable users to control both devices from the same app; the benefit to the user is increased functionality, but the additional egress channel to an unvetted app introduces risk to the system. Jailbreaking circumvents manufacturer-installed security controls, firmware integrity checks, and encryption protocols that may be integral to safeguard the functions performed and personal data processed by medical devices.

Following an alteration, the reliability of the device's authentication mechanisms, audit logs, and transmission safeguards can no longer be assured. Moreover, the altered firmware often disables automatic security updates and patches, which can create opportunities for "zero-day exploits" (whereby threat actors leverage vulnerabilities unknown to the manufacturer to gain entry to systems) and the deployment of malware to access, manipulate, or delete patient data.



“JAILBREAKING” POSES THREAT TO INTERCONNECTED HEALTHCARE ECOSYSTEMS

Equally troubling is the broader security cascade that jailbroken devices can precipitate within interconnected healthcare ecosystems. Compromised wearables frequently interface with mobile applications, cloud dashboards, and electronic health record platforms through unsecured APIs or peer-to-peer protocols.

This enables attackers to move into more robust clinical networks and facilitates cybersecurity events that can have far-reaching effects. Falsified or corrupted data streamed from a jailbroken device could induce erroneous clinical interventions or cause a device to stop functioning properly, posing direct threats to patient safety and exposing healthcare providers and device manufacturers to substantial tort liabilities.

Further, insurers, regulators, and litigants may consequently view the continued use of jailbroken hardware as negligence per se, emphasizing the importance of comprehensive security policies, device procurement standards, and ongoing monitoring frameworks to mitigate this multifaceted risk.

Malicious actors could disable medical devices’ life-sustaining functions or interfere with them to deliver incorrect dosages, potentially resulting in injury or death. Moreover, attacks that focus on making small changes on the device can be difficult to detect.

Then there is the added challenge presented by the fact that medical devices are often expensive, with users reasonably expecting them to remain functional and supported for many years.

Unlike consumer electronics, where an unsupported laptop or smartphone may be inconvenient, the consequences of a medical device becoming an unsupported “legacy” system can be dangerous.

When manufacturers discontinue updates or support, patients may be left using devices with known vulnerabilities and no path to remediation. Additionally, expecting users—who may be elderly, ill, or lack technical expertise—to consistently install software updates is unrealistic, even though those updates may be critical to address cybersecurity flaws. This gap between device longevity, user capability, and ongoing security support creates a persistent risk that is unique to the medical device ecosystem.

SOLUTIONS REQUIRE COLLABORATION BETWEEN STAKEHOLDERS

Wearables and connected medical devices are reshaping how we live our lives, but are evolving in a legal landscape that remains, at best, fragmented. In the U.S., a single data point captured on a device can migrate through a series of regulatory regimes: HIPAA when ingested by a provider’s electronic health record system; it may then be monitored by the FDA if the underlying functionality crosses the line into diagnosis or treatment; and it may also fall in scope of the FTC’s HBNR.

To add further complexity, overlaying those statutory touchpoints is a growing body of cybersecurity expectations and risks, all anchored by the FDA’s cyber requirements and enforced through recalls, warning letters, and even False Claims Act liability.

As we become more tethered to our devices, so the questions will get harder. Finding the solutions will require lawmakers, developers, and consumers to understand the regulatory framework’s shortcomings and strengths, as well as the cyber risks associated with our increasingly connected selves.

Historic UPC Court of Appeal decision changes the landscape for European generics

In a landmark ruling the UPC Court of Appeal has for the first time in the pharmaceutical sector granted a provisional injunction for imminent patent infringement, clarifying that completing administrative procedures for generic drugs may trigger injunctive relief, even before commercialization steps are taken.

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The Court of Appeal of the Unified Patent Court (UPC) has reversed a decision from the Lisbon Local Division of the UPC (LLD UPC) in the case of Boehringer Ingelheim International GmbH (Boehringer Ingelheim) v. Zentiva Portugal, LDA (Zentiva). Contrary to the LLD UPC, the UPC Court of Appeal considered that the application for a Prior Evaluation Procedure (PEP, on INFARMED, the Portuguese human medicines and health products regulator) to obtain pricing, reimbursement and acquisition conditions from public hospitals for a medicine with nintedanib as an active pharmaceutical ingredient constituted a risk of imminent infringement.
In reaching its conclusion, the UPC Court of Appeal applied a four-step test.

BACKGROUND

This case involved Boehringer Ingelheim seeking a preliminary injunction to stop Zentiva Portugal from launching generic versions of its drug Ofev, alleging imminent infringement of its European patent No. EP 1 830 843 for nintedanib in treating idiopathic pulmonary fibrosis. Zentiva obtained two marketing authorizations in August 2024 and completed the Prior Evaluation Procedure (PEP) in December 2024, allowing potential sales to public hospitals, over a year before the patent's expiry.

The LLD UPC provided detailed guidance on the assessment of imminent infringement under Articles 25 and 62 UPCA. It held that merely obtaining marketing authorizations and completing administrative steps (such as a PEP) does not, in itself, establish a concrete risk of imminent infringement. The applicant must show that the defendant's conduct makes it more likely than not that market entry will occur before patent expiry. In this case, as Zentiva had not taken any further steps towards commericialization, the LLD UPC found no imminent infringement and dismissed the application for provisional measures.

The decision highlighted the UPC's high threshold for proving imminent infringement in pharmaceutical cases, requiring compelling evidence demonstrating a real and immediate risk before granting injunctive relief.

COURT OF APPEAL DECISION

The UPC Court of Appeal confirmed the findings of the LLD UPC that the mere application or even grant of a marketing authorization for generics does not constitute patent infringement. However, the completion of national procedures concerning a health technology assessment, pricing and the reimbursement of generics may constitute a patent infringement.

To assess whether the completion of the PEP in Portugal equated to an imminent infringement, the UPC Court of Appeal considered four criteria:

- Whether Zentiva needed to take further administrative steps to commercialize the generics.
- Whether the characterization of the pharmaceutical acquisition procedures under Portuguese law as precontractual actually matters.
- Whether the acquisition of generics by public hospitals could only be acquired by public procurement procedures.
- Whether Zentiva was effectively hindered from taking part in any proceedings for the acquisition of generics.

After considering the facts in Portugal, the UPC Court of Appeal stated that there was a risk of imminent infringement, as:

- There was no need for Zentiva to take any further administrative steps to commercialize the generics—once they were labeled as blue in the INFARMED database, as they could be delivered immediately.
- The pre-contractual characterization of the acquisition procedure is not relevant—public tenders constitute an act of infringement, no matter whether direct awards or prior consultations for public tenders are precontractual.
- Portuguese public hospitals have various other ways to acquire generics besides public procurement procedures.
- Zentiva was not hindered from participating in acquisition procedures for nintedanib products in Portugal.

In addition, the UPC Court of Appeal considered that obtaining the PEP more than a year before patent expiry could only be objectively justified as a means to offer the generics and hence infringe the patent.

Accordingly, after the assessment of urgency, necessity and balance of interest, the UPC Court of Appeal granted a provisional injunction against Zentiva, assorted with a daily penalty of up to EUR10,000 for each infringing package. The injunction was granted for all UPC contracting states where the patent is in force, not just Portugal. Zentiva is ordered to pay an interim award of EUR199,000 to Boehringer Ingelheim plus its legal costs.

This ruling represents the first preliminary injunction granted in the pharmaceutical sector since the UPC's establishment, leaving no prior UPC case law from which to benchmark the level of monetary relief awarded.

IMPLICATIONS AND KEY TAKEAWAYS

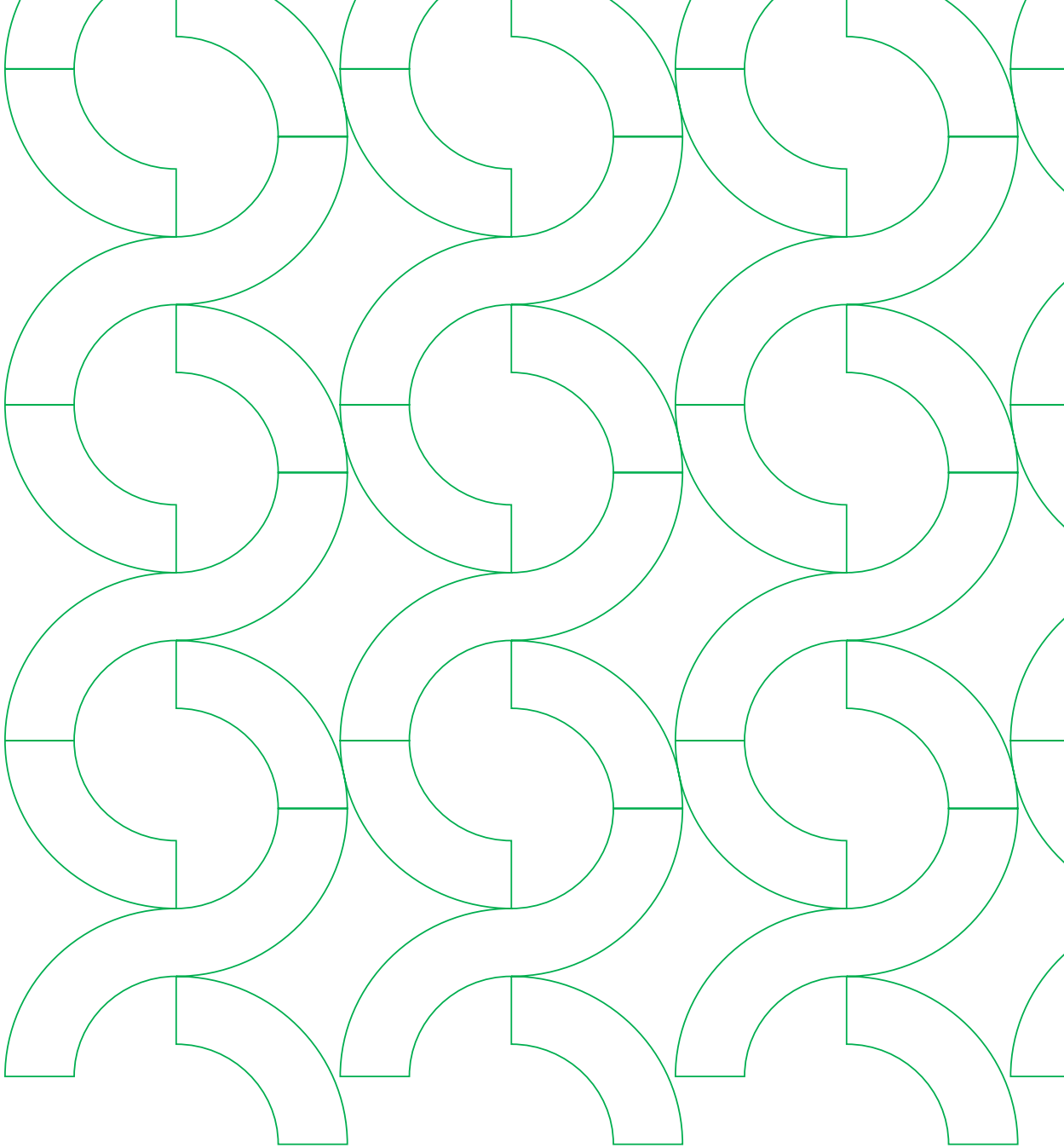
Pharmaceutical companies cannot rely on an application for or grant of a marketing authorization for generics to demonstrate an imminent risk of infringement justifying a preliminary injunction in UPC contracting states where the patent is in force.

However, they may rely on the completion of national procedures concerning a health technology assessment, pricing and the reimbursement of generics to claim imminent infringement, provided that they can demonstrate that the procedures:

(i) enable the commercialization of the generics without further administrative steps; and

(ii) have no legitimate justification other than the offering of the generics.

This means that any claim of imminent risk of infringement should demonstrate the risk of imminent commercialization of the generics in the state where a health technology assessment, pricing and reimbursement procedures have been completed. However, it remains unclear whether the UPC will consider that completion of such procedures just before the expiration of the patent also constitutes an imminent threat of infringement.



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