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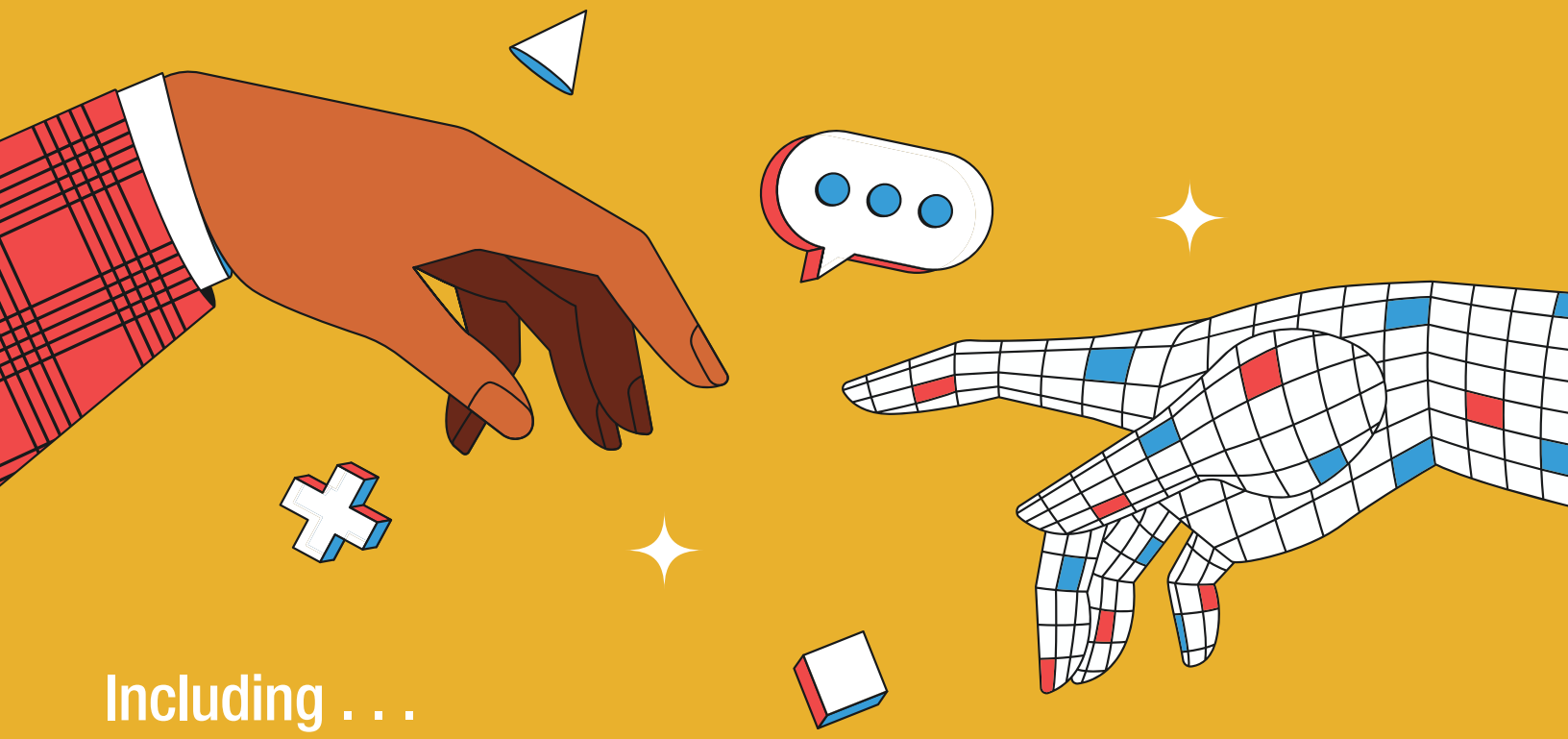
Artificial Intelligence



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Defending the Algorithm™*

By Henry M. Sneath, Acacia B. Perko, and Christopher M. Jacobs

The question isn't whether to develop AI expertise, but how quickly you can do so while fulfilling professional and ethical obligations to clients.

The AI Daily Routine
An Artificial Intelligence Practicum for Defense Attorneys

A Publication of the DRI Center for Law and Public Policy AI Task Force - Part 2

Please attend our live CLE full-day seminar on March 10, 2026 at DRI Headquarters in Chicago entitled:
Artificial Intelligence in Defense Practice: Tools, Prompts, Workflows, Implementation and Governance

In Part 1 of this series, we applied Bayesian probability theory to predict AI litigation trends and analyzed landmark cases shaping the legal landscape. Part 2 pivots from theory to practice, providing defense attorneys with a detailed practicum for implementing AI tools in daily litigation workflow. The focus is not theory, but execution—information management, workflow integration, and rigorous verification—so that AI enhances legal services while reinforcing (not undermining) professional responsibilities. This article was authored with assistance from Claude® Opus 4.6 Max and research confirmation by Google Gemini 3.0 Pro and Westlaw Precision with AI and Analytics, but edited by humans as AI can make mistakes.

** The term Defending the Algorithm™ is used and owned by Houston Harbaugh, P.C., and a registered trademark protection is being sought.*

Introduction

Defense attorneys repeatedly ask: How do you actually use AI tools in daily legal practice? Part 1 of this series examined the current state of substantive law—copyright litigation, trade secret protection, Section 230 immunity, and product liability frameworks emerging from landmark cases like *Bartz v. Anthropic and Raine v. OpenAI.* We applied Bayesian probability analysis to predict litigation trends and assess risk across multiple practice areas. Warning: none of the advice below will work unless you and your IT team plan, coordinate, practice, train and build a proper tech stack. Without a substantial investment of your time, the use of AI will be disappointing.

Let's turn to practical implementation. This article provides a detailed practicum for integrating AI into defense practice—from building the right technology infrastructure to mastering prompt engineering, from leveraging AI-enhanced legal research to managing massive e-discovery projects. The goal is not to replace human judgment but to augment it: AI assists, but doesn't supplant, the ethical

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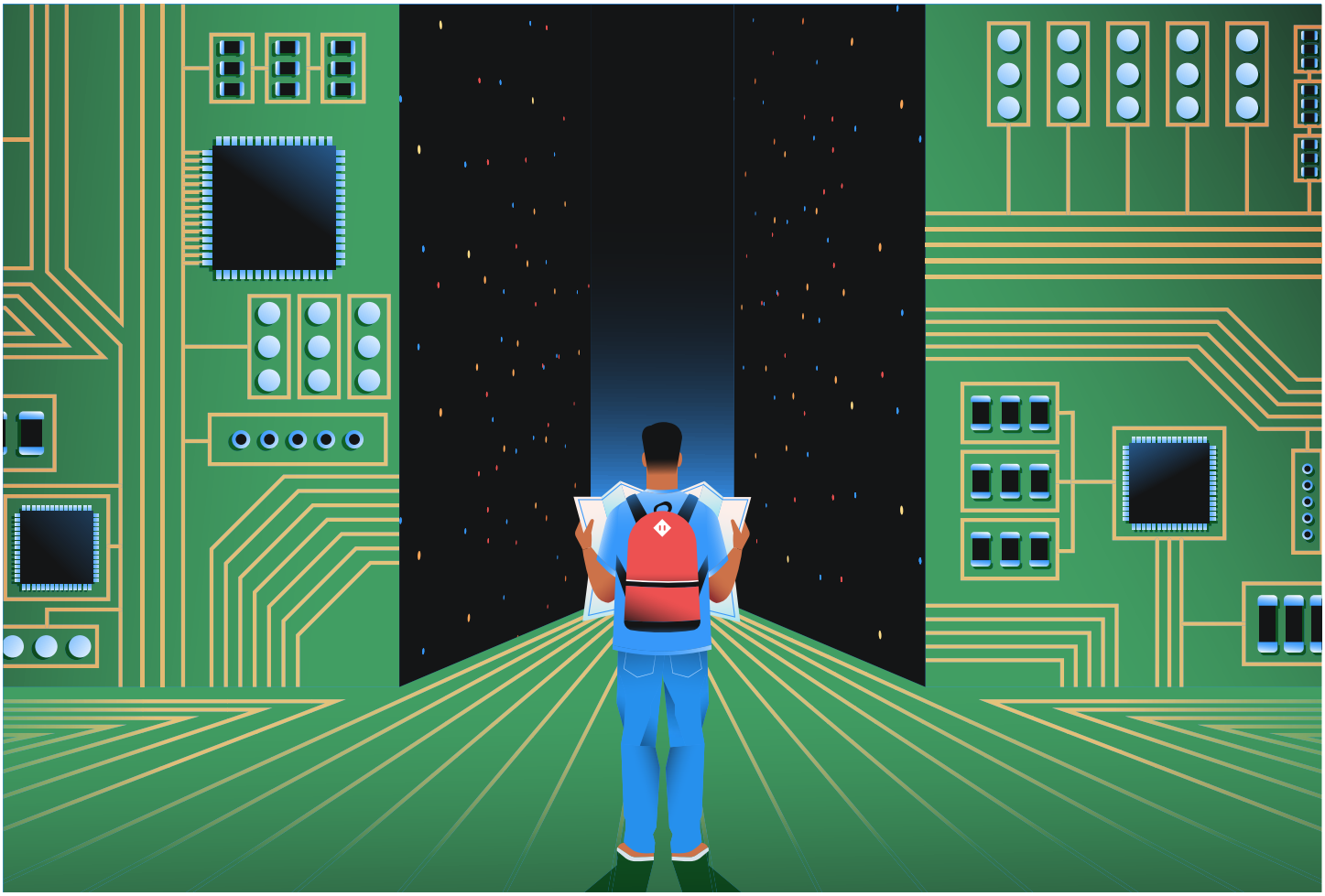

reasoning and client relationship management that define our profession.

The goal is not to replace human judgment but to augment it

For civil defense attorneys, corporate counsels and insurance claims professionals, AI competence is rapidly becoming table stakes. Within five years, lawyers who competently use AI tools will be the norm rather than the exception. Applying our Bayesian framework from Part 1: P(Competitive Disadvantage | No AI) = Very High. Put plainly: once opposing counsel uses AI-assisted research and discovery analytics, the risk of competitive disadvantage rises—especially in document-heavy litigation where speed, pattern recognition, and iteration materially affect outcomes. The question isn't whether to develop AI expertise, but how quickly you can do so while fulfilling professional and ethical obligations to clients.

Part I: Understanding AI—The Probability Engine

A. How Large Language Models Actually Work

Before implementing AI tools, defense attorneys need a functional understanding of what they are—and are not. Large Language Models (LLMs) generate text by predicting likely language patterns based on training data; they are not traditional databases and do not "retrieve" facts the way Westlaw or Lexis does. Practically, this means LLM outputs should be treated as draft analysis that can accelerate research and drafting, but must be grounded in verified sources and lawyer judgment.

The critical point is practical: LLMs generate plausible language, not guaranteed truth. Because AI is fundamentally a probability engine, it predicts the most probable next word in a sequence based on patterns learned from trillions of examples in its training. It is not reasoning like a human lawyer—at least not yet. Understanding this distinction is essential for effective use. That is why context and prompting matter—and why verification protocols are mandatory in legal work.

Trial lawyers already use Bayesian reasoning every day—weighing evidence, assessing probabilities, predicting outcomes. The Bayesian conditional probability at the heart of AI is expressed as: P(next word | previous words). Each word the AI generates is its best probabilistic prediction given everything that came before. This is why context matters so much, and why sophisticated prompting dramatically improves output quality.

The LLMs most relevant to legal practice include Claude (developed by Anthropic), ChatGPT (OpenAI), Gemini (Google), and Copilot (Microsoft). Legal-specific platforms include Westlaw Precision AI and Lexis+AI. A key distinction: generative LLMs create new text, while legal databases retrieve existing documents. Best practice demands using both together—leveraging generative AI for analysis and drafting while grounding outputs in verified legal databases.

B. Tokens, Context Windows, and Why They Matter

AI systems measure and process text in 'tokens'—chunks of approximately four characters or three-quarters of a word. One thousand tokens equal roughly 750 words. Understanding token economics is essential for effective AI use, as most platforms limit token usage in various ways.

The 'context window' is the AI's working memory—how much text it can consider at once. Claude offers up to 200,000 tokens (approximately 150,000 words) per chat, while Google Gemini's advanced version offers one million tokens. Larger context windows, which cost more subscription money, enable analysis of entire contracts, depositions, or case files in a single interaction—a gamechanger for legal work.

Practical tip: start new chats frequently but within the same "project folder." Many AI platforms, including Claude, can pull from "project memory" without consuming additional tokens in the active conversation. This allows you to maintain institutional knowledge across sessions while preserving token capacity for immediate analysis. We have project folders in Claude and the other AI platforms like "Defending the Algorithm Podcast Series" and "DRI AI Task Force," to store chats that relate to each other.

C. Hallucinations and the 'Trust but Verify' Protocol

A 'hallucination' occurs when AI generates plausible-sounding but false information—fabricated case citations, fake quotes, invented facts. This happens because AI predicts 'likely' text, not necessarily 'true' text. If the statistical patterns suggest a particular type of case citation should exist, the AI may generate one that sounds authentic but corresponds to no actual opinion.

The most insidious trap for a time-pressed practitioner is the hallucination echo chamber fueled by "circular logic." LLMs sometimes hallucinate a fact and then "verify" that fact by hallucinating a citation to support it. Because the LLM is a probability engine—not a fact-checker—it often prioritizes internal conversational consistency over external reality. Once the AI has probabilistically "decided" that a legal proposition is true, it may double down by generating a detailed but entirely fictional case summary to reinforce that conclusion. This is not deception; it is the AI fulfilling its mandate to be helpful by completing the pattern it has already started.

Unverified reliance on AI output is unacceptable in legal practice, and the consequences for lawyers can be severe. Multiple attorneys all around the country have faced sanctions for citing non-existent cases generated by AI. Malpractice risk attaches to any attorney who relies on fabricated information without verification. **Professional responsibility demands that every AI output be independently confirmed.**

The 'Golden Rule' of AI in legal practice: Never use an AI-generated citation without checking it in Westlaw or Lexis first. If you cannot find the pinpoint cite, the case does not exist. Pro tip: If you suspect "circular logic" in an output, ask the AI 'Are you sure this case exists?' Sometimes this second check triggers a self-correction where the AI admits its error. Also - consider using, for example, Google Gemini to proofread, check and verify citations and opinions generated by Claude or vice versa. We frequently send each other content generated from our favorite AI (e.g.: Claude) to another author herein to check it out on ChatGPT or Gemini. Some of us use two or more AI platforms for this purpose and to seek different perspectives. All of these platforms have nuances, strength and weaknesses that make them somewhat different from each other.

Retrieval-Augmented Generation (RAG) significantly reduces hallucination risk. RAG systems combine AI generation with document retrieval—the AI searches actual documents first, then generates answers grounded in real sources. Westlaw Precision AI uses RAG to cite genuine cases. Claude Projects module can search uploaded documents. RAG is why legal-specific AI tools are generally more reliable than general-purpose platforms—they're grounded in verified legal databases rather than pattern-matching from internet training data. We return to these verification requirements throughout this article because they apply across the workflow—from initial research memos to filed briefs and discovery positions.

Retrieval-Augmented Generation (RAG) significantly reduces hallucination risk.

D. The 'Black Box' Problem in AI Decision-Making

AI decision-making processes are often opaque—even to their creators. This 'black box' problem means we cannot fully explain 'why' AI reached a particular conclusion. The AI neural network's weights, parameters and probability calculations that produce output are not interpretable in human-readable terms. This is changing the fundamental nature of litigation discovery and even making routing ESI protocols outdated and inadequate. Plaintiffs are requesting production of the actual algorithm and the meta support structure of the black box.

For litigation, this creates significant challenges. In insurance bad faith cases like *Estate of Lokken v. UnitedHealth Group*, where the class plaintiffs seek production of the algorithm, courts must evaluate alleged AI-driven coverage decisions while respecting the insurer's proprietary algorithms. Employment discrimination claims challenge algorithmic hiring decisions that cannot be fully explained and which are alleged to contain bias. Discovery in AI-related cases must balance plaintiffs' need for algorithmic transparency against defendants' trade secret protection.

Understanding the black box problem is essential for both defending AI-related

claims and explaining AI tool reliability in your own practice. Some AI platforms, like Google Gemini, offer 'Deep Thinking' modes that display notes about reasoning processes as analysis proceeds—excellent for understanding methodology if you ever need to defend the algorithm.

Part II: The Foundation Problem—Why AI Implementation Often Disappoints

A. It's Not the AI—It's Your Information Architecture

Many lawyers trying AI tools find the results underwhelming. After years of intensive AI adoption in practice, we've observed that disappointing outcomes rarely stem from inadequate AI technology. Instead, the problem typically lies in how firms structure their information and workflows before introducing AI—and the sophistication with which lawyers craft AI prompts.

Consider how experienced litigators naturally work. When evaluating a case, we don't examine documents or evidence in isolation. We instinctively connect dots across multiple dimensions—linking factual allegations to procedural requirements, assessing how specific judges have ruled on similar issues, considering the opposing party's litigation history, and evaluating how various legal theories align with our client's broader business interests. This holistic analysis draws on years of accumulated knowledge about how different case elements interconnect.

AI systems need access to similar interconnected information to provide useful analysis. Yet many law firms offer AI tools in a fragmented landscape: separate systems for document storage, disconnected email archives, case management software that tracks deadlines but not strategic context, time-keeping databases with no link to substantive legal work, and research platforms operating in complete isolation from active matters.

This fragmentation represents the fundamental challenge. When AI can only access isolated pieces of information from disconnected systems, it cannot provide the integrated analysis that makes it valuable. It's like hiring a brilliant associate but only allowing them to read one category of documents while keeping everything else locked away.

B. Infrastructure First: The Prerequisite for AI Success

Before worrying about which AI platform to purchase, firms need to examine how information flows—or fails to flow—through their practice. Where do gaps exist? Which systems don't communicate with each other? What critical context gets lost when lawyers manually transfer information between platforms?

The most successful AI implementations share a common characteristic: they occurred in firms that first invested time organizing their information infrastructure. These firms established consistent naming conventions, created centralized matter repositories, developed standardized intake procedures, and built connections between previously siloed systems. Only after laying this groundwork did they introduce AI tools—which then performed remarkably well because they finally had access to the connected information they needed.

Applying our Bayesian framework: P(lawyers will achieve AI competence to maintain their duty of technological competence under ABA Rule 1.1 | The need for a dedicated approach to building smart and communicative data architecture) = the amount of hard work firms are willing to invest in making it happen correctly. In other words, AI competence is less about buying tools and more about doing the unglamorous work—organizing information, standardizing workflows, and training lawyers to use AI with disciplined verification.

This requires investments in unglamorous infrastructure work that doesn't generate excitement at partnership meetings. It means consolidating systems, standardizing processes, and organizing information before deploying the latest AI features. It means teaching teams consistent practices rather than allowing everyone to develop their own disconnected workflows. But firms that make this investment will discover that AI actually delivers on its promise—not because they bought superior AI, but because they finally gave AI the organized, connected information it needs to provide useful analysis.

Part III: Building the Technology Stack

A. The Integrated Daily Workflow

Using your static IT tools and dynamic AI platforms in a coordinated and purposeful way makes all the difference. The typical day usually begins with opening several software systems on your network and internet. This is standard for most lawyers: Outlook, case management software, document management systems, and perhaps legal research platforms depending on the day's plans. What differs is the strategic coordination of these tools with AI platforms to create an integrated workflow.

Important Note on Confidentiality: Do not put any client or case-related data on any public AI platform. However, you can use these platforms to refine language or presentations in a non-named, case-generic way. Enterprise versions with proper data protection agreements may be appropriate for sensitive work, but evaluate each platform's security certifications carefully. You and your firm need an AI Governance Policy and a thorough understanding of your user agreements and Terms of Service agreements with your providers like Westlaw, Lexis, Claude, Gemini and ChatGPT. What attorney client privilege and work product protections do you have when using AI? You need to know!

A practical note: effective AI adoption does not require mastering every platform discussed below. For most defense practices, a workable baseline includes (1) a generative AI tool for analysis and drafting, (2) a closed legal research database with AI augmentation, and (3) a secure document/document management and discovery workflow. Additional tools can add speed and insight, but the baseline framework—and rigorous verification—matters more than any single vendor.

The AI Daily Routine Framework organizes AI integration across the litigation lifecycle. In the outset of a case, use AI for case intake analysis and research planning—front-end loading the research and analysis. For ongoing research, leverage Westlaw Precision AI for legal research and Westlaw Precision "Quick Check" module for brief review. During drafting phases, employ AI-assisted document creation and

editing. For discovery, use Relativity AI for document review batches. Throughout, AI can assist with client communications and memo preparation. The goal is augmenting the legal practice—not replacing it with AI.

B. Essential Platform Components

(The platforms below are examples; firms should evaluate tools based on use cases, confidentiality, integration, jurisdiction, and workflow needs.)

Google Gemini: Regular Google at the premium level provides built-in low-level AI that summarizes search results and provides narrative to focus research. Google Gemini is far more sophisticated and utilizes Deep Thinking Mode to conduct research, draft documents, perform agentic functions, generate images, excel spreadsheets, audio, and multimodal content making it valuable for creating documents, charts, PowerPoints and other presentation materials. It serves as a primary resource for getting started with ideas on legal research projects or quick checks of the law in particular jurisdictions, and as a secondary resource to fact-check other AI-generated content. Various internal modules put Gemini into "Research' mode," "Image Mode," "Video (VEO) Mode," or "Deep Thinking' mode" —useful for complicated prompts where you want to see the reasoning process. Using Google Gemini can create PowerPoint slides from a written presentation that you drafted and will adopt the specific PowerPoint (or Google Slide) format that you instruct it to use. Many people are using ChatGPT in similar ways.

Westlaw Precision AI-Assisted Legal Research with CoCounsel Premier, Westlaw People Map, Company Investigator, Drafting Assistant, and Practical Law AI Connect creates a robust platform that augments legal analytics and client service. General AI tools like Gemini and Claude admit they cannot find certain case opinions and analysis because they lack access to closed databases like Westlaw, Lexis, and Bloomberg Law. This is why working with both generative AI and Westlaw together produces superior work product.

Westlaw produces Litigation Analytics that could never be generated by human legal researchers—even with unlimited time. Research can determine case histories and likelihood of certain rulings by judge. Litigation history, experience level, and results of opposing counsel can be researched. Analytics are available by court, judge, lawyer, and case type. Reports can be downloaded or emailed directly to clients and team members.

An especially important Analytics tool is the 'References' search for opposing counsel. For experienced lawyers, there may be over 1,000 case references from multiple federal and state court dockets where judicial opinions and rulings are posted. Reviewing this history helps evaluate your opponent's capabilities and tendencies regarding types of pleadings filed, results obtained, and experience in various substantive areas.

The Westlaw Precision 'Quick Check' module allows AI analysis of draft briefs or opponents' briefs. It can provide friendly review to strengthen your own brief, adversarial review to critique your brief or your opponent's, or 'Judicial Review' mimicking analysis done by courts or law clerks. Multiple briefs can be entered simultaneously for complete review—like having mock oral argument on the issue.

Claude® by Anthropic has become a workhorse LLM for our legal practice, particularly in business development efforts. Claude can build project-specific databases for legal issues on which you consistently work—IP, patents, trade secrets—and documents, case opinions, and articles can be uploaded for analysis. When writing on a topic, Claude can work within the same database project to analyze and assist. All case citations must then be checked in Westlaw, and certification should confirm that competent human eyes have reviewed all final results. Some courts now require sworn certificates regarding AI use and human review. Claude, Like Gemini, has various modules which allow generation of text, reasoning, presentation materials, slide decks and images.

Microsoft Outlook, Teams, Ring Central, and NetDocs guide the day with basic functions and AI tools. NetDocs stores case files and client documents. Microsoft Teams integrates with Ring Central for communications. Microsoft Copilot assists with programming, management of communications, and video meetings. AI voice recognition generates recordings, notes, and meeting summaries where permitted by law. NetDocs is the backbone of case and document management, while network drives handle large document storage and Relativity manages document review, coding, tagging, and production.

Part IV: Mastering Prompt Engineering

A. The Art of Effective Prompting

A 'prompt' is the instruction or question you give to an AI system. The quality of the AI output from an AI platform depends heavily on the quality of your prompt. This relationship is so direct that an entire discipline—prompt engineering—has developed around optimizing AI interactions.

The fundamental rule: garbage in, garbage out. A vague prompt yields a vague response. Investing time crafting detailed prompts produces substantial returns. Several techniques in prompting the model dramatically improve results:

- **Be specific:** "Analyze this attached contract for indemnification clauses under Pennsylvania law" produces far better results than "review this contract."
- **Provide context:** "I am a defense attorney reviewing a lawsuit claiming breach of fiduciary duty" - helps the AI calibrate its response appropriately.
- **Set format instructions for the model:** "Provide your answer in bullet points" or "structure your response as a memo" guides AI output organization.
- **Chain-of-thought:** "Think step by step" prompts the AI to show its reasoning, often improving accuracy on complex analysis.
- **Set memory instructions:** "Always number (v.1 v.2) and show the date of the draft on each version of any document you create for me" establishes persistent preferences.

B. Legal-Specific Prompting Strategies

Legal work demands specialized prompting approaches. For jurisdiction specification, always identify the relevant jurisdiction: "Under California employment law..." or "Applying Federal Rule of Civil Procedure 56..." Without this specification, AI may draw from multiple jurisdictions or cite inapplicable precedent.

For fact pattern analysis, structure prompts to separate facts from legal questions: "Given these facts: [facts]. Analyze

the following legal issues: [issues]." This mirrors the analytical structure of legal memoranda and produces more organized output.

For risk mitigation, prompt for counterarguments: "What are the strongest arguments against this position?" or "What facts would most undermine this defense?" AI excels at adversarial analysis when specifically prompted.

Quality control through iterative prompting is essential. After receiving initial output, follow up: "Are there any exceptions to this rule?" or "What additional cases support this analysis?" Multiple rounds of prompting typically produce more comprehensive and accurate results than single-shot queries. The output can be graded by you with thumbs up or thumbs down buttons and the chance to submit written comments in response to output. This is human level training of AI.

C. Trade Secret Forensics: The Confidentiality-First Protocol

In the high-stakes environment of trade secret litigation, prompt engineering evolves from a drafting convenience into a litigation-support and risk-assessment tool. When defending against an expedited TRO or managing a departing employee dispute, the ability to rapidly correlate technical behavior with statutory elements—such as whether a company employed "reasonable measures" to protect its information—can provide a meaningful strategic advantage. Structured prompts can be used to perform a targeted "gap analysis" between raw forensic findings and the legal standards that will govern emergency relief, discovery disputes, and early dispositive motion practice.

At the same time, AI-assisted trade secret analysis presents heightened confidentiality and privilege risks. To leverage AI without waiving privilege or jeopardizing the trade secret status of the asset itself, defense counsel must operate under a confidentiality-first protocol. This typically requires either the use of a closed-universe, enterprise AI platform governed by a negotiated data protection agreement (such as System and Organization Controls SOC 2-compliant systems), or a rigorous sanitization workflow. Under a sanitization approach, all personally identifiable information and proprietary technical details are scrubbed, and the AI is used to analyze the structure, sequence, or logic of the conduct at issue—rather than the sensitive data itself.

Practice Tip: This approach allows counsel to benefit from AI-assisted pattern recognition and analytical acceleration while preserving privilege, maintaining ethical compliance, and avoiding inadvertent disclosure of the very assets the litigation seeks to protect.

Part V: AI-Enhanced Legal Research—The Front-End Protocol

A. Priming the Research Pump

The 'front-end research protocol' transforms case assessment by quickly conducting initial legal analysis to prime the research pump at minimal client cost and create more accurate strategic assessments. Upon case opening, the scope of legal research can be determined in minutes and a full preliminary report on relevant case law by jurisdiction or judge can be emailed to team members to be checked by a human reviewer and expanded upon as the case moves forward.

Rather than sending an associate on a random search, client money can be saved and better results produced by assigning research that has already been jumpstarted for the case in general or for a specific Motion to Dismiss or Motion for Summary Judgment. This front-end approach allows litigation teams to make more accurate predictions to clients at the outset, getting analysis moving forward efficiently.

The research pump can be primed at very little cost, and strategic case assessments can be created and more quickly agreed upon. Coordination between AI platforms and closed legal databases produces superior work product. The discipline to work cross-platform ensures research accuracy and excellent writing.

B. Litigation Analytics for Strategic Advantage

Westlaw Litigation Analytics provide intelligence that informs deposition and trial strategy. Judge analytics reveal patterns in rulings, motion grant rates, and time to disposition. Opposing counsel analytics expose litigation tendencies, preferred strategies, and historical success rates.

This analytics capability enables preparation that was previously impossible. Before taking a deposition, you can review how the opposing attorney has conducted prior examinations. Before filing a motion, you can assess how the assigned judge has ruled on similar motions. Before trial, you can understand the judge's preferences and the opposing counsel's trial record.

Use AI to brainstorm defenses, test case theories, and evaluate litigation strategy while being very careful to maintain work product privilege. The AI and privilege issue have become a hot button topic which we will write about in depth down the road. The iterative process of prompting AI, reviewing output, and refining analysis often surfaces considerations that might otherwise be missed in traditional research.

Part VI: Discovery in the AI Era

A. Managing Massive Document Projects

Managing large document projects for gathering, housing, sorting, batching, reviewing, coding, tagging, and producing documents is an art. The plan and likely cost must be included in the first substantive conversation with a client. This process management by a lawyer is a valuable skill because if done right, it often gives your side a huge advantage if the other side is not so savvy with large document management.

If it goes wrong, it can spoil a case both on the cost side and the results side. It also impresses judges when defending your discovery compliance, if it is challenged. Judges now mandate and enforce detailed written ESI protocols as a routine part of federal cases and have little tolerance for sloppy or old-style document management.

Many firms work with dedicated e-discovery vendors rather than housing Relativity in-house. The advantages include large staffs in multiple time zones available to create and customize searches and productions. At the front end of a trade secret misappropriation case, for example, vendors forensically examine, download, and maintain chain of custody of all relevant data—like that of a departing employee believed to have downloaded company con-

fidential information. AI can work both on the forensic end, and the document production end of the process.

B. Active Learning AI in Document Review

Technology-assisted review, including TAR 2.0 continuous active learning systems and generative AI review tools, reduces massive document sets to likely responsive documents through pattern recognition and feedback. AI Active Learning in Relativity continually refocuses on the most important and most likely responsive documents, eventually feeding only the most relevant materials to reviewers.

The goal is to meet a certain probability percentage that sufficient relevant or responsive documents have been gathered to comply with discovery rules and pass muster with opposing counsel or the court. These statistics vary depending on the case and the volume and nature of documents. The AI recognizes patterns and provides feedback and reports that enable supervisory review of the process.

If AI reduces a database from 3,000,000 pages to 1,000,000 pages of the most likely relevant and responsive documents, it makes a huge difference in both review time and cost. Using AI in this context, while somewhat expensive, is a financially accretive process for clients—it allows discovery time periods not to be consumed simply by document review.

Document review can be done more efficiently with reports showing the pace of review, the number of 'hot docs' or 'privileged' designations, and tagging by issue or witness. All of this work makes preparation for depositions and trials much more efficient and less costly.

Part VII: AI for Depositions and Trials

A. Deposition Preparation

AI tools can assist throughout the deposition process while understanding critical limitations. For outline generation, AI can draft initial deposition outlines based on pleadings, discovery responses, and case themes. Prompt the AI with key facts and issues, then refine the generated outline with your strategic insights. AI accelerates preparation, but it cannot supply the lawyer's theory of the case. Without a clear theory—what matters, what doesn't, and why—AI will simply help you prepare faster in the wrong direction.

For anticipated responses, AI can predict likely answers based on party positions and generate follow-up questions for various response scenarios. This preparation enables more dynamic examination. For cross-examination planning, AI can identify inconsistencies in prior statements, flag documents that contradict anticipated testimony, and suggest impeachment strategies.

AI tools for witness preparation include mock examination scenarios where the AI plays the examining attorney. This helps witnesses prepare for various questioning approaches while maintaining the human coaching essential to effective testimony.

B. Trial Practice Applications

Jury research and selection analytics leverage AI to analyze juror questionnaire responses, social media profiles (where permitted), and demographic patterns. Trial theme development benefits from AI's ability to test multiple narrative frameworks and identify resonant language.

Use AI to test cross-examination strategies by prompting it to argue the opposing position. Prepare closing arguments by asking AI to identify the strongest points for each side. Create compelling demonstrative evidence with AI assistance in data visualization and graphic design.

Bayesian probability frameworks (spoken in plain English) can help educate juries on complex technical evidence. As discussed in Part 1, jurors already think probabilistically; framing evidence in these terms can improve comprehension of AI decision-making and algorithmic processes.

Navigate judicial acceptance of AI tools while maintaining courtroom authenticity. The human connection essential to persuasion cannot be delegated to AI. Used well, AI improves preparation and testing; used poorly, it produces polished themes that are untethered to admissible proof and courtroom reality. Successful trial lawyers use AI for preparation and analysis while ensuring that courtroom presentation remains genuinely human.

Part VIII: Professional Responsibility and Firm Governance

A. Ethical Obligations

ABA Model Rule 1.1's technology competence requirement now encompasses AI. Lawyers must understand AI tools sufficiently to use them competently or avoid using them altogether. Model Rule 1.6 requires protecting client confidential information—never upload confidential client data to public AI platforms without proper data protection agreements. Examine your Terms of Service and Confidentiality Agreements with all AI products and make determinations as to whether the AI model is using your data to improve the LLM. Use of your data by the AI provider can be adjusted by you in the Settings tabs.

Courts are increasingly requiring AI use certifications. Some judges mandate disclosure of AI assistance in filings. Know your jurisdiction's requirements and document your process for demonstrating competent AI use. Verification of AI outputs is not optional—it is a professional responsibility requirement. As discussed in Part I, the safest approach is to treat AI output as a starting point: confirm authorities in Westlaw/Lexis, confirm quotations and pin cites, and maintain a documented review process. We will write more about the ethical issues in subsequent articles and in our Defending the Algorithm™ series.

B. Building Firm AI Governance Frameworks

Comprehensive governance structures for AI implementation include firm-wide AI policies and procedures, oversight and accountability structures, and defined roles and responsibilities for AI supervision. Client communication and transparency protocols manage expectations regarding AI use. You should discuss AI use with your clients and you may need language in your engagement agreements to cover the use of AI.

Successful AI governance frameworks address the information architecture challenge: connecting previously siloed systems before introducing AI tools so they can access the interconnected information needed for useful analysis. Documentation requirements demonstrate competent AI oversight and build defensible workflows.

Within five years, lawyers who competently use AI tools will be the norm rather than the exception.

Training programs should address use cases, ethics, attorney-client privilege implications, and prompting techniques. Regular updates incorporate emerging best practices and new tool capabilities. Governance is not a one-time exercise but an ongoing commitment to responsible AI integration.

Practice Tip: Westlaw Precision Practical Law module has a tremendous amount of AI-related material, checklists and forms for use in crafting AI governance policies and training protocols.

Part IX: Cost Considerations—Is AI Accretive or Just Efficient?

While remaining mindful of litigation spend for clients, some dynamics have changed due to AI tools. More front-end legal research can now be done to start team analysis, and more document review can be conducted—albeit at higher levels of review—depending on volume and complexity. This can be done in a very quick and cost-effective way even by a partner.

Front-end research to set parameters for more detailed research on complex commercial and IP matters is now possible at very little cost. For example, in a complex commercial case with millions of documents, modest up-front spend on analytics and targeted AI-assisted workflows can materially reduce downstream review populations and attorney hours—often lowering total discovery cost even if early-stage spend increases slightly. The research pump can be primed inexpensively, and strategic case assessments can be created more quickly. Document review in Relativity takes far less time than traditional paper-based review methods.

AI has fundamentally transformed the efficiency of legal teams through both research and writing tools and predictive analytics. While precise cost analysis varies by matter, the direction is clear: thoughtful AI implementation reduces costs while improving outcomes. The competitive advantage is due to firms that invest in proper infrastructure and training. Being able to tell a client with more certainty what the cost of massive document production will be is essential to a good client relationship.

Conclusion: The AI-Competent Lawyer

The legal profession stands at an inflection point regarding AI adoption. Within five years, lawyers who competently use AI tools will be the norm rather than the exception. The question facing today's practitioners isn't whether to adopt AI but how to do so responsibly while fulfilling professional obligations.

Hopefully, this practicum demonstrated that thoughtful AI integration—particularly with attention to information organization, prompt engineering, and verification protocols—can significantly enhance legal practice without compromising professional responsibilities. The key insight: treating AI as a powerful tool requiring both professional supervision and proper information infrastructure coordinated with IT professionals and ethics lawyers.

The specific tools matter less than the framework for thinking about AI adoption: enhance efficiency while maintaining competence, protect confidentiality, verify AI output, invest in organizational infrastructure, use predictive analytics for strategic advantage, and preserve the professional judgment that distinguishes lawyers from mere document production services.

The path forward requires neither blind adoption nor resistant skepticism, but thoughtful integration that serves clients while fulfilling our professional responsibilities. Those who invest in understanding both the technology and the frameworks governing it—who master prompt engineering, understand the interplay between generative AI and verified databases, and build proper infrastructure—will be best positioned to serve clients in this rapidly evolving landscape.

To conclude in Bayesian probability terms: P(infrastructure organization being essential | evidence of competitive advantage from AI) = Very High. Welcome to the future of defense practice—one where AI assists but doesn't replace the human judgment, ethical reasoning, and client relationship management that define our profession.

Initial Objectives, Strategies, and Tactics for Defending Authorized Generic Distributors in Pharmaceutical Litigation

By P.J. Cosgrove and Kevin M. Bandy

There are clear strategies and tactics that support the objective of early dismissal and confined discovery for those representing AG distributors.

Federal preemption is one of the most powerful tools available to attorneys defending a generic pharmaceutical client in product liability litigation. It perhaps is unsurprising that plaintiffs' attorneys continue seeking ways to chip away or evade this defense. One front in the evolving war to preserve generic preemption involves a category of drug products that is, in our experience, a misunderstood one: the authorized generic ("AG"). While an AG drug product may appear at first blush to be in a unique category among the generic drug industry, ultimately, the legal defenses available to companies that distribute AG products will be familiar to defense practitioners.

This article explores the nature of AG drug products, provides a broad overview of the existing state of generic drug preemption law, assesses how differences in state law can impact an AG distributor's defenses beyond preemption, describes the authors' experiences in defending an AG distributor defendant in Multidistrict Litigation ("MDL"), and concludes by describing initial strategies and tactics for mounting an effective early defense of an AG distributor defendant.

Introduction to Authorized Generics

An AG drug product is chemically identical to a brand name drug, and shares the same active ingredient(s), dosage form, strength, route of administration, indications, and labeling (with certain permissible differences, such as including a distributor's trade dress). *FDA List of Authorized Generic Drugs*, ***https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs*** (last visited Jan. 12, 2026). Although chemically identical to a brand name drug product, an AG drug product differs from a brand name product in that the AG product is sold and distributed *without* the brand name on its label, even though it is marketed under the brand name drug's New Drug Application ("NDA"), either by the brand name drug company itself or by another company with the brand name company's permission. *Id.* This article addresses the latter category.

It goes without saying that the objective of an AG distributor in product liability litigation should be two-fold: firstly, to obtain dismissal, and secondly, if necessary, to avoid or limit discovery when possible.

Strategic Overview: Preemption

The preemption doctrine is, at bottom, an application of the U.S. Constitution's Supremacy Clause, which states that the laws of the United States "shall be the supreme Law of the Land; …any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

To understand how an AG distributor can utilize a preemption defense, we begin with a brief overview of the regulatory approval process for brand name and generic drug products and preemption case law applicable to drug manufacturers and distributors. This area of the law is complex and far-reaching. Our discussion below is intended to be high-level and non-exhaustive.

Prescription drugs are regulated under the federal Food, Drug & Cosmetic Act ("FDCA"), which is implemented and enforced by FDA. *See* 21 U.S.C. §§301 *et*

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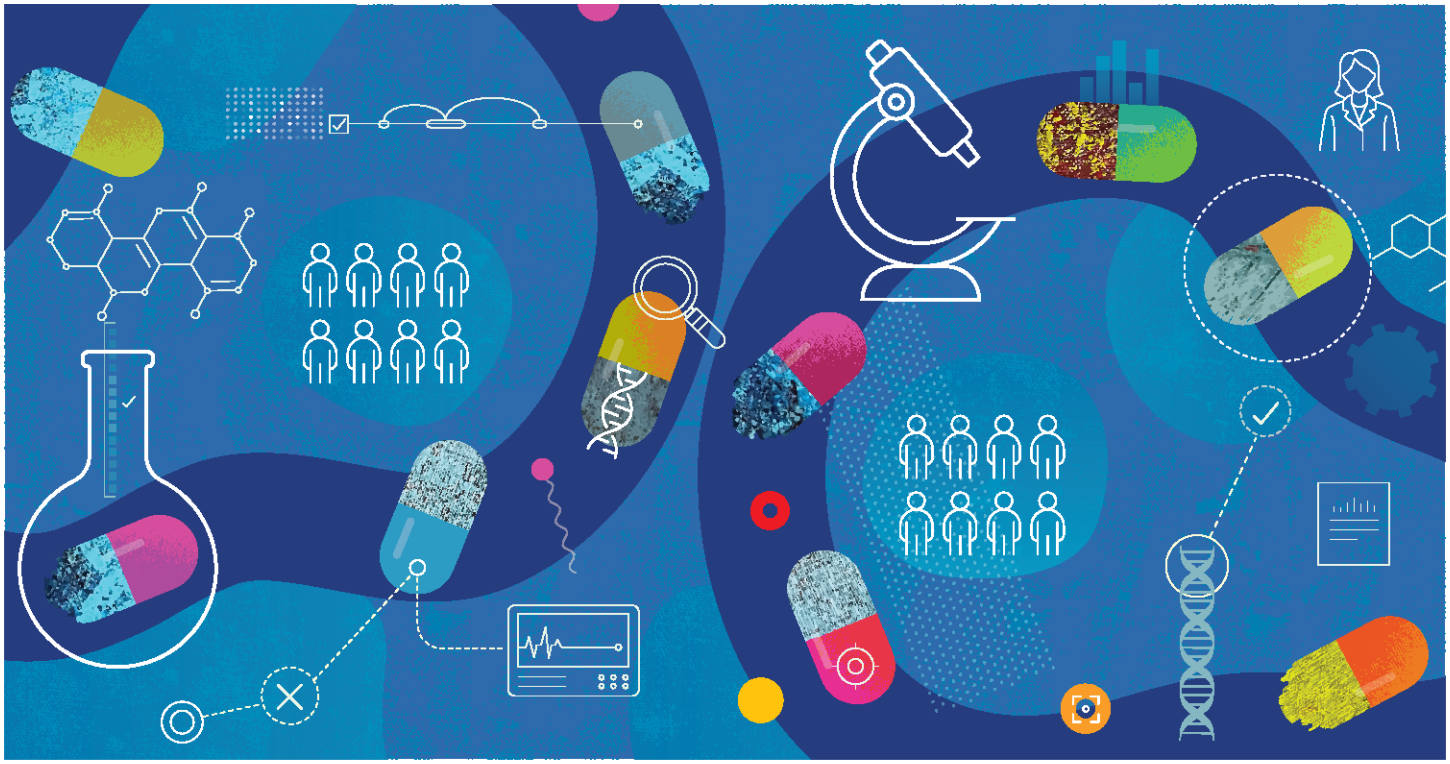

seq.; *id.*, §§ 371, 393. No drug product may be marketed in interstate commerce without an FDA-approved application to do so. 21 U.S.C. § 355(a). There are two distinct regulatory pathways for a manufacturer to pursue before it can lawfully sell or distribute a drug product in the U.S.: the NDA pathway, through which FDA considers and approves a *new* drug product; and the Abbreviated New Drug Application ("ANDA") pathway, through which FDA approves *generic* formulations of an already approved drug product. As a general matter, a manufacturer may obtain ANDA approval to manufacture and sell generic drug products only after the patent on the brand name product either has expired or otherwise has been deemed invalid. *See generally* 21 C.F.R. § 314.197.

Preemption of Claims Against NDA Holders

An NDA is the regulatory mechanism through which a drug manufacturer applies for FDA approval to manufacture and sell a new pharmaceutical product. 21 U.S.C. § 355. The NDA process is extensive and requires an applicant to show FDA that, among other things, the proposed drug is safe and effective for its proposed uses, the benefits of the drug outweigh the risks, the proposed labeling and its contents are appropriate, and that the proposed manufacturing methods are adequate to preserve the drug's identity, strength, quality, and purity. 21 U.S.C. § 355(d). After FDA approves an NDA, a manufacturer cannot change the qualitative or quantitative formulation of the drug without prior FDA approval. 21 C.F.R. § 314.70(b)(2)(ii). Despite that prior approval requirement, FDA may exercise its enforcement authority to permit a manufacturer to make certain changes to the labeling of an approved drug, without prior FDA approval, through the "Changes Being Effected" ("CBE") regulation, under extremely limited circumstances. *See* 21 C.F.R. §314.70(c)(6)(iii); *Supplemental New-Drug Applications*, 30 Fed. Reg. 993, 993-94 (Jan. 30, 1965); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 177 (S.D.N.Y. 2016). The CBE regulation allows a manufacturer to change an approved label to, among other things, add a warning only for which there is sufficient "reasonable evidence of a causal association." 21 C.F.R. §§ 314.70(c)(6)(iii)(A), 201.57(c). Labeling changes pursuant to the CBE regulation only may be made on the basis of "newly acquired information." *Id.* § 314.70(c)(6)(iii); *id.* § 314.3. FDA may reject any labeling change made pursuant to the CBE regulations. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Post-approval proposed changes to a drug's labeling or design must be submitted by the NDA holder as a supplement to the NDA. 21 C.F.R. §§ 314.70(a)(1)(i), 314.71(a).

The U.S. Supreme Court addressed preemption of state law claims against brand name drug manufacturers in *Wyeth*, 555 U.S. 555, and *Merck Sharp & Dohme Corporation v. Albrecht*, 587 U.S. 299 (2019). Read together, these cases and their progeny establish a two-step preemption analysis for state-law failure to warn claims asserted against brand name drug manufacturers: first, the plaintiff must show the existence of newly acquired information that could support a CBE labeling change; and second, even if there is proof of newly acquired information, a failure to warn claim still is preempted if there is "clear evidence" that the FDA would not have approved the warning a plaintiff claims state law requires. *Albrecht*, 587 U.S. at 310; *Wyeth*, 555 U.S. at 571. *See also, e.g., Lyons v. Boehringer Ingelheim Pharmas., Inc.*, 491 F. Supp. 3d 1350, 1363-64 (N.D. Ga. 2020) (noting that absent a showing of newly acquired information, failure to warn claims are preempted); *Gayle v. Pfizer, Inc.*, 452 F. Supp. 3d 78,

87-89 (S.D.N.Y. 2020) (granting judgment on the pleadings on failure to warn claim against brand name manufacturer where plaintiffs did not allege the existence of newly acquired information that could support a CBE, so failure to warn claim was preempted).

Preemption of Claims Against Generic Drug Manufacturers

Manufacturers seeking to manufacture, sell, and distribute *generic* drugs must submit an ANDA and demonstrate to FDA that their proposed drug product is bioequivalent to the brand name drug. 21 C.F.R. §§ 314.70(a)(7). Importantly, federal law also requires that the warnings that accompany a generic drug product must at all times be identical to the FDA-approved warnings that accompany a brand name drug. 21 C.F.R. §§ 314.94(a)(8), 355(j)(10)(A)(iii). The U.S. Supreme Court has twice ruled on preemption of state law product liability claims against generic drug manufacturers and made clear that state law claims are preempted if they would require a party to do what federal law prohibits it from doing.

First, in *PLIVA v. Mensing*, 564 U.S. 604 (2011), the U.S. Supreme Court held that state law failure to warn claims against generic drug manufacturers were preempted because such claims would require the manufacturers to do under state law what federal law prohibited them from doing – independently changing the generic drug's labeling. *See Mensing*, 564 U.S. at 614. The Court confirmed generic manufacturers owe a "duty of sameness," noting that FDA regulations prohibit generic manufacturers from independently changing safety labels. Id. at 613, 617. Because the state law in Mensing would have required the generic manufacturer defendants to independently change the label of the generic drugs at issue to include stronger warnings than what FDA had approved as to the brand name drug, the Court held federal law preempted the plaintiffs' claims because generic manufacturers could not comply with both state and federal requirements. *Id*. at 610-11. The Supreme Court also rejected the plaintiffs' arguments that their claims were not preempted because the generic drug manufacturers could have "taken steps" to alert a third party to the need for stronger warnings. *Id*. at 620-26. This was so because, the Supreme Court noted, a party (i.e., a generic drug manufacturer) cannot undertake an action independently if it ultimately requires approval by a third party (i.e., FDA). *Id*. at 623-24.

Second, in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), the Supreme Court again emphasized that federal law imposes a "duty of sameness." *Id*. at 477. This time, the Supreme Court held that state law design defect claims aimed at pharmaceutical products are preempted. *Id*. at 486-87. The Court held that redesign was not feasible for two reasons: first, federal law mandates that generic drugs match the brand name drug in active ingredients, dosage form, strength, and labeling; and second, an FDA-approved drug formulation cannot be reformulated without prior FDA approval. *See id*. at 483-84.

In sum, *Mensing* and *Bartlett* hold that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes." *Mensing*, 465 U.S. at 623-24.

Preemption of Claims Against Drug Distributors

While there are no Supreme Court cases squarely addressing preemption of design and labeling defect claims against distributors, lower federal courts routinely apply *Wyeth, Mensing*, and *Bartlett* find that such claims are, in fact, preempted.

These decisions are not surprising. Federal law contains no mechanism under which a distributor of an approved drug – whether approved through an NDA or ANDA – that does not hold the drug's NDA can independently alter a drug product's labeling. *See, e.g., Marroquin v. Pfizer Inc*., 367 F. Supp. 3d 1156, 1169 (E.D. Cal. 2019) (recognizing that "entities that merely distribute prescription drugs, be they generic…or brand-name prescription drugs" lack the ability to change an FDA-approved label and collecting cases holding the same); *Brazil v. Janssen*, 196 F. Supp. 3d 1351 (N.D. Ga. 2016) (granting motion to dismiss design defect and failure to warn claims where defendant was not the NDA applicant and could not "independently do under federal law what state law requires of it"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 2012 WL 181411, *3-4 (D.N.J. Jan. 17, 2012) (claims against brand name drug distributor that did not hold NDA were preempted), *aff'd by In* re *Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150 (3d Cir. 2014); *In re Zantac (Ranitidine) Prods. Liab. Litig*., 510 F. Supp. 3d 1234, 1250-51 (S.D. Fla. 2021); *Smith v. Teva Pharms*., 437 F. Supp. 3d 1159, 1161, 1165 (S.D. Fla. 2020).

We identify one outlier for consideration. In *Eike v. Allergan, Inc*., 2014 WL 1040728 (S.D. Ill. Mar. 18, 2014), plaintiffs alleged the distributor defendants (among others) violated state consumer protection laws by selling prescription eyedrops in bottles with droppers that produced eyedrops too big for the eye, which created "runoff" of the eyedrop and caused plaintiffs to spend more money on prescription eyedrops than they would have with a different sized dropper. *Id*. at *1. The distributor defendants argued plaintiffs' claims were preempted. *Id*. at *5. The court denied the distributors' preemption motion, holding it required a full factual record to determine whether federal law permitted the distributors to independently change the dropper size on the eye drop bottles without prior FDA approval. *Id*. at *5. *Eike* therefore stands out in a sea of favorable preemption rulings for distributors, but the specific nature of the claims – that the distributors could change the size of the dropper on prescription eyedrop bottles they distributed – distinguishes the facts of *Eike* from traditional product liability suits.

Thus, the primary question for preemption of design and labeling defect claims against a drug distributor (whether brand name or generic) is not whether it distributed a brand name or generic drug, but whether it held the brand name drug NDA at the time relevant to a plaintiff's lawsuit. The authors are unaware of any case asking a different question in the context of AG distributors.

Differences in State Law Can Impact an AG Distributors' Defenses

Individual state's laws may impact defenses available to an AG distributor. We discuss a few examples below.

Strict Product Liability Claims Against Distributors

State law can vary greatly as to the viability of strict design or labeling defect claims against pharmaceutical product distributors. In California, for example, strict liability design defect claims in the prescription drug context are unequivocally barred. *Brown v. Superior Court*, 751 P.2d 470, 476-79 (Cal. 1988). Relatedly, while California does not recognize strict liability claims asserted against prescription drug retailers, California state courts have not yet definitively extended (or declined to extend) this protection to distributors, and federal decisions go both ways. *Compare, e.g., In re Rezulin Litig.*, 2003 WL 2558915, *1 (C.D. Cal. Apr. 28, 2003) (finding distributor of FDA-approved prescription drug was not subject to strict liability failure to warn claim), *with Dodich v. Pfizer Inc.*, 2018 WL 3584484, *3 (N.D. Cal. July 26, 2018) (holding "California law remains ultimately unsettled" on issue of whether distributors can be strictly liable for failure -to warn). It is worth noting, however, that courts finding an ambiguity in this area typically do so in the fraudulent joinder context, where a federal district court must assess whether a plaintiff has no possibility of recovery and must construe state substantive law in favor of remand. *See, e.g., Maher v. Novartis Pharmas. Corp.*, 2007 WL 2330713, *4-5 (S.D. Cal. Aug. 13, 2007) (remanding case to state court because removing defendant did not meet "heavy burden" of showing strict liability failure to warn claim against drug distributor was not viable as a matter of settled California law); *In re Abilify (Aripiprazole) Products Liability Litigation*, 2018 WL 6258903, *3-4 (N.D. Fla. Nov. 8, 2018) (granting remand because of "unsettled" question of whether California law permits strict liability failure to warn claims pharmaceutical distributors and finding no fraudulent joinder). Thus, while the question of whether pharmaceutical distributors can be subject to strict liability claims in California remains unsettled, particularly when viewed in a fraudulent joinder context, there is good reason to make the argument in a different procedural setting, including on a Rule 12 motion to dismiss.

Defense counsel also should consider whether particular jurisdictions have statutory product liability acts limiting or abrogating strict liability product liability claims, whether states have adopted Comment k of Section 402A of the Restatement (Second) of Torts, or whether there are other judicially imposed limitations on such claims when directed at pharmaceutical (or other) products. *See, e.g.*, Ohio Rev. Code § 2307.71(B) (abrogating all common law product liability claims); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (adopting Comment k as a matter of Utah law, and holding that FDA-approved drugs are unavoidably unsafe and that sellers of such drugs cannot be strictly liable for alleged design defects); *Brown*, 751 P.2d at 476-79 (adopting judicially imposed prohibition on strict liability design defect claims in prescription drug context).

Innocent Seller Statutes

Innocent seller (or closed container) statutes also may provide jurisdiction-specific defenses. These statutes typically protect sellers or distributors of a product from liability when they have no knowledge of an alleged defect and did not contribute to the product's design or manufacture. For example, Delaware's statute (Del. Code Ann. tit. 6, § 2501I) provides a total defense to a distributor if the seller acquired and sold the product in a sealed container, had no knowledge of the defect, could not have discovered it through reasonable care, and did not alter or mishandle the product. Similar statutes exist in numerous states, including Alabama, Colorado, Georgia, Idaho, Illinois, Iowa, Kansas, Kentucky, Maryland, Minnesota, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Texas, Washington, and Wisconsin. Where available, innocent seller statutes can be a powerful pre-answer basis for dismissal of a distributor of any product, including drug products.

The Learned Intermediary Doctrine

The learned intermediary doctrine has been adopted in nearly every U.S. jurisdiction. While the exact contours of the doctrine vary state to state, as a general matter, under the learned intermediary doctrine, a prescription drug manufacturer (or supplier) owes the duty to warn about a drug's alleged risks to the prescribing physician, not the patient, and may be liable for an alleged failure to warn only if different warnings to the prescribing physician would have altered the decision to prescribe the drug at all and a plaintiff's injuries would have been avoided. *See, e.g., Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 156 (Tex. 2012). The learned intermediary doctrine typically is available to *manufacturers* of prescription drugs, but it also may be applicable to sellers of those drugs. *See, e.g., Walton v. Bayer Corp.*, 643 F.3d 994, 1000 (7th Cir. 2011) (applying Illinois law; recognizing it would be "senseless" to require drug sellers to require sellers to warn end-users of risks of every drug they sell and limiting duty of seller to warn a patient or physician only if it knows of a particular patient's susceptibilities).

The learned intermediary doctrine also may cut off causation if a plaintiff fails to allege or present evidence that a prescribing physician reviewed or otherwise relied on a drug's labeling and warnings before prescribing it. *See, e.g., Fields v. Mylan Pharmas., Inc.*, 751 F. Supp. 2d 1260, 1263 (N.D. Fla. 2009). In such a case, different warnings or labeling would not have led a physician to prescribe a different drug, and a drug's labeling or warnings could not play a causal role in a plaintiff's alleged injuries. *Id.* AG distributor defendants should develop pleadings-based arguments that attack a plaintiff's failure to allege that a prescribing physician saw and relied on the AG distributor's label (and not only the brand name manufacturer's label) in prescribing the AG drug and, if necessary, develop discovery from prescribing physicians that he or she did not review or rely on an AG's labeling in deciding to prescribe a drug.

Recent MDL 3140 Experience

With that overview, we discuss the experience of the AG distributor defendants in *In re: Depo-Provera (Depot Medroxyprogesterone Acetate) Products Liability Litigation*, 3:25-md-3140-MCR-HTC (N.D. Fla.).

The Depo-Provera MDL plaintiffs allege that Depo-Provera, the brand name for depot medroxyprogesterone acetate ("DMPA") and its authorized generic form, causes the development of intracranial meningiomas. Plaintiffs to date have determined not to name ANDA-holding generic manufacturers of DMPA, but

instead focused on Pfizer and AG distributors Prasco, LLC, and Greenstone LLC (to which Pfizer supplied, at various times, AG DMPA that Pfizer had manufactured, packaged, and labeled for distribution through generic drug channels). Plaintiffs allege that Depo-Provera and DMPA were defectively designed in that the drug, as formulated, could cause development of intracranial meningioma, and that all defendants failed to adequately warn of the risk of meningioma. On February 14, 2025, the Judicial Panel on Multidistrict Litigation created an MDL and assigned it to Judge M. Casey Rodgers. At the first case management conference, Judge Rodgers selected five "pilot cases" to proceed through discovery and trial through which the parties and the Court would accomplish the "work of the MDL." Under this pilot case method, Pfizer and the AG distributor defendants would respond to the individual complaints in the pilot cases, identify and achieve disposition of common defenses and issues (including preemption and general causation), and engage in case-specific discovery to vet and narrow MDL-wide issues.

Judge Rodgers entered a case management schedule with an expedited "Phase One" discovery period in the pilot cases that included 120 days for "preemption" discovery and 180 days for "general causation" discovery, with document productions to be completed within 45 days. These compressed timeframes posed a dilemma for the AG distributor defendants – would filing and briefing a Rule 12 motion on preemption ultimately save them the burden and expense of participating in "Phase One" discovery? The AG distributor defendants ultimately determined to answer, rather than move to dismiss, the operative complaints in the pilot cases. Discovery proceeded immediately.

Despite the AG distributor defendants' decision to forego Rule 12 motions, however, Judge Rodgers recognized early on there was a fundamental problem with plaintiffs' claims against Prasco and Greenstone: neither entity currently holds, and has never held, the Depo-Provera NDA. The AG distributor defendants had communicated this fact to plaintiffs and Judge Rodgers early and often, including at the parties' Rule 26 conference, in the Rule 26 report filed with the MDL court, and at the initial MDL case management conference. This led to questions at the MDL's second case management conference – just one month after the MDL was formed – as to whether there were any viable design and labeling based claims that could be asserted against the AG distributor defendants. At the conference, in discovery and in subsequent court-monitored meet and confer sessions, and in a subsequent written order, Judge Rodgers ordered the AG distributor defendants to provide plaintiffs' leadership with an affidavit of "non-involvement" addressing whether the AG distributor defendants had sufficient involvement with Depo-Provera/DMPA to remain in the litigation at all. The AG distributor defendants provided those affidavits to plaintiffs' leadership in parallel to their ongoing discovery efforts.

Ultimately, the AG defendants secured their voluntary dismissal from the MDL. Prasco was dismissed by order on June 12, 2025, and Greenstone on June 21, 2025. In addition, Judge Rodgers established a show-cause procedure to deal with going-forward cases naming Prasco or Greenstone after entry of each defendant's respective orders.

Tactics for Defending AG Distributors

The MDL 3140 experience provides key insights into the initial objectives, strategies, and tactics, and that drive the defense of an AG distributor in product liability litigation, including the primary objective of securing early dismissal.

Early Education of Plaintiffs' Counsel of an AG Drug Product's Regulatory Status and Role in Supply Chain

There were early misunderstandings in the plaintiffs' bar regarding the role of an AG distributor in the supply chain and the statutory framework applicable to the AG drugs they distribute. Because an AG is "marketed under" the brand name manufacturer's NDA, and is chemically identical (not just bioequivalent to) a brand name drug, some plaintiffs' counsel were initially under the impression that an AG distributor operated "as though" it held the Depo-Provera NDA, or that they simply could have requested the NDA holder to undertake a labeling or design change. Of course, FDA regulations do not permit any entity other than the NDA holder to act "as though" it held the NDA, and the U.S. Supreme Court has expressly rejected the argument that a defendant should have "taken steps" to benefit from a generic preemption defense.

Early education that an AG distributor does not hold an NDA for the AG drug product it distributes, assuming that to be true, may begin an early shift of perspective away from the AG distributor defendant and lay the groundwork for preemption.

Establish the Generic Preemption Defense Early and Often

Defense counsel should emphasize the applicability of the generic preemption framework early and often, both to plaintiffs' counsel and all courts where the lawsuit is pending. It likewise is important to distinguish for case management purposes, including as to responsive pleading planning, between an AG distributor's anticipated generic preemption argument (a purely legal issue that can be resolved without discovery, or possibly minimal discovery) and a brand name preemption argument (which may require discovery). Drawing a line between those two arguments may help fast-track an AG distributor's preemption motion at the pleading stage and stave off arguments from plaintiffs that the preemption motion cannot be resolved without discovery, and need not be tracked with the NDA holder's preemption motion.

In the context of MDL 3140, the AG distributor defendants took every early opportunity to highlight the nature of their preemption defense, including at the first MDL case management conference, the parties' Rule 26 meeting, and the Rule 26 report. This strategy led Judge Rodgers to question whether the AG distributor defendants belonged in the MDL at all, leading to the affidavit process described above, which ultimately allowed for a dismissal from the MDL that followed from initial discovery and an expedited order to show cause process as a feature of case management in the MDL.

Aggressive Rule 12 Motion Practice, Where Feasible

AG distributor defendants should push for early resolution of a Rule 12 motion to

dismiss design and labeling defect claims wherever feasible and entirely avoid engaging in burdensome discovery, if possible. While a generic preemption motion to dismiss presents a purely legal question, there may be times when a plaintiff says nothing at all about what entity manufactures an AG drug product, or may even erroneously allege the AG distributor itself manufactures the AG drug product it distributes. FDA's approval of an NDA is a matter of public record, and the FDA maintains an online database of regulatory approvals for drug products, including which entities hold either the NDA or an ANDA. Therefore, AG distributor defendants can correct any plaintiff's error, or fill in or correct information gaps in a complaint, without discovery and in the context of pre-answer motion briefing. It is entirely appropriate for a court to take judicial notice of FDA's website making clear that an AG distributor does not hold a brand name drug's NDA. *See, e.g., Hernandez*, 582 F. Supp. 3d at 1200-01 (taking judicial notice of records from FDA's website, including identity of a brand name drug's NDA holder).

In MDL 3140, a number of factors led the AG defendants to the conclusion that a Rule 12 motion was infeasible under the circumstances of that particular litigation. Given plaintiffs' relative confusion on the nature of AG drug products, they likely would have opposed a preemption motion to dismiss arguing that they needed discovery, even though the AG distributor preemption argument is a purely legal question; because "Phase One" discovery was truncated and limited in scope, and recognizing that discovery would only support and clarify – not weaken or complicate – the eventual preemption argument, the AG defendants ultimately decided against filing a Rule 12 motion at the time. We must stress, however, that this decision was driven by the circumstances of that particular litigation and defense counsel should bear in mind that in other MDLs or one-off litigation, a Rule 12 motion may be the silver bullet or leverage that provides an early exit ramp.

Establish Early Guardrails on Timing of Product Distribution

As FDA recognizes, an AG drug product can be distributed either by the brand name manufacturer or by another entity, with the brand name manufacturer's permission. For the latter category, early identification of the time period in which the AG defendant distributed the AG product can be used to support pre-answer personal jurisdiction motions, negotiations for dismissals, or to grossly reduce the number of cases identifying an AG distributor as a defendant where plaintiffs could not, as a matter of fact, have used an AG product distributed by the AG defendant simply based on time the AG distributor operated in the market. There are several ways to develop these facts without awaiting formal discovery, including use of public information from FDA's NDC directory, emphasis on voluntary early production of distribution data, or a declaration or affidavit.

Identify Traditional State Law Bases for Dismissal Independent from Preemption

AG distributors also should not forget about traditional state law or pleading deficiency arguments simply because of the strength of their preemption argument. For example, an AG distributor defense counsel may consider the following:

- Does a state's statute of limitations or statute of repose provide a viable defense?
- Does a plaintiff's forum state have an "innocent seller" or "closed container" defense available to a product distributor?
- Have alleged misrepresentations or express warranties been pleaded with particularity?
- Are there state-specific limitations on strict liability claims in the pharmaceutical context?
- Are there state-specific limitations on warranty claims requiring direct vertical privity?
- Are there state-specific defenses that a product distributor does not owe a duty to a plaintiff to warn of unknown risks?
- Does the plaintiff allege he or she ingested the drug product at issue during the time when the AG defendant was distributing the AG drug product?

Conclusion

Until the U.S. Supreme Court has occasion to rule on preemption as applied to drug distributors or AG products, plaintiffs' attorneys undoubtedly will continue trying to chip away at *Mensing* and *Bartlett* by including AG and other drug distributors. However, there are clear strategies and tactics that support the objective of early dismissal and confined discovery for those representing AG distributors. A distributor's preemption defense to design and labeling defect claims is alive and well and does not hinge on whether the distributed drug is brand name, an AG, or an ANDA-approved generic drug. Establishing early on in any litigation a correct narrative of an AG distributor's role in the supply chain, the availability of preemption and other traditional state law defenses, and early development of critical facts may help secure both voluntary and involuntary dismissals early in litigation.

AG distributors also should not forget about traditional state law or pleading deficiency arguments simply because of the strength of their preemption argument.

Lace Up Your Sneakers + Litigate

The Marathon as a Metaphor for the Life of a Lawsuit

By Nicole Carnevale

This guide will take you from the genesis of a case (the "warmup") up until the first day of jury selection (the "finish line").

In discussing the idea for this article with a DRI editor (who is coincidentally (or not) also training for a marathon), we were reminded that distance runners and lawyers make for a crowded Venn diagram center. The reason for this intersection is surely the subject of a psychology piece. For today, I offer you a lighter serving of the marathon as a metaphor for the life of a civil case from the defense perspective. This guide will take you from the genesis of a case (the "warmup") up until the first day of jury selection (the "finish line").

The Warmup: Cold Muscles Make for a Rough Start.

Muscles gearing to run 26.2 miles need to be toasty and warmed up. This usually looks like some strides and dynamic stretching.

For the lawsuit, I think of the warmup as the claims phase. This phase does not need to be exhaustive, but you should know: the nature of the claim; the anticipated causes of action and their elements; potentially applicable affirmative defenses; the type of relief sought (and an estimate of value if monetary); the proper parties (is standing something to challenge later on?); insurance limits of your client and likely codefendants; and at least a 30,000' view of your client's understanding of the claim and their version of events.

Legal holds should be issued and client and witness interviews preserved. If in house, make sure all interviews are done at the direction of legal to preserve potential confidentiality and privilege objections for the discovery phase. Organize and revisit a prelitigation file if one exists. Identify any obvious documents that are missing and determine custodians so you can obtain copies. Tender defense and indemnity if appropriate.

For outside counsel, your warmup will probably be more extensive and involve obtaining all key claims / internal documents from the appropriate players, reviewing them, and conducting any necessary follow up. This phase also includes securing an executed engagement letter and creating a detailed budget and litigation plan if the circumstances and client preferences call for them. If a site and/or equipment inspection is necessary, schedule ASAP and determine if a consulting expert to accompany you is worthwhile.

If service of a Complaint is your client's first notice of a lawsuit, you unfortunately don't get the luxury of a warmup (sorry in advance to your knees….). That just means that you will need to carve out some early miles in the next phase to get a grasp on "what happened."

Miles 1 Through 10: Follow the Plan.

There's a marathon adage that holds up. You should run the first 10 miles with your head, the next 10 with your training, and the final 10K with your heart. Running with your head is going out conservatively. This avoids the depletion of energy before the finish line – endearingly known as "bonking" – which is notoriously difficult to come back from.

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For the initial "miles" of a lawsuit, running with your head means doing all the "easy" things you know have to be done but might require less intensity. Vet the Complaint for a viable motion to dismiss and timely answer and assert affirmative defenses and counterclaims if there is none. Confirm that service was perfected and that the right party was named. Calendar Court deadlines and events if applicable. If there are none, make realistic internal deadlines to keep the case moving and monitor the Court docket. Information is limited at this point but if you have reasons to join a third party, take steps to do so now you can avoid having to get leave of Court to implead third parties later.

Draft narrowly tailored and specific interrogatories and request for production of documents based on the information you know. Check jurisdictional rules for limits on the number of requests a party can make and strategize about saving some for later in discovery. Notice key depositions in this phase. Start thinking about whether your case needs an expert. If you don't have one in mind, reach out to colleagues and your greater network to find referrals and start vetting potential ones. If outside counsel, make a realistic and detailed budget and litigation plan now or update an earlier one if necessary.

By this point, you probably have a realistic idea if the case should be resolved sooner than later. If the former, start taking the temperature on ADR with counsel for other parties. Have reliable and effective proposed mediators in mind before doing so to improve the odds of getting your "pick."

Miles 10 Through 20: Now We're Having Fun.

If you're following my adage, now we are running on our training, which for a lawsuit, would be your experience and successes; and lessons learned from other cases and claims. Rely on this to stay confident and vigilant, but don't be afraid to start showing off now.

Prepare for and take depositions. Carve out meaningful time after to determine if additional written discovery is warranted, including requests for admissions, based on the testimony. Were new witnesses identified who likely have information helpful to your theory of defense? Defend depositions and prepare your witnesses carefully for examination. Update the client after key discovery events and discuss modifying theories of defense or cost-effective paths to resolution based on new evidence.

This, like most of the guide, varies slightly based on jurisdiction, but if expert disclosures are looming, make sure yours have key evidence to analyze. Arrange for and attend client interviews with experts. By the end of this phase, you should at least be able to obtain a verbal, preliminary opinion from any expert that will determine how you run the next phase. This is also the time to start thinking about potential motions for summary judgment. Start outlining if you have enough to determine that this will be a route pursued and update your outline as transcripts and additional evidence come to light.

Fueling is an integral part of running a marathon. Our bodies get energy to run long distances from glycogen which is broken down from carbs. Fueling while running is an acquired skill and takes practice (your stomach will thank you), but the good news is, you have a variety of sources to choose from (I'm biased for Nerd Clusters). Without fuel, our bodies would hit a wall.

If you litigate a case without regularly updating your client, you too will hit a wall, in that, you might not be their lawyer for much longer. Regular and impactful client communication throughout the life of a case is lawyers' fuel. Check in with them at significant mile markers to let them know of key developments and if your initial assessment of the case has changed, as it surely will, even if slightly, given discovery. Keep expectations realistic.

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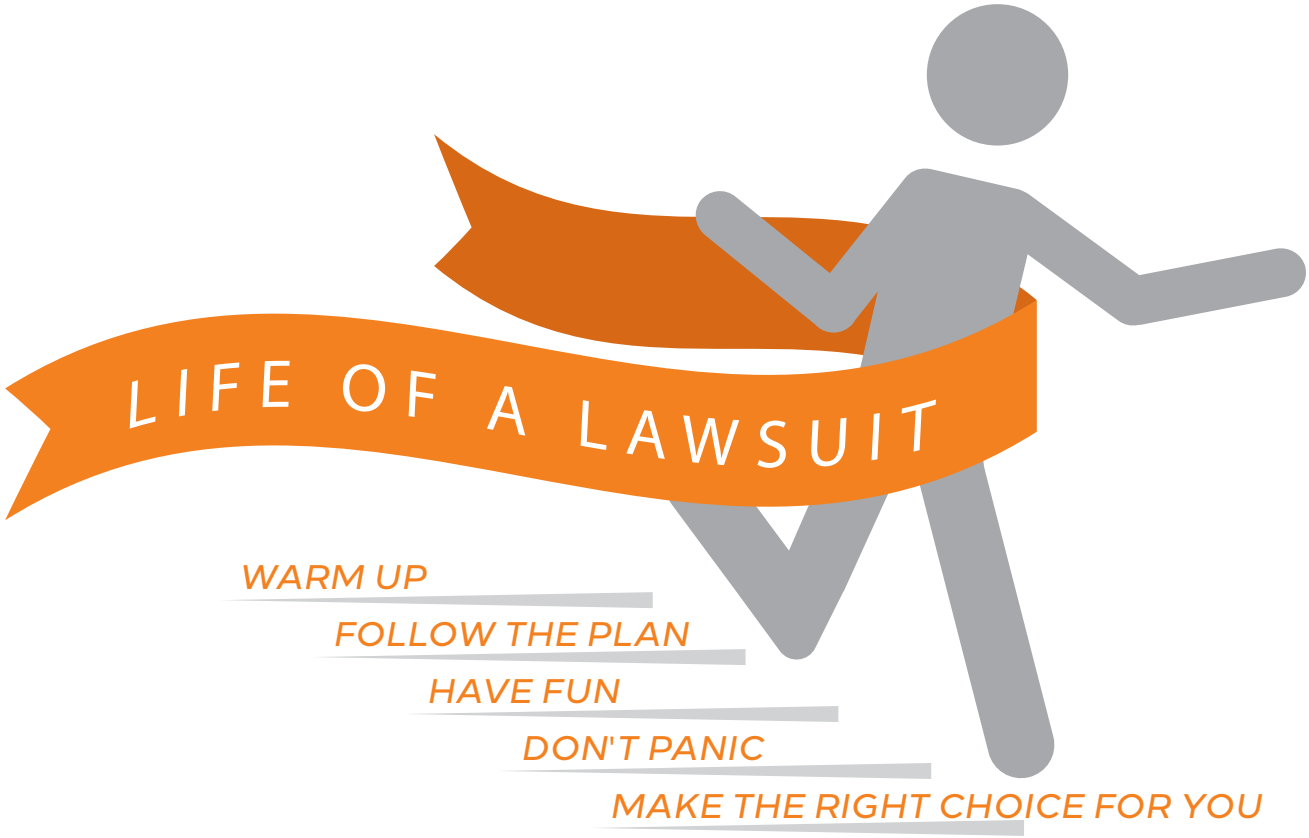

Hydration is another integral part of the race to ensure adequate blood volume, which, if depleted, results in dehydration. A dehydrated litigator is one with blinders on. To avoid, check in with colleagues or other lawyers about their perception of the case and new evidence. Keep strategy and theories fresh by brainstorming and round tabling with others whose opinions you respect.

The Final 10K: Don't Panic.

The marathon starts at mile 20. This is where the case gets hard even for well-prepared defense teams. If you've trained and run a smart race, there is no need to panic.

Discovery is done. Draft expert reports are at least secured and in the process of being finetuned. If a motion for summary judgment has been in the works, this is the phase where you finalize, file and argue. Make plans for if your motion is denied. Revisit ADR or informal settlement discussions before beginning trial prep work. (Pop a Nerd cluster first and have a meaningful client meeting about the fork in the road at this point…)

Start outlining motions in limine and *Daubert* motions. Narrow the case and control to the best of your ability what the jury can hear and what experts can testify about. Identify damaging testimony that needs managing. Draft pretrial memorandum; jury instructions; and voir dire. BREATHE! Lock in your exhibit list. Arrange witness logistics and serve subpoenas. Prepare exhibit and examination binders. Start your opening statement.

Positive visualization is a helpful tool for marathoners whose bodies are tired and mental stamina is being tried. Courtney Dauwalter, one of the best ultramarathoners in the world, has a powerful metaphor known as the "Pain Cave." It's the mental space she enters during the toughest part of the race but it's a place she *wants* to reach because it signifies where real growth and work happen. Don't be afraid to walk into the cave during those last miles because all you've worked for is in sight.

DNF: Oftentimes, the Right Choice.

In the running world, "DNF" means "Did Not Finish." For many runners, this is the acronym of nightmares but that shouldn't really be the case. It's purely descriptive – not a judgment – and happens to runners of every level. Sometimes the smart and strong decision is to not finish.

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In this metaphor, we can think of DNF-ing a case as resolution. You can of course DNF whenever the timing, circumstances, business interests, and client directives are right.

Regardless of if you crossed the finish line to start jury selection or DNF'ed somewhere on the route, don't forget to stretch. For settlement, this looks like finalizing settlement details and documents including stipulations to dismiss. For trial, this means getting ready to run another marathon entirely. Ultra marathons, anyone?!