The PRACTICAL GUIDANCE Journal

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AI IN EMPLOYMENT DECISIONS AND PERFORMANCE MANAGEMENT

Provision of Anti-Overdose Medication in the Workplace

Chevron Deference Reversal: Challenges After *Loper Bright*

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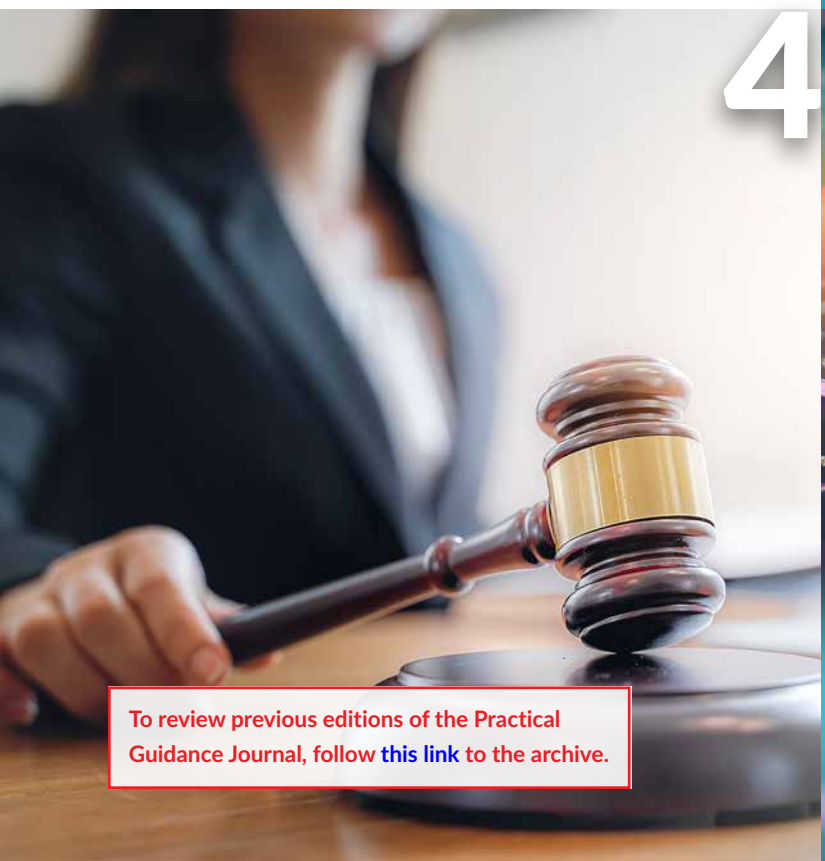

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ONE OF THE SUPREME COURT'S MOST consequential decisions in recent years upended the longstanding foundation of Administrative Law. The court's recent decision issued following review of a pair of cases, overturned the *Chevron* Doctrine, a 1984 decision that resulted in four decades of judicial deference to federal agencies' interpretations of the law when statues were broad or ambiguous. The ripple effect of the ruling is just beginning to be felt across government agencies. This edition of the Practical Guidance Journal includes a review of anticipated effects on decision-making by the U.S. Food and Drug Administration, and links to the Practical Guidance *Chevron* Reversal Impact Resource Kit, which includes full coverage across multiple practice areas.

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Our mission

The Practical Guidance Journal is designed to help attorneys start on point. This supplement to our online practical guidance resource, Practical Guidance, brings you a sophisticated collection of practice insights, trends, and forward-thinking articles. Grounded in the real-world experience of our 2000+ seasoned attorney authors, The Practical Guidance Journal offers fresh, contemporary perspectives and compelling insights on matters impacting your practice.

Chad A. Landmon and Suzanne E. Bassett POLSINELLI PC

Chevron Deference Reversal: FDA Rulemaking and Legal Challenges After *Loper Bright*

This article provides guidance on the impact of the U.S. Supreme Court's recent decisions in *Loper Bright*[1] and *Corner Post*[2] on decision-making by the U.S. Food and Drug Administration (FDA).

BY OVERRULING *CHEVRON*[3] DEFERENCE TO STATUTORY interpretations made by federal agencies, the Supreme Court has likely opened the floodgates for legal challenges to regulations promulgated by the FDA and to final decisions rendered by the FDA. Regulated industries must be mindful of this new legal paradigm when advocating before the agency, in addition to being ready for the court challenges that will undoubtedly be initiated.

This article discusses the following topics:

- Federal court jurisdiction under the Administrative Procedure Act
- Agency deference
- *Loper Bright* and *Corner Post*
- Industry best practices

Federal Court Jurisdiction under the Administrative Procedure Act

Administrative Procedure Act

Section 702 of the Administrative Procedure Act (APA)[4] grants federal courts jurisdiction to review actions taken by executive branch agencies.

Section 706 of the APA[5] states that the "reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."

Further, Section 706 directs reviewing courts to "compel agency action unlawfully withheld or unreasonably delayed"[6] and to "hold unlawful and set aside agency action, findings, and conclusions" that are:

- Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law
- Contrary to constitutional right, power, privilege, or immunity
- In excess of statutory jurisdiction, authority, or limitations, or short of statutory right
- Without observance of procedure required by law

- Unsupported by substantial evidence in a case concerning formal rulemaking and adjudicatory proceedings or otherwise reviewed on the record of an agency hearing provided by statute
- Unwarranted by the facts[7]

Defining a Final Agency Action

Judicial review under the APA is limited to final agency actions. For an agency action to be final, and thus subject to judicial review, the action must:

- Mark the end of the agency's decision-making process, rather than a tentative or interlocutory action[8]
- Determine rights or obligations, or result in legal consequences[9]

With respect to actions taken by the FDA, the following are examples of final agency actions:

- A response to a citizen's petition[10]
- Interpretation of a statute that causes an Abbreviated New Drug Application applicant to lose its 180-day exclusivity[11]
- Enforcement of the Federal Food, Drug, and Cosmetic Act through administrative procedures[12]
- Issuance of rules and regulations through notice and comment rulemaking[13]

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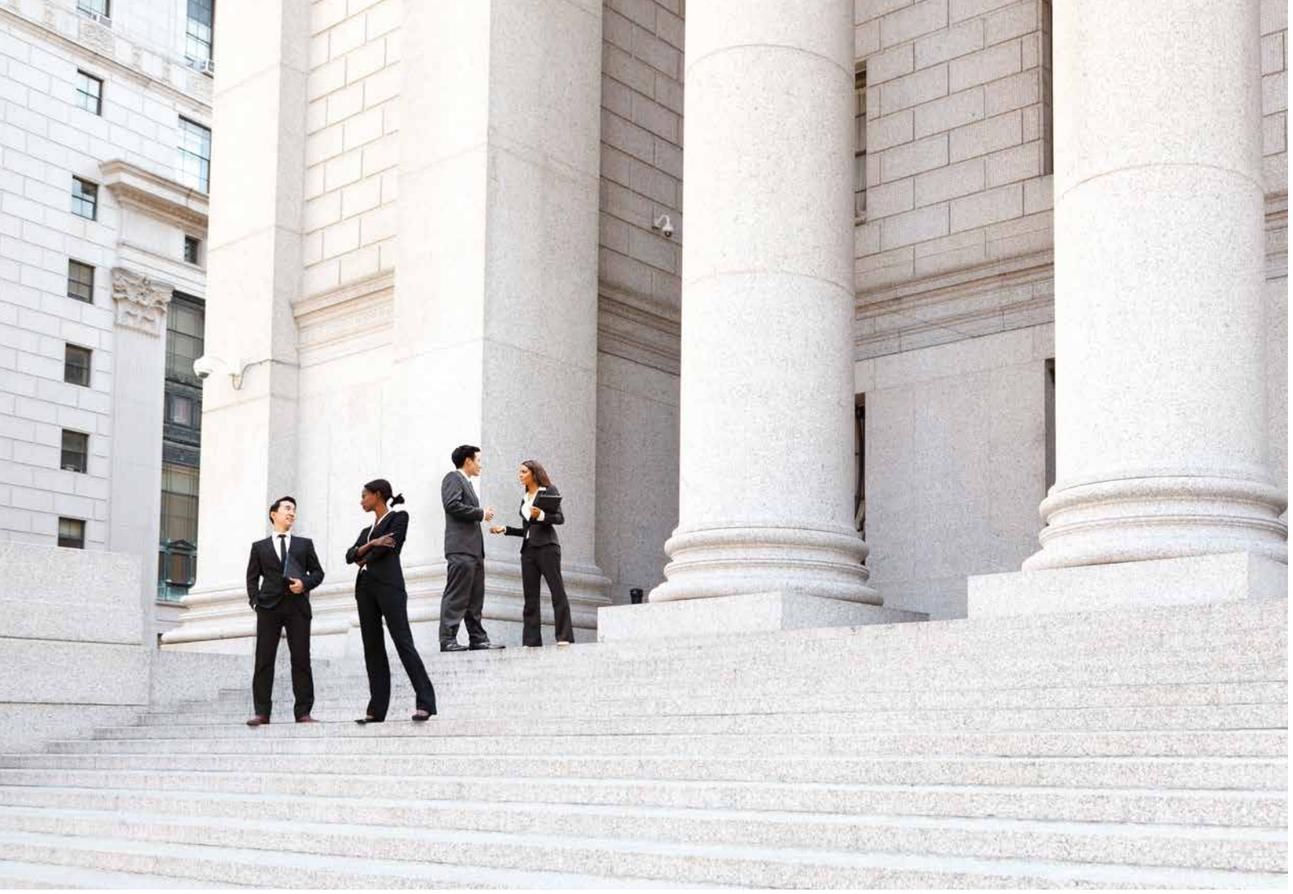
1. Loper Bright Enters v. Raimondo, 144 S. Ct. 2244, 219 L. Ed. 2d 832 (2024). **2.** Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys., 144 S. Ct. 2440, 219 L. Ed. 2d 1139 (2024). **3.** Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). **4.** 5 U.S.C.S. § 702. **5.** 5 U.S.C.S. § 706. **6.** 5 U.S.C.S. § 706(1). **7.** 5 U.S.C.S. § 706(2). **8.** *See* Bennett v. Spear, 520 U.S. 154, 178 (1997). **9.** *See* Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970). **10.** *See* Ranbaxy Labs., Ltd. v. Burwell, 82 F. Supp. 3d 159 (D.D.C. 2015). **11.** Teva Pharm. USA, Inc. v. Sebelius, 638 F. Supp. 2d 42 (D.D.C. 2009), rev'd, 595 F.3d 1303 (D.C. Cir. 2010). **12.** *See* Health Sci. Funding LLC v. FDA, 2016 U.S. Dist. LEXIS 70529 (D.N.J. May 31, 2016). **13.** *See* Ohio v. United States, 154 F. Supp. 3d 621, 631 (S.D. Ohio 2016).



The following are examples of actions taken by the FDA deemed not to be final agency actions:

- Issuance of a notice of proposed rulemaking where the notice proposed a ban on an additive but stated that it would take no action[14]
- Statements made in a preamble to final regulations[15]
- Threats made during an in-person meeting to seize mislabeled products[16]

Agency Deference

Section 706 of the APA[17] authorizes a court to "hold unlawful and set aside agency action" that it finds "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." As a result, the APA makes judges the decision-makers of all questions of law properly before them and contemplates some level of deference if the agency's interpretation of the statute is reasonable (i.e., not arbitrary, capricious, or an abuse of discretion).

To effectively carry out their statutory responsibilities, courts have created doctrinal tests to determine whether to give an agency's interpretation of a statute or regulation any deference.

Chevron Deference

In 1984, the U.S. Supreme Court established a two-step deference test when a court reviews an agency's interpretation of ambiguous statutory language.[18] The steps for *Chevron* deference are as follows:

1. Determine whether Congress has directly spoken to the issue and give effect to Congress's unambiguous intent.
2. If the statute is ambiguous, defer to the agency's interpretation, unless that interpretation is not based on a permissible construction of the statute.

The Court attempted to further narrow the *Chevron* analysis in the early 2000s, implementing what some have called "step zero." This step requires a federal court to determine if Congress intended for agencies or courts to have interpretive authority over a statute before beginning the *Chevron* two-step process.[19]

14. *See* Pub. Citizen v. Bowen, 833 F.2d 364, 366 (D.C. Cir. 1987). **15.** *See* U.S. v. Regenerative Sciences, LLC, 878 F. Supp. 2d 248, 261–62 (D.D.C. 2012) (citing 21 C.F.R. § 10.85(d)(1) and (j) (stating that a preamble constitutes an advisory opinion and not "a legal requirement"). **16.** *See* Health Sci. Funding LLC v. FDA, 2016 U.S. Dist. LEXIS 70529 (D.N.J. May 31, 2016). **17.** 5 U.S.C.S. § 706(2)(A). **18.** Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. at 842–43. EPA v. EME Homer City Generation, L.P., 572 U.S. 489, 512 (2014). **19.** *See* United States v. Mead Corp., 533 U.S. 218, 221 (2001).

> For decades, *Chevron* deference played a significant role in courts repeatedly deferring to the FDA and upholding its decisions, sometimes without a detailed consideration as to whether agency action was consistent with congressional purpose as outlined in the statutes.

Auer Deference

Auer deference provides an intermediate level of deference holding that courts must accept an agency's interpretation of its own regulation unless the interpretation is plainly erroneous.[20] The framework for *Auer* deference, as explained in *Kisor v. Wilkie*,[21] is as follows:

1. Determine whether the rule is genuinely ambiguous by employing all standard tools of interpretation.
2. If the rule is genuinely ambiguous, determine whether the agency's interpretation is reasonable. To be reasonable, the agency's interpretation "must come within the zone of ambiguity the court has identified after employing all its interpretative tools."
3. If the agency's interpretation is reasonable, determine whether the agency's interpretation "reflect[s the] agency's authoritative, expertise-based, fair, or considered judgment."

Skidmore Deference

Skidmore deference is the lowest level of deference that courts have traditionally applied to other types of agency interpretations, such as opinion letters, guidance documents, or compliance policy guides.[22] These types of agency interpretations are entitled to respect only to the extent that those interpretations have the power to persuade. When assessing how much deference to afford an agency under *Skidmore*, the court "look[s] to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position."[23]

FDA Decisions Under Chevron

Many companies have seen courts' reliance on *Chevron* as a high bar in challenging FDA action, even when there may be a legitimate argument. The *Chevron* doctrine has been cited in thousands of cases, including several FDA cases, with disputes often being resolved in the FDA's favor based on perceived ambiguity in the relevant statute.

For example, for some time, new chemical entities (NCE) have been desirable targets for drug developers because the Hatch-Waxman Act grants five years of market exclusivity for an NCE but only three years of exclusivity for FDA approval of drugs with previously approved active ingredients.[24] When a generic-drug manufacturer sued the FDA for its grant of an NCE for a molecule that broke apart upon entering the body to leave only a previously approved moiety at the site of action, the court applied *Chevron* deference and sided with the agency's interpretation.[25] Similarly, in *Athenex v. Azar*,[26] the court upheld the FDA's standard for nominations to its bulk substances list, rejecting a challenge to the agency's interpretation of clinical need as used in Section 503B of the Federal Food, Drug, and Cosmetic Act.[27]

For decades, *Chevron* deference played a significant role in courts repeatedly deferring to the FDA and upholding its decisions, sometimes without a detailed consideration as to whether agency action was consistent with congressional purpose as outlined in the statutes.

However, *Chevron* fell out of favor in recent years, with the Supreme Court appearing to completely avoid *Chevron* in more cases such as *American Hospital Ass'n v. Becerra.*[28]

Loper Bright and *Corner Post*

The Supreme Court overruled *Chevron* in its decisions in *Loper Bright v. Raimondo* and *Relentless, Inc. v. Department of Commerce.*[29] The Court's opinion in *Loper Bright* does not call into question prior cases that relied upon *Chevron.*

However, several days after the *Loper Bright* ruling, the Court issued a second ruling in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*,[30] which holds that an APA claim against an agency action does not accrue until the plaintiff is injured by the final agency action. Essentially, *Corner Post* extends the time period that parties may challenge agency rulemaking.

Loper Bright and *Corner Post* will have far-reaching implications on administrative agencies, including legal challenges to FDA actions.

20. Auer v. Robbins, 519 U.S. 452 (1997). **21.** 139 S. Ct. 2400, 2414-5 (2019). **22.** *See* Skidmore v. Swift & Co., 323 U.S. 134 (1944). **23.** *See* Mead Corp., 533 U.S. at 24. **24.** *See* 21 U.S.C.S. § 355(c)(3)(E)(ii) and (j)(5)(F)(iii). **25.** *See* Actavis Elizabeth LLC v. FDA, 689 F. Supp. 2d 174 (D.D.C. 2010) and Actavis Elizabeth LLC v. FDA, 625 F.3d 760 (D.C. Cir. 2010). **26.** 397 F. Supp. 3d 56, 63–74 (D.D.C. 2019). **27.** 21 U.S.C.S. § 353b. **28.** 596 U.S. 724 (2022). **29.** 144 S. Ct. 2244. **30.** 144 S. Ct. 2440.

Loper Bright

In *Loper Bright*, the Court overruled the longstanding *Chevron* doctrine, declaring that courts can no longer defer to agency interpretations of law simply because the statute is ambiguous and the interpretation is reasonable.

Following *Loper Bright*, courts must now exercise their independent judgment to determine the best reading of the statutes that the agencies administer. While courts may give "respectful consideration" to agency interpretation that is reflective of agency experience and expertise, courts cannot resign their responsibility to resolve statutory ambiguities.

The Court's opinion in *Loper Bright* still leaves the door open for some forms of agency deference. For instance:

- *Loper Bright* only affects agency conclusions of law. *Loper Bright* does not disturb the traditional judicial deference to "agency policymaking and factfinding" as mandated under 5 U.S.C.S. § 706(2)(A). For example, the definition of a medical device might be a question of statutory interpretation, but it remains to be seen whether a court will defer to an FDA decision that an individual product meets the definition of a medical device under the argument that such a determination is a question of fact.
- Congress retains the ability to delegate authority to an agency consistent with constitutional limits. For instance, the statute's meaning may very well be that the agency is authorized to exercise a degree of discretion.
- Courts may use agency interpretation to "help inform" the court's statutory interpretation but agency interpretation cannot bind the court.

Corner Post

Although the court signaled that *Loper Bright* would not retroactively disturb cases that had already relied on *Chevron* deference, its decision in *Corner Post* indefinitely extends the time period in which a regulation is subject to challenge under the APA. The APA itself does not have a set statute of limitations, and therefore courts have historically applied the default six-year statute of limitations under 28 U.S.C.S. § 2401(a) for civil actions against the United States.

In *Corner Post*, however, the Court ruled that the six-year statute of limitations for challenges to federal regulation accrues only when the plaintiff has been "adversely affected or aggrieved by agency action" under the APA. For example, the plaintiff in *Corner Post* did not exist at the time the federal agency finalized the regulation and thus was not subject to the six-year statute of limitations until the plaintiff was itself adversely affected by the regulation.

The Court's holding will significantly impact the calculus for potential litigants and regulated entities regarding the staying power of agency rules and regulations. While individual litigants remain subject to a six-year statute of limitations from the date of injury, there is no longer any point at which a federal regulation will no longer be subject to challenge under the APA given that companies may be newly created or may enter the regulated industry at any time.

Industry Best Practices

The overruling of *Chevron* will increase scrutiny of FDA actions, especially scrutiny of FDA interpretations that do not involve its scientific or technical knowledge. *Loper Bright* may provide an opportunity to raise new arguments in challenging agency rulemaking and agency decision appeals.

Communicate with FDA and Engage with Counsel Early to Advocate your Position at FDA

All industries regulated by the FDA know how important it is to have a collaborative relationship with the agency. Parties should frequently communicate with the FDA, particularly if there is no guidance or only older draft guidance on a pertinent topic.

Creating a detailed record with the agency is incredibly important to ensure that the agency's decision on a particular topic not only comes out correctly but also withstands greater scrutiny in court. If courts once again revert to *Skidmore* deference, the care that the agency takes in making its decision will have a big impact on how much a court considers the FDA's decision as persuasive.[31]

Related Content

For an overview of practical guidance related to the U.S. Supreme Court's recent decision overturning the ***Chevron*** *doctrine, see*

***CHEVRON* REVERSAL IMPACT RESOURCE KIT**

For an analysis of how ***Loper Bright*** *will impact the IRS and taxpayers, see*

***LOPER BRIGHT* UPENDS JUDICIAL DEFERENCE: IMPLICATIONS FOR THE IRS, TREASURY, AND TAXPAYERS**

For a discussion of the impact of ***Loper Bright*** *on employers, see*

GO FISH! U.S. SUPREME COURT OVERTURNS '*CHEVRON* DEFERENCE' TO FEDERAL AGENCIES: WHAT IT MEANS FOR EMPLOYERS

For a look at how administrative agencies and courts will be affected by the ***Loper Bright*** *ruling, see*

***CHEVRON* DOCTRINE OVERRULED: U.S. SUPREME COURT UPENDS LONGSTANDING FOUNDATION OF ADMINISTRATIVE LAW**

Use the Notice and Comment Rulemaking and Citizen Petitions to Your Advantage

Loper Bright will provide companies with a greater opportunity to challenge unfavorable regulations or decisions both in the courts and through the notice and comment rulemaking.

The FDA may be reluctant to promulgate rules with riskier interpretations of ambiguous statutes because the agency will no longer have *Chevron* deference to protect its interpretation if challenged in court. It is also possible that the FDA may want to create more open dockets, such as citizen petition dockets, before it makes decisions so that the agency can thoroughly consider the advocacy of all sides.

Without the protection of *Chevron*, the FDA may be more receptive to comment submissions that raise legitimate legal concerns regarding its authority and to modifying its rulemaking when faced with opposition from industry.

For example, when the FDA issued a Proposed Rule and Final Rule granting it authority to regulate laboratory-developed tests, the clinical laboratory industry claimed in comments that the FDA exceeded its statutory authority. The industry's opposition was ultimately ignored by the FDA in the Final Rule.[32]

Shortly after the Final Rule was published, the clinical laboratory industry filed a lawsuit challenging the FDA's authority, arguing that the FDA violated the APA by exceeding its statutory authority.[33]

Companies should use the notice and comment rulemaking and citizen petitions to their advantage when they do not believe the FDA has chosen the best interpretation of a statute because the agency may be more open to revisiting its position.

FDA May Slow Down Rulemaking and Use Other Tools at its Disposal

With more tools for companies to challenge FDA rulemaking, it is possible that FDA-regulated companies will see a slowdown in FDA rulemaking as the agency must now consider whether there is another permissible statutory interpretation. With less incentive to rely on the rulemaking process, the FDA may also rely more heavily on guidance documents, which do not carry the force of law, or individual enforcement actions against specific companies or products.

As time progresses, it will be increasingly important to monitor the FDA landscape and any changes the agency takes to its regulatory approach.

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RESEARCH PATH: ***Life Sciences > Regulatory Enforcement > Articles***

31. *See e.g.*, General Elec. Co. v. Gilbert, 429 U.S. 125, 142 (1976) (reviewing courts should consider the thoroughness evident in the agency's decision).

32. *See* 89 Fed. Reg. 37286 (May 6, 2024). **33.** *See* American Clinical Laboratory Ass'n v. FDA, Case No 4:24-CV-00479 (E.D. Tex. May 31, 2024).

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To Give or Not to Give: The Provision of Anti-Overdose Medication in the Workplace

Synthetic opioids, such as fentanyl, are responsible for thousands of deaths in California every year.[1] Nationwide, deaths due to overdose rose 30% between 2019 and 2020 and another 15% between 2020 and 2021, with synthetic opioids being the primary driver of the increased deaths.[2]

DUE TO INCREASED AWARENESS OF THE SOBERING scale of the opioid epidemic, many state lawmakers are looking for legislative solutions to increase the availability of the life-saving medication naloxone to prevent opioid overdose deaths. Several states recently passed or proposed legislation that reflect this desire to be more active in meeting this crisis, and California employers should be prepared to meet this changing legal landscape.

What is Naloxone?

Naloxone, commonly sold under the brand name Narcan, is a life-saving medication that is most often administered through a nasal spray to reverse an opioid overdose, such as those resulting from the use of heroin, fentanyl, and prescription opioid medication.[3] According to the California Department of Public Health (CDPH), naloxone is not addictive, works almost immediately, has very few side effects, and has no effect if opioids are not found in a person's system.[4]

In July 2023, the U.S. Food and Drug Administration (FDA) approved Narcan as an over-the-counter medication making it so anyone may purchase, distribute, and administer Narcan without a prescription or license.[5] In California, all other dosages and types of naloxone (such as injectable or intramuscular naloxone) are prescription only, and therefore require a standing order to distribute and administer.[6]

Recent Laws Requiring Certain Industry Employers To Provide Naloxone

In the last few years, several new laws have been introduced in California that require employers in certain industries to have Narcan (or another naloxone product) available for use and/or distribution. For instance, the Campus Opioid Safety Act, which took effect January 1, 2023, requires public universities to distribute dosages of opioid overdose reversal medication (such as Narcan) through campus health centers.[7] Public school districts are similarly required to provide naloxone to school nurses or volunteer personnel for emergency use.[8] Licensed alcohol and drug treatment programs are required to have naloxone on site.[9]

In October 2023, California passed a bill that took effect on January 1, 2024, that requires stadiums, concert venues, and amusement parks to maintain unexpired doses of naloxone on their premises at all times and to ensure that at least two employees are aware of the medicine's location.[10] Additionally, California lawmakers introduced a new bill in January 2024 that would further amend this new statute to provide that the naloxone medication at these venues be "easily accessible and its location widely known."[11]

There are indications that more widespread legal mandates regarding the employer provision of naloxone are on the horizon. On January 30, 2024, State Assembly Member Matt Haney introduced a bill that would require the California Occupational Safety and Health Standards Board to revise a regulation on first aid materials to mandate that first aid kits in the workplace contain naloxone and instructions for its use.[12] These state efforts to provide expanded access to naloxone echo federal efforts. In March 2024, President Joseph R. Biden launched the White House Challenge to Save Lives from Overdose, which called for all public and private organizations and businesses to commit to training employees on opioid overdose reversal medications, to keep such medications in first aid kits, and to distribute such medications to employees and customers.[13]

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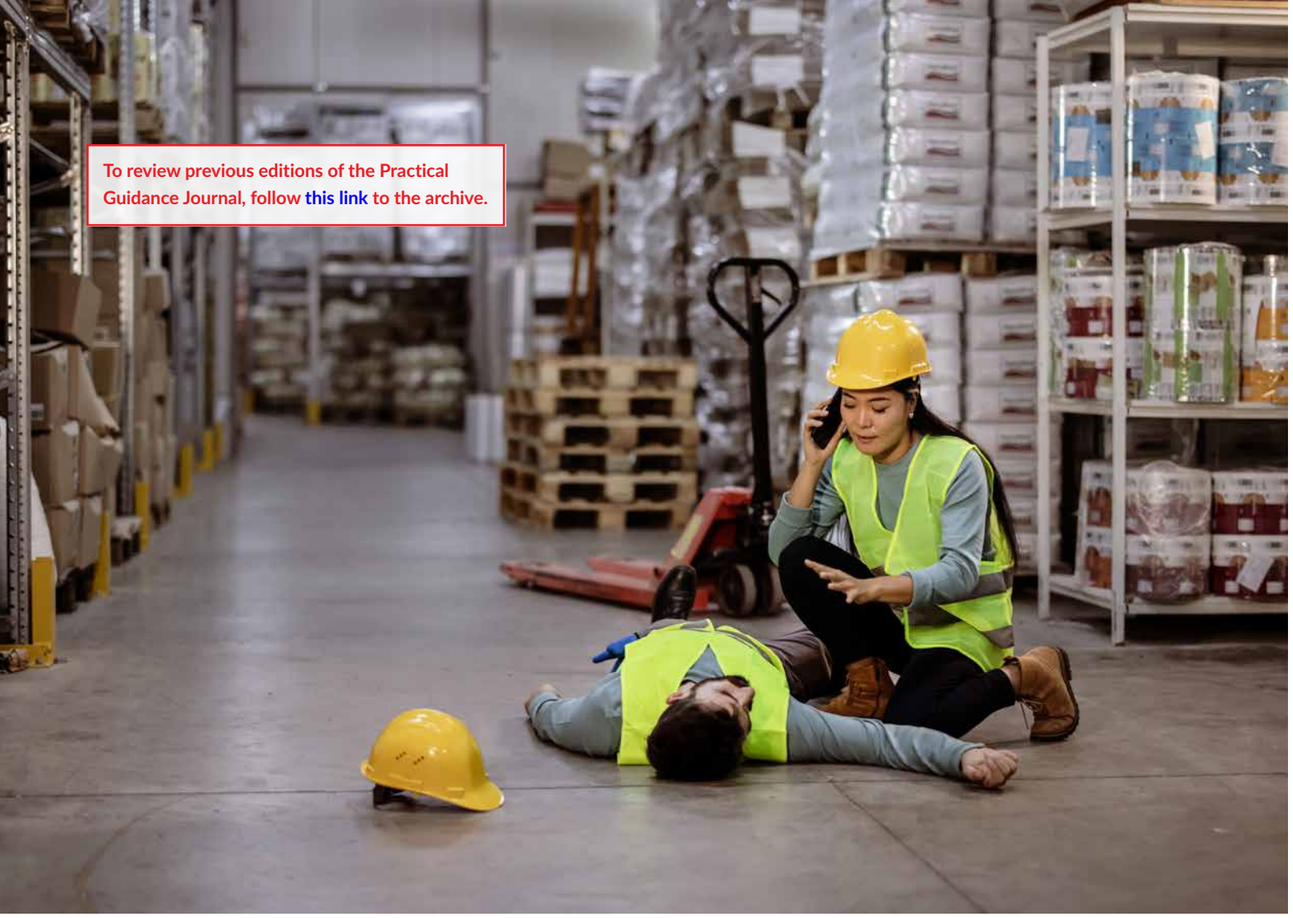
1. *See* California Department of Public Health, *California Overdose Surveillance Dashboard* (Apr. 19, 2022). 2. *See* Center for Disease Control, *U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15%* (May 11, 2022). 3. *See* California Department of Public Health, Substance and Addiction Prevention Branchg, *Stop Opioid Overdose with Naloxone* (May 20, 2024). 4. *Id.* 5. U.S. Food and Drug Administration, *FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product* (July 28, 2023). 6. *See* California Department of Public Health, *Statewide Standing Order for Naloxone* (Nov. 14, 2023). 7. 2021 Bill Text CA S.B. 367. 8. Cal. Educ. Code § 49414.3. 9. Cal. Health & Safety Code § 11834.26(f). 10. Cal. Health & Safety Code §§ 11870, 11871. 11. 2023 Bill Text CA A.B. 1996. 12. 2023 Bill Text CA A.B. 1976 (to add Cal. Lab, Code § 6723). 13. The White House, *FACT SHEET: Biden-Harris Administration Launches the White House Challenge to Save Lives from Overdose*, (Mar. 13, 2024).



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Legal Protections for the Voluntary Administration or Distribution of Naloxone

Employers likely have concerns about potential liability related to their employees administering naloxone to those experiencing an overdose, including to members of the public, patrons, or other employees. However, there are several laws in place that protect those who voluntarily use or distribute naloxone.

Since 2017, CDPH has had a statewide standing order that allows for the distribution of naloxone and for its administration during an overdose by organizations that have agreed to specified terms and conditions.[14] Since the FDA's approval of Narcan as an over-the-counter medication, the standing order is no longer required for the distribution, use, or administration of Narcan.[15]

The standing order is still applicable to other forms of naloxone (i.e., intramuscular or injectable naloxone), and provides that organizations that do not employ a medical provider may distribute naloxone to those who have completed a compliant opioid overdose prevention and treatment training program. Pursuant to the Drug Overdose Treatment Liability Law, licensed health care providers and organizations that are otherwise compliant with the standing order are immune from civil or criminal liability for possession or distribution of naloxone.[16] Individuals who are not licensed to administer naloxone, but who have been trained pursuant to the standing order's training standards, cannot be held liable civilly or criminally for administering naloxone so long as they use reasonable care and administer it in good faith and not for compensation to a person suspected of experiencing an overdose.[17]

Additional laws protect those who voluntarily administer Narcan to those experiencing an emergency overdose. For instance, California's Good Samaritan Law states that a person cannot be liable for any civil damages that result from his or her providing of emergency care if (1) the person acted in good faith, and not for compensation, (2) the person provided either emergency medical care or nonmedical care, and (3) the care was provided at the scene of an emergency.[18]

14. California Dep't of Public Health, *Statewide Standing Order for Naloxone*, *supra* note 6. **15.** *Id.* **16.** Cal. Civ. Code § 1714.22. **17.** Cal. Civ. Code § 1714.22(f). **18.** Cal. Health & Safety Code §1799.102. Pursuant to this statute, the "scene of an emergency" does not include emergency departments and other places where medical care is usually offered.

> Employers who are not already required to make Narcan/naloxone available to employees in the workplace may want to consider doing so.

Further, effective January 1, 2024, California added a section to the Health and Safety Code that specifically addresses "liability for opioid antagonist administration."[19] That section states that any person who, in good faith and not for compensation, renders emergency treatment at the scene of an opioid overdose or suspected overdose by administering an opioid antagonist such as Narcan, "shall not be liable for civil damages resulting from an act or omission related to the rendering of the emergency treatment."[20] Further, the section removes civil liability specifically for someone who furnishes an opioid antagonist to someone else for use at the scene of an actual or suspected opioid overdose.[21] Lastly, this section clarifies that individuals are not "rendering emergency medical care or furnishing opioid antagonist for compensation" if they receive compensation as a result of their unrelated employment—meaning an employee who administers Narcan during their workday is not liable for civil damages provided the employee complies with the section's other requirements.[22] However, the section states that liability may still attach to an act or omission related to the emergency treatment that constitutes gross negligence or willful or wanton misconduct.[23]

Should Employers Provide Narcan to Employees?

Employers who are not already required to make Narcan/naloxone available to employees in the workplace may want to consider doing so for several reasons. First and foremost, it is undisputed that the timely administration of naloxone saves lives by reversing an opioid overdose. Second, there appears to be a legislative push at both the state and federal level towards broad requirements to make Narcan and related training available in the workplace. Third, having life-saving medication on hand may help employers avoid liability or other concerns stemming from an opioid overdose occurring on employer property.

Employers should consider the following questions when determining whether a Narcan policy or program is needed, desirable, and/or feasible for their worksite.

- Do you have staff willing to administer Narcan in an emergency response situation?
- Does your workplace offer other first aid or emergency response interventions (first aid kits, defibrillators, trained first aid providers), and, if so, can Narcan be added?
- Are the risks for opioid overdose greater in your geographic location, in your industry, or among occupations at your workplace? Has there been evidence of opioid drug use onsite (such as finding drugs, needles, or other paraphernalia)?
- Does your workplace have frequent visitors, clients, patients, or other members of the public that may be at increased risk of opioid overdose?

If an employer desires to make naloxone available in the workplace after consideration of the issues above, some best practices should be followed. First, most employers should stock Narcan—as opposed to other forms of naloxone—given that it has been approved for over-the-counter use and does not require compliance with California's standing order to distribute or administer.

Second, employers should either provide training, or require that employees receive outside training, prior to authorizing the use of their employer's Narcan. The training should provide, at a minimum, instruction in all of the following areas: the causes of an opiate overdose, how to recognize an opioid overdose, how and when to contact appropriate emergency medical services, and how to administer an opioid antagonist. CDPH provides several training resources and videos on these topics for employer use.[24] Employers should develop a plan to purchase and store Narcan[25] and ensure that Narcan is replaced when it expires. Additional considerations

19. Cal. Health & Safety Code §1799.113. **20.** Cal. Health & Safety Code §1799.113(a)(1). **21.** Cal. Health & Safety Code §1799.113(a)(2). **22.** Cal. Health & Safety Code §1799.113(c)(1). **23.** Cal. Health & Safety Code §1799.113(b). **24.** *See, e.g.*, California Department of Public Health, *Administering Naloxone* (Aug. 30, 2018). This video equips public health agencies, community organizations, friends, family members and others with the knowledge and skills needed to prevent opioid-related deaths by using naloxone. The 11-minute training video includes a six-point checklist on how to recognize when a person is overdosing and demonstrates how to dispense naloxone and provide post-overdose care. **25.** The Department of Health Care Services created the Naloxone Distribution Project (NDP) to combat opioid overdose-related deaths throughout California through the provision of free naloxone. Effective May 6, 2024, entities participating in the NDP will receive either generic naloxone nasal spray or Narcan naloxone nasal spray. Eligible entities include first responders, schools and universities, county public and behavioral health departments, law enforcement, local city agencies, community organizations, and others. *See* California Department of Health Care Services, *Naloxone Distribution Project* (May 6, 2024).

Related Content

For an overview of employers' responsibilities under the California Occupational Safety and Health Act, see

CAL/OSH ACT: COMPLIANCE REQUIREMENTS

For a summary of Practical Guidance content addressing workplace safety and health topics, see

WORKPLACE SAFETY AND HEALTH RESOURCE KIT

For an editorially curated resource for attorneys to monitor Food and Drug Administration (FDA) regulatory activity, see

FDA DRUG REGULATORY ACTIVITY TRACKER

for establishing a program include records management, including maintaining a detailed log, chart, and/or spreadsheet reflecting any instances where Narcan was administered, including the provider, recipient, date/time of usage, symptoms observed at the scene, and related objective information pertaining to administration of the medication.

Third, employers should develop a written policy detailing the specific training requirements the employee must meet before being authorized to administer Narcan, the steps to follow prior to and following the administration of the medication, and any related emergency response requirements. The written policy should incorporate the California Health and Safety Code standards that render an individual's administration of Narcan immune from civil liability, such as reiterating that an employee's administration of Narcan must be in good faith, not for separate compensation, and provided only at the scene of an emergency to treat a suspected opioid overdose.

By following the steps outlined above, an employer can best balance the goal of providing life-saving medication when needed, while not exposing itself—or its employees—to the risk of civil and/or criminal liability.

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AI in Employment Decisions and Performance Management

Overview of Artificial Intelligence (AI) in Employment Decisions

AI tools are fundamentally changing how people work. Tasks that used to be painstaking and time-consuming can now be completed near-instantaneously with the assistance of AI. Organizations of various sizes and across an array of industries have begun leveraging the benefits of AI to improve their hiring and performance management processes.

For instance, they are using AI tools for the following in hiring and onboarding:

- Screen resumes and identify which candidates are likely to be the most qualified
- Communicate with candidates using automated chatbots, such as ChatGPT and Copilot
- Manage administrative tasks, including general training and onboarding processes
- Evaluate recorded video interviews to analyze and rate candidates' responses and behaviors
- Draft job descriptions to remove unconscious bias and attract a more inclusive group of candidates

And, they are using AI tools for the following in performance management:

- Schedule meetings between employees by automatically finding and suggesting open time slots
- Gather employee productivity data
- Predictive analytics to assess potential success
- Timekeeping
- Calculating wages

One AI use that is quickly gaining popularity, and on which we will focus in this article, is managing employment decisions and employee performance. For instance, organizations are using AI to evaluate employee engagement and flight risk, and to monitor employees' productivity levels and develop plans to boost it. Use of AI tools enables employers to constantly collect and analyze new data—such as employees' communications, browsing history, search history, and email response times—and rapidly turn that analysis into roadmaps for better performance management outcomes, while also easing the administrative burden of manually providing regular performance feedback.

The benefits of AI tools are undeniable, but so too are the associated risks. Organizations that rush to implement these tools without thoughtful vetting processes, policies, and training will quickly land themselves in hot water.

Potential Risks

AI Tools Can be Inaccurate Sources of Information

AI tools sometimes create outputs that are nonsensical or simply inaccurate, commonly referred to as AI hallucinations. These hallucinations can occur when AI tools are trained using limited, incomplete, or unrepresentative datasets.

An infamous example of AI hallucinations in the legal context is *Mata v. Avianca*, a case in the Southern District of New York. Attorneys involved in this case were sanctioned when they "submitted non-existent judicial opinions with fake quotes and citations created by the artificial intelligence tool ChatGPT, then continued to stand by the fake opinions after judicial orders called their existence into question."[1] The court ultimately imposed a monetary penalty along with sanctions on the attorneys and their law firm. *Mata* is one of many examples of the potential exposure that can stem from the lack of due diligence in confirming AI outputs.

Be Wary of the Potential for Biased or Discriminatory Results

In April 2023, several federal agencies, including the Consumer Financial Protection Bureau, Department of Justice—Civil Rights Division, U.S. Equal Employment Opportunity Commission (EEOC), and Federal Trade Commission, issued a joint statement regarding their efforts to protect against bias in automated systems and AI.[2]

1. Mata v. Avianca, 678 F. Supp. 3d 443 (S.D.N.Y. 2023). **2.** U.S. Equal Employment Opportunity Commission, *Joint Statement on Enforcement of Civil Rights, Fair Competition, Consumer Protection, and Equal Opportunity Laws in Automated Systems.*

Depending on what AI tool the organization uses, the organization's data could be disclosed to external parties or even to members of the organization that should not have access to it. Some AI tools use public web searches or third-party applications to assist with generating their outputs, which could cause the organization's confidential information to be disclosed to third-party providers.

The agencies highlighted potential sources of discrimination when using AI tools, including that:

- The datasets used to train AI tools could be unrepresentative, incorporate historical biases, or correlate data with protected classes, which could lead to a discriminatory outcome.
- The lack of transparency into the inner workings of these AI tools makes it difficult to determine whether the tool is evaluating individuals fairly.
- Developers of AI tools may not fully appreciate how employers will use those tools and may design them based on assumptions that prove not to be true across the tool's various users.

A recent experiment conducted with ChatGPT illustrated how these embedded biases can manifest in the performance management context.[3] In this experiment, the experimenter asked ChatGPT to draft performance feedback for a range of professions with limited prompts about the employee's identity. In the written feedback, ChatGPT sometimes assumed the employee's gender based on the profession and traits provided in the prompt. When the prompt included the employee's gender, ChatGPT wrote longer but more critical feedback for females compared to males. Since ChatGPT—and other generative AI tools—are trained using historical data, they can potentially perpetuate biases in performance feedback if the employee's characteristics do not align with the AI tool's standards.

AI Tools Present Data Privacy and Security Concerns

AI tools used in the employment context frequently have access to significant volumes of sensitive information held by the organization, which creates substantial data privacy and security risk.

If an AI tool has access to employees' communications and their personnel files, for example, use of that tool will likely result in a significant expansion in the number of files maintained by the organization that contain confidential information, as users will be able to seamlessly pull data from numerous sources into new files (i.e., the AI tool's output) that will then be saved, emailed, and distributed. Those new files will expand the organization's data breach footprint; could give rise to privacy claims; complicate data mapping and classification (e.g., make it harder to figure out where confidential information is stored, how it is labeled, how it is used, whether it is disclosed); and present privacy compliance challenges under data privacy laws like the California Consumer Privacy Act (CCPA)[4] (e.g., if a former employee requests deletion of their personal information, the organization would need to account for personal information stored in the AI tool's outputs).

Depending on what AI tool the organization uses, the organization's data could be disclosed to external parties or even to members of the organization that should not have access to it. Some AI tools use public web searches or third-party applications to assist with generating their outputs, which could cause the organization's confidential information to be disclosed to third-party providers.

In addition, if the AI tool sources data based on the user's permissions, and those permissions are overly expansive or erroneous (i.e., the user has access to files they should not), the organization could have significant unauthorized access to data by internal users, along with potential use and external disclosure of that data by those users. An employee with overexpansive permissions, for example, may—intentionally or unintentionally—prompt an AI tool to disclose their co-worker's performance evaluation or medical records.

3. Kieran Snyder, *ChatGPT writes performance feedback*, Textio (Jan. 25, 2023). **4.** Cal. Civ. Code § 1798.100 et seq.

AI Regulation in the Employment Context Is on the Rise

In recent years, there has been a flurry of legislative and regulatory activity focused on addressing the potential risks posed by the fast-expanding use of AI tools.

Federal Action in AI Regulation

In August 2023, for instance, the EEOC settled its first-ever AI hiring discrimination lawsuit against iTutorGroup—a group of three companies that provided English-language tutoring services to students in China. The EEOC alleged that iTutorGroup programmed its job application software to automatically reject female applicants over the age of 55 and male applicants over the age of 60, and this allegedly resulted in more than 200 applicants over the age of 55 being rejected in early 2020. Along with paying a $365,000 settlement, iTutorGroup agreed to provide training for those involved in hiring tutors, adopt a new, robust anti-discrimination policy, and remain subject to EEOC monitoring for at least five years.[5]

Title VII and AI: Assessing Adverse Impact

In May 2023, the EEOC released a technical assistance document (TAD) that assesses the adverse impact of software, algorithms, and AI use in employment selection procedures.[6] According to the EEOC, if the use of AI in the employment context has an adverse impact on individuals based on a protected class (including race, color, religion, sex, or national origin), the employer may violate Title VII of the Civil Rights Act of 1964, even when neutral criteria are being used and even where the employer was not involved in the development of the selection process criteria or the creation of the AI tool itself.

As a rule, the EEOC uses the four-fifths rule for determining whether the selection rate for one group is substantially different from the selection rate of another group. For example, if an employer's selection rate for male job applicants is 60%, and its selection rate of female job applicants is 30%, the ratio of female to male applicants selected—50%—would fall below the 80% threshold. The EEOC would therefore consider this ratio substantially different and potential evidence of discrimination against female applicants.

The ADA and AI: Applicants and Employees

The EEOC also released a TAD in May 2022 that addressed the risks of using AI tools with reasonable accommodations under the Americans with Disabilities Act (ADA).[7] According to the EEOC, the three most common ways an employer's use of an AI tool could violate the ADA are when:

1. The employer does not provide a reasonable accommodation that is necessary for a job applicant or employee to be rated fairly and accurately by the algorithm.
2. The tool intentionally or unintentionally screens out individuals with disabilities even though the individual is able to do the job with a reasonable accommodation.
3. The tool violates the ADA's restrictions on disability-related inquiries and medical examinations.

5. *See* Patrick Hoff, *EEOC Nets Deal In Novel Age Bias Suit Over Hiring Software*, Law360 (Aug. 14, 2023). **6.** U.S. Equal Employment Opportunity Commission, *Select Issues: Assessing Adverse Impact in Software, Algorithms, and Artificial Intelligence Used in Employment Selection Procedures Under Title VII of the Civil Rights Act of 1964* (May 18, 2023). **7.** U.S. Equal Employment Opportunity Commission, *The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job Applicants and Employees* (May 12, 2022).

State and Local Action in AI Regulation

State and local governments have also been active in regulating the use of AI in the employment context.

- **Illinois.** On August 9, 2019, Illinois enacted the Artificial Intelligence Video Interview Act (AIVIA), which regulates employers' use of AI to analyze and record employee interviews.[8] Along with recordkeeping and reporting requirements, the AIVIA requires employers that are considering applicants for positions based in Illinois to do three things before they ask applicants to submit video interviews:
  - Notify the applicant that the employer may use AI to analyze the applicant's video recorded interviews
  - Provide the applicant with information explaining how the AI tool works and what types of characteristics the tool uses to evaluate applicants
  - Obtain the applicant's consent to be evaluated by AI
- **Maryland**. On May 8, 2020, Maryland enacted HB 1202, which restricts employer use of facial recognition services—many of which use AI—during interviews without the applicant's prior written consent.[9] Specifically, during an applicant's pre-employment interview, Maryland prohibits an employer from using a facial recognition service to create a facial template, unless the applicant consents by signing a specified waiver. That waiver must state:
  - The applicant's name
  - That the applicant consents to the use of facial recognition during the interview
  - Whether the applicant read the consent waiver
- **New York City.** On July 5, 2023, New York City's AI law took effect, requiring, among other things, that, prior to using AI tools to make decisions regarding hiring or promotions, employers provide notice to impacted employees and applicants, conduct bias audits, post the results of those audits, and advise impacted individuals of alternative non-AI evaluation methods.[10]
- **California.** On November 27, 2023, the California Privacy Protection Agency released draft automated decisionmaking technology (ADT) regulations.[11] The ADT regulations, once in effect, will require businesses using AI tools for certain purposes to (1) issue pre-use notices to consumers, (2) provide methods for consumers to opt out of the AI tool's use, and (3) permit consumers to access information regarding the business' use of AI tools. The ADT regulations would apply to an employer's use of AI tools to make employment decisions and provide the following examples of tools that would be in scope:
  - Keystroke loggers
  - Productivity or attention monitors
  - Video or audio recording or livestreaming
  - Facial- or speech-recognition or -detection
  - Automated emotion assessments
  - Location trackers
  - Speed trackers
  - Web-browsing, mobile-application, or social media monitoring tools

8. 820 Ill Comp. Stat. Ann. 42/5. **9.** Md. Code Ann., Lab. & Empl. § 3–717. **10.** For additional guidance on New York City's Automated Employment Decision Tools law, *see* Foley Hoag, *How Employers Can Prepare for NYC's Regulation of Artificial Intelligence Tools* (June 15, 2023). **11.** https://cppa.ca.gov/meetings/materials/20231208_item2_draft.pdf.

- **Other jurisdictions.** Other jurisdictions have proposed legislation that would similarly regulate an organization's use of AI tools in making employment-related decisions. These jurisdictions include:
  - California (AB 2930)[12]
  - District of Columbia (B23–0114)[13]
  - New Jersey (A3854[14] and A3911[15])
  - Georgia (H.B. 890)[16]
  - Hawaii (H.B. 1607)[17]
  - Illinois (H.B. 5322)[18]
  - New York (AB 9314)[19]
  - Vermont (H 114)[20]
  - Washington (H.B. 1951)[21]

As more AI tools come to market, and more jurisdictions join the fray in seeking to regulate AI, organizations need to remain mindful of expanding obligations under applicable laws.

Mitigation Strategies

Vet AI Tools Currently in Use or under Consideration for Use

One major focus of AI legislation and enforcement guidance to date has been vetting AI tools for potential biases. Recognizing that some organizations will develop AI tools internally, while others will license these tools from vendors, legislators and regulators have attempted to obligate parties throughout the chain to use AI responsibly.

The EEOC, for instance, indicated in its May 2023 guidance that:

> [I]f an employer administers a selection procedure, it may be responsible under Title VII if the procedure discriminates on a basis prohibited by Title VII, even if the test was developed by an outside vendor. In addition, employers may be held responsible for the actions of their agents, which may include entities such as software vendors, if the employer has given them authority to act on the employer's behalf. This may include situations where an employer relies on the results of a selection procedure that an agent administers on its behalf.
>
> Therefore, employers that are deciding whether to rely on a software vendor to develop or administer an algorithmic decision-making tool may want to ask the vendor, at a minimum, whether steps have been taken to evaluate whether use of the tool causes a substantially lower selection rate for individuals with a characteristic protected by Title VII . . . Further, if the vendor is incorrect about its own assessment and the tool does result in either disparate impact discrimination or disparate treatment discrimination, the employer could still be liable.[22]

Bias Audits

New York City's AI law also focuses on the issue of vetting AI tools for potential bias. Before employers making hiring or promotion decisions use an automated employment decision tool (AEDT) to replace or substantially assist human decision-making, they must first conduct a bias audit. The bias audit must be an impartial evaluation conducted by an independent auditor. At a minimum, the auditor's evaluation must include calculations of selection or scoring rates and the impact ratio across sex categories, race/ethnicity

12. 2023 Bill Text CA A.B. 2930. **13.** 2023 Bill Text DC B. 114. **14.** 2024 Bill Text NJ A.B. 3854. **15.** 2024 Bill Text NJ A.B. 3911. **16.** 2023 Bill Text GA H.B. 890. **17.** 2023 Bill Text HI H.B. 1607. **18.** 2023 Bill Text IL H.B. 5322. **19.** 2023 Bill Text NY A.B. 9314. **20.** 2023 Bill Text VT H.B. 114. **21.** 2023 Bill Text WA H.B. 1951. **22.** EEOC, *supra* note 6.

> . . . it is critical that organizations contemplating the use of an AI tool take the time, and consult the necessary experts, to develop a working understanding of how the tool operates and what safeguards are available to reduce the risk that its use will result in unlawful outcomes

categories, and intersectional categories. Employers must make the summary of the bias audit public by posting this information on the employment section of their website or by providing an active hyperlink to a website containing the summary. Notably, the bias audit is only valid for one year; by the end of that year, the employer must conduct a new bias audit to continue using the AEDT.

Given the EEOC's position, and the requirements of New York City's AI law (and others likely to follow), it is critical that organizations contemplating the use of an AI tool take the time, and consult the necessary experts, to develop a working understanding of how the tool operates and what safeguards are available to reduce the risk that its use will result in unlawful outcomes. When vetting AI tools that may be used to make employment decisions, organizations should consider the following factors, among others:

- **Datasets.** What datasets the tool is trained on and what protocols are in place to detect and eliminate biases and inaccuracies in those datasets.
- **Attributes.** Employee attributes considered by the AI tool's algorithm, along with the weight each attribute is assigned.
- **Safeguards.** If the tool has access to internal data sources, whether the organization has implemented safeguards—such as adequately narrow permissions—to prevent unauthorized data access and disclosure.
- **Outputs.** How the tool's outputs will be presented to and used by the organization, including whether those outputs will replace or substantially assist human decision-making.
- **Public web searches.** Whether the tool uses public web searches or third-party applications to generate outputs, and, if it does, whether the organization maintains safeguards to prevent personal or other confidential information from leaking to outside parties.
- **Liability.** The allocation of liability between the organization and the vendor that developed and licensed the tool.
- **Audit logs.** Whether the tool maintains audit logs that, among other things, specify which user prompted the tool to access a particular document at a particular point in time.
- **Personal information.** How the tool will account for personal information stored in the tool's outputs, which will allow the organization to maintain privacy compliance under laws like the CCPA.

Related Content

For an overview of current practical guidance on generative artificial intelligence (AI), ChatGPT, and similar tools, see

GENERATIVE ARTIFICIAL INTELLIGENCE (AI) RESOURCE KIT

For practical guidance on using AI in the workplace, see

ARTIFICIAL INTELLIGENCE IN THE WORKPLACE: BEST PRACTICES

For a survey of enacted state and notable local legislation regarding AI, see

ARTIFICIAL INTELLIGENCE LEGISLATION STATE LAW SURVEY

For information on federal, state, and local legislation on the use of AI, see

ARTIFICIAL INTELLIGENCE LEGISLATION TRACKER (2024)

For a look at the legal landscape surrounding biometrics in the employment context, see

BIOMETRICS WORKPLACE COMPLIANCE AND BEST PRACTICES FOR EMPLOYERS

For a listing of laws related to biometric privacy in all 50 states and the District of Columbia, see

BIOMETRIC PRIVACY STATE LAW SURVEY

For a sample AI workplace policy, see

ARTIFICIAL INTELLIGENCE (AI) DRIVEN TOOLS IN THE WORKPLACE POLICY (WITH ACKNOWLEDGMENT)

For more resources on screening and hiring, see

SCREENING AND HIRING RESOURCE KIT

Additionally, considering the EEOC's TAD, employers using AI tools developed and maintained by a vendor should, at minimum, ask the vendor what steps it has taken to evaluate whether the tool's use causes a substantially lower selection rate for individuals in certain protected classes. Employers should be wary, however, that, in the event the vendor's assessment of the tool's impact was incorrect or incomplete, the employer may still be liable for that impact, notwithstanding any representations the vendor made regarding its auditing of the tool.

Develop Policies and Procedures to Mitigate Data Privacy and Security Risks Presented by AI Use

The data privacy and security risks posed by using AI tools to manage employee performance can be mitigated through the maintenance of thoughtful policies and procedures. For instance, it is important to regulate through policies what information employees are permitted to use to prompt these tools. With limited exceptions, employees should be prohibited from prompting AI tools with personal information or information that the organization otherwise considers confidential (e.g., internal strategy documents or documents that are subject to contractual non-disclosure obligations). If employees use AI tools in the ways they use traditional productivity tools like Microsoft Word or Excel (e.g., if employees dump confidential information into these tools as part of their processes for generating work product) they could inadvertently cause statutory data breaches and/or violations of the organization's contractual obligations.

Outputs Storage and Access

It is also important to regulate by policy where the outputs generated by the AI tools will be stored, who will have access to them, and how long they will be retained. These outputs may contain information subject to statutory and contractual obligations of confidentiality and data protection, such as the obligation imposed in many states to maintain reasonable safeguards to protect the confidentiality, integrity, and availability of personal information.

The outputs may also be subject to the data minimization obligations imposed by data privacy laws like the CCPA. For instance, employee use of AI tools could result in the generation of numerous copies of the same information (e.g., in the responses various employees receive to their prompts) that is then saved in multiple locations and/or transmitted via email, chat, or other channels. Though the organization may be able to justify retaining one copy (or even a few copies) of the data at issue, it likely cannot justify retaining 12 copies, particularly if the organization's data maps do not track where each of those copies is stored, how it is used, and how long it is retained.

Notice and Consent

To comply with the CCPA and similar mandates, organizations also need to evaluate whether it is necessary (or advisable) to provide notice to and collect consent from individuals whose personal information may be used to prompt the AI tool and/or who will be subject to decisions made or facilitated by those tools. Even where providing notice and/or collecting consent is not statutorily required, taking those steps can help mitigate the risk of tort claims like invasion of privacy.

Independent Verification

Organizations whose employees utilize AI tools should also maintain safeguards to ensure the outputs generated by those tools are independently verified. For example, if an AI tool recommends placing an employee on a performance improvement plan (PIP), the organization should evaluate the AI tool's bases for making that recommendation. Similarly, if the tool will be used to generate the PIP documentation—or other performance documentation, like annual evaluations—the information presented in that documentation should be manually reviewed for accuracy and potential legal pitfalls (e.g., statements that could be construed as discriminatory or retaliatory).

Development and implementation of the above policies, among others, requires careful consideration of:

- The organization's objectives in using AI
- Which tools are appropriate considering those objectives
- How those tools can and should be used in pursuing those objectives
- What risks are likely to arise because of that use
- How those risks can be most effectively managed

Conduct Employee Training on Use of AI Tools

Organizations should ensure all employees are trained on the use of AI tools in accordance with organization policy. This training should include information on the potential benefits and risks associated with AI tools, and the organization's policies governing the operation and use of these tools. The training should also remind employees of the organization's AI policy and provide examples of how their use of AI tools is subject to other applicable internal policies, including those related to data privacy and security, as well as workplace discrimination, harassment, and retaliation.

Managers using AI tools to manage employee performance should be trained on how to navigate potential pitfalls related to the use of AI for that purpose. For instance, if the AI tool scores or ranks employees, and the manager considers those scores or rankings when making promotion or termination decisions, the manager may need to be trained to, among other things, (1) avoid using the scores or rankings to replace or substantially assist their own decision-making and (2) be mindful of potential leave management and disability accommodation issues. With respect to the latter point, if, for example, an employee takes Family and Medical Leave Act leave for two months due to a disability, the AI tool summarizing the employee's productivity may fail to account for the impact of the employee's leave (and disability) on their raw productivity metrics. In using the tool's outputs to make decisions about that employee, the manager needs to adjust accordingly.

Such training will help minimize the misuse of AI tools, as well as bolster the organization's position that it has reasonable safeguards in place to encourage employees to use these tools in accordance with applicable law, contractual obligations, and internal policies.

Managing the Risks Going Forward

The rapid advancement of AI presents new opportunities for organizations to manage employee performance more efficiently and effectively. When pursuing these opportunities, however, organizations need to be mindful of the associated risk. Regulating AI tools is top-of-mind for legislators and regulators, and the alleged harm that the use of AI causes to employees (and others, like candidates and customers) will surely be a point of interest for the plaintiffs' bar. Rushing to implement new AI tools, and/or failing to monitor and regulate what AI tools employees are using and how, will place organizations at significant risk.

This risk can be mitigated by carefully and thoughtfully:

- Vetting AI tools to identify risks associated with their use
- Maintaining policies and procedures to manage those risks
- Training employees on those policies and procedure
- Then, repeating the above process on a regular basis, to keep pace with the rapid changes in this space

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Artificial Intelligence (AI) Considerations in **Acquisition Agreements**

This article summarizes various intellectual property and technology (IP/IT) provisions, including sample definitions and representations and warranties, for attorneys to consider when representing the acquirer of an artificial intelligence (AI) business.

FOR PURPOSES OF THIS ARTICLE, AN "AI BUSINESS" IS a business where AI, particularly generative AI (GenAI), comprises (or is a core component of) the business's products or services or where AI powers (or is otherwise material to) the business's products or services or its operations.

You should bear in mind that this article does not contain a definitive list of all possible AI considerations you may need to address when drafting an acquisition agreement, and that the IP/IT provisions of any acquisition agreement should be carefully drafted to suit the deal structure, nuances of the target business, and the client's objectives, including with respect to competitiveness, timing, materiality, and risk tolerance. Practitioners should also note that, as of the date of publication of this article, a survey by the authors of more than 400 publicly available purchase agreements involving public and private target businesses in the software industry revealed that only 10 had AI-specific definitions and/or representations and warranties. The lack of AI-specific provisions in surveyed purchase agreements may be explained in part because traditional intellectual property and technology definitions and representations and warranties already cover this technology to varying degrees. As such, your role when reviewing and drafting a purchase agreement for an AI Business is not necessarily to add a myriad of new definitions and representations and warranties, though some

may be warranted, but may instead be to augment existing provisions to ensure that they cover the specific nuances of these emerging technologies, especially GenAI. As the number of AI Businesses continues to multiply, and as the regulatory and liability landscape materializes, practitioners can expect that the number of purchase agreements with specialized definitions and/or representations and warranties will similarly increase.

Definitions

Certain customary IP/IT-related definitions in a purchase agreement will be relevant to AI, while new definitions may be required depending on the nature of the AI Business, its technology, and other deal considerations. The following are considerations for modifying customary IP/IT definitions as well as new definitions you may want to include in your acquisition agreement for an AI Business:

- Considerations when adapting customary IP/IT-related definitions may include the following:
  - **Confidential information and trade secrets.** If these terms are defined, you should ensure that the definitions cover the target's AI-specific technologies (including any underlying algorithms, models, and weights) if the business relies on trade secret law or confidentiality to protect them so that customary representations regarding protection of trade secrets and other material confidential information will cover such AI technologies.
  - **Intellectual property rights (IPR).** A customary definition will typically cover, at a minimum and depending on the nature of the transaction, the big four intellectual property rights (i.e., patent, copyright, trademark, and trade secret) and may also expressly include rights in inventions, designs, works of authorship (including software and mask works), domain names, social media accounts, moral and similar rights, and rights in other confidential or proprietary information and know-how. Given the technical abilities of AI, in particular GenAI, to produce images, audio, videos, multimedia, and music (among other outputs), including the ability to clone voices and create deepfakes, it has become increasingly important to protect name, image, likeness, voice, identity, and other rights of personality. You should consider whether to expressly include rights of publicity and privacy in the definition of IPR.
  - **Products.** A definition of products may or may not be used (or warranted) depending on whether the business sells products, services, or a blend of products and services. If warranted, you should ensure that the definition of products covers the AI products and services of the target, including any outputs therefrom, especially if GenAI is a relevant part of the target's business.
  - **Software.** You should ensure that the definition of software includes not only customary items (like traditional software and computer programs, firmware, middleware, operating systems, applications, APIs, libraries, compilers, and other software development tools), but also software implementations of AI and machine learning (ML) algorithms, models, and methodologies, and the corresponding code, whether in source code, object code, or other form, as well as all databases and compilations of data, whether machine readable or otherwise. The definition can also be augmented to expressly list material AI and/or ML solutions of the target business, if appropriate.
  - **Technology.** This definition is typically used to cover embodiments or objects of IPR, such as inventions, discoveries, improvements, know-how, ideas, processes, methods, procedures, software, and other works of authorship. You should consider also expressly covering the AI/ML software technologies discussed above, but also any related technologies, such as the digital or physical infrastructure on which they run (including any specialized hardware used for the development, deployment, and operation thereof, like processing units and memory, storage, and networking solutions).

Acquiring an AI Business may require certain IP/IT representations and warranties relating specifically to AI technologies; however, you must also consider how customary IP/IT-related representations and warranties may need to be augmented to address the nuances of AI technologies.

- New definitions to address certain nuances of an AI Business may include the following:
  - **AI, AI/ML, or AI technologies.** Depending on the nature of the transaction and the AI/ML technologies used or produced by the target, you should consider whether to include any of these definitions, and if so, whether to only include the AI/ML algorithms, models, methodologies, and technologies, or also include the data used to train or fine-tune them and/or the digital or physical infrastructure technologies upon which they run. Since AI is rapidly evolving, any proposed definition should be broad, flexible, and non-limiting.
  - **AI product(s).** If appropriate (e.g., where you wish to include such definition in connection with the noninfringement representation or the representations regarding the development, maintenance, monitoring, safety, testing, and performance of such products), you may wish to include this defined term to cover all current and prospective AI or AI-enabled products of the target business (whether generally or as currently defined on the company's product roadmap) and/or to expressly list specific products, in each case, including the outputs thereof.
  - **GenAI.** Depending on the target's exact AI Business and whether specific GenAI representations and warranties are used (as discussed further below), you should consider having a separate definition for GenAI. Given that AI technology can evolve rapidly, the definition of GenAI should be broad, non-limiting, and should cover the subset of AI technologies capable of automatically generating various types of synthetic content or other outputs (including source code, text, images, videos, audio, and data) based on user-supplied prompts and/or other input(s).
  - **Training data and/or scraped datasets.** If appropriate, you should consider defining these terms. The former would typically include any data, databases, or compilations of data that are used to develop, train, teach, fine-tune, test, and/or improve any AI/ML technologies or AI products and the latter may include any of the foregoing that were collected or generated through techniques like web scraping, web crawling, or web harvesting.

The above definitions are not exhaustive and there may be other definitions to consider including or augmenting, depending on the nature of the transaction, including the definitions of company data and IT systems.

Representations and Warranties

Acquiring an AI Business may require certain IP/IT representations and warranties relating specifically to AI technologies; however, you must also consider how customary IP/IT-related representations and warranties may need to be augmented to address the nuances of AI technologies. Some of these provisions may need to be further adapted or expanded depending on whether the target's AI technology is proprietary or sourced from a third party. For example, if the target's core product is the AI technologies it develops itself, separate representations regarding training data and/or red-teaming may be warranted.

The following is a non-exhaustive list of considerations for drafting and reviewing representations and warranties for the acquisition of an AI Business:

- **Identification of material IP.** One of the standard IP/IT-related representations and warranties in a purchase agreement requires a schedule that identifies and discloses all registered IPR owned (or purported to be owned), in whole or in part, by the target business and sometimes the identification and disclosure of, among other things all material unregistered copyrights (including proprietary software) and/or material unregistered trade secrets owned (or purported to be owned). You should also consider whether to require the scheduling of any material proprietary AI technologies of target business, if any.
- **Ownership or right to exploit.** Another customary IP/IT-related representation and warranty relates to the target's ownership of all owned (or purportedly owned) IP and its right to use all other IPR used (or practiced) in the conduct of the business. You should consider whether to expressly cover the sale (or license) of AI products and/or the use of AI technologies by the target business (including all training data, fine-tuning data, and other input data) in any representations regarding IP ownership and the target's right to use (or practice) all other IPR (or practiced) in, or held for use (or practice) in, or necessary for the conduct of the business. Moreover, because the outputs of GenAI may not be protectable as intellectual property absent a human contribution thereto, you should consider whether to account for this in the ownership representations and warranties.

Related Content

For template clauses of select intellectual property (IP) representations and warranties for an acquisition agreement, see the following:

IP REPRESENTATIONS AND WARRANTIES IN ASSET PURCHASE AGREEMENTS (NEUTRAL) (SHORT FORM)

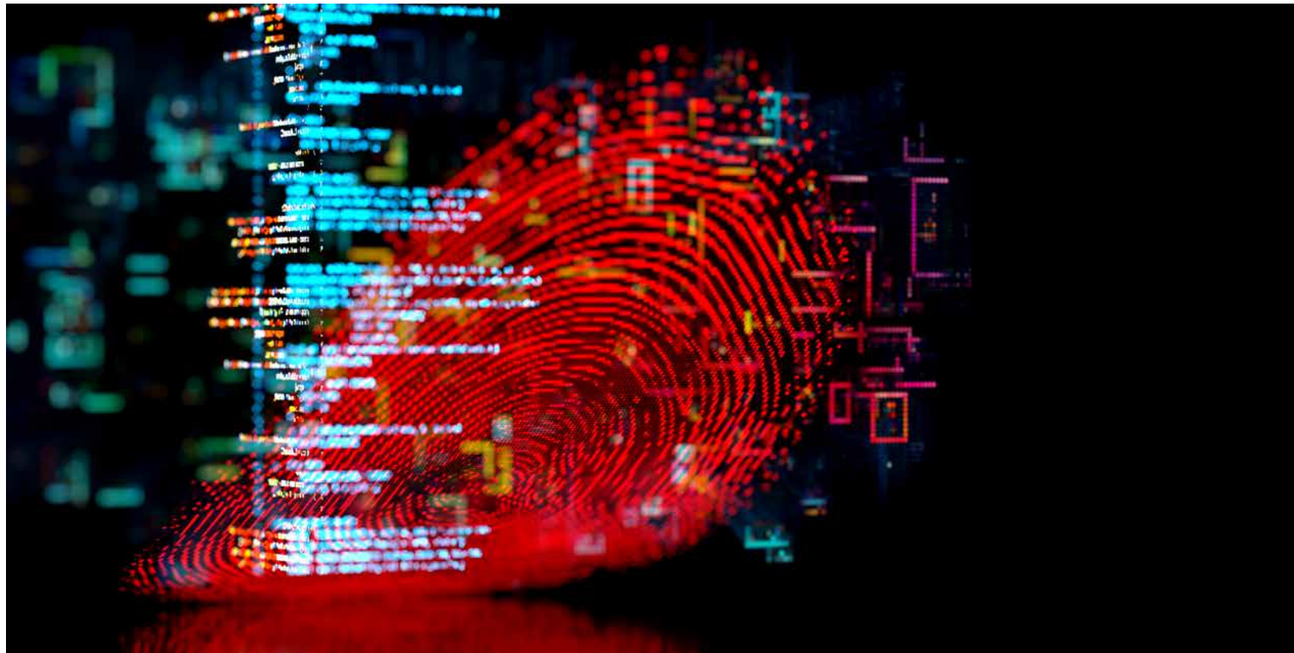
IP REPRESENTATIONS AND WARRANTIES IN ASSET PURCHASE AGREEMENTS (PRO-BUYER, LONG FORM)

IP REPRESENTATIONS AND WARRANTIES IN ASSET PURCHASE AGREEMENTS (PRO-SELLER, LONG FORM)

IP REPRESENTATIONS AND WARRANTIES IN STOCK PURCHASE AGREEMENTS (PRO-BUYER, LONG FORM)

IP REPRESENTATIONS AND WARRANTIES IN STOCK PURCHASE AGREEMENTS (PRO-SELLER, LONG FORM)

- **Noninfringement.** The noninfringement representation and warranty is typically considered one of the most important IP/IT-related representations and warranties as it may allocate the risks of infringement of third-party IP among the parties to the transaction. You should consider whether to revise or expand the noninfringement representation and warranty to address risks specific and/or inherent to the AI technologies at hand. For example, you should consider whether the definition of IPR is sufficiently broad to cover the various types of claims that are likely to arise from certain GenAI outputs (such as violations of the rights of personality, privacy, and publicity) and whether the noninfringement representation and warranty covers (or should cover) not only the AI products and/or AI technologies themselves, but also the datasets or other inputs that are used to train or fine-tune them, as well as the outputs thereof.
- **Development of IP.** Purchase agreements also typically include representations and warranties regarding the provenance and development of material owned IP. Given recent decisions in the United States opining on the copyrightability or patentability of GenAI outputs, you should consider whether to augment these representations and warranties to include a representation that no material owned IP/IT that the target intends to maintain as proprietary was developed using GenAI or that there has not been any use of GenAI in a manner that would materially affect the AI Business's ownership of or rights in such owned IP.
- **Maintenance of trade secrets and other confidential information.** Purchase agreements often also include representations and warranties regarding the measures that the target adopted to protect its trade secrets or material confidential information. For an AI Business, you should consider whether to augment these representations and warranties to provide that no trade secrets or other material confidential information of the AI Business (e.g., proprietary source code) or, if appropriate, of its customers, has been disclosed in any prompts or other inputs in connection with GenAI technologies and that the AI Business's policies and procedures with respect to the protection of trade secrets and confidential information prohibit such disclosure as prompts or other inputs in connection with third-party AI Technologies.
  - **Proprietary software.** If a target owns material proprietary software, then the purchase agreement will typically include software representations and warranties regarding the protection of and access to source code, use of open source, and the operation or functioning of such proprietary software. For an AI Business, you should consider expanding the no harmful code representation to cover not just the AI technologies themselves but also their functioning and behavior (e.g., AI technologies acting in a misaligned manner, other than in accordance with their constitution or safety parameters) and adding a new representation that provides that if the AI Business develops or fine-tunes the AI technologies itself, it retains technical descriptions and other documentation sufficiently detailed to enable the AI technologies to be modified, debugged, and even retrained, if required.
  - **Material Contracts.** The material contracts representations and warranties of most purchase agreements will typically include material inbound and outbound IP-related agreements. Although these will likely already apply to AI technologies and related IPR and AI Products, you should consider:
    1. Ensuring inbound licenses include the terms governing any third-party AI technologies used by the AI Business, given such terms sometimes prohibit commercial use of such technology and/or using such technologies to develop other AI products
    2. Ensuring outbound licenses cover the terms under which the AI Business distributes its AI products or AI technologies (if applicable), including its data policy and other terms with respect to the use of data in connection with such AI technologies or AI products
- **General data and datasets.** Although purchase agreements may include representations and warranties regarding personal data, standalone representations and warranties with respect to data generally are currently not customary to include. However, since vast amounts of data are necessary to develop, train, test, and validate AI technologies, you should consider whether to include separate representations and warranties that the use of any data obtained or collected in connection with the development, building, training, testing, validation, or other use of AI technologies does not violate any applicable laws or any contractual terms (including end user license agreements and website terms of use) or technological protocols or standards prohibiting such collection (e.g., robot exclusion protocols including robot.txt and automated content access protocols). The latter could also be achieved via the material contracts representations and warranties discussed above. Considering the challenges and costs associated with retraining an AI model, you may also consider including a representation and warranty that all necessary rights, consents, disclosures, and compliance measures required for the lawful collection, processing, and use of such data and datasets as collected, processed, and used (or proposed) have been acquired or made (and would not be impacted by the consummation of the proposed transaction).
- **IT systems.** Purchase agreements often include customary representations and warranties regarding the IT systems of the target, including their sufficiency, integrity, and operation. ith respect to an AI Business you should consider whether:
  1. To augment these representations and warranties to cover policies and procedures regarding the responsible, ethical, and lawful development, deployment, and use (as appropriate) of AI technologies, including development, testing (including red-teaming/ adversarial testing), monitoring, and use of AI technologies in a manner that promotes safety, transparency, accountability, reliability, and explainability, and reduces hallucinations and bias and discrimination and,
  2. To address the proper functioning of the AI products or AI technologies including to identify flaws and vulnerabilities (such as misalignment, model drift, harmful or discriminatory outputs, unforeseen or undesirable system behaviors or other failures to satisfy safety parameters or expected requirements, or the need for the use of a kill switch or other emergency or failsafe mechanism (including human intervention)).



Additional Considerations

Practitioners may need to address AI technologies and AI products of a target business in representations and warranties aside from traditional IP/IT representations and warranties, too.

Other Related Representations and Warranties in the Purchase Agreement

While the focus of this article is IP/IT-related representations and warranties, other representations and warranties in a purchase agreement will also be relevant to AI Businesses, such as data privacy, products liability, litigation, and compliance with laws. For example, you should ensure that the compliance with representations and warranties includes all applicable laws, regulations, and industry standards, in all relevant jurisdictions, which may be very broad for an AI Business and range from new laws or regulation directly legislating AI technologies to existing laws and regulation including consumer protection, export controls and sanctions, and antitrust and securities laws. For instance, a U.S.-based AI Business that markets or provides its AI products within the EU may be subject to the jurisdiction of the prospective EU AI Act. Indeed, the extraterritoriality provisions of the EU AI Act are so aggressive that simply using the output of an AI product in the EU may be enough to cause the EU AI Act to apply to a U.S.-based AI Business, even if such use was not intended by the U.S.-based AI Business.[1]

1. *Cf.* 2024 O.J. (L 1689) Art. 2(1)(c).

Related Content

For a discussion on key considerations in mergers and acquisitions (M&A) due diligence in the context of artificial intelligence (AI) technologies, see

ARTIFICIAL INTELLIGENCE (AI) INVESTMENT: RISKS, DUE DILIGENCE, AND MITIGATION STRATEGIES

For an overview of current practical guidance on generative AI that is organized by practice area, see

GENERATIVE ARTIFICIAL INTELLIGENCE (AI) RESOURCE KIT

For practice guidance on intellectual property matters to consider in connection with an M&A transaction, see

INTELLECTUAL PROPERTY CONSIDERATIONS IN M&A TRANSACTIONS RESOURCE KIT

For an analysis of the process of uncovering and understanding information about the status, value, and risks associated with the transfer of IP assets as part of a business deal, see

IP DUE DILIGENCE

For a review of the key industry-specific considerations that affect all aspects of technology M&A deals, see

TECHNOLOGY M&A TRANSACTIONS

For assistance in drafting privacy and data security representations and warranties, see

PRIVACY AND DATA SECURITY REPRESENTATIONS AND WARRANTIES IN M&A AGREEMENTS (PRO-BUYER) (LONG FORM)

For a template that sets forth software representations and warranties typically included in stock purchase or asset purchase agreements, see

SOFTWARE REPRESENTATIONS AND WARRANTIES IN M&A AGREEMENTS (PRO-BUYER) (LONG FORM)

You should also consider whether specific uses of AI technologies by the AI Business import higher or additional risk (e.g., making decisions in hazardous, high-risk, or regulated environments such as employee hiring, crime detection and prevention, criminal sentencing, and creditworthiness) and whether the existing representations and warranties (or those discussed in this article) adequately address them or whether new provisions are required.

Disclosure Schedules

You should consider all disclosures made in the disclosure schedules to the acquisition agreement, including with respect to the IP/IT-related representations and warranties. Broad and/or vague disclosures with respect to the AI Business's development or use of AI technologies, including GenAI, may effectively negate several of the negotiated representations and warranties. You should therefore consider requiring specific disclosures and qualifying the relevant representations and warranties with appropriate qualifiers.

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RESEARCH PATH: ***Corporate and M&A > Acquisition Agreements > Practice Notes***

Kirk A. Sigmon BANNER WITCOFF

Copyright Registration of AI-Generated Works Checklist

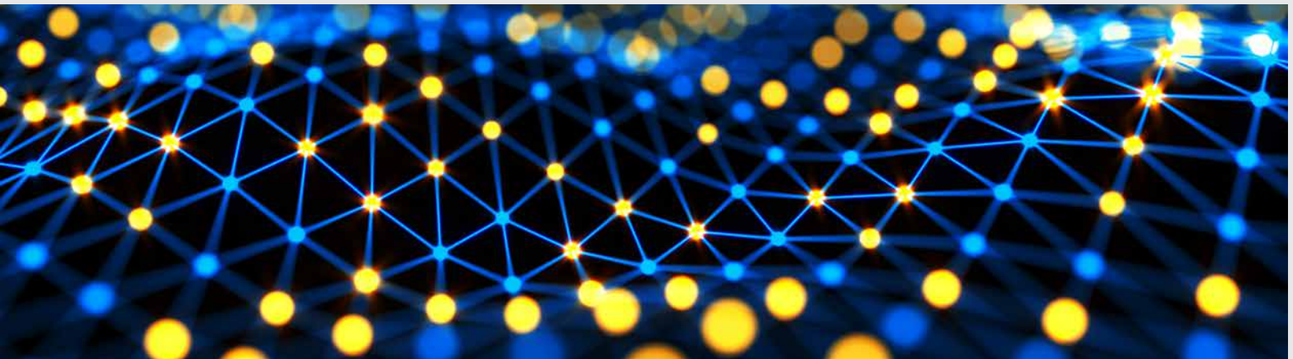
This checklist outlines key considerations that attorneys should review when advising whether and how to copyright artificial intelligence (AI) and machine learning (ML)-generated works in the United States.

The checklist provides a framework for documentation of human involvement in the creative process of an AI-generated work and for the preparation of a copyright application. It focuses on collecting information useful for both the application and for responding to follow-up by the U.S. Copyright Office.

As a preliminary matter, applicants should exercise caution when trying to copyright works generated using AI or ML models. The U.S. Copyright Office (the Office) carefully scrutinizes such applications. Specifically, the Office has issued guidance stating that individuals using AI/ML technology to create a work may claim protection "for their own contributions to that work," but if "a work's traditional elements of authorship were produced by a machine, the work lacks human authorship and the Office will not register it."[1] The Office thereby draws a line between work of an author's "own original mental conception, to which [the author] gave visible form" and creative works of a machine (including simple mechanical reproductions).[2]

Documenting human involvement in the creation of an AI or ML-generated work is important because (1) the Office expects applicants to explicitly distinguish between human and AI contributions in copyright applications, and (2) the Office sometimes requests additional information from applicants when evaluating possible limitations on a copyright application involving AI-generated content.

1. 88 Fed. Reg. 16190, 16192-193 (Mar. 16, 2023). 2. Burrow-Giles Lithographic Co. v. Sarony, 111 U.S. 53, 60 (1884).



Document the Nature of the AI

The training and capabilities of an AI model can have significant impact upon its ability to contribute—or not contribute—to a creative work. For example, if a model is rudimentary (e.g., designed to remove compression artifacts from existing images, designed to add makeup to a human face, or the like), then it might be fairly presumed to be less likely to provide creative output. As such, more human creativity might be implied in the resultant creative work. That said, if a model is highly sophisticated and trained based on previously published works, that model might be assumed to more readily provide what appears to be a creative work with relatively minimal human effort.

- **Record model(s) used.** If an existing model (e.g., a model downloaded from the internet) was used, collect information regarding the model such as:
  - When it was retrieved
  - Where it was retrieved from
  - A recorded version number
  - The date and/or time the model was used
  - Other similar information
- **Document known model uses.** Some generative models (such as Stable Diffusion) can generate wholly new images, whereas some other models (such as those used as plugins in photo editing suites) are trained to improve and otherwise modify existing images. It is generally easier to argue that the latter are similar to conventional photo editing tools.

To review previous editions of the Practical Guidance Journal, follow this link to the archive.

- **Document model training process.** If available, document how the model was trained. This can include:
  - Documenting the training data that was used, including information such as:
    - Where the data originated
    - Who owned the data
    - The format of the data
  - Documenting the training process itself, such as:
    - Which algorithms were used
    - Which loss functions were used
  - Documenting, where applicable, whether the model is designed to continually learn, such as where it might receive further training as part of a feedback loop during use

Example: Some freely available Stable Diffusion models accessible through enthusiast websites are quite sophisticated and are trained to emulate specific authors' work. It may be relatively difficult to copyright their output because those models require very little effort to produce output that appears quite creative and because the models are designed to, in effect, create permutations of another author's previously published work. In those circumstances, applicants should endeavor to document as much human creative labor as possible (and should expect an uphill battle). With that said, other models, while equally sophisticated, are designed to simply clean up and/or otherwise enhance existing works. Copyrighting the output of these models seems significantly easier, in no small part because they are roughly analogous to an advanced photo filter.

Document the Scope of AI Contribution

Once the relevant model(s) are identified, it is critical to understand how those models were used during creation of a particular work. This establishes a baseline for later assessing the scope of human involvement.

- **Record prompts and user-controllable parameters.** Collect any prompts used to generate the relevant work.
  - In the case that a model is configured to remember past prompts or is otherwise configured to generate output based on a plurality of previous prompts, collect all such prompts.
  - Where applicable, collect and record other user-controllable parameters, such as the number of steps, the selection of samplers, and seed values.
- **Document other inputs.** In some circumstances, a model might be used to enhance and/or otherwise modify an existing creative work, such as an image or sound file.
  - For example, some Stable Diffusion implementations have an "img2img" function which receives, as input, both a prompt and an input image and then outputs an image based on the prompt and the input image.
  - As another example, some language learning models are capable of proofreading (and providing recommended edits to) input text, such as a draft of a book.
  - If a model was used to enhance or otherwise modify a previous work, collect examples of the un-modified and as-modified work.
- **Collect metadata and logs.** Some models provide metadata and/or logs relating to the process via which a creative work may have been output. While this information is rarely relevant to the question of whether a human was involved in creating the work, it can nonetheless be useful when, for example, showing how a human author used an AI tool over time (e.g., iteratively improved outputs over time).

Example: If an author merely provides a single and simplistic prompt (e.g., "Show me a cat") and attempts to copyright that output (a picture of a cat), the Office's guidance suggests that the application is more likely to face pushback. The result might be different if the same user iteratively provided various prompts over time to modify the image (e.g., "Now add a flower," "Now make the image drawn in crayon," and so forth).

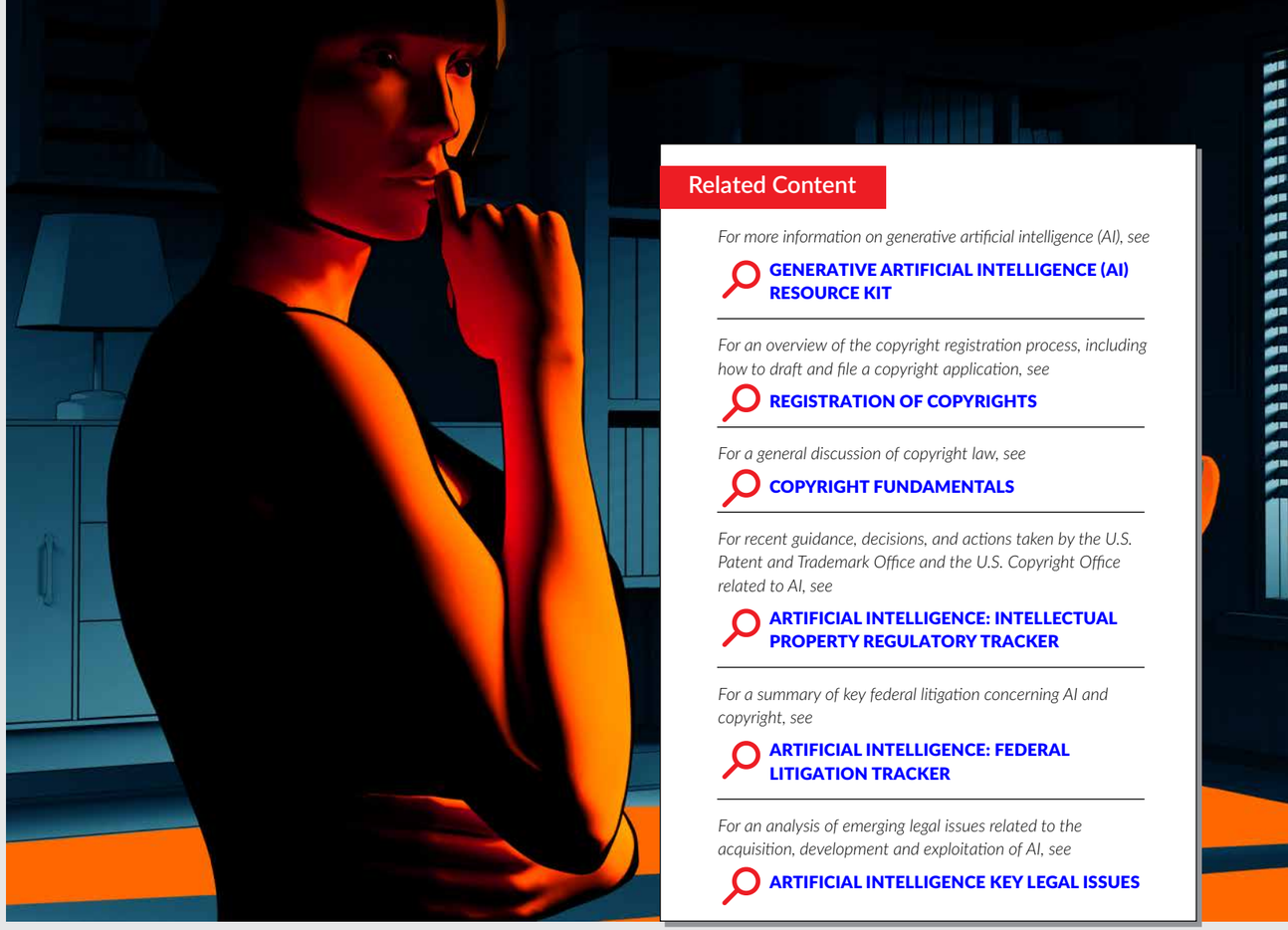
Document Human Creative Labor

Once the scope of model use is understood and relevant information about the model's use is collected, it is then extremely important to use that information to understand and document the scope of human creativity in generating the work. Where possible, applicants should endeavor to show that the work is "basically one of human authorship," with the AI model "merely being an assisting instrument."[3] Put more simply, documentation should show that "some element of human creativity must have occurred."[4] Applicants should endeavor to take a very broad approach to collecting information at this stage, recognizing that creative labor can include a wide variety of activities.

- **Determine extent of prompt engineering.** If the author spent time crafting a prompt or otherwise modifying relevant parameters, document the process by which they modified and eventually selected a prompt with the correct requirements (i.e., the trial-and-error process of finding the right prompt). Keep in mind that this process might be iterative over time in at least two ways:
  - Some models are instructed iteratively and can base subsequent output on a series of previous inputs. For example, an author might instruct a model, "Draw a house," then "Draw a car in front of the house," and so forth. Accordingly, prompt engineering (i.e., creative work on the part of an author) might be evidenced by an author providing a series of instructions over some period of time.
  - Authors might spend time making edits to a single prompt and accompanying parameters to generate a desired image. For example, an author might add words to or remove words from a large, wordy prompt and re-submit the prompt with each edit to evaluate the resulting output of a model and, over time, endeavor to reach a desired outcome. This process itself evinces creative effort on the part of the user insofar as they, through their prompt engineering, sought a desired creative output.
- **Determine inputs other than prompts.** If the input was something other than a prompt (e.g., if the author provided an image to be modified by the model), determine whether the human author made changes to this input. For instance, if an author created and/or made edits to an image (e.g., to add or remove some object) before providing it to a model for further processing, this is arguably a degree of creative effort on the part of the author.
- **Ascertain any modifications to output.** If the author made changes to the output after the fact (e.g., modification of an AI-generated image using photo editing software), determine the scope and nature of these changes. This output modification is arguably creative effort on the part of an author.

Example: If an author spends time preparing a draft of a book before providing it to a language learning model for proofreading and then makes further edits to the resultant output of the model, the author arguably has provided significant creative labor, even where the model is quite sophisticated and perfectly capable of generating a book's worth of content by itself. The model in this case might be analogized to a proofreader/editor that is but one step in an overall creative process.

3. 88 Fed. Reg. 16190, 16193 (Mar. 16, 2023). 4. Urantia Found. v. Kristen Maaherra, 114 F.3d 955, 957–59 (9th Cir. 1997).



Related Content

For more information on generative artificial intelligence (AI), see

GENERATIVE ARTIFICIAL INTELLIGENCE (AI) RESOURCE KIT

For an overview of the copyright registration process, including how to draft and file a copyright application, see

REGISTRATION OF COPYRIGHTS

For a general discussion of copyright law, see

COPYRIGHT FUNDAMENTALS

For recent guidance, decisions, and actions taken by the U.S. Patent and Trademark Office and the U.S. Copyright Office related to AI, see

ARTIFICIAL INTELLIGENCE: INTELLECTUAL PROPERTY REGULATORY TRACKER

For a summary of key federal litigation concerning AI and copyright, see

ARTIFICIAL INTELLIGENCE: FEDERAL LITIGATION TRACKER

For an analysis of emerging legal issues related to the acquisition, development and exploitation of AI, see

ARTIFICIAL INTELLIGENCE KEY LEGAL ISSUES

Draft Application

In its guidance, the Office encourages applicants of AI-generated works to use the Standard Application and "provide a brief statement in the 'Author Created' field that describes the authorship that was contributed by a human."[5] This is an area where careful drafting can prevent significant pushback from the Office.

- **Disclose any and all AI involvement.** Make known the use of AI without trying to downplay it.
  - Attempts to hide or otherwise tone down AI involvement could be perceived as fraudulent and risk the validity of the application and/or registration.[6]
  - Definitely err on the side of over disclosure, even where it might come across as pedantic.
- **Focus on human involvement in brief statement.** Focus directly on the human contributions to the work, recognizing that AI should be little more than a tool in the creative process.
  - The Office's own example of such a statement ("[s]election, coordination, and arrangement of [describe human-authored content] created by the author and [describe AI content] generated by artificial intelligence") does precisely that.
  - Avoid phrasing that incorrectly suggests passive behavior on the part of the human author (e.g., "[Author] used [AI model] to generate picture," without more).

5. 88 Fed. Reg. 16190, 16193 (Mar. 16, 2023). 6. *See* 17 U.S.C.S. § 411(b)(1)(A); Unicolors, Inc. v. H&M Hennes & Mauritz, L.P., 595 U.S. 178, 186 (2022).

- **Explicitly exclude AI-generated content.** The Office's guidance instructs that "AI-generated content that is more than de minimis should be explicitly excluded from the application."
  - Use the Limitation of the Claim section under the Material Excluded heading (and/or via the Note to the Copyright Office field). In particular, applicants should use this section to disclaim any AI-generated aspects of a work that are clearly based on previously published works.
  - Given the tenor of the Office's guidance, if your work involved generative AI in any way, it may be wise to include some sort of disclaimer of some material, however minimal. Otherwise, the Office may reach out with questions and devise its own limitations.
  - A good example of how the Office excludes AI-generated work from a copyright registration is in its letter relating to the partially AI-generated comic book Zarya of the Dawn.[7] In that letter, the Office acknowledges human authorship of "the Work's text as well as the selection, coordination, and arrangement of the Work's written and visual elements" but concludes that the "images . . . that were generated by the Midjourney technology are not the product of human authorship."
- **Use the Note to the Copyright Office field liberally.** The Standard Application permits applicants to provide freeform comments, and this field should be used to extensively detail the involvement of AI and forestall potential questions from the Office. For example:
  - Include information collected about the nature of the AI, including which model(s) were used, how the model(s) were trained, and like information.
  - Provide extensive details regarding the use of the model, including relevant prompts, parameters, and any other input to the model.
  - Explain in as much detail as possible the extent of human creativity involved, including any modifications to model input/output, trial-and-error, and other human creative effort.
- **Do not list AI as an author.** An author must be human.[8] As such, listing an AI as an author is not only incorrect, but invites scrutiny by the Office.
- **Prepare for follow-up questions.** If an application indicates that AI was used in the process of generating a creative work, the Office might contact the applicant with questions regarding the use of the AI. This is, in part, why so much early data collection is recommended; it makes the process of answering these inquiries significantly easier and prevents encouraging the Office to exclude excessive content from the application.

7. https://www.copyright.gov/docs/zarya-of-the-dawn.pdf. 8. Naruto v. Slater, 888 F.3d 418, 426 (9th Cir. 2018).

Best Practices for Follow-Up Questions

If the Office follows up regarding an application, the best approach is to be honest and comprehensive. When answering questions, keep the following in mind:

- **Focus on the "Modicum of Creativity" standard.** In the United States, the "the requisite level of creativity" for a copyrightable work "is extremely low; even a slight amount will suffice."[9] As such, even if AI was 99.9% involved in the creation of a work, a human author is still entitled to a copyright in their (admittedly small) contribution.
- **Do not downplay AI involvement.** While some applicants might be tempted to downplay (or outright attempt to hide) the extent of AI involvement in a work, this approach can border on untruthfulness and could, at minimum, invite scrutiny by the Office. Instead, be candid about the extent of the AI used—otherwise, the Office could assume that almost all of the work was AI-generated.
- **Tie human action to creative labor.** Focus on human action that involves creative effort and, where possible, tie such efforts back to known copyright principles. For example, focus your answers on:
  - Demonstration of human creative labor in the selection and arrangement of particular elements in an image (via prompts or not)
  - Coordination of various steps for a desired outcome (e.g., creation of an input image using a camera, providing that input image to a model, receipt of a modified version of the image)
  - Revision and remixing of other content (e.g., other content used to train the model). L

Kirk A. Sigmon is an attorney at Banner Witcoff's Washington, D.C. office. His work in the United States and in Asia, tied with his experience with Fortune 500 companies and startups, provides him the know-how to counsel clients at all stages of invention, patent prosecution, intellectual property enforcement, and litigation.

RESEARCH PATH: *Intellectual Property & Technology > Copyright > Checklist*

9. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 345 (1991).

Jeffrey D. Mamorsky COHEN & BUCKMANN, P.C.

ERISA at 50: **Pre-ERISA and the Need for Pension Protections**

This video series celebrates the enactment of the Employee Retirement Income Security Act (ERISA), signed by President Gerald Ford on September 2, 1974, and generally effective for plan years starting on or after January 1, 1976.[1] The law established minimum standards for most voluntarily established retirement and health plans in private industry.

IN THE FIRST VIDEO OF THE SERIES, JEFFREY MAMORSKY discusses the need for U.S. pension reform that led to consideration of legislation that would establish minimum standards for private industry's sponsorship and maintenance of pension plans. Jeff discusses the Congressional hearings and discussions that shaped the legislation, and its eventual passage with overwhelming support from both chambers of Congress.

The following is an excerpt from the first video, ERISA at 50: Pre-ERISA and the Need for Pension Protections.

What really kicked off the movement to reform pensions in America was the closure of the last Studebaker Motor Company manufacturing plant in 1963.

Studebaker was over a hundred years old, once the top manufacturer of horse drawing carriages, and by the early 1900s, the Studebaker Corporation was one of the top auto manufacturers in the United States. The company was truly iconic. The Studebaker Golden Hawk, which was made in 1958, was one of the most beautiful cars I have ever seen.

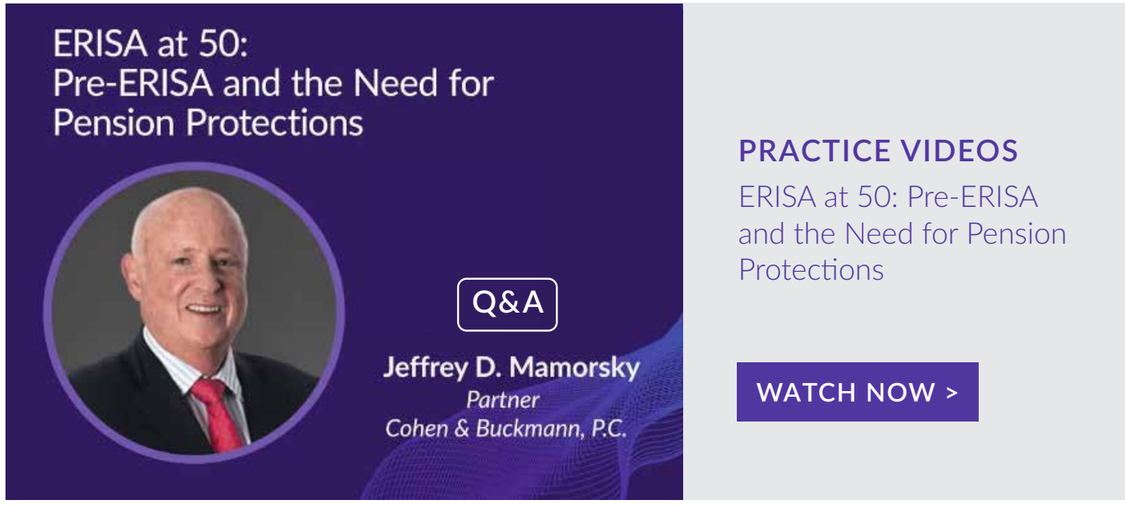
> Prior to ERISA, an employer could legally terminate a pension plan without funding all vested benefits. In the old days, there were no rules as we know them today whatsoever.

What brought to light the plight of American workers and their pension benefits was when the Studebaker Pension Plan terminated on October 15th, 1964. Only current retirees and retirement eligible employees over the age of 60 received their pensions, and more than 4,000 non-vested employees received nothing. This was not an isolated story.

Prior to ERISA, an employer could legally terminate a pension plan without funding all vested benefits. In the old days, there were no rules as we know them today whatsoever. There were labor laws under the 1947 Labor Management Relations Act, known as the Taft-Hartley Act.[2] It really didn't do very much at all.

The Taft-Hartley Act said only that it was legal for a union to set up a pension plan as long as you had a joint board of trustees consisting of both management and labor representatives. The reason why Studebaker caused such a huge brouhaha was that pre-ERISA, there was not any vesting in retirement benefits until you retired. The only real regulations then were found in the qualification rules of the Internal Revenue Code that had been in place since 1928. There were also interpretations by the IRS Pension Chief, Isidore Goodman, through his speeches and through revenue rulings, but they basically related only to maintaining the qualified status of a pension plan through compliance with the tax laws. There weren't any vesting rules, minimum accrual rules, eligibility rules, joint and survivor rules, break in service rules, or any of the other pension rules we know today, and most unbelievably, there weren't fiduciary rules at all, but things took time.

Even though the Studebaker plant closing happened in 1963, it wasn't until 1968 that bills were introduced and hearings held in Congress on why pension reform was necessary.



1. Pub. L. No. 93-406, 88 Stat. 829 (Sept. 2, 1974).

2. Pub. L. No. 80-101, 61 Stat. 136 (June 23, 1947).

Related Content

For an overview of the principal rules under Title I of the Employee Retirement Income Security Act (ERISA), see

ERISA TITLE I FUNDAMENTALS

For guidance in identifying the various fiduciaries of employee benefit plans under ERISA, their fiduciary duties and obligations, and potential liability and penalties for breach of their fiduciary duties, see

ERISA FIDUCIARY DUTIES

For an explanation of the prohibited transactions rules of ERISA and similar rules under the Internal Revenue Code, see

ERISA PROHIBITED TRANSACTIONS

For a review of the exemptions to the prohibited transactions rules of ERISA and the Internal Revenue Code, see

PROHIBITED TRANSACTION EXEMPTIONS

For an analysis of the requirements under the Internal Revenue Code and ERISA that apply to qualified retirement plans, see

QUALIFIED RETIREMENT PLAN FUNDAMENTALS

For a discussion on the progress that has been made over the years as a result of the passage of ERISA in expanding and enhancing pension participant protections and where ERISA has fallen short, see

50 YEARS LATER, ERISA REMAINS A WORK IN PROGRESS

For an evaluation of the success of 401(k) plans and how they might be improved in the future, see

IN DEFENSE OF THE 401(K) PLAN

Four legislators were the greatest proponents of pension reform. The most important one was Senator Jacob Javits from New York. Javits was passionate about passing legislation to protect workers with regard to their retirement plans. Senator Harrison Williams from New Jersey was also passionate about pension reform.

On the House side, John Erlenborn from Illinois and John Dent from Pennsylvania were very passionate about pension reform and protecting workers. These four gentlemen were driven to get pension reform passed, but even though these bills started to float around beginning in 1968, things really didn't start to happen until 1972.

View the full video, ERISA at 50: Pre-ERISA and the Need for Pension Protections, to learn about the next steps in the process that led to the creation and passage of ERISA 50 years ago.

To view the second video in the series, see ERISA at 50: Fiduciary Protections Video.

To view the third video in the series, see ERISA at 50: Impact of ERISA and Major Amendments Video. L

Jeffrey D. Mamorsky is a shareholder at Cohen & Buckmann, P.C. He is a leading ERISA and employee benefits attorney with an emphasis on legal issues involving retirement and welfare benefit plans. Jeff serves as employee benefits counsel and provides fiduciary advice to plan sponsors, which include large multinational corporations, financial institutions, insurance companies, closely held businesses, large not-for-profit organizations, governmental agencies, Big Four accounting firms, employee benefits consulting firms, large multi-employer plans, and major multi-employer pension and welfare funds.

RESEARCH PATH: *Employee Benefits & Executive Compensation > Retirement Plans > Practice Notes*

Students Preparing for Future Legal Careers Make the Most of Coaching by Seasoned Attorneys

For the second year in a row, a student group of aspiring attorneys from Chicago's Legal Prep Charter Academy took first place in an annual mock trial competition held at the specialized high school.

THE WINNING TEAM OF DEDICATED STUDENTS WAS coached by attorneys from LexisNexis and Crowell & Moring. The students worked tirelessly this year to master the fact pattern, create their trial strategy, and nail their arguments to secure the win.

Legal Prep is a legal-themed high school in Chicago that offers a typical high school curriculum along with a unique law program designed to prepare diverse students for legal careers. The legal courses are reinforced with real-world practice programs like mock trials, negotiations, and debate. Legal Prep is a highly diverse high school, with most students residing in an underserved area of Chicago's west side. Participation from the legal community in events like the mock trial competition enriches the students' learning and fosters diversity in the student-to-lawyer pipeline.

The LexisNexis coaching team of Practical Guidance attorneys was led by Jafon Fearson and and included Randi-Lynn Smallheer, Michael Bahler, Karen Yotis, and John Martin. Volunteers will soon begin preparing to coach a group of students in the next mock trial competition. For additional details see the LinkedIN Post from Legal Prep Charter Academy.

1st Place Team in the Annual Mock Trial Competition at Legal Prep Charter Academy

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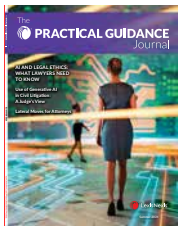

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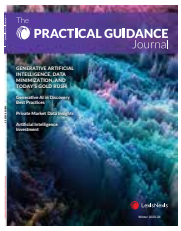

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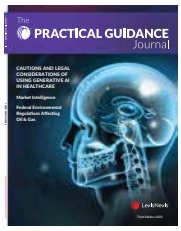

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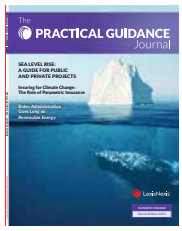

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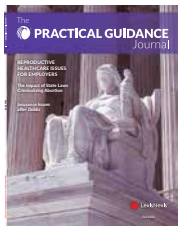

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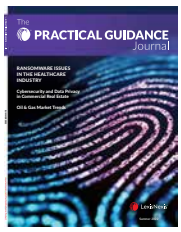

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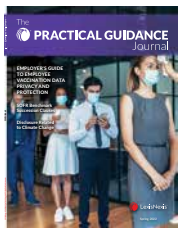

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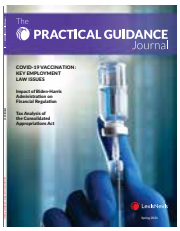

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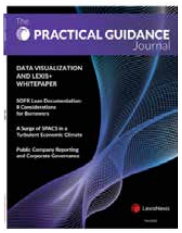

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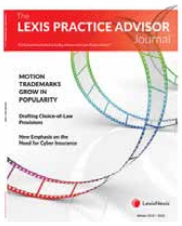

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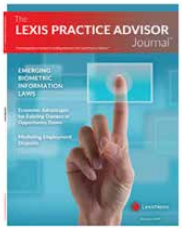

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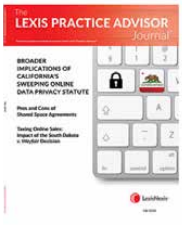

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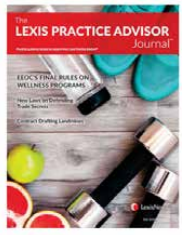

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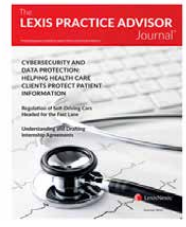

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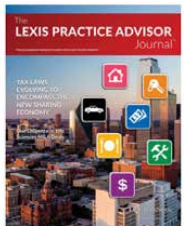

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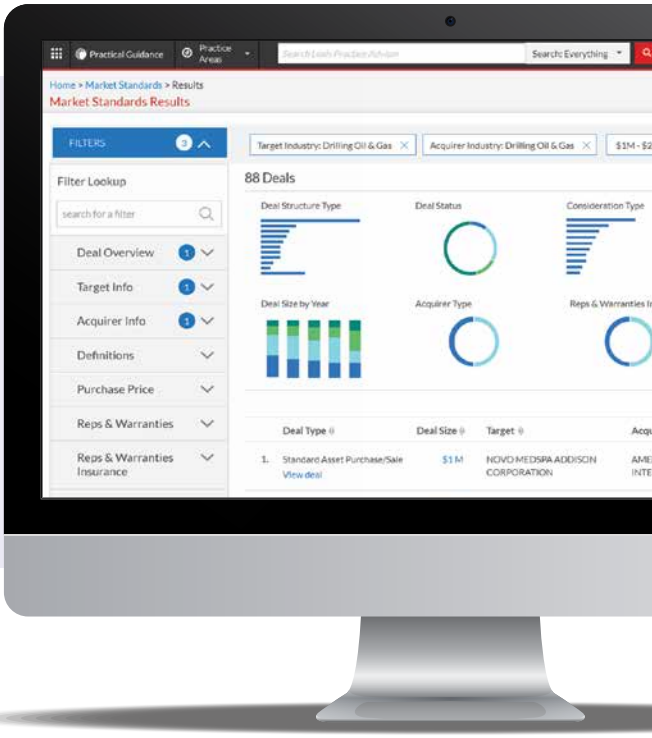

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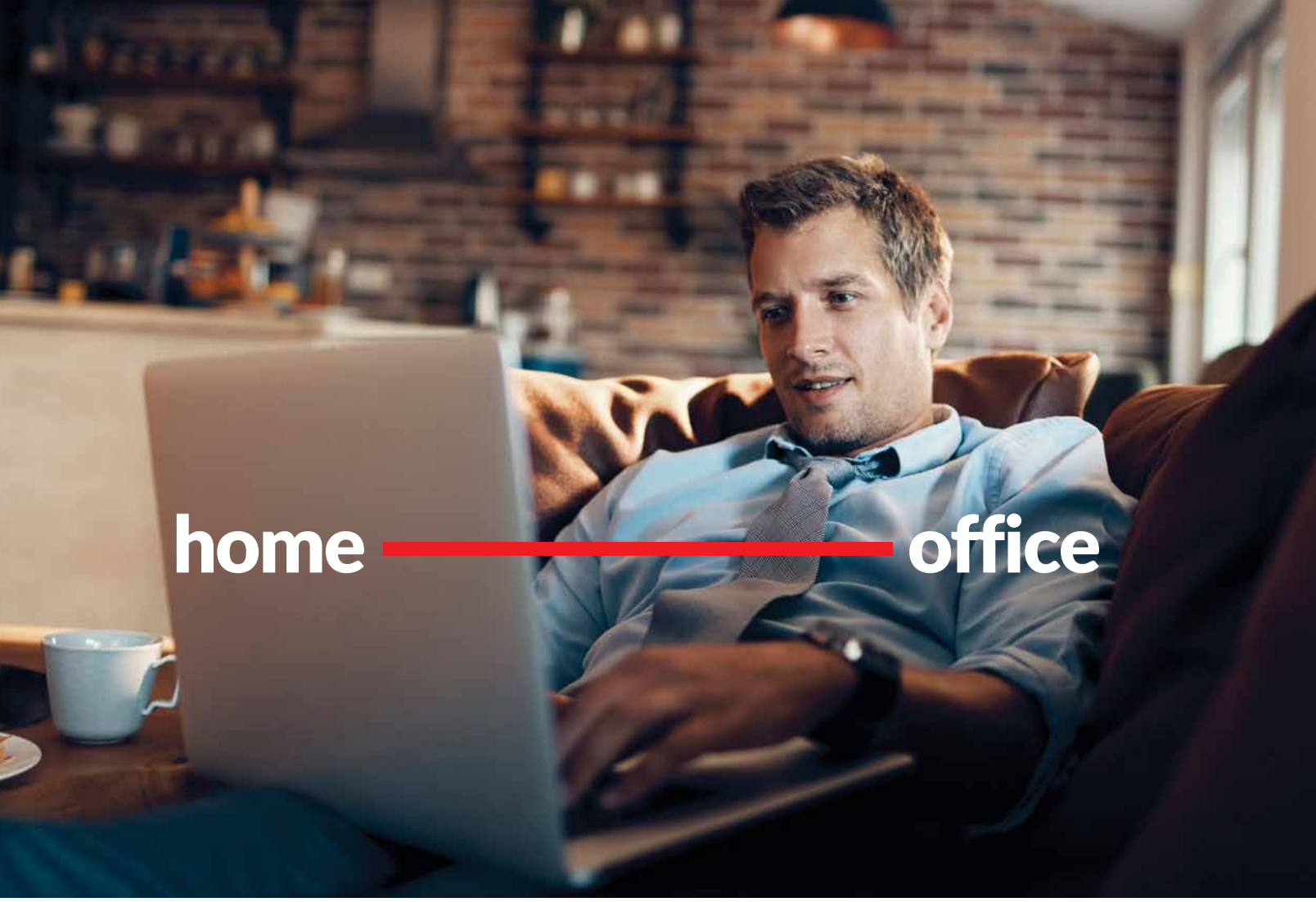

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