NEW JERSEY LAWYER

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No. 355

DRUG LAW

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CHRISTINE A. AMALFE

Young Lawyers—Make the NJSBA Your Professional Home

A generation is only as strong as the one behind it. In July, I had the pleasure of hosting a listening session with lawyers who have participated in the NJSBA Leadership Academy. What I heard was passion for the practice of law, an understanding that hard work pays off, and a universal view that being active in the NJSBA has reaped great rewards.

No profession can flourish without an invigorated and passionate generation that follows. The young attorneys I met with are putting their noses to the grindstone today to become the legal leaders of tomorrow. I am heartened to see young lawyers who strive to better themselves by giving back to the profession through mentorships, legal clinics and community outreach programs. It is inspiring, and a reminder that the future is bright thanks to the rising generation.

The difficult truth in legal practice, and in all professions, is that connections sometimes count more than credentials. Few attorneys advance their careers without help from a strong professional network. Mentorships are crucial to guide young attorneys through new experiences and the fork-in-the-road moments that can define a career. Connections help young lawyers find the next job. A network of mentors provides a lifetime of learning.

The NJSBA wants to become your professional family and home. To today's young attorneys and law students – we need your optimism, your idealism and your sincere desire to make a difference as a lawyer. To our more seasoned lawyers, we need your experience, wisdom and willingness to teach and offer advice.

Through the NJSBA, we can connect you with our vast network of members, who can provide valuable insight into how they successfully addressed the challenges you will face and how they navigated the winding road of a career in this profession. The benefits of joining, especially for young lawyers, are numerous.

The transition from law school into the profession is difficult for everyone. Law school teaches theory, but the real-world skills, professional relationships and guidance needed for career growth take time to develop. This is where the Young Lawyers Division excels. The YLD is a group within the NJSBA organized by young lawyers, for young lawyers – available to those under 36 or licensed to practice for less than 10 years. It is one of the most powerful groups available to early-career attorneys in New Jersey to network, have fun, get professional development and participate in service opportunities in the community.

By joining the NJSBA and the YLD, you can access like-minded and similar-aged attorneys who know the struggles you may face. You walk into a built-in support system. The YLD offers CLE seminars, newsletters and workshops tailored to newer attorneys. They love to have fun and give back to the community. No doubt, it provides unparalleled networking. Each month YLD members gather in a different part of the state for social events to build camaraderie at baseball games, volunteering opportunities, axe-throwing competitions and more. For those interested in giving back, the YLD provides pro bono legal services to first responders and other programs that support the community. These are initiatives led by rising attorneys who recognize the essential role that attorneys play in community service.

The NJSBA understands the financial limitations young attorneys face. For newly admitted attorneys, the first year of your membership is free, and you can join an NJSBA section of interest at no cost. Young attorneys also enjoy lower dues during the early stages of their legal careers and bar involvement.

In so many ways, the NJSBA is here to be your foundation, your community and your guide in the legal profession. I encourage you to visit the NJSBA website to explore the Association's many offerings, learn about upcoming events and connect with YLD leaders, who are eager to share their insights and welcome you aboard. ■

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FROM THE SPECIAL EDITORS

Expanding the Legal Lens on Regulated Substances in New Jersey

When the New Jersey State Bar Association Board of Trustees created the Cannabis Law Committee in 2018, the mission was to explore legal issues arising from the emergence of medicinal cannabis and the possible expansion into adult-use markets. Since then, our Committee has evolved significantly—not only encompassing cannabis, but expanding into psychedelics and broader questions about how regulated substances interact with the law. Today, these issues span multiple industries, agencies, and areas of practice—from health care and employment to real estate, intellectual property, and insurance. This issue of *New Jersey Lawyer* reflects that evolution and the widening lens through which we view "drug law" and its far-reaching impact.

The authors featured in this issue explore the intersection of emerging substances, regulation, technology, and the law—offering insight into some of the most pressing and complex issues currently facing legal practitioners.

Robert B. Hille and John W. Kaveney open the issue with a timely and thought-provoking article on the use of artificial intelligence in health care and medical insurance. Their piece examines how insurers are leveraging AI tools in clinical decision-making and the growing scrutiny this practice is drawing from regulators, courts, and policymakers alike.

MICHAEL F. SCHAFF *is co-chair of the corporate, health, and cannabis law practice groups and vice-chairman of the Board of Directors at Wilentz, Goldman & Spitzer, P.A. In addition to a robust private practice spanning over 35 years, Michael, having served as outside general corporate counsel for many privately held companies, brings to the table a multi-faceted understanding of the law, as well as a unique educational and professional background rooted in business, finance, and taxation. He is a former Trustee of the New Jersey State Bar Association, former co-chair of the Cannabis Law Committee, former two-time chair of the Health Law Section, former chair of the Computer & Internet Committee, and former chair and current member of the* New Jersey Lawyer *editorial board.*

SETH R. TIPTON *is co-chair of Florio Perrucci Steinhardt Cappelli & Tipton LLC's cannabis law practice group and is a leader in cannabis law. He has represented applicants for medical cannabis permits in New Jersey and Pennsylvania, guiding them on private capital raises, application requirements, and real estate acquisitions and approvals. Tipton counsels clients on all aspects of formation and compliance for cannabis companies, from start-ups to multi-state operators. He is the immediate past co-chair of the New Jersey State Bar Association Cannabis Law Special Committee, and an instructor for NJ Canna Certified where he teaches cannabis law basics to students at many of New Jersey's community colleges.*

Joseph M. Shapiro gives us a comprehensive look at the future of psychedelics regulation in New Jersey. His piece explores legislative initiatives and how other jurisdictions are shaping our expectations for what may soon become a new legal frontier in behavioral health and medical treatment.

John D. Williams then takes us into the complex and fast-changing world of intoxicating hemp. As the federal framework continues to create room for uncertainty—and at times, conflict—his article explores how New Jersey's hemp industry is adapting and where legal gaps remain.

Shifting focus to pharmaceutical patent law, Miriam Goldgeil breaks down a recent Federal Circuit decision involving Teva Pharmaceuticals that has significant implications for drug patent listing standards. Her article not only clarifies regulatory expectations but also highlights how court decisions continue to shape the business and legal strategies of drug makers.

As the legal community grapples with these and other issues, the NJSBA Cannabis and Psychedelics Committee remains committed to fostering thoughtful discussion and providing a forum for attorneys across practice areas to stay ahead of the curve. Whether dealing with local licensing, federal rescheduling, patent enforcement, or the ethical use of AI in health care, our members understand that the laws around drugs—and the technologies that intersect with them—are no longer confined to niche legal fields. They are everywhere, and they are evolving quickly.

We encourage all lawyers with an interest in these subjects to join us in the work of staying informed, engaged, and prepared. ■

PRACTICE TIPS

PRACTICE PERFECT

Clients Up or Out

By Jeffrey S. Krause
For Practice HQ

How to Upgrade Your Clientele

We've all been there. The phone rings and the caller ID displays the name of *that* client. You know the one. The one who thinks they are your only client. They make unreasonable demands of you and your staff. Then, after you go out of your way to help them, they dispute the bill you send them and only pay after demanding you write off some of your valuable time.

You put up with this because clients are hard to come by. On the other hand, working with clients like this is a major source of stress for you and an even bigger source of stress for your staff. The good news is that losing problem clients may not be as bad for your revenue and profitability as you think. What you need is a system for accessing your clients and moving them either up the satisfaction scale or out of your life.

Understand Your Numbers

For many years, I have presented what I call Moneyball for Lawyers at legal conferences. In that presentation, I discuss how data and technology can be used to make your firm more profitable. I devote a significant amount of time to defining what drives profitability in a law firm. In simple terms, your firm generates leads. You turn a certain percentage (conversion rate) of those leads into clients. Each client comes to you with a "number of transactions" and spends a certain "amount per transaction." This generates revenue and you get to keep some of it (margin). What is left is profit. The formula looks like this:

- Leads x Conversion Rate (%) = Clients
- Clients x Number of Transactions x Dollars per Transaction = Revenue
- Revenue x Margin (%) = Profit

I refer to this as the profit formula. As always, I will not take credit for creating it. I have seen it referred to by different names and I am not sure who originally created it. All I can do is credit it to the ActionCOACH organization where I learned it years ago.

The genius of this formula is that it gives us insight into what drives profitability. Most of us believe that more clients or more revenue makes us more profitable. While that is true, clients and revenue are products of other inputs. For example, the number of clients derives from how many leads your firm generates and what percentage it turns into clients. Clients that come back often and spend more generate more revenue. Conversely, clients that increase overhead, waste time, demand discounts or pay late decrease your profitability.

Armed with this data, you should see troublesome clients in a different light. This knowledge is the first step in the process of moving clients up or out. The question is, what will you do with this knowledge?

Grading Your Clients

Grading your clients is the process of scoring them to determine where they fall on a scale of A-F. Starting from the bottom, F clients are irretrievably bad and include those who are abusive to you or your staff. Fire them or stop taking new work from them immediately. D clients waste your time, dispute bills, and pay late. C clients sometimes do these things. B clients rarely do these things and only when justified.

While your staff and your intuition help when grading clients, the best place to start is with your technology. Running productivity and realization reports will quickly tell you which clients you are discounting, writing down or writing off and how often you are doing so. This data will often confirm what you already suspect.

Other than those who are clearly irretrievable, your goal is to move clients up the scale.

Up or Out

Moving clients up the scale is about setting ground rules and sticking to them. If a client is calling constantly and then disputing their bill, make it clear that calls are billable. Also, make it clear that properly documenting the call requires you to spend and bill a minimum of 15 minutes per call. Stick to this and send them the resulting bill. Do not automatically discount because you think someone will not pay. If they balk at paying, offer a one-time write-off while stressing that, in the future, your billing policies will be followed. For clients that do not pay on time, establish and follow a system of reminders. A bit of firmness goes a long way. You may even find that you have trained your clients to take advantage of you. It is time to break that cycle.

Most clients move themselves up the grading scale. Once they know the rules, they will call when necessary but avoid incurring a charge just to vent or complain. If they want to continue working with you, they will do so on your terms. A few will move themselves out. Any guesses as to which clients these will be?

If you are worried that this may lose you a few clients, you are right. However, it also frees you to work with the best possible clients. Another benefit is that the quality of new leads and clients will improve. People tend to associate with other people who are like them. If you dig into your referral sources, you will find that D clients refer other D clients. Better clients mean better referrals.

By the way, the definition of an A client is one that refers other A and B clients to your firm.

Conclusion

Nothing is more frustrating than working with the wrong clients. They can make you regret picking up the phone or opening your email. You do not have to put up with it. Once you realize that losing a client is not the end of the world, you can create a system that weeds out the unpleasant clients and nurtures the best ones. Start moving your clients up or out today. Your future self will thank you for it.

The New Jersey State Bar Association's Practice HQ is a free member resource designed to help you build and maintain a successful, thriving legal practice. Learn more at njsba.com/practice-hq.

WORKING WELL

Positive Ways to Accept Criticism

Do you hate being criticized even when you know you've made a mistake? If so, it's no wonder—criticism can make people feel incompetent, angry, and just plain awful.

How do you, personally, respond to criticism? Do you make excuses or lash back with criticism?

"This fight-or-flight response is natural and common but isn't very productive. It cuts off communication, often just when it's needed most," says Dr. Jean Lebedun, author of the video program *The Art of Criticism-Giving and Taking.*

Many supervisors don't give criticism in a tactful manner. Nevertheless, you should accept criticism so you can learn from your mistakes. But don't fret; it'll be easier when you use Lebedun's "4-A Formula—Anticipate, Ask questions, Agree with something and Analyze."

Anticipate

Accept the fact that everyone makes mistakes and that you'll probably be criticized for yours. That way, criticism won't come as a surprise.

"You anticipate criticism by asking yourself, 'What can I learn from this criticism?' Then, whenever you feel yourself growing defensive or getting angry, you repeat the question 'What can I learn?'" advises Lebedun.

Here's another way to anticipate: Take the wind out of the sails of criticism by admitting your mistake first, before your supervisor has an opportunity to say anything to you. This makes your supervisor's job easier and makes you appear more professional.

Ask Questions

Many times, people who criticize are letting off steam and may be exaggerating the problem. This is especially true when the criticism contains the words "always" and "never." Therefore, it's important to pinpoint the criticism by asking questions like these:

"What part of the report didn't you like?" "What aspect of my attitude makes life at work difficult for you? Could you give me an example?"

Asking questions accomplishes two things: It gives you specif-

ic information on how to improve and teaches people they'll have to be specific when they criticize you.

Agree with Something

When faced with criticism, most people focus on the part of the negative feedback that may not be true and ignore the rest. This doesn't solve any problems, and you don't learn anything.

You become open to learning when you agree with one part of the criticism. An easy way to agree is to say, "You might be right; my report doesn't have all the details."

"You don't have to agree with everything; even agreeing with one small aspect of the criticism will create an atmosphere of teamwork," says Lebedun. "The focus then can become how you'll work together to solve a problem, which will lessen your feeling of being attacked."

Analyze

Finally, take a break and evaluate what you've heard.

You need time to process the information, determine if it's a valid criticism, and decide how to solve the problem or correct the mistake. If this is a complaint you've heard repeatedly, you should think about what you can learn from the situation so it doesn't happen again.

The benefits of the 4-A Formula are that you'll look for solutions rather than excuses and you'll be in control of your emotions, Lebedun says. "You'll also appear more professional."

This article is from Charles Nechtem Associates, which provides the New Jersey State Bar Association Member Assistance Program, connecting NJSBA members to trained, experienced mental health professionals and resources. Learn more at njsba.com/member-assistance-program.

WRITER'S CORNER

The Psychology of Persuasive Writing

By Veronica J. Finkelstein
Litigative Consultant, U.S. Attorney's Office
Eastern District of Pennsylvania

As lawyers, our job often requires us to persuade. Sometimes, the medium through which we must persuade is writing. Whether in the form of a letter to opposing counsel or a motion to a judge, we often find ourselves trying to compel action that benefits our client.

Unlike other types of writing designed solely to educate or inform, the ultimate goal of persuasive writing is to influence behavior. This goal is more easily achieved by understanding human psychology. Using techniques such as emotional appeals, storytelling, and cognitive triggers can help increase the likelihood of persuading the reader.

Emotional Appeals

Appeals to emotion tap into a primal urge that all humans share. Emotional responses can be positive or negative. When writing, consider how you want the reader to feel while reading a particular passage. Stacking a series of policy justifications can create the feeling of a "parade of evils," evoking fear in the reader. Conversely, using a hypothetical scenario where a proposed rule is applied to a sympathetic "next case" can evoke a feeling of happiness in the reader. Each emotion has its unique characteristics and can be evoked through various techniques, such as metaphor, juxtaposition (to suggest connection), and vivid sensory descriptions.

Too often, legal writing is sterile and devoid of emotion. Consider using emotion sparingly, where it will have the most impact. While some emotion can be helpful because it engages the reader, in a legal setting, emotional appeals must be balanced with appeals to reason. Without this balance, the reader may dismiss the writing as being intentionally manipulative. Tailor your use of emotion to your audience, and apply it selectively.

Storytelling

Storytelling in persuasive writing involves crafting a narrative that captures the audience's attention and holds it until the end. It is a powerful tool that has been used throughout human history, across cultures and societies, for entertainment, education, and communication.

A compelling story should have a clear beginning, middle, and end, with a well-defined plot, characters, setting, and conflict. The characters should be relatable, with distinct personalities,

motives, and emotions that bring them to life. The setting should be vividly described, with sensory details that allow the reader to experience it vicariously. The conflict should be compelling, with high stakes and consequences that keep the reader engaged.

To tell a story, put yourself in the shoes of an audience member watching your client's case unfold. Take stock of the characters, setting, and the problem that requires solving. Imagine what the movie poster would look like if this story were adapted to film. In the introduction to your text, frame the argument to follow by describing, in words, what the viewer would see on that movie poster.

Storytelling creates a sense of empathy and understanding between the reader and the subject matter of the writing. In addition, stories are more memorable than lists—information conveyed as a story will stick with a reader longer after they've finished reading. Storytelling is particularly useful for illustrating complex ideas or concepts in a relatable way.

Cognitive Triggers

Cognitive triggers refer to any element within a persuasive text that can evoke a mental reaction, which, in turn, influences decision-making processes. These triggers form an essential component of any successful persuasive writing.

There are several types of cognitive triggers, including social validation, perceived scarcity, and appeals to authority.

- *Social Validation*: Also known as social proof, this cognitive trigger causes a reader to make decisions based on the actions of others. Citing other courts within the circuit by name is a subtle method of using social validation when arguing to a judge. Doing so suggests that the judge would be in good company by finding in your favor, as those other judges would similarly rule.
- *Perceived Scarcity*: This involves creating a sense of urgency to make the reader feel they may miss out on an opportunity. Arguing that a judge could be the first to decide a key issue in the circuit or adopt a new rule appeals to the judge's sense of scarcity. Only one judge can be "first," so the judge must "act now" or lose that chance.
- *Appeal to Authority*: This refers to a reader's willingness to follow the guidance of an established and credible figure. Citing a judge's own opinions back to that judge is a form of appealing to authority.

Cognitive triggers exploit unconscious biases. They consider the reader's decision-making processes and convey information in a way that aids that process. Cognitive triggers are also useful for creating a sense of urgency or establishing the writer's credibility.

For all these reasons, lawyers benefit from understanding the psychology behind effective persuasive writing. With this understanding, we can enhance our ability to write in a way that resonates with readers, influences their perceptions and decisions, and ultimately motivates their actions.

TECH TIPS

Robot Rhetoric

By Veronica J. Finkelstein
Litigative Consultant, U.S. Attorney's Office, Eastern District of Pennsylvania

The integration of artificial intelligence into the legal profession has transformed the way attorneys draft, edit, and analyze legal documents. AI-powered tools like ChatGPT, Grammarly, and legal-specific platforms like Lexis+ AI and Casetext CoCounsel offer previously unimaginable efficiencies. However, robotic use of this technology without concern for ethical pitfalls would be a mistake. AI tools should be used intelligently, not blindly, to enhance legal writing.

Understand Capabilities and Limitations

AI tools can assist with a range of legal writing tasks, from generating first drafts and summarizing legal opinions to checking grammar and suggesting stylistic improvements. However, these tools are simply that—tools. Like any tool, AI is designed to supplement, not replace, attorney judgment. AI tools lack discretion, contextual awareness, and an understanding of professional responsibility requirements. Although AI can process language, it cannot verify the accuracy or applicability of legal rules in a particular jurisdiction unless specifically designed and trained to do so.

As such, the best practice is to use AI for tasks like brainstorming, editing, and organizing ideas, but not for parts of the writing process where judgment is required, such as substantive legal

analysis. Always verify any legal citations, case summaries, or rule interpretations provided by an AI tool.

Use AI Tools Where They Excel

Writer's block can be a challenge for any legal writer. An AI tool can help jump-start the writing process. For example, if you're struggling to write an opening statement, AI can help organize your case file and provide a draft from which you can begin. AI tools are also useful at the end of the process, for cleaning up typos and other "no-brainer" mistakes that you might miss because you're too close to the writing.

The time when AI tools are less useful is during the middle stages of the writing process. The voice and tone of a legal document should reflect the author's professional judgment and the client's specific factual circumstances. Generic AI-generated text often lacks the nuance necessary for persuasive legal argument or tailored client communication. Use AI to generate outlines, draft introductions, and review work product for errors—but ensure your own work goes into the bulk of the research and writing. The final draft should reflect your voice, your strategy, and your ethical duties to your client and the court.

Use AI Ethically

Many AI platforms, especially free or consumer-grade tools, process input data on external servers, potentially exposing sensitive or privileged information. This presents a serious risk in legal contexts where confidentiality is paramount. If you upload a deposition transcript or internal memorandum to one of these tools, you may inadvertently be sharing those documents with the world.

Never input client-specific facts, names, or identifying information into a public AI platform unless you are certain it complies with your jurisdiction's data security and confidentiality standards. Use only trusted, secure platforms, preferably those designed specifically for legal professionals with built-in privacy protections.

Take the Laboring Oar on Citations

As has become clear from legal ethics opinions in the news, AI tools often fabricate cases, statutes, or quotes. This phenomenon, known as citation "hallucination," is particularly dangerous in legal writing, where accuracy is critical and false citations can lead to sanctions.

Do your own research. If your AI tool suggests a citation, verify it using traditional research methods. If AI suggests a case, statute, or legal principle, double-check it in a primary source. Never rely on AI alone for legal authority.

Maintain Control Over the Final Work Product

Good legal writing is about more than just correct grammar and formatting. Effective legal writing is primarily a matter of persuasion, clarity, and storytelling. AI tools may suggest sentence rewrites or restructured paragraphs that are grammatically correct but legally imprecise or stylistically inconsistent with your intended tone.

Treat AI suggestions as helpful, but optional, recommendations. Exercise your own personal judgment to decide whether a change improves or weakens your argument. You are the author; AI is the assistant.

Despite many fears to the contrary, AI is not replacing lawyers. Instead, AI tools are changing how lawyers work. When used responsibly, AI can enhance efficiency, reduce errors, and support high-quality legal writing. But these tools should never replace critical thinking, ethical decision-making, or the human touch that makes good legal writing persuasive and trustworthy. Use AI tools to augment, not automate, your advocacy. ■

Insurer Use of AI in Medicine and Health Care Draws Expansive Scrutiny

By Robert B. Hille and John W. Kaveney

The concept of artificial intelligence has permeated almost all aspects of society. AI is being implemented more and more each day by major technology companies to try to improve daily living and optimize the delivery of data and information in our daily lives. AI is also being viewed as a tool that will revolutionize and improve the delivery of health care.

On the provider side, AI is being used as a tool to improve patient care. For example, efforts are being made to use AI to improve the diagnosing of patients, analyzing medical images, and predicting patient outcomes to better anticipate complications and best courses of treatment, including which prescription medications to incorporate.

Insurers are also using AI tools to personalize health services and products, predict future events and potential patient health risks more accurately, and improve the processing and payment of medical claims.

However, while these uses by insurers can have a positive impact on the delivery of care, many in the health care industry, and federal government, have raised concerns about other uses of AI by insurers. Specifically, insurers are increasingly using AI to process and evaluate claims absent the human element and the necessary expert review, resulting in concerns that outcomes are being determined solely by algorithms. In such scenarios, individual patient reviews by an experienced and qualified reviewer is taking a back seat to where a case fits within a data population. While patients and patient outcomes may form data, they are not simply data points to be subjected to a formulaic approach. Each case is unique and fluid.

Federal Definition of AI

The federal government has statutorily defined AI as, "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments."[1] AI systems use machine- and human-based inputs to "perceive real and virtual environments;...abstract such perceptions into models through analysis in an automated manner; and...use model inference to formulate options for information or action."[2] It is these machine- and human-based inputs that greatly shape how such a system functions and can lead to potential problems.

Problems with AI use arise with inherent data biases, incomplete or unreliable data and inaccurate or inflexible algorithms that lead to skewed results. Care then is misdirected to the individual based on the population's needs rather than the individual's. The resulting care the tool directs is consequently population rather than patient driven.

An analogy would be if a robotic surgical instrument was programmed on the sum total of the surgical patient population rather than to respond to the individual patient's particular anatomy. Cutting into a patient on where an artery should be rather than where it is demonstrates the harm from eliminating individual patient needs from the care rendered.

Federal Concerns Regarding Coverage and Claim Denials

AI's recent spotlight has been in the Medicare Advantage (MA) arena. There, fears have been raised that AI is being used to enhance improper coverage and claims denials on medications and other health procedures and treatments.

Accusations of improper denials by Medicare Advantage Organizations (MAO) are not new. Such abuse has been on the federal government's radar for several years. In 2018, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued its report on "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials."[3] There, the OIG found "widespread and persistent problems related to denials of care and payment in Medicare Advantage plans."[4] The OIG's report also noted that MA plans "overturned 75 percent of their own denials" while at the same time, "beneficiaries and providers appealed only 1 percent of denials to the first level of appeal."[5] Largely predating AI use by insurers, the widespread denial errors noted in the report may form, inadvertently or by design, a biased data population that would skew MAO claims outcomes in favor of denials. This would place greater sums in the pocket of insures despite them receiving that money based on representations to the government that the money was needed to compensate for the care they later denied.

A June 2022 OIG claims study further substantiated government fears of abuse.[6] Reviewing a random sample of prior authorization and payment denials by 15 large MAOs in 2019, the OIG found only 13% of coverage denials and only 18% of payment denials met Medicare MA rules.[7]

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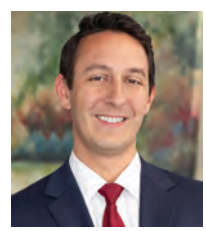

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The report also identified the avoidable delays, additional work, and administrative burdens that the inappropriate denials caused that negatively impacted patient care and placed avoidable burdens on providers.[8] Based on its review, the OIG recommended the Centers for Medicare and Medicaid Services (CMS) "issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; update its audit protocols to address the issues identified in this report…; and direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors."[9]

Following these troubling OIG findings, on Nov. 3, 2023, members of the United States House of Representatives noted their concerns to the Centers for Medicare and Medicaid Services (CMS) over the "increased reliance on artificial intelligence…or algorithmic software" by MA plans to guide coverage decisions.[10] These representatives expressed that the use of AI software, such as naviHealth, myNexus, and CareCentrix, "led to coverage decisions that are more restrictive than allowed under traditional Medicare rules, as well as more frequent and repeated denials of care."[11]

MA plans responded by saying AI was providing guidance to improve patient care, but those representatives feared it was instead being used to make coverage determinations. Thus, they called on CMS to "increase oversight" of the AI tools being used by MA plans.[12]

The American Medical Association's AI Concerns

The American Medical Association (AMA) has also weighed in on the debate over the use of AI by insurers. At its June 2023 annual meeting, the AMA House of Delegates adopted a new policy "calling for greater regulatory oversight of insurers' use of AI in reviewing patient claims and prior authorization requests."[13] The policy also "calls for health insurers utilizing AI technology to implement a thorough and fair process that is based on clinical criteria and includes reviews by physicians and other health care professionals with expertise for the service under review and no incentive to deny care."[14]

Following up on this policy, in November 2023, the AMA Board of Trustees issued seven principles for the development of equitable and responsible AI tools and use in health care.[15] These key principles "call for comprehensive policies that mitigate risks to patients and physicians, ensuring that the benefits of AI in health care are maximized while potential harms are minimized."[16] The AMA principles include the following categories:[17]

- **Oversight**—encouragement of a "whole of government" approach to mitigating the risks of AI in health care while also acknowledging the critical role non-government entities must play in this oversight
- **Transparency**—emphasis on transparency and developing laws that mandate the sharing of key characteristics and information regarding the design, development, and deployment processes for AI in health care
- **Disclosure and Documentation**—appropriate disclosure and documentation when AI directly impacts patient care, access to care, medical decision making, communications, or the medical record
- **Generative AI**—development and adoption of policies to anticipate and minimize negative impacts that have been associated with generative AI
- **Privacy and Security**—prioritization of robust measures to protect patient privacy and data security when developing AI tools
- **Bias Mitigation**—proactive identification and mitigation of bias in AI algorithms to promote fair and inclusive care that is free from discrimination
- **Liability**—advocacy for the limitation of physician liability when using AI tools

Patient Suits Challenging the Use of AI

The OIG, Congress, and the AMA are not the only ones responding to AI's expansion into health care and raising concerns over its misuse. Patients are also pushing back as evidenced by recent lawsuits against several insurers.

In July 2023, a lawsuit was filed against Cigna Health in the United States District Court for the Eastern District of California.[18] That complaint alleges that during two months in 2022, over 200,000 payment requests were denied using AI tools, with an average estimated review time by a doctor of only 1.2 seconds per request.[19] If proven, this case would validate the concerns that under the guise of a tool to assist employees and speed up approvals and the delivery of care/reimbursement, AI is being misused with the purpose of denying pre-authorizations and/or reimbursement to increase insurers' bottom lines.

Similarly, a lawsuit was filed in November 2023 against UnitedHealthcare in the United States District Court for the District of Minnesota.[20] According to that complaint, "[t]he nH Predict AI Model determines Medicare Advantage patients' coverage criteria in post-acute care settings with rigid and unrealistic predictions for recovery. Relying on the nH Predict AI Model, Humana purports to predict how much care an elderly patient 'should' require but overrides real doctors' determinations as to the amount of care a patient in fact requires to recover."[21] Moreover, the lawsuit alleges Humana limits employees from deviating more than 1% from the number of days predicted by the AI Model thereby creating a financial windfall to Humana due to the increased number of denied claims.[22]

In December 2023, a lawsuit was filed

against Humana, in the United States District Court for the Western District of Kentucky. That suit alleges that Humana is improperly using an AI Model to "override real treating physicians' determinations as to medically necessary care patients require."[23] To do so, it is claimed that Humana wrongfully bases its claim denials on aggregated patient data rather than the opinions of doctors reviewing the specific circumstances of individual patients.[24]

Federal Government Action

Amid these various investigations, policy statements/positions, and lawsuits, the White House has been asserting its position on standards for the use of AI in health care.

When President Donald Trump took office in January, he issued Executive Order 14179, titled "Removing Barriers to American Leadership in Artificial Intelligence," which laid the groundwork to negate parts of the executive order President Joe Biden released in October 2023, titled "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." Biden's order had included a series of directives to the Secretary of Health and Human Services (HHS) "[t]o help ensure the safe, responsible deployment and use of AI in the healthcare, public-health, and human-services sectors."[25] Trump's order sets U.S. policy to "sustain and enhance America's global AI dominance in order to promote human flourishing, economic competitiveness, and national security,"[26] mandating a review of the Biden order and other regulations within 180 days in order to develop an action plan.

Conclusion

While many questions remain regarding what direction AI will take in the future, this new technology is only going to further integrate itself into the fabric of the health care sector. In response, insurers are almost certain to continue deploying this technology in the claims adjudication, payment, and appeal processes.

For those insurers and those responsible for their oversight, the focus must be on ensuring AI technology is being used appropriately to advance care rather than as a tool to withhold patient medical benefits and provider reimbursement.

This is only the first chapter in the AI story. There are many more yet to be written.

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Endnotes

1. 15 U.S.C. 9401(3).
2. *Id.*
3. oig.hhs.gov/oei/reports/oei-09-16-00410.pdf
4. *Id.*
5. *Id.*
6. oig.hhs.gov/oei/reports/OEI-09-18-00260.asp?hero=mao-report-04-28-2022
7. *Id.*
8. *Id.*
9. *Id.*
10. chu.house.gov/sites/evo-subsites/chu.house.gov/files/evo-media-document/chu-nadler-ma-ai-oversight-letter-11.3.2023.pdf
11. *Id.*
12. *Id.*
13. ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-prior-authorization
14. *Id.*
15. ama-assn.org/system/files/ama-ai-principles.pdf
16. ama-assn.org/press-center/press-releases/ama-issues-new-principles-ai-development-deployment-use
17. *Id.*
18. s3.documentcloud.org/documents/23885679/cigna-complaint.pdf
19. *Id.*
20. cdn.arstechnica.net/wp-content/uploads/2023/11/class-action-v-unitedhealth-and-navihealth-1.pdf
21. *Id.*
22. *Id.*
23. storage.courtlistener.com/recap/gov.uscourts.kywd.128636/gov.uscourts.kywd.128636.736.0.pdf
24. *Id.*
25. whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/
26. whitehouse.gov/presidential-actions/2025/01/removing-barriers-to-american-leadership-in-artificial-intelligence/

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What's Next for Regulation of Psychedelics in New Jersey

By Joseph M. Shapiro

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Psychedelics present a unique set of legal and policy challenges that set them apart from other controlled substances. Despite these challenges, there remains widespread interest in policy changes at all levels of government driven by a growing body of clinical research indicating the safety and efficacy of these substances.[1] This interest is evident in the approximately 60 psychedelic-focused bills introduced across 22 states over the last year,[2] as well the recent appointment of a well-known psychedelic policy litigator to a Deputy General Counsel role at the U.S. Department of Health and Human Services.[3]

New Jersey maintains strict prohibition of psilocybin and other psychedelics under its Controlled Dangerous Substances Act, despite growing national momentum toward reform.[4] The stalled Psilocybin Behavioral Health Access and Services Act (S2283/A3852) would have made New Jersey the first east coast state—and the third in the nation—to establish a comprehensive, state-regulated psilocybin program.[5] However, the bill's failure to advance highlights complex legal, political, and regulatory challenges which distinguish psychedelic reform from other controlled substances.

Recent national surveys show that more than 61% of U.S. registered voters support legalizing regulated therapeutic access to psychedelics, with 35% expressing strong support.[6] Additionally, 78% support making it easier for researchers to study these substances, while approximately 56–66% favor FDA approval of psychedelics by prescription.[7] This widespread public support creates significant opportunities for lawyers to engage with lawmakers and regulators in developing reform measures, and to represent stakeholders in litigation seeking court-ordered reforms. Effectively participating in these efforts requires an understanding of psychedelics themselves, their regulatory history, and their diverse applications.

Background: Two Waves of Research

Modern research into psychedelics can arguably be divided into two distinct waves. While naturally occurring psychedelic substances have been used in traditional healing and spiritual practices for millennia,[8] the first wave of modern research began with Albert Hoffman's synthesis of lysergic acid diethylamide (LSD) in 1938 and his discovery of its psychoactive properties on April 19, 1943[9]—now celebrated as "Bicycle Day."[10] Hoffman subsequently identified and synthesized both psilocybin and psilocin while working with Sandoz Laboratories, which widely distributed those compounds for clinical research.[11]

These breakthroughs led to serious clinical research spanning the 1950s through the early 1970s. Years before the counterculture movement, psychedelics were considered a breakthrough tool for professional healing, with psychedelic-assisted therapy gained national prominence—Cary Grant reportedly underwent approximately 100 LSD-assisted therapy sessions between 1958 and 1961.[12] However, this first wave ended with the enactment of the federal Controlled Substances Act of 1970,[13] which effectively shuttered government-sanctioned research and clinical trials by the early 1970s.[14]

After decades of dormancy, a second wave began with landmark studies including a 2006 Johns Hopkins study demonstrating that psilocybin, when administered in a safe and controlled setting, could occasion experiences with enduring psychological value.[15] That same year, the Supreme Court unanimously ruled in favor of a religious group's right to use a psychedelic, ayahuasca, in their religious ceremonies.[16] This resurgence has spurred sustained clinical research investigating applications ranging from treatment-resistant depression and addiction to performance enhancement.[17]

Federal Developments

Recent federal developments have created both opportunities and obstacles for psychedelic reform. The federal scheduling framework under the Controlled Substances Act continues to present barriers, with psychedelics classified as Schedule I substances based on eight factors including potential for abuse, accepted medical use, and safety for supervised treatment.[18]

Notable advances include the U.S. Food and Drug Administration's issuance of its first draft guidance on clinical trials for psychedelic drugs in June 2023, titled "Psychedelic Drugs: Considerations for Clinical Investigations."[19] This guidance acknowledges the growing therapeutic interest in psychedelics while outlining unique challenges in designing clinical studies for these substances.

Matthew Zorn's appointment as Deputy General Counsel at the U.S. Department of Health and Human Services represents another significant development. Zorn, a well-known drug policy reform litigator, is anticipated to lead HHS policy efforts on psychedelics, signaling potential federal reforms.[20]

However, setbacks include the FDA's denial of Lykos Therapeutics' new drug application for MDMA-assisted therapy to treat post-traumatic stress disorder.[21]

State and Local Trends

As outlined by Professor Mason Marks, state and municipal psychedelic laws generally fall into six models: (1) decriminalization, aimed at reducing enforcement; (2) supported adult use

requiring supervised access; (3) medical use with health care professional gatekeepers; (4) clinical research for data collection; (5) policy analysis through task forces; and (6) trigger bills for swift rescheduling upon federal approval.[22] Innovative hybrid models also exist, such as the permit-based framework developed by Allison Hoots and proposed in the Regulated Health Access and Support Services for Psilocybin Act, which aims to balance public health priorities with practical implementation considerations.[23]

State-level victories include Colorado's first psilocybin session under its Natural Medicine Program,[24] New Mexico's passage of its Medical Psilocybin Act establishing the third state-regulated program,[25] and Texas' bipartisan approval to invest $50 million in ibogaine research.[26] Setbacks include Massachusetts voters' rejection of a ballot initiative to legalize certain psychedelics[27] and the Iowa governor's veto of bipartisan legislation allowing doctor-prescribed psilocybin upon FDA approval.[28]

Local decriminalization efforts have achieved notable success in several municipalities. Seattle City Council passed a resolution in October 2021, declaring that "investigation, arrest, and prosecution of anyone engaging in entheogen-related activities" should be among the city's lowest enforcement priorities.[29] Detroit voters approved a proposal in November 2021 decriminalizing personal possession and therapeutic use of entheogenic plants by adults.[30] Santa Cruz, Calif. adopted a resolution in January 2020 making investigation and arrest of adults for personal use and possession of entheogenic plants among the city's lowest priorities.

However, Oregon municipalities have increasingly opted out of the state's psilocybin program.[31] Despite state implementation of that program, in November 2024, psilocybin bans passed in 16 municipalities including Lake Oswego, Oregon City, Seaside, Lebanon, and Brookings, with only the small coastal town of Nehalem defeating an opt-out measure by three votes. These bans joined 25 counties and 26 cities that had previously locked out Oregon's program in 2022.[32]

New Jersey's Reform Efforts

Following the federal Controlled Substances Act of 1970, New Jersey enacted its Controlled Dangerous Substances Act, placing psilocybin in Schedule I, representing a finding that it "(1) has high potential for abuse; and (2) has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision."[33] Until recently, simple possession carried penalties of up to five years imprisonment and fines up to $35,000.[34]

In 2021, Gov. Phil Murphy signed legislation downgrading possession penalties, reclassifying possession of up to 1 ounce of psilocybin-containing mushrooms to a disorderly person's offense.[35] Sen. Nicholas P. Scutari introduced the Psilocybin Behavioral Health Access and Services Act in 2022 (S2934), later reintroduced as S2283/A3852 in 2024 with significant revisions removing broader decriminalization provisions.[36]

The bill proposed establishing "safe, legal, and affordable psilocybin service centers" for adults 21 and older, with the New Jersey Department of Health overseeing four licensed business categories and a 15-person Psilocybin Advisory Board.[37] June 2024 amendments required licensed health care providers in screening, administration, and integration services.[38]

Even if the Psilocybin Bill is enacted, municipalities may bar psilocybin businesses through zoning ordinances, similar to how 394 of 565 localities opted out of adult-use cannabis licensing in 2021.[39] New Jersey's Home Rule provisions of the state constitution confer broad regulatory powers on municipalities.[40] The Municipal Land Use Law grants additional zoning authority that could heavily impact access to psilocybin service centers.[41] Lawyers advising clients and stakeholders should track local land-use hearings and consider preemption challenges under precedent limiting municipal power to frustrate state policy.

Despite poll data showing a slim majority of New Jerseyans supporting legalization of psilocybin under medical supervision,[42] and backing from policy reform coalitions,[43] the bill stalled by the end of 2024 after initially garnering substantial bipartisan support.

Challenges and Scientific Critiques

The "underground" nature of much psychedelic research throughout the late 20th century contributes to skepticism about therapeutic claims.[44] Further complicating matters, rapidly evolving scientific understanding—both of psychedelic neurobiology and clinical outcomes—continues to create confusion about the legitimate uses, safety, and effectiveness of these substances.

Reform efforts face five key challenges that distinguish psychedelics from other controlled substances:

- **Chemical Complexity**: Psychedelics encompass multiple compound classes including tryptamines, phenethylamines, and ergolines, creating regulatory complexity absent in substances like alcohol (ethanol content) or cannabis (THC concentration).[45]
- **Pharmacological Effects**: These substances cause alterations in sensory perception, cognitive processing, and consciousness through serotonergic and dopaminergic receptor systems, with effects lasting several hours.[46]
- **Diverse Applications**: Uses range from therapeutic treatment of depression and PTSD to recreational, spiritual, and research contexts.[47]
- **Regulatory Inadequacy**: Current

laws remain designed for prohibition rather than regulated access, with even cannabis frameworks inadequately addressing psychedelic oversight.[48]

- **Cultural Stigma**: Decades of stigmatization continue to shape implementation of reforms, particularly at local levels.[49]

Future Outlook

With New Jersey's Psilocybin Bill stalled, the near-term future remains uncertain. However, understanding these challenges provides a roadmap for stakeholders. The complex interplay of federal scheduling, state lawmaking processes, municipal home rule powers, and scientific evidence creates both obstacles and opportunities. Lawyers must navigate this evolving landscape while addressing concerns about research validity, implementation challenges, and public safety.

Regardless of immediate political developments, continued public and municipal education about psychedelics remains essential for meaningful progress. State- and local-level reforms cannot succeed without sufficient public and municipal support, requiring continued education efforts. As demonstrated in cannabis policy, municipal acceptance—particularly regarding land use approvals—proves crucial for program success.

The widespread public support demonstrated in national polling suggests potential for future reform efforts, but success will require addressing legitimate critiques while building broad-based coalitions capable of overcoming entrenched opposition. ■

Endnotes

1. Barnett, B. S., Mauney, E. E., & King, F., 4th (2025). Psychedelic-assisted therapy: An overview for the internist. *Cleveland Clinic journal of medicine*, 92(3), 171–180. doi.org/10.3949/ccjm.92a.24032.
2. Josh Hartman *et al.*, *Psychedelic Policy Push Continues: Over 60 Bills Introduced Across 22 States*, PSYCHEDELIC ALPHA (Feb. 27, 2025) psychedelicalpha.com/news/psychedelic-policy-push-continues-over-60-bills-introduced-across-22-states.
3. Erin Scumaker, A psychedelics hire at HSS, POLITICO (May 28, 2025) politico.com/newsletters/future-pulse/2025/05/28/a-psychedelics-hire-at-hhs-00371416.
4. N.J.S.A. § 24:21-1 *et seq.*
5. Bobby Brier, *Medical psilocybin bill advances*, NJ SPOTLIGHT NEWS (June 7, 2024), njspotlightnews.org/2024/06/nj-psilocybin-medical-use-legalization-legislative-committee-no-on-decriminalization.
6. *Berkeley Psychedelics Survey* (June 21, 2023), psychedelics.berkeley.edu/berkeley-psychedelics-survey-2023.
7. *Id.*
8. John W. Rick et al, *Pre-Hispanic ritual use of psychoactive plants at Chavín de Huántar, Peru*, 122 PROC. NAT'L ACAD. SCI. e2425125122 (2025), doi.org/10.1073/pnas.2425125122.
9. Albert Hofmann, LSD: MY PROBLEM CHILD (Jonathan Ott trans., McGraw-Hill 1980).
10. Andew DeAngelo, *Bicycle Day: Honoring The Onset Of The Psychedelic Revolution As It Zooms Across The Globe* (April 14, 2022), npr.org/2024/04/19/1245810413/bicycle-day-marks-an-unofficial-commemoration-of-the-first-use-of-lsd.
11. Haden A. Geiger et al., DARK Classics in Chemical Neuroscience: Psilocybin, 9 ACS CHEMICAL NEUROSCIENCE 2438 (2018).
12. Brooks, Xan, *Cary Grant: how 100 acid trips in Tinseltown 'changed my life'* (May 12, 2017), The Guardian, theguardian.com/film/2017/may/12/cary-grant-how-100-acid-trips-in-tinseltown-changed-my-life-lsd-documentary
13. 21 U.S.C. § 812 *et seq*.
14. NPR Staff, *The '60s Are Gone, But Psychedelic Research Trip Continues*, NPR (Mar. 9, 2014), npr.org/2014/03/09/288285764/the-60s-are-gone-but-psychedelic-research-trip-continues#:~:text=But%20the%20pervasive%20image%20of,was%20not%20an%20acceptable%20treatment.
15. Roland R. Griffiths et al., *Psilocybin Can Occasion Mystical-Type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance*, 187 PSYCHOPHARMACOLOGY 268 (2006).
16. *Gonzales v. O Centro Espirita Beneficente União do Vegetal*, 546 U.S. 418 (2006).
17. *See generally* Psychedelic Alpha, psychedelicalpha.com.
18. 21 U.S.C. § 811(c).
19. FDA, Psychedelic Drugs: Considerations for Clinical Investigations (Draft Guidance June 2023), fda.gov/regulatory-information/search-fda-guidance-documents/psychedelic-drugs-considerations-clinical-investigations.
20. Erin Scumaker, *A psychedelics hire at HSS*, POLITICO (May 28, 2025), politico.com/newsletters/future-pulse/2025/05/28/a-psychedelics-hire-at-hhs-00371416.
21. Rae Ellen Bichell, *FDA Rejects MDMA, Disappointing Drugmaker Lykos and Psychedelics Industry*, NPR (Aug. 9, 2024), npr.org/sections/shots-health-news/2024/08/09/nx-s1-5068634/mdma-therapy-fda-decision-ptsd-psychedelic-treatment.

22. Mason Marks, The Varieties of Psychedelic Law, 226 NEUROPHARMACOLOGY 109399 (Mar. 15, 2023).
23. A.B. 10375, 2023-2024 Leg., Reg. Sess. (N.Y. 2024); NEWS CHANNEL 13, Bill to legalize psychedelic mushrooms in New York set to be re-introduced (Dec. 31, 2024), wnyt.com/top-stories/bill-to-legalize-magic-mushrooms-in-new-york-is-set-to-be-re-introduced/.
24. Ben Adlin, *Colorado Healing Center Facilitates First Psilocybin Session Under Voter-Approved Psychedelics Legalization Law*, MARIJUANA MOMENT (June 16, 2025), marijuanamoment.net/colorado-healing-center-facilitates-first-psilocybin-session-under-voter-approved-psychedelics-legalization-law.
25. Sam Reisman, *New Mexico Lawmakers Approve Medical Psilocybin Bill*, LAW360 (Mar. 21, 2025), law360.com/healthcare-authority/articles/2314193/new-mexico-lawmakers-approve-medical-psilocybin-bill.
26. Andrew Jacobs, *Texas OK's $50 Million for Ibogaine Research*, N.Y. TIMES (June 14, 2025), https://www.nytimes.com/2025/06/14/health/texas-psychedelics-ibogaine-veterans.html.
27. Steph Solis, *Massachusetts Voters Reject Psychedelics*, AXIOS (Nov. 6, 2024), axios.com/local/boston/2024/11/06/massachusetts-psychedelics-psilocybin-mushrooms-ballot-question.
28. Cami Koons, *Governor's Veto of Bill on Synthetic Psilocybin Drugs Takes Key Lawmaker by Surprise*, NEWS FROM THE STATES (June 13, 2025), newsfromthestates.com/article/governors-veto-bill-synthetic-psilocybin-drugs-takes-key-lawmaker-surprise.
29. Seattle Res. 32021 (Oct. 4, 2021), clerk.seattle.gov/search/resolutions/32021.
30. Detroit Proposal E (Nov. 2, 2021), ballotpedia.org/Detroit,_Michigan,_Proposal_E,_Decriminalization_of_Entheogenic_Plants_Measure_(November_2021).
31. OPB, *Psilocybin Bans Were on the Ballot in 17 places in Oregon* (Nov. 7, 2024), opb.org/article/2024/11/07/psilocybin-ban-mushroom-hallucinogenic-ballot-politics-elections-oregon/.
32. Harris Sliwoski, *Oregon Psilocybin: State of the State (2024)*, harris-sliwoski.com/psychlawblog/oregon-psilocybin-state-of-the-state-2024/.
33. N.J.S.A. § 24:21-1 *et seq.*
34. N.J.S.A. § 24:21-5.
35. N.J.S.A. § 2C:35-10(a)(1).
36. N.J.S.A. § 2C:35-10 (as amended by P.L.2021, c.19).
37. S. 2934, 220th Leg., Reg. Sess. (N.J. 2022); S. 2283, 221st Leg., Reg. Sess. (N.J. 2024).
38. S. 2934, 220th Leg., Reg. Sess. (N.J. 2022), pub.njleg.state.nj.us/Bills/2022/S3000/2934_I1.PDF.
39. *See* N.J. Cannabis Regulatory Comm'n, Municipal Decision Tracker, nj.gov/cannabis/businesses/municipal-decision-tracker/.
40. N.J. CONST. art. IV, §7, ¶11.
41. N.J.S.A. 40:55D-1 *et seq.*
42. Bill Duhart, *N.J. Residents Favor Legalization of Medical Psychedelic Mushrooms*, Poll Finds, NJ.COM (June 10, 2024), nj.com/news/2024/06/nj-residents-favor-legalization-of-medical-psychedelic-mushrooms-poll-finds.html.
43. Katie Sobko, *NJ Senate panel advances bill to make magic mushrooms legal for medical purposes* (Oct. 11, 2024), northjersey.com/story/news/new-jersey/2024/10/11/nj-magic-mushrooms-bill-medicine-moves-forward-senate/75612595007.
44. Sydney M. Isralowitz, *The Historical Opposition to Psychedelic Research and Implications for Credibility in Psychiatry*, 29 CNS SPECTRUMS 23 (2024).
45. Bekim Kelmendi et al., *Psychedelics*, 32 CURRENT BIOLOGY R63 (2022).
46. Robin L. Carhart-Harris & Karl J. Friston, *REBUS and the Anarchic Brain: Toward a Unified Model of the Brain Action of Psychedelics*, 71 PHARMACOLOGICAL REVIEWS 316 (2019).
47. Robin L. Carhart-Harris & Guy M. Goodwin, *The Therapeutic Potential of Psychedelic Drugs: Past, Present, and Future*, 42 NEUROPSYCHOPHARMACOLOGY 2105 (2017).
48. M. N. Mian et al., *Psychedelic Regulation Beyond the Controlled Substances Act: A Three-Dimensional Framework for Characterizing Policy Options*, 182 AMERICAN JOURNAL OF PSYCHIATRY 6 (2025).
49. *Id.*

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New Jersey's Intoxicating Hemp Industry Evolves Amid Legal Uncertainty

By John D. Williams

JOHN D. WILLIAMS *has concentrated his legal practice in alcoholic beverage law for 30 years and cannabis law for eight years. As an attorney for Law Office of John D. Williams and Of Counsel at Porzio, Bromberg & Newman, he represents clients in various sectors of these highly-regulated industries; including cultivators, manufacturers, wholesalers, distributors, delivery services, and retailers.*

This article provides an overview of the origins of the legalization of cannabis-hemp, the ensuing emergence of an industry nationwide in intoxicating hemp products, and the status of the related law in New Jersey. Notably, industry participants and legal practitioners await legislation that is expected to be introduced in the late summer or early fall resolving the pending legal issues discussed below.

The 2018 Farm Bill

The 2018 Farm Bill decriminalized hemp and established a legal framework for the development of a national hemp and hemp products industry. (Agriculture Improvement Act of 2018, Pub. L. 115-334.) The federal bill's impact was immediate and significant.

Principally, it removed hemp from the federal Controlled Substances Act (CSA). This allowed an "industrial hemp" industry to develop (e.g., hemp building supplies, clothing and textiles, animal bedding and feed, etc.).

The cannabidiol (CBD) industry also arose and quickly flourished. CBD is a cannabinoid (chemical compound) found in the cannabis plant and is not psychoactive; it does not alter the mind or mental processes. Although CBD products are labelled as dietary supplements, they are used by consumers for a variety of human (and domestic pet) wellness purposes. The products are sold in a wide variety of forms for ingestion or topical use.

The 2018 Farm Bill also exempted hemp-derived tetrahydrocannabinols (THC) from the CSA. Cannabinoids can be derived from either the hemp or marijuana strains of the cannabis plant. Among the many cannabinoids found in cannabis, THC is the primary psychoactive compound. Other psychoactive cannabinoids are present in cannabis (delta-8-THC and delta-10-THC), and still others can be obtained from the plant (delta-11-THC, THCA and HHC). Delta-9-THC is widely known as the most prevalent psychoactive cannabinoid in cannabis-marijuana.

Lawful hemp is defined in the 2018 Farm Bill as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (7 *U.S.C.* §1639o(1).) The bill does not include in the 0.3% limit any other of the variety of THC cannabinoids, and it does not define any distinction between "naturally occurring" or "synthetic" THC cannabinoids.

Finally, the 2018 Farm Bill prohibited individual states from interfering with the transportation and shipment of hemp and hemp products through interstate commerce. (2018 Farm Bill Sec. 10114 "Interstate Commerce"; 7 *U.S.C.* §1639o "Note".)

The Intoxicating Hemp Industry Emerges and Flourishes

Cannabis industry participants are indeed knowledgeable and industrious. Soon after the CBD industry established itself via retail stores, itinerant sales (festivals, concerts and other such public events) and online sales of hemp and hemp products, the cannabis-hemp industry began to extract from lawful hemp (containing less than .03% delta-9-THC) from intoxicating hemp products. The first was delta-8-THC, but others soon followed.

Proponents of intoxicating hemp products rely upon the plain language of the 2018 Farm Bill and its 0.3% delta-9-THC limit, as well as the assertion that the products are derived in a manner consistent with the bill's definition of hemp. Opponents argue that Congress did *not* intend to allow for the development of intoxicating hemp products, and that in contravention of the bill's terms these products are not derived naturally but synthetically. The fundamental legal dispute regarding intoxicating hemp products became whether they are lawful, adhering to strict statutory compliance, or are they improperly exploiting a loophole?

The legal debate intensified as the intoxicating hemp products industry developed and flourished. Most notably as sales of these products increased in existing CBD stores, as well as with the proliferation of "smoke shops" that sell intoxicating hemp products in many municipalities throughout the state. These retailers do not require Cannabis Regulatory Commission licensing or regulation, like the cannabis-marijuana industry. Moreover, some of the storefront retailers of intoxicating hemp products began to sell indisputably unlawful product—marijuana diverted from lawful out-of-state markets and "traditional" illicit cannabis.

Despite some federal court attention to the Farm Bill Compliant vs. Unlawful Loophole debate,[1] judicial resolution of the issue was not decisive. Nationally, some states adopted legislation regulating intoxicating hemp products to foster the market, particularly beverages. Other states legislatively banned the products outright. In New Jersey both state and municipal enforcement actions against unregulated retailers produced mixed results. Ultimately, New Jersey sought to resolve the issue with legislation allowing very-low-limit hemp products (effectively, not intoxicating) to continue to be marketed, while placing intoxicating hemp products under the auspices of the Cannabis Regulatory Commission, to be licensed and regulated like cannabis-marijuana.

Legislation, Litigation, and a Stay of Enforcement

On Sept. 12, 2024, New Jersey enacted Senate Bill 3235 (L.2024, C.73) regulating "intoxicating hemp products" by prohibiting sales to individuals under 21 years of age (immediately), and by modifying the state's law as to the production and sale of hemp and hemp products (effective 30 days later). The New Jersey Hemp Amendments Act (NJHAA), as Senate Bill 3235 came to be known, created a new definition of "hemp" that fixed the maximum concentration of THC, (the psychoactive compounds in cannabis, as not more than 0.3%, accounting for *all* THC compounds, rather than only delta-9 THC. In addition to this restrictive "total THC" threshold for hemp, any finished "hemp product" (pre-rolls or joints, vapes, gummies and, notably, beverages) was limited to "not more than .5 milligrams of total THC per serving and 2.5 milligrams of total THC per package." The act also sought to distinguish and allow only naturally occurring "chemical constituents," implicitly banning synthetically derived cannabinoids.

The NJHAA requires licensure by the CRC pursuant to the CREAMM Act[2] to engage in the sale or distribution of any intoxicating hemp product, and to sell intoxicating hemp beverages requires a plenary wholesale license or a plenary distribution license, issued by the New Jersey Alcoholic Beverage Commission under Title 33 (Intoxicating Liquors).[3] Intoxicating hemp products were placed on Schedule I of the New Jersey CSA, and unlicensed production, distribution or sale are subject to both criminal and civil enforcement. Hemp products not exceeding the NJHAA definition remain lawful, but for all intents and purposes the thresholds and limitations are universally

regarded by the hemp industry as untenable for sale, effectively eviscerating the industry in New Jersey. The intoxicating hemp industry promptly responded to the NJHAA with litigation seeking to enjoin and prohibit enforcement of the NJHAA. On Sept. 24, 2024, a group of hemp industry participants consisting of in-state and out-of-state cultivators, manufacturers, distributors and retailers sued in New Jersey Federal District Court.[4] The validity and enforceability of the NJHAA was challenged as violating federal constitutional and statutory law. The plaintiffs claimed that by changing the definition of hemp and hemp products and by criminalizing their transportation through the state of New Jersey, the NJHAA contravened the 2018 Farm Bill, in violation of the Supremacy Clause. Also, the plaintiffs charged that the NJHAA favored the economic interests of in-state hemp industry participants at the expense of out-of-state participants, and criminalized out-of-state products but not the production and sale of those same products in-state, in violation of the dormant Commerce Clause. Finally, the plaintiffs alleged that the NJHAA violates constitutional protections of due process by being vague regarding both the criminal and civil-penalty enforcement provisions of the law.

Due to the impending effective date of the act, the matter proceeded as a Motion for Summary Judgment. The District Court entered its order and issued a written opinion on Oct. 10, 2024, two days before the act was to take effect.[5] The District Court denied all of the relief sought, but did permanently enjoin the state from enforcing those provisions of the NJHAA that exempt otherwise compliant out-of-state hemp and hemp products from the definition of intoxicating hemp products. These provisions were deemed exclusionary because they effectively barred out-of-state hemp industry participants from participating in the New Jersey market. The plaintiffs filed an appeal and the matter is pending in the Third Circuit.[6]

The NJHAA became effective on Oct. 12, 2024, intoxicating hemp products are presently unlawful, and neither the Cannabis Regulatory Commission nor the Division of Alcoholic Beverage Control have promulgated any rules regarding the licensing and regulation of either intoxicating hemp products or beverages. Yet the day before enforcement of the act, the state announced a stay of enforcement, via a notice issued by the CRC and posted on its website.

The hemp industry awaits judicial resolution or, more likely, revisions to the NJHAA. The intoxicating hemp beverage industry anticipates revisions to the act that allow it to continue uninterrupted. The remainder of the intoxicating hemp products industry await a determination whether it must license and operate under the CRC or it can continue in some modified manner in its existing framework.

Cannabis: Protean, Mutable and Mercurial

The NJHAA renders the currently existing intoxicating hemp industry to be illegal, but the law is not enforced. This is identical to the status of medical and adult-use marijuana at the federal level. Well-resourced market participants have an impact on the development of both the cannabis-marijuana and cannabis-hemp industries. As to the latter, the cannabis beverage industry is markedly ascendant. In this context, both the marijuana and hemp industries co-exist alongside the illicit cannabis industry, which is not gone, and which is a larger and older industry participant than the two of them combined.

The marijuana and hemp industries have developed differently, and they have directly divergent views on the lawfulness of intoxicating hemp products. Investments of time and money as well as personal livelihoods are at issue. The NJHAA has declared intoxicating hemp illegal, and civil and criminal enforcement will follow. (Reminiscent of the impact of the pre-legalization "war on cannabis"). Tensions have arisen. Some speak of a "civil war" between the industries.

It is said that the only constant in the cannabis industry is change, and that all industry participants must be ready to alter course, often in unanticipated directions. These adages will soon be applicable to New Jersey Intoxicating Hemp Law. With substantial revisions to the New Jersey Hemp Amendments Act anticipated soon (if not having already occurred), practitioners in the areas of cannabis law, alcoholic beverage law, municipal law, and criminal law should be watchful and ready to respond accordingly. ■

Endnotes

1. *Anderson v. Diamondback Investment Group, LLC*, 117 *F.4th* 165 (4th Cir. 2024); *AK Futures LLC v. Boyd Street Distro, LLC*, 35 *F.4th* 682 (9th Cir. 2022).
2. The CRC regulates the sale of medicinal and recreational marijuana products in New Jersey, pursuant to the state's marijuana legalization statute, the "New Jersey Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act" (P.L. 2021 c.016, adopted February 22, 2021).
3. *N.J.S.A.* 33:1-1 to 5-5.
4. *Loki Brands, LLC, et al., Plaintiffs v. Matthew Platkin, et al., Defendants,* Civ. A. No. 24-9389 (D.N.J. Filed Sept. 24, 2024).
5. *Loki Brands, LLC v. Platkin*, Civ. A. No. 24-9389, 2024 WL 4457485 (D.N.J. Oct. 10, 2024).
6. *Loki Brands, LLC v. Platkin*, Case No. 24-3120 (3d Cir. Filed Nov. 14, 2024).

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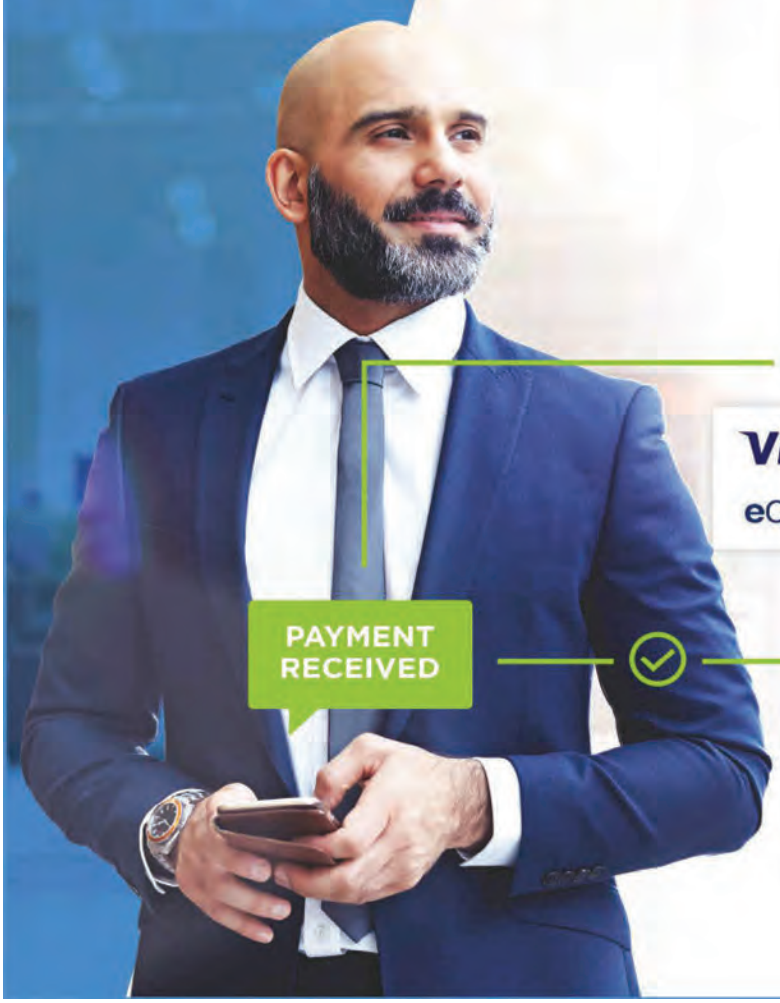

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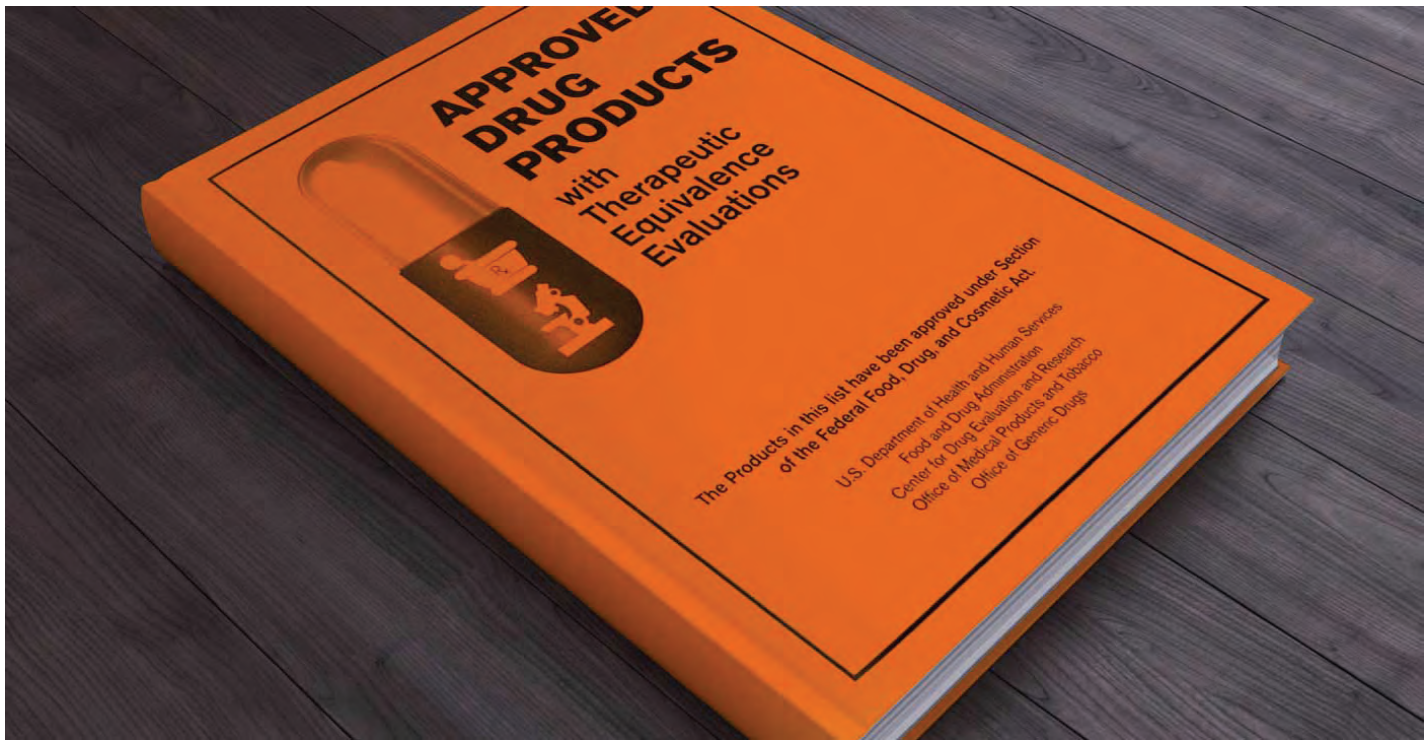

Federal Circuit Affirms NJ District Court *Teva* Ruling, Refining Drug Patent Listing Standards

By Miriam Goldgeil

MIRIAM GOLDGEIL *is a Senior Research Analyst at The Brattle Group, where she supports expert analysis in complex litigation and regulatory matters, with a focus on the health care and pharmaceutical industries. She serves as an Economics Ambassador for the Health Care and Pharmaceuticals Committee of the American Bar Association Antitrust Section.*

On Dec. 20, 2024, the U.S. Court of Appeals for the Federal Circuit lifted its stay and affirmed a district court's order requiring Teva to delist five patents from the U.S. Food and Drug Administration (FDA) *Orange Book*.[1] The Federal Circuit's opinion noted that these patents claimed inhaler devices but did not claim albuterol sulfate, the active ingredient used in Teva's FDA-approved ProAir HFA Inhalation Aerosol product.[2]

The Federal Circuit concluded that, in order for a patent to be properly listed in the *Orange Book*, it must claim the drug from the applicant's submitted and approved drug application. Moreover, for a manufacturer to properly claim that drug, the patent must include the active ingredient. The Federal Circuit also discussed device patents at large and noted that when patents claim only the device components of a product approved in a drug application, they do not meet the listing requirement of claiming the active ingredient or drug for which the application was submitted.[3]

In this matter, Amneal Pharmaceuticals alleged that Teva improperly listed patents in the *Orange Book* and delayed the entry of generic products onto the market.[4] The U.S. District Court for the District of New Jersey agreed with Amneal and ordered that Teva

The Federal Circuit concluded that, in order for a patent to be properly listed in the *Orange Book*, it must claim the drug from the applicant's submitted and approved drug application. Moreover, for a manufacturer to properly claim that drug, the patent must include the active ingredient.

delist its patents from the *Orange Book*. They noted that "the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate," but instead "are directed to components of a metered inhaler device." Teva appealed, and the Federal Circuit stayed the district court's order pending their resolution of the case, eventually lifting the stay and affirming the district court's delisting order.[5]

The Federal Circuit's ruling aligned with growing scrutiny from the Federal Trade Commission (FTC) over the potential misuse of *Orange Book* listings. In September 2023, the FTC issued a policy statement addressing the alleged improper listing of patents in the *Orange Book* by some drug manufacturers. The statement aimed to alert market participants that the FTC would be scrutinizing such listings to determine if they constituted unfair competition under Section 5 of the FTC Act. The FTC noted that improperly listed patents could discourage investment in competing products, delay generic drug entry, and increase health care costs.[6]

In November of that year, the FTC challenged over 100 patents and notified 10 drug companies, leading some to delist the contested patents while others argued they were properly listed.[7] The patents challenged included the five patents at issue in Teva's case against Amneal.[8] By April 2024, the FTC had challenged an additional 300 patents and sent new warning letters to 10 more drug companies regarding patents on various brand-name drugs, including those for asthma and injectable treatments such as Ozempic and Saxenda.[9]

The FTC filed an amicus brief on March 22, 2024, arguing that Teva improperly listed patents in the *Orange Book* and urged the court to order the listings to be removed. The FTC questioned whether Teva's listed patents meet the requirements for being listed in the *Orange Book* and considered whether they are an example of illegal monopolization. The FTC argued that "device patents that do not mention any drug in their claims do not meet the statutory criteria for *Orange Book* listing, and a device patent that is improperly listed in the *Orange Book* must be delisted."[10] On Dec. 20, 2024, the FTC announced its agreement with the Federal Circuit's decision to request Teva to delist its inhaler patent listings from the *Orange Book*.[11]

Background: Teva and Amneal

Teva, established in 1901 in Israel, is a pharmaceutical company that specializes in generic drugs and develops specialty and biopharmaceutical treatments.[12] The company has a portfolio of over 3,600 medicines and produces approximately 76 billion tablets and capsules a year. Teva has over 53 manufacturing facilities in over 33 countries and employs approximately 37,000 employees.[13]

Amneal began as a start-up generics company in 2002 and later developed into a specialty pharmaceutical company. The company is headquartered in Bridgewater.[14] Amneal has developed, manufactured, and distributed a portfolio of over 280 generic and specialty pharmaceuticals, primarily within the U.S. The company employs over 7,800 employees.[15]

The FDA's Drug Approval Process

Generally, the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 governs how the FDA approves and regulates medical products. Before a company can market and sell its drug, regulations require the company to submit a new drug application (NDA). The NDA must provide a complete description of the components and manufacturing process for the drug, proposed labeling, information on which patents claim the drug, and other information. If the application shows the drug is safe and effective, the FDA will likely approve the drug.[16]

In 1984, Congress enacted the Hatch-Waxman Act, which revised the FDCA. The act resulted in changes to the process for approving generic products, with the aim of bringing them to market faster while still encouraging companies to invest resources in developing new drug products. One major change the act brought about was the introduction of an abbreviated new drug application (ANDA). The ANDA process for generics allows the company to show bioequivalence[17] instead of having to conduct new, costly clinical trials to prove the safety of a drug. Rather, the generic manufacturers can rely on clinical studies and data generated by other manufacturers to prove that the drug is safe.[18]

Separately, the FDA oversees a publication called the *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is more commonly referred to as the *Orange Book*. The *Orange Book* includes all the small-molecule drugs approved by the FDA to be marketed in the United States, information on the approved drugs (such as dosages and

forms), and the FDA's therapeutic equivalence evaluations. The latter are the approved products that are pharmaceutically equivalent as well as bioequivalent to an existing approved product, such as the generic form of a brand-name drug. Moreover, the *Orange Book* provides information on patents and exclusivities that can protect a brand-name drug from generic competition.[19]

Only certain types of pharmaceutical patents can be listed in the *Orange Book*. A company applying for FDA approval of a new drug must include in its NDA any patent that (1) is an active ingredient patent or a formulation patent that claims the relevant drug or (2) a patent that claims a method of using the drug for which approval is being sought. If the FDA approves the drug, the NDA's patent information and any updates are listed in the *Orange Book*. FDA regulations state that patents claiming processes, packaging, metabolites, or intermediates must not be included in an NDA. As a result, these types of patents should not be listed.[20]

The FDA does not actively check the patent information in NDAs to confirm that the listed patents claim the drug or a method of using the drug. The agency notes that it takes on a "ministerial" role regarding *Orange Book* patents; its role is only to list the patent information provided by drug companies without necessarily verifying the validity of the patents themselves.[21]

Under the Hatch-Waxman Act, a drug company can seek FDA approval for the generic version of an approved brand-name drug by filing an ANDA. An ANDA must provide one of four certifications, considering every patent listed in the *Orange Book*: Paragraph I certifies that no patents are listed for the drug in question; paragraph II certifies that all the patents included in the *Orange Book* for the drug are expired; paragraph III certifies that the ANDA filer does not provide a challenge to the patents listed; and paragraph IV certifies that the filer of the ANDA challenges the patents listed as invalid or inapplicable.[22]

The FDA can approve ANDAs with paragraph I or II certifications instantaneously, and if the generic applicant makes a paragraph III certification, then the FDA cannot approve the ANDA until the relevant patents have expired. If the generic applicant makes a paragraph IV certification, however, and the NDA filer subsequently sues for patent infringement, this results in a 30-month stay. This means the FDA cannot approve the ANDA for 30 months unless the relevant court resolves the patent dispute before the stay is over. As such, it is in the interest of NDA holders to submit an exhaustive list of all relevant patents in the *Orange Book*.[23]

The Facts of the Case

The product at issue in *Teva v. Amneal* was Teva's ProAir HFA Inhalation Aerosol, which the FDA approved on Oct. 29, 2004. The product is primarily used for the treatment or prevention of bronchospasm associated with reversible obstructive airway disease in adults and children aged 12 or older. The ProAir HFA, delivered in canisters containing 200 doses each, combines the active ingredient albuterol sulfate with the propellant ethanol and an inhaler device to deliver the medication.

Although the ProAir HFA was approved by the FDA as a drug, it includes both the active ingredient albuterol sulfate and the device (or the physical machinery) of the metered-dose inhaler. The FDA reviews and approves metered-dose inhalers as drugs because the primary mode of therapeutic action is derived from the active ingredient, which in this case is albuterol sulfate.[24]

Teva listed nine non-expired patents in the *Orange Book* for its ProAir HFA. Five of these patents were central to the case and generally focused on the device components of the inhaler—such as the dose counter—and addressed various problems related to dose counting. However, none of the patents explicitly claimed the active ingredient albuterol sulfate.[25]

Amneal filed an ANDA to market a generic version of Teva's ProAir HFA, which uses albuterol sulfate, the same active ingredient as Teva's product. In response to Teva's listing of multiple patents in the *Orange Book* claiming its ProAir HFA product, Amneal filed a paragraph IV certification asserting that its generic product did not infringe on the nine listed patents. Amneal notified Teva of this certification on Aug. 24, 2023. Following Amneal's paragraph IV certification notice, Teva initiated a lawsuit against Amneal, claiming infringement of six of the listed patents. Teva later amended its complaint to focus on the five specific patents referenced earlier.[26]

Amneal responded with several counterclaims, including antitrust violations, declaratory judgments of noninfringement and invalidity, and a request for an order to delist the five patents asserted by Teva. Amneal argued that Teva's infringement suit triggered a 30-month stay of the FDA's final approval of Amneal's ANDA. Amneal further alleged that if Teva had not listed these patents, it would have filed a paragraph I certification, which would not have resulted in a 30-month stay. In response, Teva moved to dismiss Amneal's antitrust and delisting counterclaims, which resulted in Amneal cross-moving for a motion for judgment on the pleadings, arguing that Teva did not properly list the asserted patents.[27]

The Initial Decision of the United States District Court for the District of New Jersey

On June 10, 2024, the district court ultimately denied Teva's motion to dismiss Amneal's counterclaims and granted Amneal's motion for judgment. Furthermore, the district court ordered Teva to delist their five asserted patents, con-

cluding that the company improperly listed the asserted patents because they did not claim the active ingredient, albuterol sulfate, but were directed at components of the inhaler device.[28]

The district court rejected Teva's primary argument that a patent claims a product if it could be infringed by that product. It also dismissed Teva's claim that the patents were listed properly because they claimed components of the ProAir HFA (albuterol sulfate) Inhalation Aerosol.[29] The court noted that Teva's reasoning did not account for the statutory phrase "for which the applicant submitted the application," which requires the claim to explicitly include albuterol sulfate.

Teva then appealed the district court's interlocutory delisting order to the Federal Circuit. Following the appeal, the Federal Circuit issued a stay of the district court's order pending its review, thereby temporarily halting the requirement for Teva to delist the patents from the *Orange Book*.[30]

The Federal Circuit's Decision and Opinion

Teva argued that the district court erred by interpreting the listing provision too narrowly, limiting it to patents that claim the active ingredient. The company contended that a patent can be listed in the *Orange Book* if it claims any part of the NDA product. Specifically, Teva's ProAir HFA inhaler included features like an active ingredient, a dose counter, and a canister, and the patents in question claimed the dose counter and canister components—which, according to Teva, meant that its patents were properly listed in the *Orange Book*.

The Federal Circuit noted that Teva's argument relied on two key points: (1) that a patent "claims the drug" if the NDA product infringes the claim, meaning that the claimed invention is found in any part of the NDA product, and (2) that the FDA's broad definition of "drug" includes any component of an article intended to treat disease. Therefore, the court explained that Teva asserted that its patents, which claim components of the ProAir HFA, should be listed.[31]

The court rejected Teva's interpretation and stated that a patent claims the drug only if it "particularly points out and distinctly claims the drug as the invention." Simply describing the features of the approved drug is insufficient. Additionally, the court rejected the notion that a patent claiming any component of a drug is listable. Instead, a patent must claim at least the active ingredient that made the product approvable as a drug.[32]

Teva further argued that even if its statutory arguments were rejected, the Federal Circuit should remand for the district court to construe the claims. The Federal Circuit also rejected this argument, stating that even with Teva's proposed construction, the patents do not qualify for listing because they do not claim the active ingredient. The court upheld the district court's order to delist the patents and affirmed that only patents claiming the active ingredient can be listed in the *Orange Book*.[33]

The court delved into the above topics in more detail in its opinion. It first rejected Teva's interpretation of what it means to claim a drug and then explained why a listable patent is one that distinctly claims the relevant active ingredient. Lastly, the court evaluated Teva's argument that its patents include claims requiring the presence of an "active drug."[34]

Teva's Interpretation of 'Claims the Drug'

The court rejected Teva's argument that a patent claims the drug if it describes any part of the NDA product, emphasizing that the patent must claim at least the active ingredient. The court further rejected Teva's interpretation that the scope of what a patent "claims" is the same as the products that infringe a patent. Teva's argument was found to be defective by the court as it conflates two distinct statutory requirements: claiming and infringing.[35]

The court emphasized that the listing provision in the statute identifies "infringing" and "claiming" as separate requirements. Accepting Teva's interpretation would render parts of the statute redundant. As such, Teva's argument, that the specialized meanings of "claim" and "infringe" in patent law support its interpretation, was dismissed. The court emphasized that these terms have distinct meanings. Claims define the invention, whereas infringement occurs when someone unauthorized makes, uses, or sells the invention.[36]

The court further explained that claims and infringement are analyzed differently. Claims focus on what the patent document specifies as the invention, while infringement is assessed by examining if an existing product meets the claim's limitations. Literal infringement exists when each claim limitation is found in the accused product. The court referenced case law and statutory provisions to clarify that a patent claims something by distinctly identifying it as the invention, whereas infringement involves determining if each element of the pre-existing claim is found in the accused product. The court concluded that whether Teva's NDA infringes its patents is separate from whether those patents claim the drug for which Teva submitted the application.[37]

Combination Products

Although Teva's ProAir HFA was approved as a combination product (drug and device), the court explained that device components alone do not qualify as a drug for the purpose of listing patents in the *Orange Book*. The approval pathway for a combination product does not transform the device parts into a drug, and the active ingredient must still

be claimed.[38] Teva argued that a patent should be listed in the *Orange Book* if it claims any part of the NDA product.

According to Teva, the statutory definition of "drug" under the FDCA includes any component intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As a result, the company contended that patents claiming device parts of its NDA product should also be listed. The court rejected Teva's argument, stating that the FDCA's definition of "drug" must be understood within the broader statutory context.[39] The court emphasized that a patent must claim at least the active ingredient identified in the application to "claim the drug for which the applicant submitted the application." The presence of a safe and effective active ingredient is ultimately what makes a product FDA-approved as a drug.[40]

The FDCA distinguishes between drugs and devices based on their primary mode of action. Drugs are composed of complex chemical compounds or biological substances. In contrast, devices are defined by their mechanical nature. A device does not achieve its primary intended purpose through chemical action or metabolization, which are essential for drugs to achieve their intended purpose. This distinction informs the approval pathways and regulatory oversight for drugs and devices. The court emphasized that the active ingredient is central to the new drug approval process. The FDA evaluates the safety and efficacy of a drug based on its active ingredient under the conditions prescribed in the proposed labeling. Additionally, ANDAs must demonstrate that the active ingredient is the same as that of the listed drug. This focus on the active ingredient reinforces the requirement that patents must claim the active ingredient to be listed in the *Orange Book*.[41]

The court argued that while the FDA approved Teva's ProAir® HFA as a drug, the device parts of the combination product remain classified as devices. While the approval pathway used by the FDA depends on the primary mode of action, this does not transform the device components into a drug. As such, the court concluded that patents claiming only the device parts do not meet the listing requirement of claiming the drug for which the application was submitted and approved.[42]

Teva's Claim Construction

The court explained that Teva argued that "even if a patent must claim at least the active ingredient to be listed in the *Orange Book*, its patents do claim an active ingredient." Furthermore, Teva argued that each relevant patent does include one claim requiring the presence of an "active drug." The court adopted this proposed construction from Teva for the sake of argument but found that a claim requiring "an active drug" is too broad to meet the requirement of distinctly claiming the approved drug with albuterol sulfate as the active ingredient. The court concluded that Teva's construction does not meet the legal standard of distinctly claiming the specific active ingredient in the approved drug product. Consequently, the court upheld the district court's order to delist the five asserted patents, as they determined that Teva's patents do not meet the criteria for listing in the *Orange Book*.[43]

The Federal Circuit's decision sets a precedent for the proper listing of patents, particularly medical device patents, in the *Orange Book*. This ruling reinforces the FTC's ongoing efforts to address potentially improper patent listings, as the agency has expressed concerns about the misuse of the *Orange Book* to delay generic drug entry. The decision not only impacts Teva but also suggests the importance for pharmaceutical companies to claim the active ingredient of the approved drug in their patents to avoid scrutiny from the FTC and other regulatory bodies.

Endnotes

1. *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC* Opinion, 24–1936, (Fed. Cir.) (December 20, 2024) [hereinafter Opinion], p.38.
2. *Id.*, p. 33
3. *Ibid.*
4. Opinion, p.2
5. Opinion, p.3
6. Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), available at crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval
7. *Id.*
8. FTC Files Amicus Brief in Asthma Inhaler Patent Dispute, FTC (March 22, 2024), available at ftc.gov/news-events/news/press-releases/2024/03/ftc-files-amicus-brief-asthma-inhaler-patentdispute
9. Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), available at crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval
10. Brief for the FTC as Amicus Curiae, p. 2, in *Teva v. Amneal*, No. 24–1936 (2024), available at ftc.gov/system/files/ftc_gov/pdf/ftc_brief_as_amicus_curiae_teva_amneal.pdf.
11. FTC Statement on Appellate Court

Decision Ordering Delisting of Teva Inhaler Patents, FTC (December 20, 2024), available at ftc.gov/news-events/news/press-releases/2024/12/ftc-statement-appellate-courtdecision-ordering-delisting-teva-inhaler-patents
12. Improving health since 1901, Teva, available at tevapharm.com/our-company/teva-history/.
13. Company Info: Teva in Facts and Figures, Teva, *available at* tevapharm.com/our-company/tevafacts-figures/.
14. Our Story, Amneal, *available at* amneal.com/about/our-story/.
15. Amneal at-a-glance, Amneal, *available at* amneal.com/about/our-story/amneal-at-a-glance/.
16. Opinion, pp.3–4
17. The FDA defines bioequivalence as the following: "Two products are considered to be bioequivalent when they are equal in the rate and extent to which the active pharmaceutical ingredient (API) becomes available at the site(s) of drug action." Bioequivalence, U.S. Food & Drug Administration, available at fda.gov/animal-veterinary/abbreviated-new-animal-drug-applications/bioequivalence
18. Opinion, p.4
19. Patent Listing in FDA's Orange Book, Congressional Research Service (December 27, 2024), available at crsreports.congress.gov/product/pdf/IF/IF12644#:~:text=By%20statute%2C%20a%20company%20seeking,such%20drug%20for%20which%20approval
20. *Ibid.*
21. *Ibid.*
22. *Ibid.*
23. *Ibid.*
24. Opinion, p.12
25. Opinion, pp.13–15
26. Opinion, p.15
27. Opinion, pp.15–16
28. Opinion, pp.2–3
29. Opinion, p.16
30. Opinion, pp.16–17
31. Opinion, pp.17–18
32. Opinion, p.18
33. Opinion, pp.18–19
34. Opinion, p.19
35. Opinion, pp.20–21
36. Opinion, p.21
37. Opinion, pp.27–28
38. Opinion, p.36
39. Opinion, pp.33–36
40. Opinion, p.37
41. Opinion, pp.34–36
42. Opinion, pp.35–36
43. Opinion, pp.37–38

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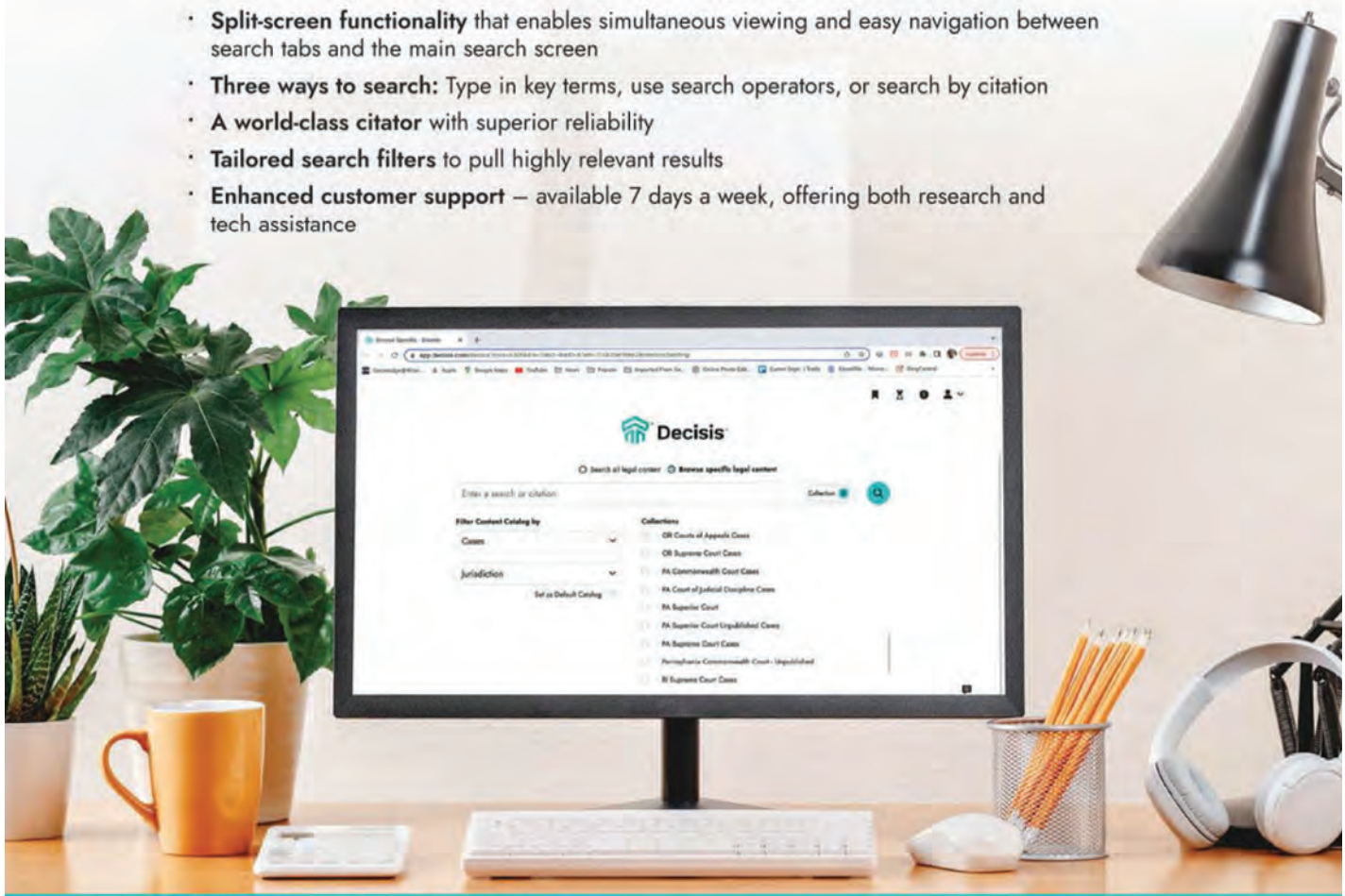

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NJSBA Events Highlight Justice, Pride, Professionalism and Care

Over the past two months, the New Jersey State Bar Association has hosted and participated in events that highlight its deep commitment to diversity, equity, professional excellence, and attorney well-being.

NJSBA Celebrates Juneteenth with MIPS

The New Jersey State Bar Association celebrated Juneteenth with a dinner hosted by the Minorities in the Profession Section. Dozens came to the New Jersey Law Center on June 18 to commemorate the freedom of enslaved people in the United States. The event featured music, food and a chance for attendees to showcase their historical knowledge with Juneteenth Jeopardy.

Pride Month Celebrated with Flag-Raising Ceremony

The New Jersey State Bar Association kicked off Pride Month with a flag-raising ceremony on June 4. NJSBA President Christine A. Amalfe joined members of the Association's LGBTQ Rights Section to hoist the rainbow-colored Pride Flag over the New Jersey Law Center in New Brunswick, where it flew until the end of June.

In a speech at the Law Center, Amalfe said Pride Month is a time to reflect on the important history of the LGBTQ community and its fearless push for equality in our society.

"The NJSBA will never waver in support of diversity, equity and inclusion in the legal profession. LGBTQ rights are civil rights; LGBTQ rights are human rights. Today's Pride flag raising reflects the Association's commitment to those ideals," Amalfe said.

NJ Commission on Professionalism in the Law Honors Three Distinguished Attorneys, Dozens More at Annual Awards

The 2025 New Jersey Commission on Professionalism in the Law Awards on June 12 celebrated individuals who uphold the profession's highest ideals and who have accomplished significant career achievements.

Theodore H. Ritter, managing partner at The Ritter Law Office LLC, received the Daniel J. O'Hern Award. Former New Jersey Public Defender Joseph A. Krakora, now a faculty fellow at the Princeton School of Public Affairs and International Policy, was recognized with the Charles J. Hollenbeck Award. The Lighthouse Award was presented posthumously to Van W. Lane, former Monmouth County deputy public defender.

Dozens of attorneys representing bar associations across the state also received Professional Lawyer of the Year Awards, given to those who are respected by colleagues for their character, competence and exemplary professional behavior.

NJSBA Takes Part in Attorney Wellness Event

The New Jersey State Bar Association attended a Judiciary program about well-being in the law. The conversation focused on how to manage professional demands with those of being a caregiver, as well as healing from grief and loss.

The event in Trenton included retired state Supreme Court Justice Lee Solomon, chair of the Supreme Court Committee on Wellness in the Law; Rev. Dr. Eric M. Brewer, director of field education at Howard University; and attorney Melissa Rosenblum. Judge Michael Blee, Administrative Director of the Courts, moderated the discussion. Nicole Perskie, administrative director of the New Jersey Lawyers Assistance Program, and Patricia Adams, president of the Monmouth Bar Association, also addressed the virtual and in-person audience. NJSBA President-Elect Norberto A. Garcia and First Vice President G. Glennon Troublefield attended.

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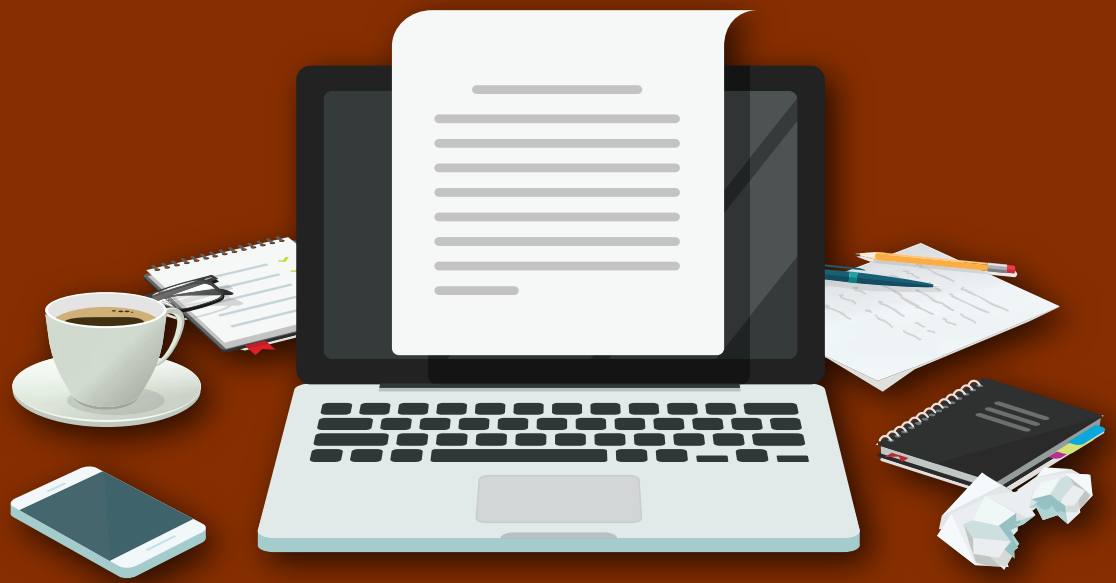

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