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Turning Insight into Action: A Life Sciences Playbook for 2026

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Clients & Friends,

Looking back on 2025, one word comes to mind: resiliency. The life sciences sector has taken some hits, but it kept moving. Public markets are showing real signs of life again. The private side - frozen at times - is beginning to thaw. Investors are stepping back in, deals are returning and companies that spent two years tightening their belts are coming to market with a clearer sense of purpose. It's a welcome shift that appears to be rewarding those who remained patient.

Our team has been steady through it all, helping clients move through the uncertainty with practical, grounded advice. We're also proud that Polsinelli was recently recognized by Chambers and Partners for excellence in Life Sciences. It reflects the work we do every day as a unified, cross-department life sciences team and reinforces the trust our clients place in us.

With the industry heading to San Francisco soon for the J.P. Morgan Healthcare Conference, we're looking forward to seeing many of you at our [networking reception](#) on Tuesday, January 13, now at a [new venue](#).

With high hopes for 2026,




Rick Jordan

Lead, Life Sciences Industry Group
Co-Chair, Venture Capital and Emerging
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M&A-Ready from Day One



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Corporate, IP and Regulatory housekeeping should not be an afterthought.

As the calendar turns to a new year and the Life Sciences and BioPharma sectors look forward to gathering in San Francisco for the J.P. Morgan Healthcare Conference, there is a palpable sense of excitement about the direction of Life Sciences and BioPharma dealmaking, particularly in M&A. The last 4-5 years have seen significant choppiness in M&A activity: decreases, then increases, then decreases again in both the number of M&A deals and the total value of M&A deals. Each year just before the JPM Conference, the optimists

became vocal, predicting an upmarket in terms of both number and size of deals. In 2024, the optimists were wrong, as a number of factors contributed to a sluggish 2025 for M&A dealmaking, extending the lethargy of the prior few years. As we move into 2026, however, the headwinds that have been negatively impacting the M&A markets, such as a slower economy, increasing inflation, higher interest rates and greater regulatory confusion and decreases in government funding, are expected to be less impactful. They may be outweighed by an improving inflation rate, lower interest rates, significant deployable capital within Big Pharma, upcoming patent expirations and increased interest in the industry by private equity firms.

With an expected increase in M&A activity, you may decide that now is the time to sell. Or an acquirer may approach you with a lucrative offer. Alternatively, you may think that now is the time to

start interviewing investment bankers about a possible exit in the next few years. In any case, you will want to be as ready as possible to start the due diligence process when acquirers come knocking. What you don't want is to discover at that stage that structural or historical issues exist that could slow the process, reduce the acquisition price or, in some extreme cases, jeopardize the deal altogether.

Whether you're an early-stage startup with M&A still years down the road or you are a later stage company anticipating an acquisition in the near term, it's important to understand the structural corporate, legal and financial issues that should be avoided or addressed as soon as possible, before they become obstacles.



1. Cap table – keep it clean and simple.

An acquirer wants a clear record of **who owns what**. That record is your capitalization table. A clean cap table means:

- One official system that matches signed documents for every share of common and preferred stock, option, warrant, convertible note, SAFE or other securities issued by the company.
- An up-to-date valuation that reflects material events such as funding rounds, IND/IDE clearance or the readout of pivotal data, supported by either a recent third-party 409A valuation or by a reasoned, informed board determination.
- Grants of stock options and restricted stock approved in writing by the board, with clear and unambiguous vesting schedules, early exercise and company repurchase rights and vesting acceleration triggers (including acceleration upon a change of control) spelled out clearly in the grant documents.
- SAFEs and convertible notes whose conversion terms at a sale are unambiguous and easy to understand and calculate.
- All discussions about equity among founders, including previously undocumented promises, have been documented and ratified by the board.

The goal here is to ensure that all potential dilution is understood and that there are no potential arguments with securityholders, especially former founders or employees who retained equity post-separation.

2. Prove you own and can use the science.

Two of the critical questions that drive value in life sciences M&A are: “Do you own the rights?” and “Can you use those rights without violating someone else’s rights?” To help answer these questions in the affirmative, we suggest you prioritize the following:

Assignment of Inventions.

Require execution of invention assignment agreements by anyone who has contributed or could possibly contribute to the company’s core inventions, including founders, employees, consultants, CRO partners and manufacturing partners, so that the company can demonstrate that it clearly owns all intellectual property created. In cases of employees and consultants, be sure that

these agreements are signed by any new employee or consultant who could possibly, however remote, later be deemed to have contributed to the science. Ideally and typically, this would include all employees and consultants.

Ownership. Establish and maintain a comprehensive, easily accessible library of all license and sublicense agreements and any amendments.

Freedom to Operate. Maintain an up-to-date view of relevant third-party patents you may encounter and your strategy for avoiding or licensing them, along with any FTO opinions from counsel.

ACTION: In short, be sure that you can demonstrate that the buyer is getting what they are paying for.



3. Identify contract provisions that may be triggered upon a change of control or assignment.

Many agreements require consent by the other party to an assignment of the contract or trigger other counterparty rights in the case of a sale or change of control of the company. Be sure to identify these provisions early in the process and consider negotiating to eliminate them, ideally before you are required to disclose a potential deal to the contract counterparty and lose negotiating leverage. You won't always be able to change these clauses, but knowing early that third-party consent may be required, or other third-party rights may be triggered, allows you to inform a buyer upfront that this could be a gating issue.

Look closely at:

- **University licenses.** Many prohibit assignment and/or charge an assignment fee if you sell the company.
- **Other licenses, joint development and similar agreements.** Some may prohibit assignment without consent or may grant a right of first negotiation or right of first refusal to the counterparty with respect to a sale of the company. These types of provisions are critical to identify as early as possible, as they may chill potential buyer interest. These types of agreements also often contain cross-licenses between the parties; consider whether any cross-licenses may be impacted by an M&A transaction. As drafted, a buyer may be obligated to cross-license its own IP to the counterparty following an M&A transaction and may be unwilling to do so.
- **Sponsored research and material transfer agreements with universities or hospitals.** Look at who owns derivatives or cell lines and whether you need permission to assign the agreement to a buyer.
- **Contracts with CDMOs and CROs (manufacturing and research partners).** Make sure the company owns the data, methods and improvements, and that the partner must help transfer know-how to a buyer.
- **Hospital pilots, payer and customer contracts.** Upon a sale some end automatically, include automatic price increases, or give the other side a right of first refusal or first offer on the company.
- **Notes, warrants and SAFEs.** Check for cash penalties or required cash payout (rather than conversion) if you sell, as well as rights of first refusal and rights of first offer.

ACTION: Third parties can stall a deal and add risk, so it's advisable to get an early handle on who they are and how you plan to manage them during a potential transaction.



4. Due diligence and reps and warranties: where life sciences deals can break down.

Representations and warranties are critical parts of an M&A purchase agreement. They allocate risk and help protect the buyer from potential issues after a transaction closes. In life sciences transactions, representations and warranties (particularly regarding intellectual property and regulatory matters) are often much more robust than in transactions in tech and other industries. Extensive due diligence will likely be performed by a potential buyer, and such diligence will inform the reps and warranties requested. The following are likely to be key areas of focus in a life sciences M&A transaction:

IP and FTO. As noted above, a buyer will trace a seller's intellectual property ownership or license rights from the originating institution through every amendment and assignment. They will look for field-of-use holes, sublicensing limits and background IP that never truly transferred and may use any issues discovered to lower the purchase price offered, among other things. It is advisable for potential sellers to trace ownership, identify any holes and attempt to fix them before engaging with potential sellers.

Regulatory correspondence and quality. Buyers want the complete picture of a company's FDA interactions, including minutes of FDA meetings, commitments, inspection history, FDA warning letters, quality manuals and evidence of your quality management system.

If the FDA ever raised a question, a prospective buyer will expect to see the FDA's inquiries and the company's documented response.

Compliance, privacy and healthcare laws. Exposure under anti-kickback, Stark and similar laws, interactions with healthcare professionals, transfers of value, business associate agreements, data use agreements and security testing history will all surface as part of the due diligence process. Even for pre-revenue companies, the diligence bar is high for anything touching patients, protected health information (PHI) or clinical sites.

ACTION: In summary, sellers should identify key due diligence issues early and fix what can be fixed prior to the transaction.



5. Setting up a buyer-friendly virtual data room.

Strong virtual data rooms share three traits:

- **Organization and context.** Folders are created that correspond to a broad table of contents. Each folder starts with a short overview and a simple index. If there's an exception or a gap, include a brief note explaining it. Examples of typical folders include:
 - Corporate Governance and Cap Table
 - IP and Licenses
 - Regulatory and Quality
 - Clinical and Scientific
 - Manufacturing
 - Commercial and Contracts
 - Privacy/Security/Compliance
 - Finance and Tax
 - People
 - Litigation and Insurance
- **Consistency.** Items contained within each folder should be labeled with clear, consistent file names and dates (e.g., License Agreement between X and Y dated Z). Avoid duplicate or unlabeled PDFs.
- **Speed.** Assign an owner for each folder so that you can respond quickly to questions and update the data room as appropriate during diligence.

A good data room allows the buyer to relatively quickly review its contents and to search for specific items. While an incomplete or disorganized data room won't kill a deal, it can make the due diligence process frustrating and more expensive for both sides.

A sample 90-day plan.

Life sciences sellers can become significantly more “acquirable” by focusing on the matters identified above well in advance of sitting down at the negotiating table with a potential buyer. Below is an illustrative 90-day plan to implement the foregoing:

Weeks 1-2

Ownership and IP. Tie every security on the company’s cap table to a signed document. Paper any missing invention assignments. Get an updated 409A valuation if a big milestone has occurred or consider getting a 409A valuation if you have not previously gotten one.

Weeks 3-4

Build the virtual data room. Create a table of contents and a clear folder structure based on it. In every folder, include a short note to the reader and identify the dates that the documents were uploaded, who at the company is responsible for each document, and notes about documents with multiple versions. Be sure to add new documents to the virtual data room as they are executed by the company.

Weeks 5-6

Audit contracts. Review all contracts for assignment and other critical provisions. Negotiate amendments for the risky ones while you still have leverage (i.e., before there is a deal on the table that requires disclosure to the counterparty).

Weeks 7-8

Gather regulatory information and data. Assemble agency meeting notes and inspection history. Finalize the data integrity archive and document and close out open corrective actions.

Weeks 9-10

Privacy and security. Map what sensitive data you have and where it flows. Make sure data-sharing agreements with hospitals and partners are in place. Pull the latest security test or assessment and a brief incident history (even “no incidents”).

Weeks 11-12

Dry-run diligence. Do a mock Q&A with your key officers/employees and counsel. Fix weak spots in the process, not just the files.

The Bottom Line

Being M&A-ready is not about fancy binders. It’s about no surprises: clear ownership, clean contracts, trustworthy data and a data room that is easy to follow and to search. Sweat the details early so your science gets full value later.



Reshaping the FDA: 2025's Key Trends and the 2026 Outlook



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For the life sciences industry, changes at the U.S. Food and Drug Administration (FDA) can directly affect business risk and opportunity. The first year of the new Trump administration has been no exception, and understanding key trends from 2025 — along with monitoring new signals in the coming year — will be critical to developing regulatory strategies and maximizing opportunities for success.

A New Guard

2025 saw a historic leadership exodus at the FDA that is likely to cause the most

significant reshaping of agency direction in decades. The directors of the FDA's drug, biologics, veterinary medicine and tobacco centers have departed, as have many key deputies and the heads of the Human Foods Program, Office of Inspection and Investigation and Digital Health Center of Excellence. Already, new leaders are making dramatic breaks from their predecessors, such as Dr. Vinay Prasad's swift change in approach to COVID-19 vaccines after being named to head the biologics center. Top political leadership at the FDA and U.S. Department of Health and Human Services (HHS) also appear to be actively involved in other product- or class-specific decisions, such as potential labeling changes for acetaminophen.¹ While these shifts make many FDA decisions less predictable, they also create unique opportunities to advocate for new regulatory approaches.

ACTION: Companies should assess their pending and planned submissions to the agency with this landscape in mind.

Targeted Deregulation

The administration's agenda has created a seesaw dynamic of deregulation in some areas and aggressive new scrutiny in others. In February 2025, President Trump issued an executive order² mandating that for each new "regulation" (defined to include guidance), agencies must eliminate ten others. Though some worried this move could dramatically reduce output of updated FDA recommendations, the agency continued to issue new guidance documents in 2025; it also increasingly used other means, such as journal articles published on accelerated timelines, to announce new policy. Several new initiatives aim to reduce regulatory burden, including a roadmap to eliminate animal testing in preclinical studies and draft guidance indicating that many biosimilars will no longer require comparative efficacy studies for approval.

However, the FDA's overall deregulatory message has been coupled with increased regulatory scrutiny in areas prioritized by HHS Secretary Robert F.

¹ <https://www.hhs.gov/press-room/hhs-trump-kennedy-autism-initiatives-leucovorin-tylenol-research-2025.html>; <https://www.federalregister.gov/documents/2025/09/24/2025-18510/approval-of-previously-withdrawn-new-drug-application-for-wellcovorin-leucovorin-calcium-tablets>

² <https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/>



Kennedy Jr. For example, as part of its “crackdown” on direct-to-consumer (DTC) drug advertising, the FDA announced that it will pursue rulemaking to require full provision of risk information in broadcast and digital ads, unsettling its longstanding approach. Disruption of the status quo in favor of tightened regulatory controls also extended to the food industry. Currently, companies can self-affirm that an ingredient is generally recognized as safe (GRAS) and market food containing that ingredient without notifying the FDA. But following a directive from Secretary Kennedy, the FDA is working on a rulemaking to mandate FDA notification for such ingredients — a major shift from how most new food ingredients currently enter the U.S. market.³ At the same time, many states

are passing legislation to restrict food chemicals or “ultraprocessed” foods.⁴

This could quickly create a patchwork of inconsistent state requirements, making compliance far more complex.

Speeding Development and Review Amidst Staffing Losses

The FDA commissioner has focused on speeding medical product development and review, starting with the rollout of the “Elsa” generative AI (GenAI) tool to boost scientific review efficiency. The FDA has since announced multiple pilot programs and initiatives for products and companies aligned with the administration’s goals, such as onshoring, accelerating cures and curbing drug costs.

These include the:

- **Commissioner’s National Priority Review Voucher Pilot;**
- **“PreCheck” Program;**
- **ANDA Prioritization Pilot;** and
- **Plausible Mechanism Pathway.**

These programs could meaningfully benefit a select group of eligible drug and biologic companies, but do not address other types of products and may draw staff from reviewing “standard” submissions. While staff losses have affected some review teams more than others, sobering FDA data from October show net losses of 1,093 employees in the drug center and 224 in the biologics center for fiscal year (FY) 2025.⁵

³ <https://www.hhs.gov/press-room/reviving-gras-pathway.html>

⁴ <https://kffhealthnews.org/news/article/ultraprocessed-foods-states-maha-rfk-dyes-additives-california/>

⁵ <https://www.fda.gov/industry/fda-user-fee-programs/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data-fy-2023>

NET
STAFFING
LOSSES AT FDA

1,093
EMPLOYEES
IN DRUGS

224
EMPLOYEES
IN BIOLOGICS



Those numbers make it difficult to see how the FDA can avoid productivity gaps, even with AI efficiency gains. The FDA also likely experienced a surge in new submissions after the government shutdown, so companies should brace for delayed response times through at least the second quarter of FY 2026 as the agency works through its backlog.

Unprecedented Transparency

As part of its “radical transparency” push, the FDA began releasing complete response letters (CRLs) shortly after issuance.⁶ Historically, these letters — which detail the deficiencies identified by the FDA in a drug or biologic application — were not disclosed before the underlying product was approved. While often heavily redacted, the newly public letters reveal far more than the FDA has typically released outside the context of an advisory committee meeting on a specific company’s application. Drug and biological product manufacturers should carefully consider

their disclosure and communication strategies before submitting a new application, with the expectation that any CRL they receive will become public. Expanding the “radical transparency” initiative in other areas may also result in the FDA proactively releasing categories of documents that have typically been available only through individual FOIA requests.

Developments to Watch for in 2026

Review Goal Performance:

When the FDA releases its annual user fee reports for FY 2025, look for any trends in review times. Consistent signs of slower FDA reviews will be a strong indicator that staffing levels are insufficient and for companies to build more cushion into their planned timelines.

User Fee Negotiations:

Negotiations between the FDA and industry representatives over the prescription and generic drug, medical device and biosimilar user fee programs are underway, and draft “commitment letters” for each program should be

released by the fall of 2026. The letters will be a key window into new initiatives — like increased fees for foreign establishments — and changes to review goals and processes for FYs 2028-2032. In addition, significant White House or HHS involvement in the user fee negotiations will clearly signal that officials within higher levels of the administration intend to take a much more active role in managing FDA affairs than the historical norm.

Continued Onshoring

Emphasis: With tariff policies in flux, rising cost pressures may accelerate strategic shifts in manufacturing geography, despite efforts to seek tariff relief through delays and exemptions. Expect the FDA to maintain its push for supply-chain resiliency, including through additional onshoring incentives — which the agency is already pursuing as part of the user fee negotiations⁷ — and increased scrutiny of foreign manufacturing.

⁶ <https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89>

⁷ <https://www.fda.gov/media/189620/download?attachment>; <https://www.fda.gov/media/189873/download?attachment>



Federal Food Legislation:

As Congress weighs various bills related to food ingredient safety, including reforms to the FDA's GRAS notification process, the key legislative battle may be over federal preemption. Congress could pass a law with language to override the emerging patchwork of state-level restrictions on food additives, but such efforts have faced opposition from Make America Healthy Again (MAHA) activists.⁸

AI Surveillance of Product

Promotion: In announcing its DTC advertising crackdown, the FDA noted its use of AI tools “to proactively surveil” drug ads.⁹ Use of such tools will likely expand to other areas, such as promotion of medical devices and tissue products.

ACTION: Companies should review their product-related content, including on their own social media channels and those of any paid influencers, in anticipation of increased FDA scrutiny.

Updated Digital Health

Policies: 2026 has already seen two updates in the digital health space with the January 6 release of revised guidance documents on clinical decision support software and general wellness products. In the year ahead, look for the FDA to update other digital health guidance¹⁰ and to offer more insight into its planned regulatory approach for GenAI-enabled devices.

⁸ <https://www.nytimes.com/2025/11/06/health/rfk-big-food-companies-maha.html>

⁹ <https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising>

¹⁰ <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2026-fy2026>

Fraud & Abuse Enforcement in the Life Sciences: The Year In Review



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Federal fraud and abuse enforcement in 2025 remained intensely focused on life sciences and medical technology companies. Despite broader shifts in white-collar priorities with the change in administration, the Department of Justice (DOJ), the Department of Health and Human Services (HHS) and the HHS Office of Inspector General (OIG) continue to deploy the False Claims Act (FCA) and Anti-Kickback Statute (AKS) aggressively in this sector, and the government has announced some new areas of focus.

DOJ–HHS FCA Working Group: A New Focal Point for Life Sciences

In July 2025, DOJ and HHS formally reestablished and relaunched a **False Claims Act Working Group** to coordinate health care fraud enforcement with a list of priority enforcement areas, many focusing on life sciences and med tech, including:

- Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees and formulary placement and price reporting;
- Kickbacks related to drugs, medical devices, durable medical equipment and other products paid for by Federal health care programs;
- Materially defective medical devices that impact patient safety; and
- Manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services.

Although summary data for cases resolved in 2025 is not yet available, DOJ has announced settlements and judgements totaling millions of dollars in life sciences cases, largely aligning with the priorities announced by the Working Group.

DOJ continues to rely on whistleblowers to initiate the majority of cases under the False Claims Act. The Working Group also announced plans to identify new leads and investigations via data mining.

Kickbacks and Speaker Programs: Life Sciences Still in the Crosshairs

As highlighted above, the Working Group announcement makes clear that the government remains interested in investigating violations of the AKS in the life sciences industry. An area of consistent focus has been industry-sponsored speaker programs that provide educational content to prescribing physicians. After a wave of settlements, OIG had published a **Special Fraud Alert** in 2020, which highlighted certain “inherent risks” in these programs and warned the industry about “suspect characteristics” that could indicate a speaker program is at a higher risk of enforcement under the AKS. Since that alert, the government has announced a steady stream of case resolutions, including at least two sizeable settlements in the past year.¹

¹ <https://www.justice.gov/opa/pr/pfizer-agrees-pay-nearly-60m-resolve-false-claims-allegations-relating-improper-physician>; <https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs>



In most of these cases, the government and whistleblowers alleged that manufacturers paid honoraria to speakers and sponsored high-end restaurant meals to induce physicians to prescribe the companies' products. The government also has alleged that physicians attended multiple overlapping sessions with the same content, and that some physicians brought spouses, family members and friends who had no legitimate need for the educational content presented. Under the Working Group, the industry should expect government scrutiny of speaker programs and similar activities to continue.

An Emerging Enforcement Area: Defective Devices and False Claims

In other cases, whistleblowers have successfully used the False Claims Act to bring lawsuits alleging that medical device manufacturers sold implantable devices and components that the manufacturers knew were defective or that failed at a higher-than-acceptable rate.² The government has argued that, because the devices failed prematurely,

they were not reasonable and necessary to use on patients, and therefore any claims under Federal health care programs — including Medicare and Medicaid — were false. Although this theory has been used in previous whistleblower cases, the Working Group's decision to include defective medical devices in its priority list could signal more cases like these on the horizon.

Increased Enforcement and Regulatory Overhaul: The Wound Care Industry

The use of skin substitutes, a broad category of wound care products made from donated tissue or synthetic materials, has rapidly grown in popularity and in cost. According to the Centers for Medicare & Medicaid Services (CMS), Part B spending for these products rose from approximately \$250 million in 2019 to over \$10 billion in 2024, a nearly 40x increase. This Federal spending attracted significant enforcement and regulatory attention in 2025.

In June 2025, DOJ **announced** criminal charges involving \$1.1 billion in allegedly fraudulent Medicare

² E.g., <https://www.justice.gov/usao-md/pr/exactech-agrees-pay-8-million-resolve-false-claims-act-allegations-selling-defective>.



claims for skin substitutes, including charges targeting health care professionals accused of prescribing skin substitutes in exchange for kickbacks. In September 2025, OIG published a **report** highlighting fraud and abuse risks in the Medicare reimbursement methodology for skin substitutes, including the potential for the “spread” — the difference between providers’ acquisition cost and the Medicare reimbursement — to create an incentive for overutilization. This regulatory and enforcement interest culminated in a major change in payment. CMS, citing “dramatic” increases in spending, **announced** that beginning in January

2026, skin substitutes will be reimbursed at a flat rate, dramatically reducing reimbursement for the use of many products in this category and cutting the payments physicians receive to administer them. CMS is also planning future changes to its payment approach for these products, based on pricing data it collects this year.

Geographic Hot Spots: Strike Force Expansion

In addition to enhanced federal oversight, the industry can expect additional local focus. For example, DOJ recently **announced** an expansion of the Health Care

Fraud Unit’s New England Strike Force into the District of Massachusetts, citing Boston’s role as a hub for the life sciences. The U.S. Attorney’s Office in Boston already has a reputation for health care fraud enforcement: the office recovered more than \$450 million in health care fraud cases in FY2025. According to DOJ, expanding the Strike Force will expand efforts to detect, investigate and prosecute health care fraud in that region. Keep an eye out for new enforcement activity in at least one region that has a longstanding connection to the life sciences.



From Scattered Logs to Connected Insight: How Eschbach is Transforming Frontline Documentation in Life Sciences

Eschbach, a Polsinelli client with offices in both Boston and Germany, is helping life sciences manufacturers rethink how critical operational knowledge is captured, communicated and applied on the plant floor. Known for its Shiftconnector® platform — already in use across chemical and biotech facilities — the company is now expanding deeper into pharma with tools that unify real-time human insight and structured production systems to strengthen compliance, documentation and quality.

To understand how Shiftconnector supports that goal, we took a closer look at how the platform is helping pharma teams connect frontline insight with system data.

The Problem: Communication Breaks Between People and Systems

In many plants, Manufacturing Execution System (MES), Enterprise Resource Planning (ERP), maintenance systems and shift notes all hold pieces of the truth — but they're siloed. That makes it hard to see connections that matter for compliance, quality, or equipment reliability. For example, a slight isolator pressure dip or a reseated gasket might sit unnoticed in a shift log. But when connected with MES batch data and maintenance history, it can reveal the root cause of a recurring sterility-risk alarm.

Shiftconnector helps bridge that gap. It links frontline observations and maintenance actions with the structured data in other systems — giving companies in heavily regulated industries, like pharma, real-time clarity. "Acting as a single source of truth," Shiftconnector unifies people, processes and data, boosting production quality and accelerating confident decisions.

Designed for Life Sciences from the Ground Up

Highly regulated industries share similar challenges: heavy documentation loads, complex handoffs, strict traceability and the constant risk that small communication gaps will turn into quality issues. Pharma faces these pressures daily. While Shiftconnector was originally built for regulated process industries, the Eschbach team has deliberately evolved it to address the unique demands of pharmaceutical manufacturing.

The team focused on streamlining documentation and embedding compliance into daily workflows, adding features like configurable electronic logbooks, robust audit trails, standardized deviation and shift-handover processes and seamless QA and batch record integration. These enhancements were designed to reduce compliance risks, strengthen operational integrity, and help pharma teams maintain consistent quality while meeting stringent regulatory standards.

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Smarter Insight with SAMI

To make data easier to work with, Eschbach has introduced SAMI: Shiftconnector Artificial Manufacturing Intelligence. SAMI helps teams sift through data faster and make better decisions by enabling natural-language queries and providing context-aware results from shift reports, electronic logbooks, deviations and maintenance records.

Pharma manufacturing teams use SAMI to accelerate troubleshooting and root cause analysis by revealing connections between automated data, human observations and events that would otherwise take hours to find manually. It streamlines operations by guiding users to the most relevant past events, improving knowledge transfer and helping new employees learn from real operational history.

Looking Ahead: Clarity for Complex Operations

Life sciences manufacturing is only getting more complex, with tighter regulations, leaner teams (to help control costs) and rising expectations for speed and quality. Looking ahead, the industry needs systems that don't just record what happened but also help teams understand why it happened and what to do next.

For Eschbach, that means continuing to evolve Shiftconnector into a connected intelligence platform. And for pharma companies, it's one way to stay ahead — by rethinking how knowledge moves across the plant floor.



When Biology Meets Computing: The Patent Challenges of Bioinformatics



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Bioinformatics is the interdisciplinary field that applies computational methods, algorithms and software tools to analyze, interpret and manage biological data. The field emerged from the processing power needed to handle massive datasets generated by genomic sequencing. What once took years to analyze can now be accomplished in days or hours.

Bioinformatics applications span the life sciences. Protein structure prediction helps drug developers understand interactions. Gene expression profiling reveals which genes are active in diseased tissue. In medical diagnostics, these tools identify disease biomarkers, predict drug response and assess disease risk through complex analyses.

Yet as bioinformatics innovations advance, many inventors discover that securing patent protection is difficult. Bioinformatics inventions often are rejected as being directed to patent-ineligible subject matter.¹ Specifically, the U.S. Patent and Trademark Office (USPTO) may assert that bioinformatics inventions are directed to the “abstract ideas” grouping of judicially-created exceptions, which includes “mathematical concepts.”² Consider a hypothetical example illustrating these challenges: a method to diagnose Chronic Traumatic Encephalopathy (CTE) in living patients.

Hypothetical: Revolutionary Diagnostic Test Faces Patent Obstacles

CTE can currently only be diagnosed after death through brain tissue examination. Imagine a researcher develops a bioinformatics method to diagnose CTE in living patients — obtaining blood and saliva samples, sequencing the DNA fragments in both samples, and using a mathematical formula to analyze specific DNA properties that correlate with CTE presence and severity.

This breakthrough of bioinformatics in action would surely enable early intervention. But under current patent law, this innovation would face significant hurdles in making its way to market.

¹ *Alice v. CLS Bank*, 573 U.S. 208, 216 (2014)

² Manual of Patent Examining Procedure (MPEP) § 2106.04(a)



USPTO examiners often evaluate claimed inventions of this kind under the framework established by *Mayo v. Prometheus*, 566 U.S. 66 (2012) and *Alice v. CLS Bank Int'l*, 573 U.S. 208 (2014).

These cases created a two-step analysis, examining whether:

1. The claim is directed to a patent-ineligible concept, such as an abstract idea, natural phenomenon or law of nature; and
2. If so, whether the claim contains something “significantly more” than the ineligible concept.

For our hypothetical CTE diagnostic method, examiners might identify multiple judicial exceptions. The relationship between DNA properties and CTE could be characterized as a natural phenomenon; the mathematical formula might be deemed an abstract idea; and the examiner may characterize the remaining claim elements — obtaining blood and saliva samples and sequencing DNA — as conventional techniques.

Here, we will assume that the examiner rejects the claim — deeming it an abstract idea³ without “significantly more.”

³ Based on the authors' experience with prosecuting bioinformatics patent claims, such claims are more often rejected as being directed to “abstract ideas” than “natural phenomenon.”



Strategies for Success

Despite the above challenges, patent applicants have several different strategies to overcome the rejection:

1. Have the claim recite a particular treatment.⁴

With the CTE claim example, adding a step of a neuroprotective intervention for diagnosed CTE would likely make the claim eligible. But such strategy is not without pitfalls — a treatment may implicate patent enforceability issues where no single actor infringes all the steps in a claim. For example, the analysis of blood and saliva samples and analysis of the mathematical formula may be performed by a computer, but the treatment itself may be performed by a physician.

2. Have the claim show an improvement to the relevant technology field.⁵

In our example, the CTE diagnosis method arguably improves medical technology and diagnostic technology. But patent examiners may reject this argument and counter that the claimed improvement — the diagnostic step — cannot be directed to the abstract idea itself, the CTE diagnosis.⁶ Instead, applicants may overcome the rejection if the claim recites technical improvements in the field, such as improvements in sample acquisition technologies. For example, the claim may recite improved sample preparation or assaying techniques, which can be improvements to technology that overcome the eligibility rejection.

3. Include unconventional combinations. While blood draws and saliva sampling may each be conventional, their specific combination for CTE diagnosis might be unconventional. The USPTO clarifies that “conventional” means routine and widely known, not merely discussed in scientific papers. Evidence showing limited practice of using both saliva and blood DNA sequencing for diagnosing neurodegenerative disease can significantly strengthen the argument.

⁴ MPEP § 2106.04(d)(2)

⁵ MPEP § 2106.04(d)(1)

⁶ The MPEP does not define what qualifies as a “technology” to be improved.



The Path Forward

Beyond our hypothetical, the stakes extend far beyond CTE. Diagnostic methods for detecting cancer biomarkers, identifying genetic disorders in fetuses and measuring disease risk through multi-gene panels all face similar challenges. The uncertainty surrounding bioinformatics patents creates real consequences — investors hesitate to fund startups when intellectual property protection remains

uncertain. The chilling effect on innovation could slow the development of precision medicine tools that patients desperately need.

Yet a path forward does exist, as described above. Companies developing bioinformatics innovations should work closely with experienced patent counsel to overcome challenges from the USPTO to obtain valuable patents.

Breakthrough diagnostic methods may be discovered tomorrow or ten years from now; and when they arrive, practitioners will need to be ready. Securing patent protection will require not just scientific innovation, but also legal strategy calibrated to navigate a challenging patent system.

“Bioinformatics inventions are often rejected as patent-ineligible subject matter — but innovators who understand the USPTO’s framework can still prevail.”

University Tech Transfer in Transition: Highlights from Polsinelli's Life Sciences Tech Transfer Office Roundtable

Polsinelli's **David Hsu** and **Andrew Merken** recently hosted two virtual discussions with leaders from university technology transfer offices across the country. The discussions brought together **Beth Fischer**, Director of Life Science Intellectual Property at the Wisconsin Alumni Research Foundation (WARF); **Jordan Bell**, Director of Intellectual Property for Life Sciences at SkySong Innovations (Arizona State University); **Nichole Mercier**, Assistant Vice Chancellor and Managing Director of Washington University's Office of Technology Management; **Gazell Call**, Senior IP Specialist for Life Sciences at the University of Texas at Austin's Discovery to Impact; **Martin Son**, Senior Director of Technology Commercialization at Tufts University; and **Mitch Graffeo**, Licensing Manager for Life Sciences at Tech Launch Arizona (University of Arizona). Together, they explored how academic discoveries move from lab to market amid changing technologies and funding pressures. The following includes lightly edited highlights from our conversation.

Q: How are your offices structured, and how does that shape your work?

Beth Fischer, WARF: WARF is a nonprofit independent from the university, which gives us flexibility and an endowment to fund our own operations. That independence means we can be candid with researchers and experiment with programs like our Therapeutics Development Group and Accelerator Fund. We still align closely with the university's mission, but we have room to move quickly when opportunities arise.

Nichole Mercier, Washington University: We are fully integrated into the university. I call our model "modified cradle-to-grave"—our licensing team manages disclosures, patenting and licensing, but we also have dedicated marketing, venture and technology-development functions. That structure keeps us connected to academic departments and nimble with faculty.

Jordan Bell, SkySong Innovations (ASU):

SkySong is also a separate nonprofit, which lets us take equity in startups — something Arizona's public universities can't do directly. We are lean, about 25 people total, with IP and business-development teams working hand in hand. That agility helps when we're negotiating with founders or responding to investors.

Gazell Call, University of Texas at Austin:

We have 42 team members at Discovery to Impact, organized across three main pillars: Tech Transfer, Longhorn Ventures, and operations. Within Tech Transfer, we work in functional teams — IP development, business development, licensing and collaborative research — with specialists assigned by discipline. A disclosure moves from IP to BD to licensing as it progresses. We also manage gap funding that overlaps with our venture arm to support promising early-stage projects.



Martin Son, Tufts University: Our office is small and focused — four licensing professionals aligned by discipline, supported by operations staff who handle IP administration, compliance and financials. We also have embedded legal counsel from the university. Being lean does keep us closely connected to inventors and lets us stay hands-on across the portfolio.

Mitch Graffeo, University of Arizona: Tech Launch Arizona has just under 40 people, including eight licensing managers and a venture team that supports startups pre-license. Licensing managers are embedded across colleges and handle outreach, disclosures and commercialization strategy. I work closely with the College of Medicine, building relationships and helping faculty map out a path for their technologies.

Q: How do you decide which technologies to pursue for patenting or commercialization?

Beth Fischer, WARF: We meet monthly as a committee — IP, licensing, ventures and legal — to review every disclosure. The group weighs scientific merit, patent strength and potential market fit. It's an inexact science in many of our technology spaces because it's early-stage research. We try to balance commercial potential with the long-term value of protecting Wisconsin innovation.

Nichole Mercier, Washington University: We are liberal about filing provisional patents, but the 12 months before conversion from provisional to non-provisional is key. We test the technology with marketing campaigns, industry feedback and domain-expert panels to see if it resonates. The decision to invest further depends on what we learn in that period.

Jordan Bell, SkySong Innovations: Our IP managers have discretion within a decision matrix we've built. We file provisionals, then spend that year marketing aggressively to gauge real-world interest before moving to PCT or national phase.

Q: What does your current life-sciences portfolio look like, and how is AI influencing it?

Nichole Mercier, Washington University: We've always been strong in neuroscience, oncology, inflammation and imaging. What's changed is the rise of AI, especially in medical imaging and diagnostics. When paired with our clinical datasets, these tools can speed validation and open new predictive applications.

Beth Fischer, WARF: We see everything from quantum computing to ag-tech to drug development. Pharma translation has become harder, but we're seeing exciting cross-disciplinary work — AI for oncology diagnostics, smart agriculture, even animal health.

Gazell Call, University of Texas at Austin: AI now appears in many of our new life-sciences disclosures — digital-twin models, precision oncology, data-driven therapeutics. We often co-manage these inventions with our computing specialists because the boundaries between biotech and software have blurred.

Martin Son, Tufts University: Much of our life-sciences innovation sits at the intersection of engineering and biology, like drug-delivery platforms, imaging technologies and devices. We're also starting to see AI used in drug-discovery optimization, though commercialization there is still early-stage.



Q: Faculty engagement can make or break tech transfer. How do you encourage researchers to participate?

Jordan Bell, SkySong Innovations: We hold weekly office hours across multiple campuses and visit faculty meetings to give quick “IP 101” overviews. We also employ graduate “patent scouts” who flag potential inventions, and even use AI tools that scan publications for unreported innovations.

Beth Fischer, WARF: Outreach is a huge part of our work. We meet with new faculty, speak at training grants, and run our “WARF Ambassadors” student program so grad students can spread the word in labs. Data monetization has become a new talking point. Many researchers are just starting to realize their datasets have commercial value.

Gazell Call, University of Texas: We’re experimenting with tools to make the disclosure process easier. Faculty told us the internal disclosure forms can take 2-3 hours to complete, so we’re piloting an AI feature that lets them upload a manuscript and auto-populate the form — cutting that time to 30 minutes. We also host monthly “coffee clubs” and join lab meetings to build trust.

Mitch Graffeo, University of Arizona: I try to keep things informal. I’ll set up a table at the medical school with candy and just talk to whoever stops by, no strings attached. The idea is to demystify tech transfer and make it approachable.



Top Row: David Hsu, Ph.D., Shareholder, Polsinelli; Nichole Mercier, Ph.D., Assistant Vice Chancellor & Managing Director, Washington University; Andy Merken, Shareholder, Polsinelli

Bottom Row: Beth Fischer, Ph.D., Director of Life Science Intellectual Property, Wisconsin Alumni Research Foundation; Jordan Bell, Ph.D., Director of Intellectual Property for Life Sciences, SkySong Innovations



Top Row: Gazell Call, Ph.D., Senior IP Specialist for Life Sciences, University of Texas at Austin’s Discovery to Impact; David Hsu, Ph.D., Shareholder, Polsinelli

Bottom Row: Mitch Graffeo, JD, Licensing Manager for Life Sciences, Tech Launch Arizona; Martin Son, Senior Director of Technology Commercialization, Tufts University

Q: How are universities balancing revenue goals with broader impact?

Mitch Graffeo, University of Arizona: For us, “impact” isn’t code for profit, it’s about making a difference. If a technology improves patient outcomes or even serves a small population, that’s success. The revenue follows if the science finds its way into the world.

Gazell Call, University of Texas: We deliver the same message to our researchers: commercialization is a university priority because it creates societal value, not because it’s a revenue engine. Few tech transfer offices actually turn a profit; the real metric is whether the innovation helps people.

Martin Son, Tufts University: More than three-quarters of tech transfer operations nationwide operate at a loss. Revenue generation plays an important role, but tech transfer is first and foremost a vital service function: ensuring compliance with Bayh-Dole, helping faculty navigate IP and translating publicly funded research for public benefit.

Q: What are your strategies for managing patent costs and international filings?

Beth Fischer, WARF: I budget a fixed amount for each provisional, adjusting only when needed. International filings are selective, mostly for pharma or high-potential assets. Diagnostics or research tools typically stay U.S.-only because the return doesn’t justify the cost.

Nichole Mercier, Washington University: We use fixed-fee arrangements with outside counsel, including Polsinelli, to manage predictability. We go to national phase only when there’s a clear path, ideally after a license or venture investment.

Jordan Bell, SkySong Innovations: We follow a “three-strike rule” for office actions: after three rejections, we re-evaluate. PCTs are filed only for technologies showing faculty or industry interest; otherwise, we stay domestic.

Q: Licensing to Founder startups versus established-companies — how do you decide which path to take?

Nichole Mercier, Washington University:

We study what works. At WashU, the most successful spinouts had external investors and CEOs — not faculty doubling as founders and operators. Our ventures team now helps build those teams early and connects inventors to VCs.

Beth Fischer, WARF: We look for the best partner, period. A startup can move fast but also demands more resources and patience. Established companies often bring scale and speed. Either way, our goal is getting the technology to market responsibly.

Jordan Bell, SkySong Innovations:

We defer to inventors who are truly committed to building a company, but we'll also introduce outside entrepreneurs or venture studios if that's a better fit.

Gazell Call, University of Texas: Longhorn Ventures supports faculty founders through programs like "Startup in a Box," connecting them to mentors and investors. Our focus is helping them form strong, viable teams.

Q: How are funding shifts and federal policy changes affecting your work?

Martin Son, Tufts University: The uncertainty around federal research budgets and possible changes to indirect-cost recovery is forcing universities to rethink sustainability. We may have to be more selective with patents and seek more industry collaboration.

Gazell Call, University of Texas: We haven't seen a slowdown yet, but most current projects stem from already-allocated funds. We expect more demand for internal gap-funding soon.

Beth Fischer, WARF: It's challenging, but it's also motivating. Faculty who never thought about commercialization before are now exploring it as part of their funding strategy, which ultimately strengthens the bridge between academia and industry.

Q: Any closing thoughts?

Martin Son, Tufts University: Tech transfer isn't just a profit center — it's a public service dedicated to helping researchers turn ideas into impact. At the same time, revenue from licensing and partnerships fuels reinvestment in research, ensuring the innovation engine keeps running for everyone's benefit.

Polsinelli provides intellectual property support to Washington University in St. Louis, Arizona State University's SkySong Innovations, the University of Texas at Austin's Discovery to Impact and the University of Arizona's Tech Launch Arizona.

Watch the
full roundtable.

[VIEW VIDEO](#)



Practical Strategies for Drug Labeling Amendments



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In October, Polsinelli and Consilio (a provider of legal technology solutions and enterprise legal services) co-hosted the first annual New Jersey Pharma Forum. The event brought dozens of pharmaceutical company executives and lawyers together in Princeton for a one-day seminar on developments across legal and regulatory disciplines.

Among the topics discussed, Polsinelli's Hatch-Waxman and Biologics team presented actionable takeaways from recent court decisions concerning section viii statements under Section 505 of the Federal Food, Drug, and Cosmetic Act (which requires

applicants to list patents for which infringement claims could be asserted against the generic drug).

So-called “skinny labels” — and now, “chubby labels” — modify product labeling to avoid patent-protected uses. By adhering to best practices, generic drug applicants can increase the likelihood of successfully avoiding infringement of such patents.

Skinny Labels Do Not Grant Automatic Immunity

Surviving label language and marketing statements will be scrutinized for inducement.

In 2021, the Federal Circuit issued a decision¹ that called into question the utility of section viii statements. The applicant had omitted an indication for congestive heart failure to avoid patents listed in the Orange Book with the use code “decreasing mortality caused by congestive heart failure.” Nonetheless, the Federal Circuit held that a patent holder could obtain

a judgment for induced infringement based on evidence that the applicant was marketing the drug in a manner that encouraged the patented therapeutic use.

Applicants Should Tread Carefully

A clean label carve-out may not be enough if your marketing tells a different story.

More recent Federal Circuit decisions have helped map the contours as to when an applicant may be liable for inducing infringement of a carved-out indication. In 2023, the court upheld² a finding of no induced infringement where the applicant omitted the patented indication and related data, and there was no evidence of efforts to market the drug for the patented use. Conversely, in 2024, the court reversed³ the early dismissal of an inducement claim based on allegations that surviving parts of a label and other public statements could be found to encourage a patented use.

¹ *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021)

² *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361 (Fed. Cir. 2023)

³ *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024)



Section viii Statements Can Also Carve “In”

Section viii isn’t only about removing language — sometimes adding the right words is the safest path.

While label amendments typically omit information, a Polsinelli-led team won a favorable D.C. Circuit decision that demonstrates that a generic applicant can effectively avoid a patented-use by adding information to the proposed label.⁴ In *Novartis v. Kennedy*, the FDA approved MSN’s label that omitted a modified dosing regimen in Novartis’s latest label and instead used an earlier indication and dosing regimen that Novartis had since removed. Novartis argued that the carve-out was improper because it added words, but the D.C. Circuit disagreed, finding the additional words had the effect of omitting an indication.

⁴ *Novartis Pharmaceuticals Corp. v. Kennedy*, 156 F.4th 626 (D.C. Cir. 2025)

⁵ *Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.*, 98 F.4th 1056 (Fed. Cir. 2024)

Litigation May Be Unavoidable

Label amendments can reduce patent risk — but they don’t eliminate the threat of litigation.

Section viii statements are a tool for simplifying patent litigation. By carving-out indications and uses, rather than making Paragraph IV certifications, applicants can sidestep some Orange Book patents. These recent decisions, however, suggest that the inquiry may be more factually nuanced, such that induced infringement cannot be determined simply as a matter of law, but must be explored through litigation — particularly if there has been a launch at risk.

This concern led a district court to decide to not reopen a judgment of infringement after an applicant amended its ANDA to carve out patents after a trial found them valid and infringed.⁵



Takeaways

The lesson for applicants has been to be more aggressive with timing and the extent of their label carve-outs, omitting not only information implicated by the use code, but other information that may relate to the full scope of the patent claims. Think carefully about marketing statements, emphasizing AB-ratings or other strategies that can be seen as promoting the patent-protected method. In addition, involve not only patent counsel, but also FDA regulatory counsel to best evaluate potential patent infringement issues along with achieving regulatory success.

What Companies Should Do Now

Micro-checklist

- Audit all label language — not just the part tied to the use code
- Ensure marketing teams are aligned with carved-out uses
- Consider creative strategies to add language to exclude patented use
- Engage both FDA regulatory and patent counsel early



Polsinelli attorneys pictured from left to right: Chad Landmon, Hatch-Waxman & Biologics Chair; Brian Larivee, Shareholder; Corey Casey, Pharm. D., Shareholder; Pat Woolley, Intellectual Property Department Chair; Mark Deming, Hatch-Waxman & Biologics Vice Chair; Kendall Gurule, Shareholder; Andrew Solomon, Of Counsel; Chris Jones, Associate



Pictured from left to right: Mark Deming, Vice Chair, Hatch-Waxman and Biologics Litigation; Bonnie Fletcher Price, Chief Scientific Officer, Deputy General Counsel, Belcher Pharmaceuticals

Join us at one of our upcoming events

Reception during JP Morgan Healthcare Conference

Tuesday, January 13 | 5:00 PM - 9:00 PM PT

[Register](#)

JPM: The Takeaways

Tuesday, February 24 in Chicago
3:30 PM - 6:30 PM CT

[Request an Invitation](#)

FDA: Year in Review and Looking Ahead

Tuesday, January 27 | 12:00 PM - 1:00 PM CT

2025 brought dramatic and disruptive change to FDA and the industries it regulates. Join Polsinelli's experienced FDA team and special guest, Wayne Pines, for a roundtable discussion to reflect on the most notable developments of 2025 and explore whether 2026 will bring further change. How should stakeholders adjust to the new realities at FDA?

[Register for Webinar](#)

What's the Skinny on Skinny Labeling?

Wednesday, February 11 | 12:00 PM - 1:00 PM CT

Join Polsinelli for a webinar that will discuss case law developments over the past year, strategic considerations for induced infringement claims in patent litigation in the pharma and biologics space, and how to handle product label amendments at FDA.

[Register for Webinar](#)

Save the date for our future industry events

More details will become available as we get closer.

Reception during BIO International Conference

Monday, June 22

Events during Biotech Week Boston

Tuesday, September 22 to
Thursday, September 24



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