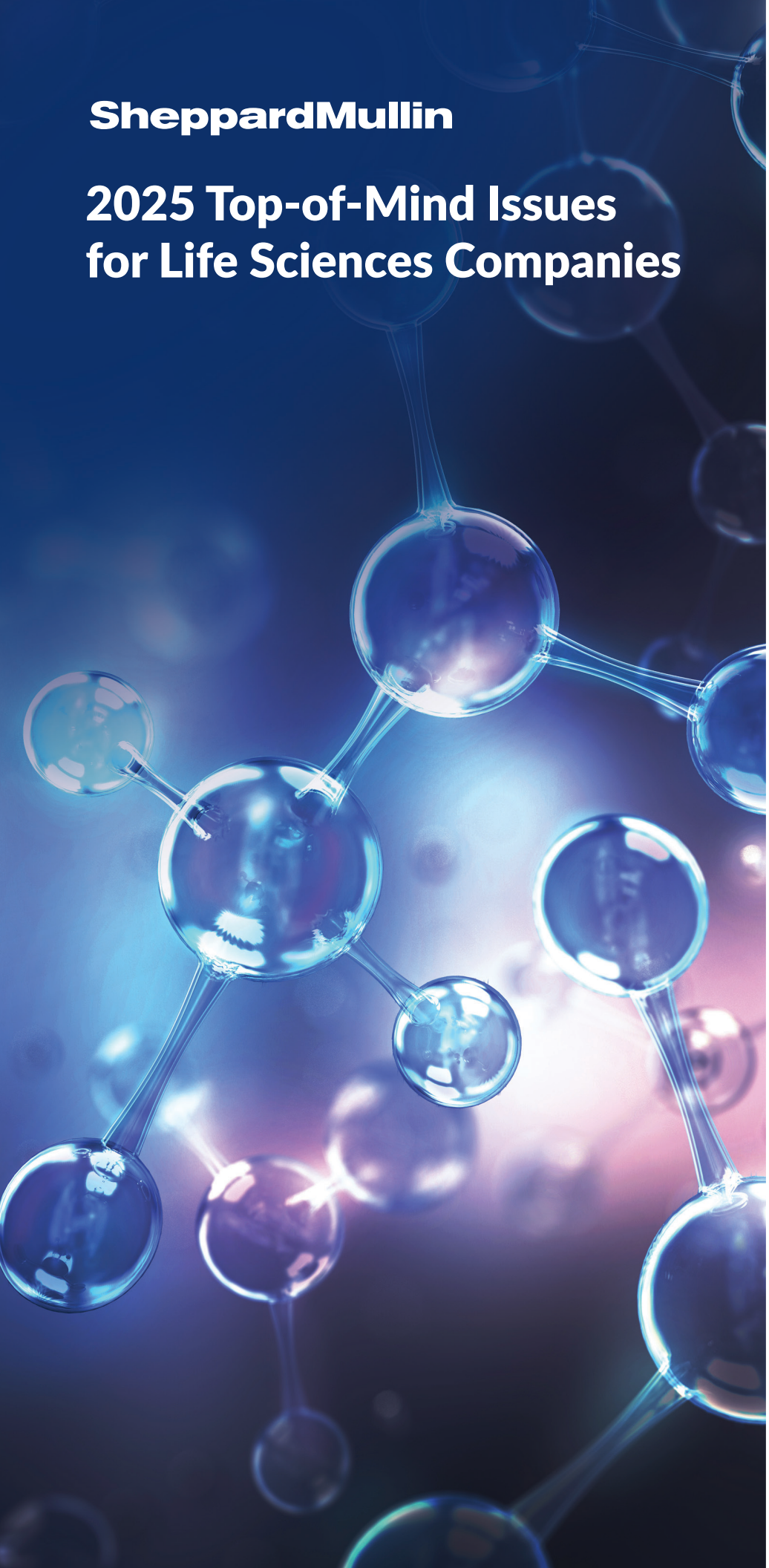
SheppardMullin

2025 Top-of-Mind Issues for Life Sciences Companies



CONTENTS

Gathering topics and reviewing the articles for our annual Top-of-Mind publication is always one of my favorite yearly endeavors, allowing me to talk to clients, colleagues and industry experts about the overall state of the life sciences industry. The timing of this publication usually coincides with the J.P. Morgan Healthcare Conference, providing a key opportunity to vet our articles. The breath and scope of comments, concerns, predictions have been remarkable.

The excitement, fear, anxiousness—depending on the individual—is palpable. Change is coming. At the time of writing this opening, a flurry of new executive orders and rescissions of existing executive orders have impacted everything from diversity in clinical trial design to pricing. Rumors are swirling about everything from banning direct-to-consumer advertising for drugs to reducing the efficacy standard for clinical trials. This is all just in week one.

Uncertainty in the life sciences industry will be a big focus in 2025. As always, we will keep you informed with insights and trends as they unfold throughout the year. Be sure to follow the Sheppard FDA Law Update to stay current.

Co-Chair, Life Sciences Practice
Chair, FDA Practice

Scott Liebman
Co-Chair, Life Sciences Practice
Chair, FDA Practice
212.634.3030
sliebman@sheppardmullin.com

Jeffrey Fessler
Co-Chair, Life Sciences Practice
212.634.3067
jfessler@sheppardmullin.com

Lorna Tanner
Co-Chair, Life Sciences Practice
650.815.2658
ltanner@sheppardmullin.com

DTC Telehealth Platforms

By: Arushi Pandya

Arrangements involving telemedicine and direct-to-consumer ("DTC") business services are expected to be a source of major regulatory scrutiny. In 2024, such arrangements were the focus of proposed legislation targeting promotional statements, specifically the Protecting Patients from Deceptive Drugs Ads Online Act (the "Act"), and fraud and abuse scrutiny from legislators. The structure of telehealth arrangements, as well as promotional material involving the same, are ripe for additional scrutiny and enforcement in the upcoming year.

The Telehealth Climate

Attention to telehealth arrangements is not new and began during the COVID-19 public health emergency when the use of telehealth expanded and concerns around controlled substance tele-prescribing grew. In 2022, the Health and Human Services ("HHS") Office of Inspector General ("OIG") released a Fraud Alert which warned practitioners about potential fraud schemes involving telemedicine platforms in violation of the federal Anti-Kickback Statute. Focus on these arrangements has continued in light of increased online and DTC advertisements by social media influencers and telehealth providers, especially as semaglutide and GLP-1 drugs became pervasive in recent years.

Telehealth was initially utilized by smaller pharmaceutical companies but has recently been adopted by large pharmaceutical manufacturers. Often, the telehealth arrangement is comprised of a process by which patients can select to speak with a physician via a drug ad or manufacturer website and then complete a questionnaire to assess their eligibility for a drug. If eligible, the patient can schedule a telehealth visit through a third-party provider network that can occur face-to-face or asynchronously. During this visit, the patient may receive a prescription for the drug which can be filled and shipped from an online pharmacy. With the rise of social media, influencers and telehealth companies themselves are engaging in DTC advertising of drug products.

Overview of the Act

In September 2024, Sens. Dick Durbin, D-Ill., and Mike Braun, R-Ind., proposed the bipartisan Act. The Act proposes a number of mechanisms for increased oversight, including providing a basis for the U.S. Food and Drug Administration ("FDA") to issue warning letters and fines to drug manufacturers, social media influencers and healthcare providers directly, as well as financial reporting requirements for both drug manufacturers and now healthcare providers. The Act came in the wake of a lack of FDA guidance addressing social media and internet advertising and promotion as well as the rise in social media advertisements by influencers and telehealth companies, which are generally outside FDA's purview unless there is a financial relationship with a pharmaceutical manufacturer.

Significant proposals of the Act include: (1) the provision of authority to FDA to issue warning letters to social media influencers and telehealth companies who make false or misleading communications regarding an approved drug, (2) amendment of transparency reporting obligations to create a new reporting obligation for pharmaceutical manufacturers and healthcare providers when certain payments are made involving telehealth companies and social media influencers and (3) expansion of the definition of "manufacturer, packer or distributor" to encompass certain telehealth providers and subject them to prescription drug advertisement requirements.

Status and Significance of the Act

The Act was referred to the Committee on Health, Education, Labor and Pensions, but its significance lies not only in its content but also in the breadth of support it has received. The Act is endorsed by numerous patient groups and also received lobbying support, indicating notable consumer support for increased transparency. Especially in light of an upcoming populist administration, the support the Act has received could indicate a greater focus on telehealth companies and their DTC promotional activities.

Overview of Senatorial Letters

In October 2024, Sen. Durbin and others sent letters to Pfizer and Eli Lilly regarding the companies' establishment of DTC telehealth platforms. The letters sought information, including quantitative data, about the companies' relationship with healthcare providers that may prescribe medications on the telehealth platforms in order to evaluate the platforms' compliance with the federal Anti-Kickback Statute and to assess whether improper prescribing may be occurring. The letters emphasize the concern that DTC telehealth platforms established by pharmaceutical manufacturers may cause patient-steering as well as unnecessary treatment.

Key Takeaways

The letters, in conjunction with the Act, demonstrate that DTC telehealth arrangements involving pharmaceutical manufacturers should once again be closely monitored because currently they are a source of significant scrutiny. As consumers and legislators push for greater transparency in telehealth arrangements, these arrangements are increasingly likely to be the source of enforcement actions. Both pharmaceutical manufacturers and telehealth companies should carefully evaluate the structure of their relationship to ensure compliance.

"Patent Thicket" Bill: A Patent Legislation to Watch in 2025

By: Lorna Tanner, Joy Nemirow, and Nathan Lee

In July 2024, the U.S. Senate unanimously passed the Affordable Prescriptions for Patients Act of 2023 (S.150), also known as the "patent thicket" bill. "Patent thicket" refers to the practice of obtaining multiple, overlapping patents for a single product, which may delay the entry of biosimilar or generic alternatives into the market. According to the sponsors of the bipartisan bill, the legislation was introduced to help lower drug prices by targeting actors "who game the patent system" and "ensur[ing] access to lower-cost alternatives."[1]

BPCIA Framework

The Biologics Price Competition and Innovation Act of 2009 (BPCIA)[2] provides an abbreviated approval pathway for a biologic by filing an abbreviated Biologic License Application ("aBLA") based on a previously approved biologic product. Among other requirements, it must be shown that the biologic product is "biosimilar" to a previously approved "reference product."

The BPCIA also provides a step-wise mechanism to resolve patent disputes between a reference product sponsor ("RPS") and a biosimilar applicant, which is often called the "patent dance." The patent dance is initiated by the biosimilar applicant by sending a copy of its aBLA to the RPS, or the biosimilar applicant may choose not to participate in the patent dance. The patent dance provides steps and a timeline for the parties to exchange statements. At the end of the patent dance, the parties negotiate the final patent list to be litigated, and the RPS files a patent infringement litigation ("first wave litigation"). Later, after the patent dance, the biosimilar applicant should provide a notice of commercial marketing to the RPS, and the RPS may file another patent infringement action ("second wave litigation"). For the second wave litigation, the RPS can assert any patents that the RPS listed at the beginning of the patent dance but not asserted in the first wave litigation. Therefore, technically, the RPS can assert dozens of patents in the second wave litigation, as far as they were initially included in the list of the patents provided by the RPS during the patent dance.

S.150

The bill proposes to amend the statute governing the patent infringement[3] by limiting the number of patents the RPS can assert in the patent infringement litigation against the biosimilar applicant under the BPCIA framework. Specifically, under the amended statute, the RPS may assert a total of no more than 20 qualifying patents. Further, no more than 10 of the 20 patents may have been issued or have been exclusively licensed after the RPS provided its initial list of the patents to the biosimilar applicant in the patent dance.

Limitation of S.150

On the other hand, the cap is not absolute and has several key limitations. First of all, for the cap of 20 patents to apply, the biosimilar applicant should have followed all requirements throughout the patent dance. Also, only certain patents meeting specified conditions are subject to the cap of 20. For example, a patent that is filed before the product approval or within 4 years after the product approval would not be counted towards the 20-patents limit. Additionally, the court has discretion to increase the cap under certain conditions (e.g., "if the interest of justice so requires" or "for good cause shown"). Therefore, in effect, the RPS may still be able to assert more than 20 patents under the statute amended as proposed by the bill.

20 PATENT LIMIT

Key Takeaways

The bill, if enacted, would limit the number of the asserted patents and put pressure on the RPS. Currently, there is no such cap on the number of patents that can be asserted. Biologics companies and patent holders should consider investing more on building a solid and extensive patent portfolio that does not count toward the 20 patent limit. For example, one can file more patents before the four-year date past the product approval. On the other hand, one should be selective in filing and prosecuting patents that count toward the limit and strategize well to make sure that such patents provide useful protection against biosimilar products even with the limited number of patents. Patents filed more than four years after the product approval are likely to have later expiration dates, therefore they can still have significant value even if only a limited number of them could be asserted.

For biosimilar manufacturers, the bill provides motivation to participate in the patent dance. The reduced number of asserted patents is likely to reduce the complexity and cost of patent litigation, and such benefit is available only if they participate in the patent dance. Further, as the cap for the asserted patents applies to later-filed (and thus likely later-expiring) patents, biosimilar applicants may have a chance to enter the market earlier if the bill is enacted.

While the House of Representatives has not picked up the bill, it is expected to be discussed in the House sometime in 2025.

IRA's Drug Pricing Negotiation

By: Arushi Pandya

The 2022 Inflation Reduction Act ("IRA") authorizes the Department of Health & Human Services ("HHS") to directly negotiate drug prices with pharmaceutical manufacturers for certain high expenditure, qualifying single source Medicare Part B & D drugs without generic/biosimilar competition. The Centers for Medicare and Medicaid Services ("CMS") has selected fifteen Part D drugs for price negotiation with drug manufacturers to go into effect in 2027. The fifteen drugs include Ozempic/Rybelsus/Wegovy, Trelegy Ellipta, Xtandi, Pomalyst, Ibrance, Ofev, Linzess, Calquence, Austedo/Austedo XR, Breo Ellipta, Tradjenta, Xifan, Vraylar, Janumet/Janumet XR, and Otezla.

Drugs qualify for price negotiation if they are covered under Medicare Part D, Medicare's outpatient prescription drug benefit program and are single-source, brand-name drugs or biological products without therapeutically equivalent generic or biosimilar alternatives that are approved or licensed and marketed on a "bona fide" basis. In addition, a drug product must be at least seven years (for small-molecule drugs) or eleven years (for biologics) past its FDA approval or licensure date, as of the date that the list of drugs selected for negotiation is published.

The status of the IRA's Drug Pricing Negotiation program is in flux. President Trump has vowed to repeal certain provisions of the IRA but has also historically supported drug negotiations, leaving the future of the IRA's drug negotiation provisions uncertain. Additionally, pharmaceutical manufacturers have challenged the negotiation program in courts and Republican Congressmembers have stated their intent to repeal the drug negotiation program. With President Trump already targeting other drug pricing negotiation programs, the future and scope of the negotiation program remain to be seen.

Pharma and Life Sciences Investigations and Prosecutions Update – January 2025

By: Joe Jay and Tom Reklaitis

With a second Trump administration beginning this year, our annual summary of enforcement trends in life sciences considers not only recent trends but also the future of enforcement priorities in the near and medium term. While some have wondered whether the second Trump administration would bring material differences to enforcement priorities, we have considered the past as prologue—that is, whether there were differences in enforcement during the first Trump administration, and believe that, at least with respect to life sciences, the change of administration likely means little meaningful change for enforcement priorities.

False Claims Act Enforcement

In February 2024, DOJ announced that it was a party to 541 False Claims Act ("FCA") settlements and judgments during fiscal year 2023 ("FY2023"), the highest yearly figure on record.[4] Of the $2.68 billion in settlements and judgments obtained by DOJ, more than $1.8 billion was related to the healthcare industry.[5] In addition to the settlements and judgments, the DOJ also initiated a record 500 non-qui tam actions under the FCA—almost two per business day.[6] While this trend bears monitoring, DOJ continues to rely predominantly on whistleblowers in the healthcare space as the number of qui tam actions outnumbered non-qui tam actions almost four-to-one.[7]

While the number of settlements and judgments entered into in FY2023 dwarfs all prior years, the aggregate total recovery by DOJ through healthcare fraud settlements does not constitute a stark departure from those secured during the first Trump administration.[8] Thus, we do not believe a second Trump administration portends a significant shift in DOJ's enforcements efforts (and dedication of resources) in civil False Claims Act matters.

Criminal Prosecutions

In its recently issued annual report of healthcare fraud and abuse control, DOJ revealed that it initiated 802 new criminal healthcare fraud investigations and brought criminal charges in 346 cases involving at least 530 defendants.[9] DOJ specifically highlighted the efforts of the national strike force teams, with the national rapid response strike force team's efforts receiving particular acclaim.[10] The strike forces filed charges against 406 defendants alleged to have fraudulently billed federal healthcare programs.[11]

Similar to FCA enforcement, these figures do not constitute a stark departure from statistics in the earlier Trump DOJ.[12] The published figures for 2020 indicate that DOJ opened 1,148 healthcare fraud investigations with criminal charges filed in 412 cases.[13] Therefore, companies should not expect DOJ to reduce its criminal investigations in life sciences and/or healthcare in the new administration.

In a June 2024 speech summarizing a national healthcare fraud enforcement action, Attorney General Merrick Garland emphasized the evolving nature of healthcare fraud schemes and DOJ's commitment to keeping pace with that evolution through the use of data analytics.[14] Attorney General Garland highlighted the rise of schemes employing telemedicine technology

to unlawfully dispense medically unnecessary prescriptions to defraud federal healthcare programs.[15] Even with a new attorney general set to take over, we do not believe that DOJ will cease its focus on enforcement in the telemedicine area. Instead, we believe DOJ will continue to rely on emerging technology to detect, investigate and prosecute fraud across the industry and particularly in life sciences and healthcare.

Civil Enforcement

The impact of the Supreme Court's ruling in *Securities & Exchange Commission v. Jarkesy*, which held that an agency's assessment of civil monetary penalties against an individual was violative of the Seventh Amendment Right to a Jury Trial, 603 U.S. 109 (2024), remains to be seen. Civil penalties—particularly when imposed by Executive branch agencies—increasingly may be challenged.

Also worth watching is a recent FCA decision issued in the Middle District of Florida, *U.S. ex rel. Clarissa Zafirov v. Fla. Med. Assocs., LLC*, which held as unconstitutional the relatorprovisions of the FCA. In handing down the decision, Judge Kathryn Kimball Mizelle (who was among the youngest judges nominated by President Trump and received a rare "not qualified" rating by the American Bar Association)[16] held that the FCA's relator provision "directly defie[d]" the Appointments Clause by permitting private individuals to exercise executive functions with no accountability to the public.[17] Finding the relator's suit wholly unconstitutional, Judge Mizelle granted the defendant's motion for judgment on the pleadings and dismissed the case in its entirety.[18] The case is now on appeal to the Eleventh Circuit and its assessment of the ruling (and any review by the Supreme Court) should be followed closely. For now, the decision appears to be an outlier, but whether and how a new DOJ chooses to handle the matters is worth considering. Given DOJ's historically heavy reliance on relators in pursuing healthcare fraud enforcement, the effects of the ruling could be resounding if the Eleventh Circuit and/or the Supreme Court affirm Judge Mizelle's opinion.

Corporate Integrity Agreements

The past year presented a significant uptick in the number of Corporate Integrity Agreements ("CIAs") entered into by the Department of Health and Human Services Office of Inspector General ("HHS-OIG") to settle federal healthcare investigations since 2020, with 28 CIAs entered into during 2024.[19] This constitutes an almost twofold increase over the prior year.

The number of CIAs entered into during the first Trump administration steadily increased, beginning with a low of eight CIAs in 2017 and concluding with 33 during 2020. The number of these agreements—33 in the final year of the first Trump administration and 28 in the final year of the Biden administration—is not surprising. However, President Trump's HHS and HHS-OIG in this term may choose different enforcement priorities; much remains to be seen under Secretary Robert F. Kennedy, Jr.

Conclusion

In sum, life sciences and healthcare companies can reasonably expect business as usual on the enforcement front during the second Trump administration. While the targets and mechanisms may shift—as they often do for nonpolitical reasons—the published figures strongly suggest that enforcement in life sciences and healthcare will likely remain a priority for federal law enforcement going forward.

Shifting Landscape of Antitrust Merger Enforcement Will Likely Continue Under the New Trump Administration

By: Leo D. Caseria and Helen C. Eckert

Antitrust enforcement under President Biden, particularly with respect to mergers, has undergone notable policy shifts and rule changes. There have been public pronouncements about ending "decades of industry consolidation [which] have often led to excessive market concentration" in many industries, including life sciences.[20] The groundwork for these changes has been laid in the last four years, including new Merger Guidelines from the Federal Trade Commission (FTC) and Department of Justice (DOJ), significant changes to the Hart-Scott-Rodino (HSR) rules and pursuit of novel theories of alleged competitive harm in challenges to pharmaceutical industry transactions. Whether the FTC and DOJ under the Trump Administration will continue to aggressively challenge proposed mergers in life sciences or will take a more permissive stance remains to be seen.

The new Merger Guidelines significantly broaden the types of mergers presumed to be anticompetitive

Under the new Merger Guidelines finalized in December 2023, more transactions in life sciences and other industries will be presumed to substantially lessen competition. In particular, transactions that result in a post-merger combined market share of 30% or more are presumptively anticompetitive in most situations under the new guidelines. The lower thresholds under the new Merger Guidelines significantly expand the range of transactions that may be investigated and challenged by the FTC or DOJ.

If the new guidelines continue to be enforced by the FTC and DOJ under President Trump, it may have a chilling effect on innovation in drug development. For example, biotech startups need to partner with larger pharmaceutical companies with sufficient resources, capital and know-how to successfully navigate costly clinical trials, regulatory approvals, and manufacturing hurdles to be able to reach the market to help patients. These partnerships can often involve full or partial acquisitions, without which most new startup drug assets would not make it beyond the R&D pipeline. But under the new guidelines, acquisitions may be anticompetitive if they eliminate the possibility of market entry by a nascent firm that would have resulted in new competition in the future.

The new guidelines also expand antitrust scrutiny of vertical mergers to include mergers involving "related" products or services. While prior guidelines focused on "traditional" vertical relationships such as a supplier-to-distributor relationship, the new guidelines also consider whether a merger can limit access to a rival's related products or services even if the merger falls outside of a traditional vertical merger structure.

This broader concern with limiting access to rivals' related products was the focus of the FTC's challenge against Illumina's proposed acquisition of GRAIL. According to the FTC's challenge, the proposed vertical acquisition of GRAIL, a developer of multi-cancer, early-detection (MCED) tests, would provide Illumina the ability to harm GRAIL's MCED competitors.[21] FTC asserted Illumina could do so by foreclosing competitors' access to Illumina's next-generation gene sequencing platform, a necessary input for running MCED tests. In 2023, the FTC ordered Illumina to divest GRAIL to protect competition in research, development and commercialization of competing MCED tests. The Fifth Circuit affirmed the FTC's finding of the likelihood of competitive harm, and Illumina announced its divestment of GRAIL in December 2023.[22]

Changes to the HSR Rules will significantly increase the burden of HSR filings if the Trump Administration allows them to take effect

In furtherance of the Biden Administration's more aggressive stance on merger enforcement, the FTC has finalized changes to the HSR Form and Instructions (HSR Rules) that will overhaul and substantially expand the amount of information and documents that must be submitted. This will significantly increase the amount of time, cost and resources needed to submit HSR filings. Some estimates indicate that more than 100 additional hours of work may be required. The new HSR Rules require, among other things, disclosure of more ordinary-course business documents, more drafts of documents relating to the transaction, more data and information about overlapping business lines or supply relationships between the parties, recent sales data, top customers and disclosure of products in each party's research and development pipeline which may potentially compete with the other parties' products. The FTC has indicated that the additional information will allow it to better determine which transactions warrant further scrutiny. In the past, much of this additional information would have been requested only if the FTC or DOJ decided to investigate a certain transaction after receiving the HSR filing, typically through a Voluntary Access Letter.

The new HSR Rules are scheduled to take effect on February 10, 2025. The new administration may delay or backtrack on the new HSR Rules, but whether or to what extent this occurs remains to be seen.

The FTC has pursued novel theories of anticompetitive harm in recent challenges to transactions in life sciences

The FTC under President Biden has pursued novel theories of anticompetitive harm in challenging proposed life sciences transactions. For example, in May 2023, the FTC filed a lawsuit seeking to block Amgen Inc.'s acquisition of Horizon Therapeutics plc.[23] The FTC alleged that the acquisition would allow Amgen to leverage its large portfolio of blockbuster drugs to pressure insurance companies and pharmacy benefit managers to favor Horizon's two monopoly drugs, Tepezza and Krystexxa, over its rivals' products. The FTC argued that the acquisition would raise barriers to entry and discourage smaller firms from researching and developing new drugs that may compete with Tepezza and Krystexxa. The FTC's challenge was resolved in a consent order that prohibited Amgen from bundling any Amgen product with either Tepezza or Krystexxa or offering rebates on Amgen products conditioned on the sale of Tepezza and/or Krystexxa.

In December 2023, the FTC also moved to block an exclusive licensing arrangement between Sanofi S.A., and San Francisco startup, Maze Therapeutics.[24] Here, the FTC argued that Sanofi had one of only a few approved treatment options for Pompe disease, a rare genetic disorder, and that it was trying to "buy out" Maze's potentially competing drug in early phase development. The FTC's challenge thus focused on *potential* future competition, assuming without proof that Maze's pipeline asset would successfully complete Phases 2 and 3, obtain regulatory approval and then brought to market to compete with Sanofi's treatment.

While President-Elect Trump has voiced clear opposition to what he views as exorbitant drug costs, few specifics have been set out in his 2024 campaign on this issue. It is unclear whether the FTC and DOJ will continue to aggressively challenge proposed mergers in life sciences under the Trump Administration.

Health Data Outside the Confines of HIPAA – New Wrinkles in an Ever-Evolving State Data Privacy Space

By: Julia Kadish and Samantha Davis

When it comes to privacy laws and their applicability, life sciences companies continue to find themselves situated within a confusing and evolving legislative patchwork. While no one law neatly applies to all data collection and use activities typical for a life sciences company, no one law expressly excludes those activities, either. Adding to the complexity, life sciences companies' often biggest stakeholders—healthcare providers—*are* regulated by the Health Insurance Portability and Accountability Act (HIPAA). This means that life sciences companies need to not only understand but respect and play within the parameters of HIPAA's sandbox—all the while trying to avoid becoming regulated by HIPAA. While respecting and staying out of HIPAA territory had long been the primary focus for U.S. privacy compliance efforts now, life sciences companies must also address the burgeoning series of "comprehensive," "health" and AI state privacy laws. Each of these focuses of state privacy laws are addressed in turn below.

"Comprehensive" State Privacy Laws

Over the past few years, states have picked up the slack where universal privacy legislation is concerned. There is no "comprehensive" federal privacy law on the books, which some argue leaves gaps in privacy regulation in the United States. In response, nearly 20 states and counting have passed laws similar to California's CCPA (which, in turn, takes after some aspects of GDPR in Europe). Many of these regulations have heightened standards for the processing of "sensitive information," which almost always includes health or medical information by definition. As of the end of January 2025, 14 states have privacy laws in effect. By the end of the year, three more will be on the books.

When evaluating the impact of these state privacy laws, life sciences companies must first determine whether the laws apply, which—except for California—is dependent upon whether a company does business in the state and whether a certain volume of personal information is processed about individuals from that state. In California, the law can apply based upon doing business there and meeting an annual revenue threshold. If the law applies, companies should then consider to what extent exceptions to certain information collection and use activities may exist in lieu of entity-based exemptions (like the ones that may exist for HIPAA-regulated entities). For example, many states exempt data collected pursuant to the Common Rule (which will typically cover data collected in a clinical trial). This does not necessarily mean life sciences companies are in the clear. As other activities become more common for life sciences companies such as patient support HUBs, clinical nurse education programs, co-pay assistance and patient marketing, these data-type based exceptions are unlikely to apply. This means that life sciences companies may want to implement a broader privacy program addressing areas covered in these "comprehensive" laws such as privacy notices, processes for individual rights requests, data protection assessments, vendor contracts and more.

State Health Privacy Laws

Over the past few years, due to increased use of technology to capture and analyze health-related information, the public (and its lawmakers) began to realize the gap in regulations applying to certain health-related data because of HIPAA's fairly narrow scope and application. As a result, three states have enacted what are being called "consumer health data" laws that impose various privacy requirements on companies that process health information but are not subject to HIPAA.[25]

Washington was the first to enact this kind of legislation with the My Health My Data Act, which went into effect for non-small businesses in March 2024. Nevada soon followed. Connecticut amended its statewide privacy law to include provisions that closely mirror the heightened requirements in Washington and Nevada.[26] These statutes contain threshold requirements for entities within the state's jurisdiction who "collect, process, share, or sell 'consumer health data'." In Washington, this is broadly defined as "personal information that is linked or reasonably linkable to a consumer and that identifies the consumer's past, present, or future physical or mental health status."[27] These laws generally restrict the processing of health-related information to instances in which a consumer has either given consent or when necessary to provide a requested service.[28] These laws also provide for consumer rights requests such as access, deletion, withdrawal of consent and nondiscrimination in a similar fashion to state comprehensive privacy laws, though with a few key differences.

Not unlike comprehensive state privacy laws, these consumer health data laws contain exceptions for data that is subject to HIPAA, originates from a HIPAA-covered entity or business associate or has been de-identified in accordance with HIPAA.[29] Some "consumer health information" shared with typical life sciences companies is likely to be bound up with data that is subject to these exceptions. However, given the myriad of patient services being offered in light of advances in the industry, life science organizations should be aware of these regulatory changes that may impact them.

State AI Laws

While both the White House and the Federal Trade Commission discussed the use of AI in 2023, 2024 saw additional guidance at the federal level. Furthermore, a few states began to regulate AI. This past summer, Colorado became the first U.S. state to enact a "comprehensive" AI law, which goes into effect in 2026.[30] At a high level, the Colorado law requires that businesses using AI attempt to mitigate issues of bias and caution users of high-risk systems. It also requires that businesses employing AI adopt reasonable risk management procedures and conduct impact assessments.

Utah also implemented more narrowly focused AI legislation aimed at consumer protection, requiring that businesses disclose the use of AI.[31] Although most businesses only have to make such disclosures upon request, certain "regulated" professions, including many healthcare professions, must do so at the same time as providing their services. In California, an array of AI-related bills were enacted, including one aimed specifically at the health industry taking effect in January 2025.[32] Under the law, regulated entities, such as healthcare facilities, are required to disclose the use of generative AI in communications with patients and provide instructions on how the patient can communicate with a human instead. Regulating AI remains a quickly evolving area that should be top of mind for any company in 2025. AI used in conjunction with more sensitive data or in a healthcare setting will likely take priority for lawmakers.

Summing it Up

For life sciences companies, HIPAA is no longer the be-all end-all. Compliance programs will need to catch up with novel legal obligations arising at the state level. This year, companies should focus on the importance of data collection and use in the context of their business model—from identifying the purpose of and basis for collecting information to implementing robust contractual safeguards with parties who process it. Organizations should also be cautious about the development and/or deployment of AI systems, particularly those that interact with patients, and determine if the benefits outweigh potential risks and compliance costs. With the ever-increasing attention on privacy, this complex legislative web is likely to only continue to tangle. Companies that may have avoided direct regulation up until now may be subject to privacy-compliance scrutiny sooner than they may think.

OPDP Year in Review

By: Audrey Mercer

In recent years, it would appear that the Office of Prescription Drug Promotion ("OPDP" or the "Agency") has lost some of the enforcement momentum it enjoyed on the heels of its so-called "Bad Ad" Program launch over a decade ago. This past year was no different, with OPDP issuing only five Untitled Letters and not a single Warning Letter. However, OPDP may be owed more credit here, as this decrease in the frequency of enforcement activity could be part of a strategy (i.e., OPDP trying to get ahead of false and/or misleading drug promotion through proactive policymaking instead of reacting to the problem through retroactive enforcement) rather than merely a loss in momentum. After all, the decrease in enforcement activity over the past few years has been balanced by a steady uptick in proactive policymaking through rules and/or guidances. For example, OPDP had a big year in 2023 with two Final Guidances and a Final Rule (all pertaining to Direct to Consumer ("DTC") promotion), and kept similar pace in 2024 with two draft guidances – an FAQ on Biologics Promotion and an FAQ on Addressing Misinformation for Drugs and Devices (and three if you count the Scientific Information of Unapproved Uses Guidance it slipped in six days into the new year). And although this year's Untitled Letters were few and far between, they provided insightful takeaways about the Agency's enforcement priorities, which provide critical direction to pharmaceutical companies as they finalize their promotional plans for 2025.

Below is the full list of takeaways from OPDP's enforcement activity in 2024 that should be incorporated into every pharmaceutical company's approach to advertising and promotion in 2025, much of which you can read about in greater detail on our blog:

- **Celebrity Endorsements:** Over the past couple of years, OPDP has shown an interest in the effect of celebrity endorsements on drug promotion – particularly through research and data-gathering efforts – but this past year, no doubt driven by results from these research initiatives, the Agency expressed a relatively new concern about promotion that incorporates endorsements from celebrity spokespersons, with three of the five Untitled Letters involving celebrity endorsements. The concern here is that the reach and effect of false and/or misleading drug promotion can be amplified when communicated by a celebrity endorser who has broad influence and is likely to be perceived as a trusted source.

- **Social Media Platform:** In 2024, OPDP continued its focus on drug promotion disseminated through social media platforms, with two of the five Untitled Letters involving promotional materials published on Instagram. Through these letters, the Agency continued to define its standards for risk presentation in social media promotion, breaking somewhat with its past guidance by communicating that it is ***not*** always sufficient to simply place risk information at the end of a social media post.

- **DTC Communication:** OPDP also continued its focus on DTC advertising, with two of the five Untitled Letters involving traditional DTC advertisements. As discussed above, this enforcement comes on the heels of OPDP's 2023 Final Rule on DTC Promotion – the first rule issued by the Agency in over a decade – which, when considered with continued enforcement in this area, clearly communicates that DTC promotion is a top priority for OPDP and will continue to be so moving forward. Of course, as part of the tidal wave of change promised by the Trump administration, there has been discourse about following in the steps of the rest of the world and banning DTC drug promotion altogether; however, in the absence of such a stark left-turn in policy, we can expect OPDP to keep a close eye and a tight leash on DTC drug promotion.

- **Consistent with Label ("CFL"):** Finally, this past year saw a continued focus on the FDA's so-called consistent with label ("CFL") policy, which focuses on the way that promotional materials characterize safety and efficacy data, with the Untitled Letters targeting claims that either overstated efficacy data or were not substantiated at all. In two of the letters, OPDP specifically honed in on temporal efficacy claims (i.e., claims related to the "onset of action" for a drug product). Accordingly, companies should ensure that all promotional claims accurately reflect the supporting data, and should pay special attention to claims addressing timing considerations, such as a product's onset of action.

Developments in Reverse Merger Transactions – Understanding the Definition of "Shell Company" in the Context of Reverse Mergers in the Life Sciences Industry

By: Jeffrey Fessler and Nazia Khan

On January 24, 2024, the U.S. Securities and Exchange Commission ("SEC") adopted rules related to special purpose acquisition companies ("SPACs") and other shell companies, including Rule 145a under the Securities Act, which rules became effective on July 1, 2024[33]. The SEC noted that it "…is adopting rules intended to enhance investor protections in initial public offerings by special purpose acquisition companies (commonly known as SPACs) and in subsequent business combination transactions between SPACs and private operating companies (commonly known as de-SPAC transactions)."[34] For example, the newly adopted Rule 145a imposes increased disclosure and liability burdens on a private company in a reverse merger when the public company in the transaction is classified as a shell company.

In 2024, life sciences companies emerged as the leading industry announcing their intention to explore strategic alternatives as a result of clinical setbacks they encountered including reverse mergers. In connection with such development in the life sciences industry, the SEC began issuing comment letters in the context of life science reverse merger transactions which has affected the attractiveness of such strategic alternative. A reverse merger in this context typically involves a private company merging with a "fallen angel" to access benefits like the fallen angel's cash and exchange listing as well as access to the public markets.

Historically, reverse mergers did not result in a post-closing shell company. Under the Securities Act, a "shell company" is defined as a company with (A) no or nominal operations, and (B) either (i) no or nominal assets, (ii) assets consisting solely of cash and cash equivalents or (iii) assets consisting of any amount of cash and cash equivalents and nominal other assets. Recently, however, the SEC also included the following in its determination of whether a company is a "shell company": (i) whether the primary purpose of the reverse merger is to provide cash and a stock exchange listing to a private company; and (ii) whether the transaction is accounted for as a reverse capitalization.

The foregoing position taken by the SEC has many negative impacts on traditional fallen angel reverse mergers that may result in the post-closing company being classified as a shell company including but not limited to the following:

- *Delayed Short Form S-3 Eligibility*: The post-closing company is not eligible to use Form S-3 to register securities for public offerings until 12 months after it has ceased being a shell company.

- *Delayed S-8 Eligibility for Employee Stock Plans*: The post-closing company is not eligible to use Form S-8 for 60 calendar days after closing.
- *Rule 144 Implications*: The post-closing company is not eligible to use Rule 144 for a period of 12 months from the time the company ceases to be a shell company. Furthermore, the post-closing company will be subject to the ongoing requirements in Rule 144(i) applicable to former shell companies which requires former shell companies to have adequate information publicly available for the preceding 12 months.
- *Ineligible Issuer Status*: The post-closing company will be deemed to be an "ineligible issuer" under Rule 405 of the Securities Act for a period of three years after the closing and, as such, it cannot, among other things, qualify as a well-known seasoned issuer or use a free writing prospectus.
- *No Incorporation by Reference for Form S-1*: While the post-closing company can utilize a Form S-1 for primary and secondary offerings, it cannot incorporate information by reference, which means that it will need to file post effective amendments to its secondary S-1 to keep such S-1 effective.
- *Restrictions on Sales of Shares Acquired by Affiliates in Reverse Merger*. Investors who were affiliates of the private company and receive securities of the public company in the reverse merger (i.e., Rule 145(c) securities) will be deemed statutory underwriters with respect to resales of those securities and, as such, those securities may not be included in a Form S-1 resale shelf and instead may be sold only in a fixed price offering in which such investors are named as underwriters in the prospectus.

- *Nasdaq Listing Determination*. If the "fallen angel" is listed on Nasdaq and it is determined that the "fallen angel" is a shell company, Nasdaq will apply its standard analysis in determining stockholders' equity post-merger. This means that Nasdaq could include the shell company's operational losses in its determination as to whether the post-closing company satisfies Nasdaq listing requirements.
- *S-4*. If the "fallen angel" is listed on Nasdaq and it is determined that the "fallen angel" is a shell company, it will be required to use a Registration Statement on Form S-4 to register the securities being issued in the reverse merger.

Companies contemplating reverse mergers should be mindful of the recent changes in the SEC's position as such changes could affect a post-closing combined company's ability to raise capital and lead to potential liquidity challenges following the reverse merger.

****

OIG Compliance Program Guidance Update

By: Alexandra Kitson

For over twenty-five (25) years, the Compliance Program Guidances (CPGs) published by the Office of Inspector General, Department of Health and Human Services (OIG) have been instrumental in shaping compliance programs across the healthcare industry. Life sciences companies, in particular, continue to rely heavily on the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers to develop and maintain their compliance functions.

In our 2024 *Top-of-Mind Issues for Life Sciences Companies* publication, we explored OIG's efforts to modernize its body of CPGs, including the release of a general CPG (GCPG) offering best practices to the wider healthcare industry and a plan to release new versions of its industry-specific CPGs (ICPGs). While we expected to see new ICPGs for both nursing facilities and Medicare Advantage in 2024, only the Nursing Facility Industry Segment-Specific Compliance Program Guidance (NF-ICPG) was published last year.

While the NF-ICPG is tailored to nursing facilities, it illustrates OIG's thinking on various compliance issues, offering valuable insight for life science firms. Notably, the guidance addresses the risks of two common business arrangements between pharmaceutical manufacturers and nursing facilities: discount programs and consulting relationships.

Discounts

In the NF-ICPG, OIG reiterates the importance of structuring discount programs to fit within the bounds of discount safe harbor wherever possible. Specifically, discounts should be: (1) based on an arms-length transaction and (2) disclosed on any relevant cost reports. Additionally, firms should also avoid swapping arrangements in which a manufacturer offers a discount in exchange for referrals of other federal healthcare program business.

Consulting Relationships

In a section on conflicts of interest, the NF-ICPG addresses the fraud and abuse risks inherent in financial relationships between pharmaceutical manufacturers and nursing facility providers. The concern here, as with any provider-manufacturer relationship, is that a financial relationship could create a conflict of interest, potentially leading to "overprescribing and inappropriate prescribing." OIG's focus on this area emphasizes the importance of maintaining a robust needs-assessment process to carefully evaluate all financial relationships with providers and minimize potential kickback concerns.

Only time will tell if one CPG per year is a pattern or an anomaly. We should expect to see at least the Medicare Advantage ICPG before the end of 2025; however, it may take some time before the entire suite of modernized ICPGs is available.

Turning Over a New Leaf? DEA's Proposed Rescheduling of Marijuana and Implications for Traditionally Taboo Medicines

By: Cortney Inman

The past year was a whirlwind for historically taboo medicines marked by setbacks and significant progress. Key among these developments was the U.S. Department of Justice's ("DOJ's") and Drug Enforcement Agency's ("DEA's") highly anticipated Notice of Proposed Rulemaking ("NPRM") to move marijuana from Schedule I of the Controlled Substances Act ("CSA") to Schedule III. Although this rule is currently in limbo – with hearings before the DEA Administrative Law Judge ("ALJ") now delayed several months –if finalized it could have a significant impact not only on cannabis research and development but could ease future rescheduling of other Schedule I substances as well. Before diving into our predictions, let's recap some of the background underlying this rule and the details of the NPRM itself.

Cannabis Regulation Today

The legal status of marijuana in the United States has been a controversial issue for decades and has received increasing scrutiny as more and more states have legalized marijuana for medical and recreational purposes. Since the enactment of the CSA in 1970, marijuana has been categorized as a Schedule I substance.[35] This classification signals that the federal government considers marijuana to have a high potential for abuse, no currently accepted medical use ("CAMU") and that there is no "accepted safety for use of the drug . . . under medical supervision."[36]

As a Schedule I substance, marijuana in clinical research is subject to the most stringent restrictions. For example, investigators are required to, among other things, obtain a Schedule I research registration from the DEA; submit an Investigational New Drug ("IND") application to FDA *and* a research protocol to the DEA; comply with DEA security, storage and reporting protocols; and obtain "research-grade cannabis" from a federally authorized source.[37]

These restrictions are designed to curtail diversion and abuse, however, in practice, they have been criticized as impeding the quality, accessibility and progress of marijuana research.[38] This has resulted in what many have labeled a "catch-22" for marijuana policy: marijuana remains a Schedule I substance because there is insufficient research on medical use, however, there are significant barriers to conducting such research because of its Schedule I status.[39]

Rescheduling Under the CSA

The CSA sets forth a complex and collaborative framework for rescheduling controlled substances. At a high level, the AG has authority to initiate formal rulemaking to reschedule a drug, but may do so only after the Department of Health and Human Services ("HHS") has first conducted a medical and scientific evaluation of the drug and provided its recommendation to the AG.[40] Here, the current proceedings were initiated in October 2022 at the request of President Biden. HHS provided its evaluation and recommendation to the AG in August 2023, and the AG published the proposed rule in May 2024.[41]

The CSA also identifies various criteria for rescheduling a drug. Importantly, a controlled substance may be classified into one of five schedules based on: (1) the drug's potential for abuse, (2) whether the drug has a CAMU and (3) "the safety or dependence potential of the substance."[42] In evaluating these elements, the CSA requires that HHS and the AG consider eight statutorily prescribed factors including: "actual or relative potential for abuse," "scientific evidence of its pharmacological effect, if known" and "what, if any, risk there is to the public health."[43]

HHS Recommendations & OLC Involvement

The proposed rule itself provides a detailed and lengthy discussion of HHS's findings and recommendations with respect to each prong of the eight-factor test. HHS's evaluation was largely based on various epidemiological studies regarding abuse potential and adverse effects associated with the drug, and often contrasted the effects of marijuana to other controlled substances such as heroin (a Schedule I substance) and ketamine (Schedule III), as well as noncontrolled substances like alcohol.[44] Ultimately, HHS concluded that (1) although marijuana has "a high prevalence of abuse, the profile of and propensity for serious outcomes related to that abuse . . . is most appropriately controlled in schedule III;" (2) "for purposes of drug scheduling criteria . . . marijuana has a CAMU for: anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced); and pain;" and (3) "clinical studies have demonstrated that marijuana produces physical and psychological dependence," however, "the likelihood of serious outcomes is low."[45]

In so doing, HHS notably departed from DEA's traditional approach to evaluating a substance's CAMU. The CSA does not ascribe any one method for assessing CAMU, however, historically, DEA has applied one of two tests:

- whether "the substance has been approved by FDA for marketing under the FDCA;" or
- whether "the substance satisfies a five-part test" created by the DEA that is purportedly based on the following so-called "core FDCA standards for acceptance of drugs for medical use:"
    - (1) "There must be adequate safety studies;"
    - (2) "The drug's chemistry must be known and reproducible;"
    - (3) "There must be adequate and well controlled studies proving efficacy;"
    - (4) "The drug must be accepted by qualified experts;" and
    - (5) "The scientific evidence must be widely available."[46]

Instead, HHS introduced a new two-prong test that looks first at whether there is "widespread current experience with medical use of the substance in the United States by health care practitioners . . . operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine," and second, "the scientific basis for any identified medical use."[47]

Faced with this new test, the AG turned to the Office of Legal Counsel ("OLC") – a separate arm of the DOJ which "serv[es] as, in effect, outside counsel for the other agencies of the Executive Branch."[48] OLC ultimately agreed with HHS, finding that the DEA's traditional approach was "an impermissibly narrow interpretation of" CAMU under the CSA.[49] In so doing, OLC reasoned that DEA's tests were disproportionately focused on FDA-approval standards, and that DEA had apparently "erroneously equat[ed] identification of an 'accepted' medical use under the CSA with the 'approval,' or potential approvability, of the drug under the FDCA."[50]

OLC further approved of HHS's proposed two-part test, noting that "[s]o long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU."[51]

DEA Findings and Proposed Hearings

Interestingly, the proposed rule contained very little commentary from the DEA. Aside from a few paragraphs indicating that the AG agrees with HHS (which is unsurprising given that HHS's recommendations are binding on the DEA prior to initiating formal rulemaking),[52] it is difficult to glean DEA's stance from the text of the NPRM alone. To be sure, DEA's repeated references to increased potency and THC concentrations and requests for additional evidence signal some level of skepticism, but these concerns alone do not seem sufficient to doom the rule.

However, since publication, DEA's actions have provided some additional context to the agency's potential thinking and suggest there may be underlying disagreement with HHS's assessment. In August 2024, the DEA notified stakeholders that it would convene a hearing on the NPRM to "receiv[e] factual evidence and expert opinion" and solicited requests from interested persons to speak at such hearings.[53] In the months following this request, the agency has come under fire for allegations of conflicts of interest, favoring parties opposed to the NPRM, and engaging in impermissible *ex parte* communications with the same.[54] Indeed, hearings were set to kick off on January 21, 2025 but have since been cancelled and proceedings stayed pending further review and resolution of these allegations.[55] While the extent of DEA's bias remains unclear, the ALJ reviewing the matter did not hide its disapproval of the agency's conduct, describing the alleged actions taken by DEA as "arguably disturbing," "unseemly and troubling" among other choice words.[56]

Going forward, the parties are to provide the ALJ overseeing the proceedings with a joint status update in April 2025, leaving the future of the NPRM in limbo.[57]

Key Takeaways

While the path forward remains unclear, the DEA's proposed rule highlights the evolving landscape of cannabis regulation and the increasing recognition of its medical potential. Regardless of recent controversy, it is only a matter of time before marijuana is rescheduled. In light of shifting tides, it only makes sense to begin to take a realistic look at what lays ahead under this new regime.

From an FDA perspective, if finalized, the proposed rule would significantly ease restrictions on clinical research of the drug and in turn dramatically expand this historically stymied industry. As a Schedule III substance, cannabis would then be subject to FDCA requirements and corresponding regulations, leaving FDA as the primary federal regulator for the drug. FDA has left breadcrumbs over the past few years signaling that it is ready to take on the task. For example, FDA has published guidance directed at Botanical Drug Development and Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, and more recently, permitted a Phase 2 trial studying botanical cannabis as a treatment of PTSD to proceed.[58] To be sure, this is uncharted territory, and it remains to be seen whether congressional action will be needed to supplement FDA's resources.

Furthermore, aside from the direct effects that rescheduling has on marijuana, OLC's affirmation of HHS's CAMU test likely will make it easier for rescheduling of other similarly restricted substances. As aforementioned, the new test focuses on what medical practitioners are doing on the ground and in compliance with state board requirements. This is a massive paradigm shift in how we look at the interplay between the federal CSA and state drug laws. Under this scheme, state decriminalization of federally controlled substances may be viewed less as an act of defiance against the federal government and more as a step towards medical innovation.

Looking ahead, we may expect to see this exact scenario play out with psychedelic drugs. For example, Colorado, Oregon and Utah have passed legislation to permit limited medical applications of psilocybin and MDMA,[59] and a number of other states have introduced and/or passed legislation establishing state-led working groups to study clinical effects of these drugs.[60] Psychedelics have even garnered bipartisan support at the federal level, with the Veterans Health Administration's Office of Research Development "funding research on psychedelic compounds in Veterans" including trials for psilocybin and MDMA for treatment of conditions such as PTSD, alcohol use disorder, depression and OCD.[61] It remains to be seen whether other states will follow this path, however, the trajectory thus far seems to suggest that may be the case.

If so, these reforms could pave the way for showing that, like cannabis, these Schedule I drugs have CAMU as well and are thereby deserving of a less restrictive status.

For now, we will continue to closely watch how the DEA hearings and rescheduling proceedings develop, and the impact that the changing administration may have on the future of marijuana.

Life Sciences Meets Homeland Security: Is There More to Come?

By: Scott Liebman, Dominick DiSabatino, Audrey Mercer

One piece of legislation we followed closely in 2024 was the BIOSECURE Act. Although, to our surprise, the legislation did not pass in 2024, there are a number of reasons we could ultimately see it – or similar legislation – pushed through in 2025, including its close alignment with the bullish homeland security policy of the incoming Trump administration. If this happens, it will cause a major supply shake-up and create a new landscape for drug and device development—necessitating a proactive posture by U.S. biotech companies.

A. History of the Act

In December 2023, the Senate introduced the original version of the Act and shortly after in January 2024, the House introduced its version (the "Act"). The Senate version of the bill stalled in March but in September, the House version passed by a bipartisan majority (306-81) as part of its self-titled "China Week," during which it advanced legislation targeting Chinese-affiliated industry activities in the name of alleged national security concerns. The Act was touted by proponents as a necessary tool to prevent companies affiliated with foreign adversaries and currently operating in the U.S. from becoming even more embedded with the U.S. economy than they are already.[62] However, opponents warned that the Act could result in disastrous supply chain disruptions, which would ultimately harm American patients by stifling global collaboration and causing shortages, delays and increased costs.

B. What the Act Says

The Act would prohibit executive agencies from contracting with, or procuring so-called "biotechnology equipment or services" from a so-called "biotechnology company of concern." Additionally, the Act would prohibit executive agencies from contracting with a company that uses any "biotechnology equipment or service" produced or provided by a "biotechnology company of concern" and prohibit recipients of federal funds from using those funds to procure "biotechnology equipment or services" from a "biotechnology company of concern."

In a relatively rare move by Congress, the Act specifically names five entities considered de facto "biotechnology companies of concern"—including industry giants WuXi AppTec and WuXi Biologics (as well as any subsidiary, parent, affiliate or successor entities of the five named companies). The Act would also require the Office of Management and Budget ("OMB"), in conjunction with the Department of Defense, to name additional "biotechnology companies of concern" and remove currently named companies that do not belong on the list within one year of enactment.[63]

C. What Opponents Say

Opponents of the legislation, including opposing lawmakers, entities named as "biotechnology companies of concern" and interested industry groups, have criticized the legislation on procedural and substantive grounds.

Procedurally, opponents, such as Sen. Rand Paul (R-KY) and Rep. James McGovern (D-MA), have criticized the lack of clear methodology behind the decision to name the five companies and other entities that may be named as "biotechnology companies of concern" in the future.[64] But from a substantive—and arguably far more consequential—perspective, opponents warn that the Act could result in catastrophic supply chain issues that could jeopardize patient access by stifling global collaboration and innovation and causing delays and shortages, as well as increased costs (a direct result of a decrease in supply without a decrease in demand). This warning is underscored by the fact that the U.S. biotech industry's reliance on Chinese products and services is deeply entrenched. A recent Reuters study found that nearly 80% of U.S. companies represented by Biotechnology Innovation Organization ("BIO")—a trade organization that has also publicly disfavored the Act—have at least one contract or product agreement with a Chinese-based or Chinese-owned manufacturer,[65] and WuXi alone is estimated to have a hand in the development of a whopping 25% of drugs sold on the U.S. market.[66]

D. Predictions and Key Takeaways

U.S. biotech companies, as well as domestic suppliers, should begin thinking through potential supply chain strategies in the event that the Act—or a reworked version—passes in 2025, as a number of factors point to potential success for some form of the legislation this year. First, WuXi recently divested some of its U.S. and European operations, with plans to divest more in 2025, presumably to get ahead of the Act's impact,[67] which could indicate that the company may intend to concede instead of investing in a fight. Further, despite highly publicized criticism from big players in the House and Senate, the reality is that the Act has been backed by strong bipartisan support. Additionally, the spirit of the legislation aligns with the strong and specifically anti-China homeland security platform touted by the incoming Trump administration. And finally, Congress passed a bill five years ago that used the same model to restrict government contracting with Chinese telecommunications suppliers, showing that it is, at least to some extent, comfortable applying this model to major industries.[68] However, it ultimately remains to be seen whether these factors are strong enough to overcome opposition by key leaders, especially those in particularly influential positions like Rand Paul, and lobbying headwinds by industry players like WuXi.[69]

In the short-term, we will be closely monitoring for the potential reintroduction of the Act (or a reworked version) and, if such legislation is ultimately passed, will continue to closely monitor its implementation.

Keeping Tabs: Were We Right or Wrong in 2024

By: Julian Klein

Every January in this publication, the Sheppard Life Sciences group forecast how important issues might unfold in the coming year. We thought it would be "fun" to take a look back to see what we got right and what we got wrong. So, here it goes.

AI:

We predicted that AI would continue to be top of mind in nearly every industry, adding that policymakers and regulators would try to keep pace with the rapid development. Since regulation inevitably lags behind development, we said that life sciences companies should consider integrating AI policies into existing policy programs, particularly with regard to privacy.

This was largely accurate; several states enacted laws regulating the development and use of AI. Most notably, Colorado passed the broadest state AI law, providing key definitions and creating the "consequential decision" standard to determine if an AI model is high-risk.

Additionally, FDA's recent release of guidance for developers of AI-enabled medical devices and proposed framework addressing the credibility of AI models used for drug and biologics submissions underscores the heightened focus that agencies are placing on this issue.

Life sciences companies should continue to consider the integration of AI governance into existing policy frameworks so that they remain equipped in the rapidly developing space and avoid privacy violations and other risks.

Overturning *Chevron*:

We discussed the potential of the overturning of *Chevron v. Natural Resources Defense Council*, a landmark Supreme Court case from 1984 that established a standard of deference shown to the decisions made by federal agencies. We asserted that, if *Chevron* were to be overturned in cases being heard by the Supreme Court in January of 2024, there could be significant impact on regulation of the life sciences industry.

Somewhat unsurprisingly, a conservative-led Supreme Court overturned *Chevron* in favor of allowing the courts to use their own judgment to interpret laws rather than deferring to agency judgment. The impact of the ruling has yet to fully reach the life sciences space in the courtroom, as the first cases citing the decision in *Loper Bright Enterprises v. Raimondo* relate to EPA and FCC decision-making. However, since the ruling, FDA has issued much guidance to the industry, suggesting that the agency may increasingly regulate through guidance as a result of the Court's decision.

Proposed Rule on LDT Regulation:

A major point of interest last year was the proposed rule that would make Laboratory Developed Tests ("LDTs") regulated as medical devices, phasing out the enforcement discretion approach. We correctly predicted that the rule, proposed in October 2023, would be finalized in April 2024. We recommended that manufacturers of LDT products prioritize compliance with the final rule based on the staged approach set forth by the FDA and, despite changes in the administration, this approach should continue to be heeded.

The Enablement Requirement (*Amgen Inc. v. Sanofi*):

Turning to patents, we highlighted a 2024 Supreme Court case surrounding the enablement requirement of the Patent Act, which requires that an invention be communicated to the interested public in a meaningful way. The ruling narrowed the scope of what satisfies the requirement, which we predicted would make it more challenging for companies to obtain patents for broad classes of inventions.

To date, there have been numerous patent challenges in Federal Courts citing Amgen as a basis to argue that patents at issue are not enabled.[70] As we anticipated, the ruling has opened the door for patent challenges on the basis of enablement.

Efforts to Control Drug Prices:

We discussed the Biden Administration's efforts to control drug pricing, including the Department of Health and Human Services' ("HHS") authority to regulate prescription drug prices for drugs that make up a large portion of Medicare expenditures, as part of the Inflation Reduction Act ("IRA"). We noted the challenges to the Drug Price Negotiation Program by drug manufacturers, PhRMA and the U.S. Chamber of Commerce, and expected more to come. We discussed additional efforts to control drug pricing, including an Interagency Draft Guidance to determine when the Government may exercise "march-in" rights and take a pharmaceutical company's drug patents developed with federal funds and share them with other companies.

We ultimately predicted that the administration's efforts would continue to be challenged. This turned out to be true, including a revived challenge in the U.S. Circuit Court of Appeals for the Fifth Circuit in September 2024.[71]

However, we did not forecast what could happen under an incoming Trump Administration. This question remains murky—with some suggesting the program will be supported as a means to save the Government money, others suggesting the IRA as a whole faces uncertainty.[72]

340B Program:

We discussed the 340B Drug Pricing Program, which is administered by the Health Resources Services Administration ("HRSA") and requires drug manufacturers that participate in the Medicaid drug rebate program to provide covered outpatient drugs to enrolled covered entities at or below a statutorily defined ceiling price. We forecasted a continued struggle between manufacturers and covered entities (each seeking mechanisms to retract or expand 340B pricing access) that would prompt agency action and legal challenges.

2024 ended up being a big year for the 340B program, with HRSA issuing its final rule pertaining to the alternative dispute resolution process for manufacturers and covered entities to resolve 340B disputes. Furthermore, proposed legislation including the SUSTAIN Act seeks to clarify uncertainties in the 340B process as HRSA's authority declines. We were right in the continued "tug of war" between manufacturers and covered entities, and with agency action and proposed legislation on the horizon, 340B continues to be an area of interest for 2025.

Copay Accumulators:

We discussed the U.S. District Court for the District of Columbia's decision to vacate a Trump-era HHS and the Centers for Medicare and Medicaid Services ("CMS") regulation giving insurance companies free rein to decide whether to exclude manufacturer assistance when calculating whether a patient has met their annual cost-sharing obligation. We noted three things to keep an eye on: (1) future HHS rulemaking; (2) what response, if any, the court will have to HHS's proposed enforcement policy; and (3) whether the district court's decision is upheld on appeal.

The appeal was ultimately dismissed in 2024, and we await new HHS rulemaking as any new enforcement action will have to wait until a new rule is finalized.

SIUU Guidance:

We discussed the FDA draft guidance titled Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers ("SIUU Draft Guidance"), and recommended that manufacturers pay close attention to communications about new, unapproved uses of medical products. Our recommendation rings more true now as FDA recently finalized the aforementioned draft guidance, further emphasizing the need for manufacturers to ensure compliance.

Device-Enabling Software:

In light of a Warning Letter issued to Abiomed Inc. in 2023, we predicted that device-enabling software, particularly Clinical Decision Support ("CDS") software would remain an area of focus for FDA in 2024.

Although there was no enforcement action taken in relation to CDS software in 2024, device-enabling software remained an area of FDA focus evidenced by multiple Warning Letters issued.[73] Furthermore, FDA recently released draft guidance on Artificial Intelligence-enabled device software.[74]

Non-Compete Agreements in M&A Transactions:

We highlighted recent developments in Non-Compete provisions for Life Sciences M&A transactions, particularly state bans on non-compete provisions in California, Colorado, Oklahoma, North Dakota and Minnesota. We noted that while there was no federal ban, there was a proposed rule by the Federal Trade Commission ("FTC") that would prohibit non-compete provisions.

This certainly was an area to keep an eye on for M&A transactions. In April, FTC issued the final rule banning non-compete agreements nationwide, however, in August 2024, the U.S. District Court for the Northern District of Texas ruled that the ban was unlawful. FTC is in the appeals process, but still retains the authority to address non-compete agreements on a case-by-case basis.[75]

Modernization of Clinical Trial Process:

Finally, we highlighted FDA's continued efforts to modernize and enhance the clinical trial process. This included guidance related to clinical trial requirements for the accelerated approval pathway, externally controlled clinical trials, decentralized clinical trials occurring at non traditional sites and the overall design and conduct of clinical trials. We predicted that FDA would continue its approach to advance and modernize the clinical trial process.

We were right about FDA's focus—new draft guidance related to clinical trials were released throughout 2024, ranging from Cancer Clinical Trial Eligibility to Bioresearch Monitoring Inspections. Furthermore, FDA released new draft guidance for the accelerated approval pathway, clarifying requirements for post-market confirmatory trials.

CONTRIBUTING AUTHORS

Leo Caseria
Partner | Washington, D.C.
202.747.1925
lcaseria@sheppardmullin.com

Dominick DiSabatino
Partner | Washington, D.C.
202.747.1957
ddisabatino@sheppardmullin.com

Jeffrey Fessler
Partner | New York
212.634.3067
jfessler@sheppardmullin.com

Joseph Jay
Partner | Washington, D.C.
202.747.1953
jjay@sheppardmullin.com

Julie Kadish
Partner | Chicago
312.499.6334
jkadish@sheppardmullin.com

Scott Liebman
Partner | New York
212.634.3030
sliebman@sheppardmullin.com

Joy Nemirow
Partner | Silicon Valley
650.815.2634
jnemirow@sheppardmullin.com

Lorna Tanner
Partner | Silicon Valley | San Francisco
650.815.2658 | 415.774.3161
ltanner@sheppardmullin.com

Helen Eckert
Special Counsel | San Francisco
415.774.3233
heckert@sheppardmullin.com

Alexandra Kitson
Special Counsel | New York
212.653.8173
akitson@sheppardmullin.com

Samantha Davis
Associate | New York
212.896.0670
skdavis@sheppardmullin.com

Cortney Inman
Associate | Washington, D.C.
202.747.1869
cinman@sheppardmullin.com

Nazia Khan
Associate | Washington, D.C.
202.747.2651
nkhan@sheppardmullin.com

Nathan Lee
Associate | Orange County | Silicon Valley
714.424.8273 | 650.2600
nlee@sheppardmullin.com

Audrey Mercer
Associate | Dallas
469.391.7454
amercer@sheppardmullin.com

Arushi Pandya
Associate | Washington, D.C.
202.747.3228
apandya@sheppardmullin.com

Tom Reklaitis
Associate | Washington, D.C.
202.747.2335
treklaitis@sheppardmullin.com

Julian Klein
Law Clerk | New York
212.896.0686
jklein@sheppardmullin.com

"Patent Thicket" Bill: A Patent Legislation to Watch in 2025 Endnotes

[1] https://www.cornyn.senate.gov/news/cornyn-blumenthal-introduce-bill-to-lower-drug-costs-by-preventing-patent-system-abuse/
[2] 42 U.S.C. § 262(k)
[3] 35 U.S.C. § 271(e)

Pharma and Life Sciences Investigations and Prosecutions Update – January 2025 Endnotes

[4] Department of Justice, False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023, https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023 (Feb. 22, 2024).
[5] See id.
[6] See id.
[7] See id.
[8] Department of Justice, Fraud Statistics – Overview, https://www.justice.gov/opa/media/1339306/dl?inline (last visited January 9, 2025).
[9] See The Department of Health and Human Services and the Department of Justice, Health Care Fraud and Abuse Control Program annual Report for Fiscal Year 2023, https://oig.hhs.gov/documents/hcfac/10087/HHS%20OIG%20FY%202023%20HCFAC.pdf (Dec. 2024).
[10] See id.
[11] See id.
[12] See, e.g., The Department of Health and Human Services and the Department of Justice, Health Care Fraud and Abuse Control Program annual Report for Fiscal Year 2020, https://oig.hhs.gov/documents/hcfac/1155/OIG-HCFAC-2020-Complete%20Report.pdf (July 2021); The Department of Health and Human Services and the Department of Justice, Health Care Fraud and Abuse Control Program annual Report for Fiscal Year 2018, https://oig.hhs.gov/documents/hcfac/1179/OIG-HCFAC-2018-Complete%20Report.pdf (July 2019).
[13] The Department of Health and Human Services and the Department of Justice, Health Care Fraud and Abuse Control Program annual Report for Fiscal Year 2020, https://oig.hhs.gov/documents/hcfac/1155/OIG-HCFAC-2020-Complete%20Report.pdf (July 2021).
[14] The Department of Justice, Attorney General Merrick B. Garland Delivers Remarks on a National Health Care Fraud Enforcement Action Resulting in 193 Defendants Charged and Over $2.75 Billion in False Claims, https://www.justice.gov/opa/speech/attorney-general-merrick-b-garland-delivers-remarks-national-health-care-fraud-0 (June 27, 2024).
[15] See id.
[16] American Bar Association, Letter to Chairman Graham and Ranking Member Feinstein re: Nomination of Kathryn Kimball Mizelle to the United States District Court for the Middle District of Florida, https://www.americanbar.org/content/dam/aba/administrative/government_affairs_office/2020-09-08chair-rating-letter-to-graham-and-feinstein-re-nomination-of-kathryn-kimball-mizelle.pdf (Sept. 8, 2020).
[17] U.S. ex rel Zafirov v. Fla. Med. Assocs., LLC, 2024 WL 4349242, at *19 (M.D. Fla. Sept. 30, 2024).
[18] See id.
[19] See U.S. Department of Health and Human Services Office of Inspector General, Corporate Integrity Agreement Documents https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp (last visited Jan. 10, 2025).

Shifting Landscape of Antitrust Merger Enforcement Will Likely Continue Under the New Trump Administration Endnotes

[20] July 9, 2021 Executive Order on Promoting Competition in the American Economy.
[21] In the Matter of Illumina, Inc. and GRAIL, Inc., FTC Matter/File Number: 2010144, available at Illumina, Inc., and GRAIL, Inc., In the Matter of | Federal Trade Commission.
[22] FTC, Statement Regarding Illumina's Decision to Divest Grail (Dec. 18, 2023), available at Statement Regarding Illumina's Decision to Divest Grail | Federal Trade Commission.
[23] In the Matter of Amgen, Inc. and Horizon Therapeutics pls, FTC Matter/File No. 2310037, available at Amgen, Inc. and Horizon Therapeutics plc, In the Matter of | Federal Trade Commission.
[24] In the Matter of Sanofi and Maze Therapeutics, Inc., FTC Matter/File No.: 2310091, available at Sanofi/Maze Therapeutics, Inc., In the Matter of | Federal Trade Commission.

Health Data Outside the Confines of HIPAA – New Wrinkles in an Ever-Evolving State Data Privacy Space Endnotes

[25] See, e.g., Conn. Gen. Stat. Ann. § 42-524; Wash. Rev. Code Ann. § 19.373.005 to 19.373.900; Nev. Rev. Stat. Ann. §§ 603A.400 to 603A-490.
[26] See Conn. Gen. Stat. Ann. § 42-524.
[27] Wash. Rev. Code Ann. § 19.373.010(8)(a).
[28] See generally Conn. Gen. Stat. Ann. § 42-524; Wash. Rev. Code Ann. § 19.373.005 to 19.373.900; Nev. Rev. Stat. Ann. §§ 603A.400 to 603A.490.
[29] Conn. Gen. Stat. Ann. § 42-517(b); Wash. Rev. Code Ann. § 19.373.100(1)(a)-(b); Nev. Rev. Stat. Ann. § 603A.490.
[30] C.R.S. SB 24-205.
[31] Utah Code Ann. § 13-2-12.
[32] CA AB 3030.

Developments in Reverse Merger Transactions – Understanding the Definition of "Shell Company" in the Context of Reverse Mergers in the Life Sciences Industry Endnotes

[33] https://www.sec.gov/files/rules/final/2024/33-11265.pdf
[34] Id.

Turning Over a New Leaf? DEA's Proposed Rescheduling of Marijuana and Implications for Traditionally Taboo Medicines Endnotes

[35] DEA, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44600 (May 21, 2024).
[36] See 21 U.S.C. § 812(b)(1).
[37] See U.S. Food & Drug Admin., FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.
[38] See e.g., Challenges and Barriers in Conducting Cannabis Research - The Health Effects of Cannabis and Cannabinoids - NCBI Bookshelf; Marijuana reclassification will make it somewhat easier to study, scientists say : Shots - Health News : NPR.
[39] See, e.g., Medical Marijuana Faces Fed's Catch-22 | Scientific American; Padilla Urges Biden Administration to Swiftly Deschedule Marijuana - Senator Alex Padilla.
[40] See 89 Fed. Reg. at 44599 – 01.
[41] See id.
[42] Id. at 44615.
[43] 21 U.S.C. § 811(c).
[44] See 89 Fed. Reg. at 44601–15.
[45] Id. at 44616 –19.
[46] See id. at 44616-17. Of note, this approach to evaluating marijuana's CAMU has been the key reason why DEA has previously rejected attempts to reschedule the drug. See Questions Related to the Potential Rescheduling of Marijuana, 45 Op. OLC ___, at 9 (Apr. 11, 2024), https://www.justice.gov/olc/media/1352141/dl?inline ("OLC Opinion").
[47] See OLC Opinion at 10-11.
[48] Office of Legal Counsel: About the Office, U.S. Dept. of Justice, https://www.justice.gov/olc. In addition to questions relating to evaluation of a drug's CAMU, OLC also opined on the binding nature of HHS's recommendations and United States international obligations.
[49] OLC Opinion at 12.
[50] Id. at 14.
[51] See id. at 17.
[52] See 89 Fed. Reg. at 44601.
[53] DEA, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 70148, 70149 (Aug. 29, 2024).
[54] Village Farms International and Hemp for Victory File Request for Reconsideration of Prior Motion to Disqualify DEA from Participation in Rescheduling Hearings - Village Farms International Inc.
[55] See Order Regarding Village Farms Int'l, Hemp For Victory, and OCO, et al.'s Motion to Reconsider, DEA Dkt. No. 1362, Hearing Dkt. No. 24-44, at 5 (Jan. 13, 2025),
[56] See id. at 3 n.5, 4.
[57] See id. at 5.
[58] See MAPS Successfully Clears Path for Cannabis Research through FDA Formal Dispute – Multidisciplinary Association for Psychedelic Studies – MAPS.
[59] Colo. Rev. Stat. § 12-170-102; Or. Rev. Stat. tit. 37, Ch. 475A; Utah Code § 58-37-3.5.
[60] See, e.g., Minn. Dept. of Health, Psychedelic Medicine Task Force; Nev. Dept. of Health & Human Servs., Psychedelic Medicines Working Group; Tex. H.B. 1802; Wash. Rev. Code § 19.410.010;
[61] See U.S. Dept. of Veterans Affairs, Psychedelic-Assisted Therapy for PTSD.

Life Sciences Meets Homeland Security: Is There More to Come? Endnotes

[62] See Press Release, Comer Delivers Remarks in Support of Bipartisan BIOSECURE Act, Comm. on Oversight and Accountability (Sept. 9, 2024).
[63] The Act would also require OMB to publish a guidance for companies named as "biotechnology companies of concern" within 120 days of its enactment.
[64] See Rep. McGovern Statement, X (Sept. 9, 2024).
[65] See Trade Association Survey Shows 79% of U.S. Biotech Companies Contract with Chinese Firms, Reuters (May 8, 2024).
[66] See Chinese Company under Scrutiny Makes Key U.S. Drugs, New York Times (Apr. 5, 2024).
[67] See, e.g., WuXi Companies Plan to Divest Business, Chemical & Engineering News (Jan. 8, 2025).
[68] See John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, 132 Stat. 1636 (2019).
[69] However, WuXi may be showing us that these companies might choose to refrain from exerting their heavy-hitting influence in the first place, which would remove a significant obstacle on the legislation's road to final passage.

Keeping Tabs: Were We Right or Wrong in 2024 Endnotes

[70] See Wyeth LLC v. Astrazeneca Pharms. LP, 2024 U.S. Dist. LEXIS 144596 *30 (Del. D. Ct. Aug. 14, 2024); 10X Genomics, Inc. v. Vizgen, Inc., 2025 U.S. Dist. LEXIS 847 *19 (Del. D. Ct. Jan. 3, 2025).
[71] Natl Infusion Center v. Becerra, No. 24-50180 (5th Cir. 2024).
[72] Joshua P. Cohen, What To Expect Under Trump For IRA's Medicare Drug Pricing Provisions, Forbes (Dec. 9, 2024), https://www.forbes.com/sites/joshuacohen/2024/12/09/what-to-expect-under-trump-for-iras-medicare-drug-pricing-provisions/.
[73] Becton, Dickinson, and Company Warning Letter; Rolence Ent. Inc. Warning Letter; Micro-X Ltd. Warning Letter; Augustine Temperature Management, LLC Warning Letter; Royal Philips Warning Letter.
[74] Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations, FDA (Jan. 7, 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing.
[75] FTC Announces Rule Banning Noncompetes, FTC Press Releases (Apr. 23, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-announces-rule-banning-noncompetes.

2025 Top-of-Mind Issues for Life Sciences Companies

SheppardMullin

www.sheppardmullin.com/life-sciences