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Adapting by Design: Navigating Complex Times in Life Sciences

Polsinelli Life Sciences Spotlight | Volume 2

September 2025

Contents

Clients & Friends,

Welcome to the second edition of our newsletter. The response to our inaugural issue reinforced what we already knew to be true: the life sciences community thrives on active dialogue. As we move deeper into 2025, continued active – and thoughtful – dialogue will help us navigate the challenges and transformative opportunities that lie ahead.

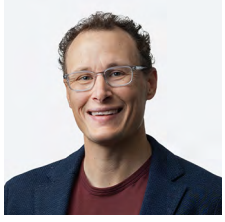
We believe this edition captures some of the complexity we've all been seeing in the marketplace. New PFAS regulations are reshaping compliance requirements across medical devices, pharmaceuticals and beyond. Digital threats are requiring innovative protection strategies like our Solare brand protection program to safeguard brands and reputations. And the shifting tariff landscape is prompting supply chain conversations that would have been unthinkable just a few years ago, when pharmaceutical products enjoyed broad duty-free status.

Yet across all these areas, we see the same pattern: the companies that succeed are those that engage proactively, seek diverse perspectives and build relationships that enable them to anticipate and adapt. In fact, we witnessed that firsthand at BIO Week in Boston — where more than 350 leaders joined us at our various events that week.

At Polsinelli, we remain committed to fostering these connections and providing insights that help our clients anticipate and manage industry developments. Whether through our networking events, programs like our Healthcare Dealmakers City Series, or delivering timely thought leadership, our goal is to be both a trusted advisor and an active participant in advancing the life sciences industry.

As always, we welcome your thoughts on the topics we've covered and suggestions for future issues.

Enjoy,



Rick Jordan
Lead, Life Sciences Industry Group
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Pharma Tariffs are Coming – Are You Ready?

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Washington, D.C.

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Long exempt from most U.S. import duties, pharmaceuticals and pharma ingredients are now in the tariff crosshairs. Preparing now can help companies mitigate the impact of higher costs and supply chain disruptions.

Framework Then and Now

As a signatory to the World Trade Organization's 1994 Agreement on Trade in Pharmaceutical Products, the U.S. committed to eliminating tariffs on finished pharmaceutical products, whether sold in bulk or in dosified packages for retail sale, as well as more than 7,000 pharmaceutical active ingredients and chemical components used in pharmaceutical supply chains. Since 1995, nearly all pharmaceutical goods now classified under Chapter 30 of the Harmonized Tariff Schedule of the U.S. (HTSUS) (and certain pharmaceutical goods classified in other chapters) have been duty free when imported into the U.S. from major trading partners.

A New Tariff Reality for Pharma

That framework has now shifted. Since early February 2025, most Chinese-origin pharma products have been subject to duties – first at 10%, now 20% – upon importation into the U.S. Twenty-five percent duties on Mexican- and Canadian-origin pharma products not eligible for preferential treatment under a free trade agreement followed in early March 2025. And although the breadth and impact are still unclear, more tariffs are likely to come.

The U.S. recently reached an agreement on a framework for a trade deal with the European Union that, if finalized, would subject U.S. imports of certain European pharma products to a 15% import tariff (exempting generic pharmaceuticals and their ingredients and chemical precursors from any additional tariffs). This alone could have a huge impact: the European Union is the third-largest source of pharmaceutical imports into the U.S. by weight after China and India, and the largest source by value. But it may have been a worthwhile concession by the EU to avoid looming — and potentially substantially higher — tariffs on pharmaceutical products across the board. The U.S. Department of Commerce is currently investigating whether imports of pharmaceuticals and ingredients harm U.S. national security under Section 232 of the Trade Expansion Act of 1962, as amended (Section 232), and the President has previewed that he may thereafter take action to impose tariffs as high as 200% on covered pharma imports. Announcements of a potential deal with China on tariffs have not touched on pharma, and the U.S. has yet to announce a potential deal with India that would provide stability to the pharma industry tied to that country.

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What You Can Do Now

Despite uncertainty surrounding long-term tariff rates and coverage, businesses can take action now to prepare for potential increased import costs down the road:

- ***Qualify alternative suppliers, even if you don't make a switch (yet).*** Whatever the outcome of ongoing trade negotiations and the Section 232 investigation, it is clear that certain countries could obtain a better tariff position than others. And, in many instances, the origin of active pharmaceutical ingredients (API) may confer the origin of a finished dosage product manufactured outside of the U.S. To hedge against those uncertainties, proactive planning is key. Understand alternative suppliers for key or high-value U.S. imports and/or the API for those products and begin the qualification process to give yourself more options down the line.
- ***Consider your supply chain.*** In a duty-free environment, our experience suggests that importers may not be paying careful attention to supply chain or payment restructuring to optimize import valuation. All U.S. imports have a declared import value to which the appropriate tariff rate is applied to calculate duties owed. Import valuation rules are complex, and there may be opportunities to mitigate dutiable value – and, therefore, your import duty burden – through restructuring your transactions. Alternatively, utilizing import structures such as first sale, foreign trade zones or bonded warehouses, or other such options may aid cash flow and mitigate overall tariff burden.

  Companies should also be aware that there is a large amount of disinformation circulating on the internet proposing potentially illegal actions, such as transshipments through third countries, that could result in enforcement actions and accompanying penalties.
- ***Review and revise your contracts to clarify tariff-related obligations.*** The importer of record of any product has a direct obligation to pay tariffs to the government. But contractual terms can allow downstream flow-through of those tariffs or price increases stemming from increased importation costs. In this dynamic tariff environment, it is key to revisit your contracts. Do they clarify which party is serving as importer of record? What provisions, if any, do they make to mitigate price increases or a cost-sale price squeeze?
- ***Strategize with experienced counsel and your customs brokers.*** Most importers work with customs brokers to facilitate logistics for their shipments, and brokers are essential players in a well-run trade compliance program. But your customs broker may not be proactively considering alternative supply chain strategies or duty mitigation options. Together with your key supply chain personnel, trade counsel can strategize with you to develop plans to weather the coming business impacts of a new trade and tariff landscape for pharmaceuticals and pharma inputs.

End of Lifecycle Challenge for Biologics: How to Avoid the Pitfalls Near the End of Exclusivity

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At June's BIO International Convention in Boston, Polsinelli's Hatch-Waxman and Biologics team shared new research on the types of patents asserted in Biologics Price Competition and Innovation Act (BPCIA)[1] litigation and highlighted opportunities and strategies available to both biosimilar and originator companies.

The end of regulatory exclusivity under the BPCIA is a critical time for both originators and biosimilars. Originators facing the loss of exclusivity contend with the risk of revenue decline, investor pressure, marketing and commercial challenges and, of course, the cost and complexity of the BPCIA's "patent dance." Meanwhile, a timely and successful BPCIA launch for biosimilars can be crucial because the first biosimilar to market enjoys a massive first-mover advantage, with physicians often switching their patients from the originator's product to the earliest available biosimilar.

The lead-up to the BPCIA patent dance, which allows for a proactive and potentially accelerated approach to patent litigation driven by the biosimilar applicant, is filled with potential pitfalls and opportunities for both originators and biosimilars, making early and proactive preparation essential.

Potential Pitfalls for Originators and Biosimilars

1. *Enormous number of applicable patents*

Before BPCIA litigation even begins, both originators and biosimilars will need to be prepared to wade through hundreds of patents. Our research shows that, on average, a BPCIA suit commenced in the last three years included 34 asserted patents. But that number is just a fraction of the patents that both originators and biosimilars will analyze in the months and years before the patent dance, creating an enormous amount of uncertainty. For originators with large patent estates, evaluating which patents to assert can be a significant undertaking. For biosimilars, the freedom-to-operate analysis can be daunting, particularly as it occurs alongside drug product development and formulation — forcing lawyers and scientists to balance trade-offs between infringement risk and commercial viability.

2. *Falling patent quality near end of lifecycle*

Originators of biologic medicines continue to patent throughout the product lifecycle, with some analyses showing that more patents are actually filed after FDA approval than before. Patents filed later in the lifecycle, however, must contend with the risk that earlier research

1 The BPCIA, enacted in 2010, created a pathway for FDA approval of biosimilars, which resulted in increased innovation and competition – and therefore lower prices - for when a drug's patent protection expires. The BPCIA allows approval of a biosimilar with no meaningful differences in safety, purity and potency from the previously approved biologic product.

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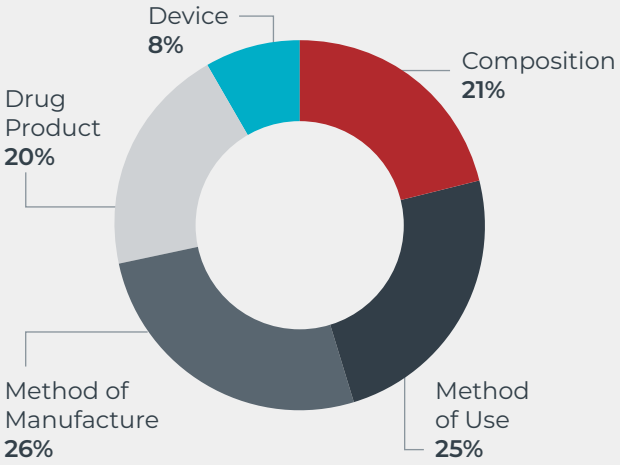
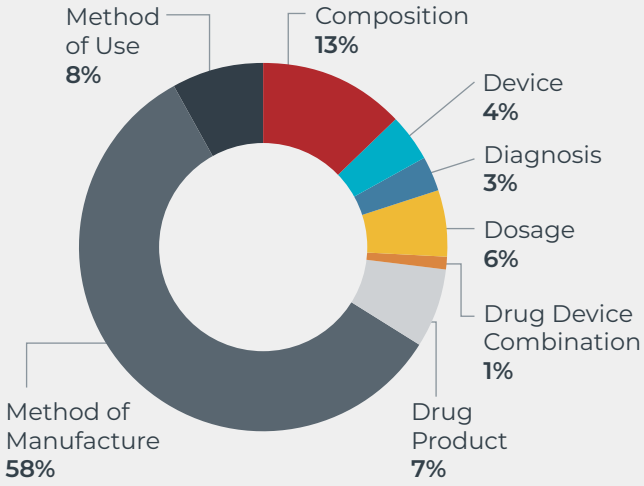
and development efforts may be treated as novelty-destroying prior art. So, as the FDA regulatory exclusivity period ends, the quality of the patents covering a biologic often begins to fall. By the end of regulatory exclusivity, the highest quality composition-of-matter claims — invented during the development phase — have often already expired.

While the patent estate for biologics usually contains a robust combination of drug product, device, composition-of-matter, method-of-manufacture and method-of-use claims, our research shows that the patents actually asserted in BPCIA litigations skew towards method-of-manufacture patents.

Patents Obtained - Six Largest Biologics



Patent Assertion Over Last Three Years



- Originators typically asserted **about 34 patent per suit**
- **Average of 9.1 years between the date of the suit and the expiration of the patents** [2, 3]

3. *Challenges with global markets and supply chains*

Biosimilars are developed for a global market, which can complicate litigation at the end of exclusivity.

Coordinating consistent infringement and validity positions across multiple jurisdictions, including the U.S., EU, and other countries, poses a problem for both biosimilars and originators.

Biosimilars must also contend with complex supply chains that may spread injunction risk across multiple jurisdictions. Recently, shifting biopharma manufacturing and tariff policy frameworks have made this increasingly challenging.

[2] Patents Obtained: Horrow et al., "Patent Portfolios Protecting 10 Top-Selling Prescription Drugs," *JAMA Intern Med.*, Vol. 184, No. 7 (May 13, 2024).
[3] Patents Asserted: Polsinelli analysis of biologics patent assertion of 477 patents in 18 BPCIA suits over last 3 years.

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Strategies to Mitigate Risk and Maximize Opportunity

There is no silver bullet for success around the end of exclusivity and the launch of a biosimilar. The best strategy is to practice the seven P's: Prior Preparation and Planning Prevents Poor, Poor Performance.

1. *Embed legal in the development process*

Embedding legal counsel in the development process is important for both originators and biosimilars. An originator should collaborate with legal counsel to develop a system of IP capture during research and development. Carefully reviewing clinical trial protocols and external communications may help capture inventions and prevent "leakage" of novelty-destroying prior art.

Early legal involvement can also lower the development process risk for biosimilars. For example, IP attorneys may provide "design around" assistance for non-infringement and help spotlight patentable improvements that can spur new drug substance or method-of-manufacture patents. Finally, regulatory counsel can assist in navigating approval issues and complicated regulatory exclusivity provisions.

2. *Start early*

Starting early is crucial for originators of biologics. It may take a significant amount of time to determine which patents from a large patent estate should be asserted. With more biosimilars skipping the patent dance and issuing 180-day notices of commercial marketing instead, biosimilars place originators under intense time pressure to file complaints and preliminary injunctions. These pressures mean originators should have expert witnesses, inventors and lawyers ready in each jurisdiction in which they expect to litigate to be able to quickly pivot to a complaint and preliminary injunction.

Having a head start is just as important for biosimilars. With a large number of patents to clear and long lead times for invalidation, early assessment of IP risk is crucial for potential course correction during development. Likewise, finding expert witnesses and preparing noninfringement and invalidity positions ahead of BPCIA litigation can help even the playing field.

3. *Coordinate*

Coordination is crucial for originators. Between pharmaceutical alliances, sprawling and matrixed organizations and outside counsel, robust communication will optimize development, IP protection and commercialization. For biosimilars, robust communication will improve development, supply chain problem solving and preparing invalidity and noninfringement positions across jurisdictions.

The Bottom Line

The end of BPCIA exclusivity presents tremendous business uncertainty. For both originators and biosimilars, embedding legal counsel early — ideally several years before the patent dance — presents the best opportunity to de-risk either a biosimilar launch or the end of the originator's exclusivity period.

Q&A with VivoSim CEO Keith Murphy

Keith Murphy
CEO
VivoSim

Polsinelli is proud to represent VivoSim Labs, Inc., a pharmaceutical and biotechnology services company advancing drug testing through three-dimensional human tissue models of the liver and intestine. We recently sat down for a Q&A with Keith Murphy, CEO of VivoSim, to discuss their proprietary NAMkind™ technology, its place within the broader category of New Approach Methodologies (NAMs) and how these techniques are revolutionizing drug testing and disease research.

How does VivoSim's NAMkind™ technology build on New Approach Methodologies (NAMs) to offer an alternative to traditional drug testing?

We use human cells and human-relevant conditions. NAMs are revolutionary, and we're world leaders in NAM technology. The alternative to NAMs is animal-based testing, which while beneficial, eventually reaches a natural limit. In areas like liver toxicity prediction, traditional testing hits a wall — and the result is that drugs still regularly fail in the clinic or are withdrawn from the market due to liver toxicity that simply didn't show up in the animal trials.

The challenge with animal models is not just a species difference — even with an animal test subject, you still have to create the disease you're trying to test. If I want to make a strawberry smoothie, I could head to the organic chemistry lab and mix chemicals to try to match the taste, sure — that's the equivalent of engineering a disease in an animal. But why not just start with strawberries that naturally taste right and use those? That's what we do at VivoSim: start with human cells and test on those since they have the biology we're looking for. By taking cells from patients and building a NAMs model, we get the right results.

NAMs cover a range of non-animal testing approaches. What distinguishes NAMkind™ from other methods in this category?

NAMs can mean anything from in silico prediction, to organoids, to spheroids to organ-on-a-chip. NAMkind™ uses a blend of methods — not only one subtype. We use high-end, cell-based models and also offer AI prediction tools built with the best input data in the world: the data from our world-leading cell-based models.

Our models are distinguished by three things. First, we have the ability to create real tissue with multiple layers and cell-cell interaction. The best models aren't one or two layers of

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cells on plastic, but actual complex multilayer tissue. Second, we use multiple cell types — usually four or more cell types per model — which while difficult to achieve, gives closest result to native tissue. Most other groups' models involve one or two cell types.

Finally, we take the cells directly from human donors. This is how you get the best representation of human biology; engineered or manipulated cell lines make it harder to get a true picture.

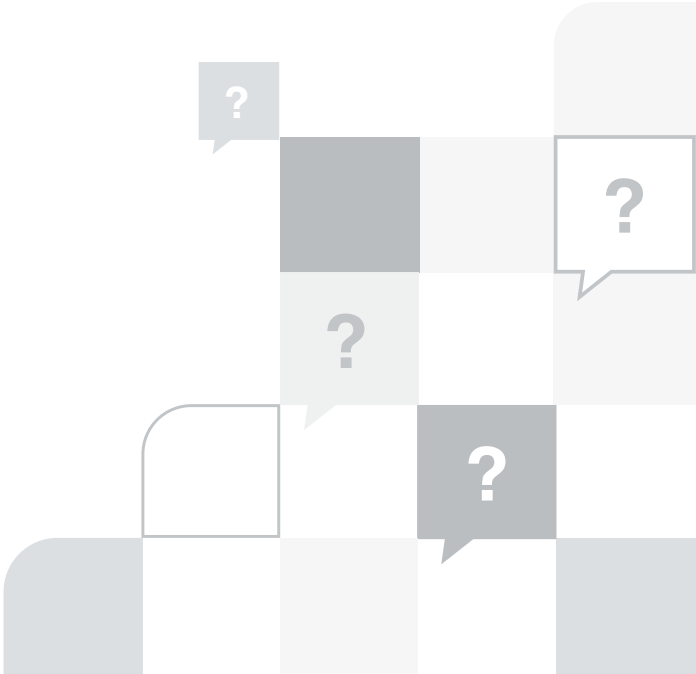
These real-world cell models in the lab produce accurate data, and that data is used to train AI models. We say it's "golden in, golden out" — whereas most AI models are relying on data that's less predictive.

Your initial focus for NAMkind™ has been on liver and intestinal models. What made these organ systems the right starting point, and what kinds of insights can they reveal about drug safety and efficacy?

Liver is a case where there was a big need for two reasons. First, liver toxicity prediction is very important because unforeseen toxicity causes a high rate of drug program failure and surprises. Second, human liver cells are used in traditional lab testing to try to predict liver toxicity — but human liver cells, in particular, quickly lose their signals when in cultured in a single layer on lab plasticware in standard 2D cultures. Meanwhile, liver in 3D in a tissue — with four cell types touching each other — is far superior. Intestinal models made sense for us because we already had access to cells and were able to build the initial intestine model in partnership with Merck, who funded the work.

The FDA's support for NAMs, including the 2022 FDA Modernization Act 2.0, has created new opportunities for non-animal methods. From your perspective, what additional steps or incentives could help accelerate adoption of technologies like NAMkind™ across the industry?

The single biggest thing to accelerate adoption of these technologies would be for the FDA to set the expectation that NAMs are being used in testing before allowing clinical studies to proceed — or at key times during a clinical program. For example, some NAM models now naturally detect the toxicity of compounds that older methods missed in the past, not because they've been tweaked or backfitted to do so, but because the models simply replicate liver well enough that the normal biology shows up. The FDA needs to move from the perspective that these models require exquisite standalone validation to recognize that our current system is already fully validated to NOT work well enough. NAMs pick up additional things, and the more we use them, the more they uncover. The FDA needs to adopt the view that it's considered unethical to put something in humans without first evaluating it by these methods.



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As NAMkind™ models generate more real-world data, how do you see that information being used — both within your own development work and in collaboration with other researchers or industry partners?

We're reaching the point where enough work has been done that we'll be able to make some big claims in publications about our prediction rates. The next real-world applications will be additional modalities. We have development work going on with antibody drug conjugates, monoclonal antibodies and for gene therapies — all to establish the platform's value for someone advancing drugs with those modalities.

That data will be transformative for our partners because it will slot exactly into what they need to check the box for toxicity for their therapeutic candidates.

You've discussed how improving efficacy rates with NAMkind™ could make it more viable to develop drugs for underserved conditions and populations. What types of therapies or disease areas do you think could become more accessible?

Well, it's worth pointing out here that Vertex, for its cystic fibrosis drugs, already uses NAM-type models to demonstrate the value of their drugs for rare genetic types. In these cases, it wouldn't even be possible to do clinical trials because the subtypes are so rare — but the FDA reviews their complex cell culture data with cells with that genotype and allows those patients to be treated if the in vitro results are suitable.

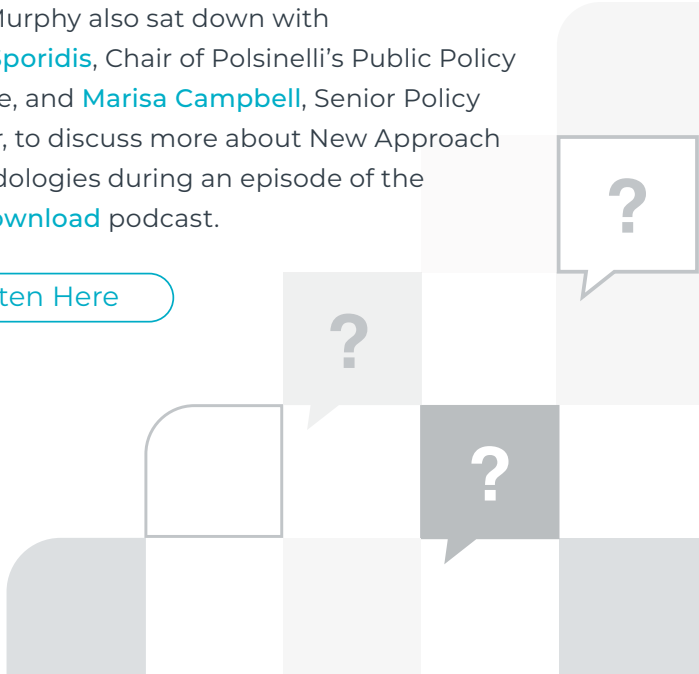
In less extreme cases, if we're right that NAM models can produce drugs that are successful 30-40% of the time in clinical trials instead of 8%, that's a game-changer. Instead of pharma spending $2 billion on ten drugs to get one approved, it could spend $1 billion. If the development cost is cut in half, more drugs become economically justifiable to invest in. For example, the models can make the risk justifiable if a targeted drug for MASH liver fibrosis is possibly going to particularly benefit a Latino population. Plus, we can invest in twice as many things with the same amount of money.

Looking ahead, what role do you envision VivoSim playing in the global NAMs and drug development ecosystem?

We have all the tools to dramatically and widely impact drug development. We're also rolling out new tools, like our newer intestine prediction model. This tool allows you to give us a set of drugs in development and receive input on how likely each one is to cause diarrhea. Our predictive accuracy is greater than 90%, and no tool like this has previously been available. That means that, for example, a new cancer therapeutic will be able to choose the best drug candidate that a patient can have at a higher dose — making it more potent in its cancer-killing role, because it isn't limited by dose limits meant to reduce patient distress. In the future, we'll be helping on more areas — really allowing drug developers to dial in the characteristics of their lead drug candidates using data with high human fidelity and relevance to clinical trials!

Keith Murphy also sat down with Harry Sporidis, Chair of Polsinelli's Public Policy practice, and Marisa Campbell, Senior Policy Advisor, to discuss more about New Approach Methodologies during an episode of the D.C. Download podcast.

Listen Here



The Rising Threat of Brand Abuse — and How Life Sciences Companies Can Respond

Taryn Elliott
Product Design & User Interface Patent Prosecution Chair
Phoenix

The New Reality of Online Brand Abuse

It is now virtually impossible for any company, including those in the life sciences space, to exist without a digital presence. Marketing, consumer engagement, sales, employee recruiting and communications are largely conducted online. And if your brand doesn't already have a digital footprint in a certain channel, there's a good chance a bad actor is masquerading as you — and making costly missteps in your name.

Brand abuse takes different forms, but there is no question — it is ubiquitous. Maybe you view it as a cost of doing business that has no practical solution. Perhaps you're unaware of the scope of the damage. It may even be that the culprits are your own distributors. Whatever the source, the threats are constant, evolving and capable of causing both financial and reputational harm.

From Counterfeits to Compromised Safety

Just as no two companies in the life sciences space are the same, so too are the kinds of threats they face. Consumer brands selling health, beauty and personal hygiene products often contend with counterfeit and infringing products on ecommerce platforms that siphon their sales and erode brand trust. Meanwhile, pharmaceutical brands may struggle to combat fake, fraudulent compounded or unauthorized drugs sold through social media, sham "wellness providers" and unlicensed pharmacy websites.

Bad actors may even dupe desperate consumers with malware-laden links or, through sophisticated phishing scams, gain unauthorized access to digital health platforms — potentially compromising sensitive company and patient data. These dangers pale in comparison to the consumer health and safety threats posed when compromised or low-quality products are passed off as genuine in the food, medical device, drug, and personal health markets. Look no further than the Food and Drug Administration's recent warnings for unapproved weight loss drugs[1] or the prevalence of fake face masks being sold during COVID[2] for examples of these dangers.

Why the Challenge Persists

These threats are often difficult to identify, monitor and prevent, particularly in an increasingly decentralized online environment where bad actors can hide in anonymity and leverage emerging technology, like artificial intelligence, to modify their approach. Combating brand abuse requires a proactive and multifaceted strategy tailored to a company's specific risks and objectives, and which can evolve dynamically in response to the threat landscape. For many life sciences companies, this can quickly become a full-time job that takes resources away from other business priorities.

1 https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss
2 https://www.ice.gov/news/releases/millions-counterfeit-masks-seized-during-operation-maine

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And internal efforts to combat threats too often become reactive or disjointed from overall strategy, giving bad actors an unfortunate advantage.

An Adaptive Framework for Brand Defense

Polsinelli's Solare brand protection program is designed to provide a practical solution to these challenges, customized to a company's unique business, goals and threats. The Polsinelli team develops a full suite of tools like agreements, policies and intellectual property assets to reinforce protective measures, obtain data about various brand threats and automate the more routine and time-consuming aspects of online enforcement.

Leveraging data analytics and other evaluation tools, the Polsinelli program elevates enforcement as necessary via the most strategic channels. And as the company, relationships, market, industry and risks change over time, the program adapts, anticipating new threats rather than reacting to them. The result is a comprehensive program that helps companies:

- Manage the WHERE, HOW, and WHO of product sourcing, sale, and distribution;
- Optimize end consumer experience;
- Protect reputation and proactively identify threats to data security;
- Develop a deeper understanding of the competitive and business landscape; and
- Translate brand threats into revenue or other measurable results for your business.

Protecting companies and consumers from brand abuse has never been more challenging, or more critical. Success depends on a holistic approach that integrates data analytics into an aligned business and legal strategy and leverages cutting-edge tools to outpace bad actors. Solare delivers that, giving companies the edge against constantly evolving threats.

PFAS Regulations Impacting the Life Sciences Industry

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The U.S. Environmental Protection Agency (EPA) has made regulating per- and polyfluoroalkyl substances (PFAS) a top priority, with numerous states following suit through new restrictions and, in some cases, outright bans. These efforts reflect growing concern over the potential health and environmental impacts of PFAS — synthetic compounds commonly referred to as "forever chemicals" and which are utilized given their durability and resistance to heat, water, grease and oil.

Today, PFAS are used in a variety of different products and life sciences applications, including medical devices, pharmaceutical packaging, laboratory equipment and cosmetic products.

This article highlights key developments in federal and state PFAS regulation, their potential impact on the life sciences industry and what companies can do to ensure compliance.

1. PFAS Usage in the Life Sciences Industry

PFAS compounds are used across the life sciences industry, appearing in medical devices (catheters, surgical grafts, implantable devices), pharmaceutical and biotech packaging (blister packs and vial stoppers), laboratory equipment (tubes, seals and containers) and cosmetic products. In these products, PFAS often serve as a coating to resist water, heat and chemicals and to give certain materials non-stick properties. They are also used to maintain purity and chemical resistance and to insulate leads for devices like pacemakers.

While PFAS offer important performance benefits in various applications, their persistence in the environment and bioaccumulative potential in groundwater and other ecosystems have made them a primary target for regulatory action.

2. Federal Regulatory Landscape

In 2023, the EPA finalized a rulemaking under the Toxic Substances Control Act (TSCA) requiring any person that manufactures (including imports) or has manufactured (including imported) PFAS or PFAS-containing articles in any year since January 1, 2011, to report information regarding "PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects" through EPA's Chemical Data Exchange (CDX) portal. Although the rule was finalized in October 2023, compliance deadlines have been pushed twice: now to **October 13, 2026** for manufacturers/importers and **April 13, 2027** for small manufacturers (defined as those who meet one of two standards: a manufacturer [including importer] with combined annual sales of less than $120 million *and* annual production [or importation] volume of a specific PFAS substance not exceeding 100,000 pounds at any single site, or a manufacturer [including importer] with annual sales of less than $12 million [combined with

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any parent company], regardless of production volume).

Notably, there is no *de minimis* threshold — meaning that even manufacturing/importing a small quantity of PFAS or PFAS-containing articles triggers a reporting obligation.

3. State Regulatory Landscape

Several states — including California, Colorado, Illinois, Maine, Minnesota, Vermont and New York — have finalized regulations restricting, requiring notification for, labeling or outright banning PFAS in various consumer products, which could directly impact the life sciences industry.

The largest state-level impact on the life sciences industry is on certain textiles, cleaning products, cosmetics and products like dental floss. Almost every state listed above has directly banned PFAS in cosmetic products.

Meanwhile, Colorado, Illinois and Maine have banned PFAS in dental floss beginning January 1, 2026, and Colorado has likewise banned cleaning products with intentionally added PFAS —potentially impacting certain laboratory cleaning supplies. California has banned certain textiles with intentionally added PFAS, meaning commonly used medical textiles like hospital gowns, surgical drapes and masks could be affected. Vermont has banned menstrual products with intentionally added PFAS beginning in 2026, and New York most recently introduced a bill banning the sale of medical adhesives and bandages containing PFAS, which if passed, would become effective December 31, 2026.

Crucially, some states, like Colorado and Minnesota, have specifically exempted U.S. Food and Drug Administration (FDA)-regulated medical devices and drugs from their broad product bans. Maine also provides exemptions for certain medical prosthetics/orthotics and FDA-regulated drugs and has a "currently unavoidable use" (CUU) process, which is significant for critical medical applications.

Inconsistency in regulation across states means a product that is legal in one state may be banned in another. This lack of uniformity means that, not unlike disparate data privacy rules and employment laws, companies need to proactively monitor legislative developments and assess their potential impact on product lines and supply chains.

4. Compliance Considerations

This evolving PFAS regulatory landscape presents significant compliance challenges for life sciences companies — and is further compounded by complex global supply chains, suppliers hesitant to disclose chemical compositions, extensive data inquiries, potential data gaps and varying state regulations with little uniformity.

To effectively navigate this environment, life sciences companies should engage with their suppliers to obtain PFAS content information for directly imported products and send standardized questionnaires inquiring about PFAS content in their supply chain. We also recommend conducting internal product assessments to the extent possible and checking products and materials for potential PFAS.

Finally, companies should identify states where their products are manufactured and/or sold and determine whether any potential notifications, warnings or restrictions apply.

BIO in Boston: Highlights & Takeaways

Thank you to everyone who joined us in Boston in June during the week of the BIO International Convention 2025! We were pleased to host a series of events that brought together leaders from across the life sciences and health care industries and enjoyed connecting with some of the 20,000 BIO Convention attendees, including almost 10,000 who came from international locations.

We kicked off the week with our annual BIO International Convention Reception on Monday, June 16, which has been growing in popularity each year. More than 350 attendees came together for an evening of networking and dialogue in a beautiful waterfront venue, a testament to the importance of collaboration within the life sciences community.

The following day's events centered around thought leadership and industry collaboration. Attorneys Chad Landmon and Brian Larivee offered strategic insights into the pharmaceutical product lifecycle, particularly around Hatch-Waxman and ITC litigation considerations, at their breakfast presentation, "Seeing the Beginning from the End: Thinking about the Product Lifecycle from the Perspective of Hatch-Waxman and Biologics Litigation Lawyers."

Polsinelli Reception during BIO International Convention

Pictured from left to right:
Chad Landmon (Hatch-Waxman & Biologics Chair at Polsinelli) and Brian Larivee (Counsel at Polsinelli).

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Later that afternoon, our Healthcare Dealmakers City Series traveled to Boston and welcomed a select group of industry leaders and decision-makers for an exclusive panel discussion and networking reception. Powered by the Polsinelli Healthcare Dealmakers Conference and led by shareholders Matt Murer and Bobby Guy, the event explored emerging trends and opportunities shaping the future of health care, offering a unique forum for dialogue and connection among key stakeholders.

We were also excited to be a Title Sponsor of the 3-day RESI (Redefining Every Stage of Investment) Seed to Exit Conference and its Landing Your Company in the Boston Life Science Ecosystem pre-conference event. RESI saw almost 1,000 early stage life science innovators looking to raise capital, investors (Venture Capital Funds, Corporate VC investors and Family Offices) and pharmaceutical and strategic partners connect for one-on-one Partnering and a series of panels and workshops. Shareholders Prithvi Tanwar and Matt Eckert led a session on corporate and commercial issues impacting non-U.S. companies coming to the US. Shareholder Andrew Merken moderated an investor panel on Family Office Investing, and Shareholder Jeremy Arak led a workshop on equity term sheets.

Thank you again to all who joined us. We look forward to continuing the conversation and hope to see you in San Diego in June at the 2026 BIO International Convention!

Pictured from left to right: Matt Murer (Health Care, Public Policy and Government Investigations Department Chair at Polsinelli), David Sopp (CDO of Specialty Smile Partners), and Bobby Guy (Shareholder at Polsinelli)

Upcoming Polsinelli Events

Join us at one of our events during Biotech Week Boston 2025 next week.

Congresswoman Trahan Fundraising Luncheon Presented by Polsinelli's Public Policy Group

Monday, September 15 | 11:00 AM - 12:30 PM ET

Request an Invitation

Happy Hour Sponsored by Polsinelli's Women in Life Sciences

Tuesday, September 16 | 5:30 PM - 8:00 PM ET

RSVP

Executive Leadership Dinner

Wednesday, September 17 | 6:00 PM - 9:00 PM ET

Request an Invitation

Polsinelli Pulse: Boston Life Sciences Leadership Series Kickoff Event

Thursday, September 18 | 8:00 AM - 10:00 AM ET

Request an Invitation

Editorial Board

Polsinelli's multidisciplinary Life Sciences team provides clients with a full-service approach through every lifecycle stage and can serve as outside counsel for any legal need including those unique to the industry.

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