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Pepperdine University School of Law
Legal Summaries

TABLE OF CASES

SUPREME COURT OF THE UNITED STATES

Sebelius v. Cloer, 133 S. Ct. 1886 (2013)	233
Vance v. Ball State University, 133 S. Ct. 2434 (2013)	237
Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013).....	243

UNITED STATES COURTS OF APPEALS

Ketchikan Drywall Services, Inc. v. Immigration & Customs Enforcement, 725 F.3d 1103 (9th Cir. 2013).....	248
Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292 (D.C. Cir. 2013)	252
Mortgage Bankers Ass’n v. Harris, 720 F.3d 966 (D.C. Cir. 2013)	256

SUPREME COURT OF THE UNITED STATES

Sebelius v. Cloer,
133 S. Ct. 1886 (2013)

Synopsis:

Under the National Childhood Vaccine Injury Act of 1986 (NCVIA, or the “Act”),¹ an injured claimant may recover compensation paid out from a federal trust fund for a vaccine-related injury, provided that the claimant’s petition is filed within thirty-six months after the date of the injury.² A court may award attorneys’ fees to a claimant who files a petition in good faith and upon “a reasonable basis for the claim for which the petition was brought.”³ The claimant, Dr. Melissa Cloer, did not file her petition for compensation within the statutory period of thirty-six months of the first symptoms of her illness.⁴ The issue that ultimately reached the U.S. Supreme Court was whether Cloer was entitled to reasonable attorneys’ fees and costs in connection with her untimely petition.⁵ The Supreme Court, in a 9–0 decision, affirmed the en banc Federal Circuit’s opinion, which allows such awards for untimely petitions under the NCVIA.⁶

¹ 42 U.S.C. §§ 300aa-1 to -34 (2006).

² *Sebelius v. Cloer*, 133 S. Ct. 1886, 1890 (2013).

³ *Id.*

⁴ *Id.* The statute provides:

[I]f a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury

42 U.S.C. § 300aa-16(a)(2).

⁵ *Sebelius*, 133 S. Ct. at 1892.

⁶ *Id.*; *Cloer v. Sec’y of Health & Human Servs.*, 675 F.3d 1358 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 638 (2012), *aff’d sub nom. Sebelius v. Cloer*, 133 S. Ct. 1886 (2013).

Facts, Analysis, Ruling:

From September 1996 to April 1997, Cloer received three Hepatitis-B immunizations and began to experience symptoms of numbness and strange sensations about a month after the final vaccination.⁷ The symptoms “waxed and waned” throughout the subsequent years and Cloer sought treatment in 1998 and 1999 from two neurologists.⁸ However, she was not diagnosed with multiple sclerosis (MS) until late 2003, when she began to experience the full manifestations of the demyelinating disease.⁹ Cloer learned of the link between MS and the Hepatitis-B vaccine in 2004 and filed a claim for compensation under NCVIA in September 2005.¹⁰ Her petition alleged that the vaccinations she received had caused or exacerbated her MS.¹¹

The sole procedure for reviewing a vaccine claim brought under NCVIA begins at the Court of Federal Claims’ Office of Special Masters.¹² The chief special master assigned by the Court of Federal Claims to Cloer’s petition determined that her claim was untimely because the thirty-six-month limitations period of the NCVIA began to run in 1997, when she first experienced MS symptoms.¹³ The legal basis of the special master’s determination was section 300aa-16 of the Act, which states that “no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation

⁷ *Sebelius*, 133 S. Ct. at 1892; *Cloer v. Sec’y of Health & Human Servs.*, 85 Fed. Cl. 141, 143 (Fed. Cl. 2008), *rev’d*, 603 F.3d 1341 (Fed. Cir. 2010), *aff’d*, 665 F.3d 1322 (Fed. Cir. 2011).

⁸ *Cloer*, 85 Fed. Cl. at 144.

⁹ *Sebelius*, 133 S. Ct. at 1892. Cloer was given a “provisional diagnosis” of MS. *Cloer*, 85 Fed. Cl. at 144.

¹⁰ *Sebelius*, 133 S. Ct. at 1892.

¹¹ *Id.*

¹² *Vaccine Claims/Office of Special Masters*, U.S. COURT OF FEDERAL CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Feb. 26, 2014); *see also* 42 U.S.C. § 300aa-12(a) (providing that the U.S. Court of Federal Claims and its special masters shall have jurisdiction to determine whether a petitioner is entitled to compensation and the amount of compensation under the NCVIA program).

¹³ *Sebelius*, 133 S. Ct. at 1892.

of such injury.”¹⁴ Cloer appealed the issue of timeliness, and the Federal Circuit panel agreed with her that the statute of limitations period began to run in September 2004, the earliest date when the medical community at large was put on notice in regards to the link between MS and the vaccine.¹⁵ The en banc Federal Circuit reversed, holding that Cloer’s petition was untimely, citing the language of 300aa-16.¹⁶ However, the en banc court did grant Cloer her motion for attorneys’ fees, quoting section 300aa-15(e)(1) for the provision of providing “reasonable attorneys’ fees and other costs . . . if the special master or court determines that that petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.”¹⁷ The Government submitted a petition for writ of certiorari, and upon review, the Supreme Court affirmed the grant of attorneys’ fees to Cloer.¹⁸

First, the Government argued the Act’s thirty-six-month statutory limitation for filing a petition was a statutory prerequisite to obtaining compensation from the program.¹⁹ In other words, only timely petitions were considered to be “filed.”²⁰ The Court stated that it found no textual support for this argument,²¹ and held that a

¹⁴ 42 U.S.C. § 300aa-16(a)(2) (2006). The special master cited Federal Circuit cases that were waivers of the United States’ sovereign immunity, such as the Vaccine Act, and emphasizes that such waivers “must be strictly and narrowly construed.” This meant that “subtle” symptoms or manifestations of onset trigger the statute of limitations for the Act. *Cloer v. Sec’y of Health & Human Servs.*, No. 05-1002V, 2008 WL 2275574, at *4, *5 (Fed. Cl. May 15, 2008), *aff’d*, 85 Fed. Cl. 141 (Fed. Cl. 2008), *rev’d*, 603 F.3d 1341 (Fed Cir. 2010), *aff’d*, 654 F.3d 1322 (Fed. Cir. 2011).

¹⁵ *Sebelius*, 133 S. Ct. at 1892. September 2004 was when an article on the causal link between MS and a vaccine was published in the medical periodical, *Neurology*. *Cloer v. Sec’y of Health & Human Servs.*, 603 F.3d 1341, 1349 (Fed. Cir. 2010).

¹⁶ *Sebelius*, 133 S. Ct. at 1892.

¹⁷ *Id.* (quoting section 300aa-15(e)(1)).

¹⁸ *Id.*

¹⁹ *Id.* at 1893.

²⁰ *See id.* at 1894 (“[T]o adopt the Government’s position, we would have to conclude that a petition like Dr. Cloer’s, which was ‘filed’ under the ordinary meaning of that term but was later found to be untimely, was never filed at all because, on the Government’s reading, ‘no petition may be *filed* for compensation’ late.”).

²¹ *Id.*

“petition filed in violation of the limitations period . . . is still a petition filed under § 300aa-11(a)(1),” and thus subject to the attorneys’ fees provision under section 300aa-15(e)(1).²² Second, the Court indicated that the lack of cross-reference to the limitations period in the relevant sections was further evidence of Congress’s lack of intent to exclude untimely petitions from the award of attorneys’ fees.²³ Third, the Court stated, it would be inconsistent to read “filed” as limited to those petitions that were submitted within the limitations period; there were “numerous instances throughout the NCVIA” where “filed” is meant to include untimely petitions as well.²⁴ For example, section 300aa-12(b)(2) requires the Secretary of Health and Human Services to publish notice of any petition filed under section 300aa-11 in the Federal Register within thirty days of receiving service for such a petition.²⁵ If the Government’s narrow reading of “filed” applies, then it is expected of the Secretary to strike untimely petitions from the Federal Register, but the Secretary does not make such exclusions in the publications.²⁶ Based on the preceding statutory analysis, the Court was satisfied that the statutory language was “unambiguous” in allowing untimely petitions brought in good faith, “like any other unsuccessful petition,” to receive attorneys’ fees.²⁷ Lastly, the Court pointed out that the Government’s reading was contrary to the goals of the fee provisions

²² *Id.* at 1893–94.

²³ *Id.* at 1894. The Court cited *Bates v. United States*, 522 U.S. 23, 29–30 (1997), for the proposition that it is “generally presumed that Congress acts intentionally and purposely” when it “includes particular language in one section of a statute but omits it in another section.” *Id.* The Court found it significant that compliance with the NCVIA limitations period was expressly provided in section 300aa-11(a)(2)(A), which prevented claimants from suing vaccine manufacturers unless the petition complied with the section 300aa-16 limitations period. *Id.*

²⁴ *Id.*

²⁵ *Id.* at 1894–95.

²⁶ *Id.* at 1895. Interestingly, the discussion of this requirement before the Court revealed that the Department of Health and Human Services had “not been complying with that provision for the last few years”; but when it was last complied with, “it included timely and untimely filings in the published list.” Ronald Mann, *Argument Recap: Justices Dubious of Limits on Attorney’s Fees in Vaccine Cases*, SCOTUSBLOG (Mar. 21, 2013, 10:25 AM), <http://www.scotusblog.com/2013/03/argument-recap-justices-dubious-of-limits-on-attorneys-fees-in-vaccine-cases/>.

²⁷ *Sebelius*, 133 S. Ct. at 1895.

because Congress had stated that the purpose of the fees scheme was to enable claimants to launch good-faith claims, regardless of whether the claims ultimately prevailed or not.²⁸

Impact:

The 9–0 majority opinion delivered by Justice Sotomayor is a signal that the statutory language of the NCVIA was clear in its goal of reducing the financial burden on victims of vaccine injuries,²⁹ and thus the Court owed no level of deference to the implementing agency’s interpretation of the statute.³⁰ Indeed, Congress enacted the NCVIA to set up a no-fault compensation program to circumvent the “inefficiencies and costs” of litigating vaccine injuries that burdened injured parties and vaccine manufacturers.³¹ *Sebelius* is an important decision made by the Court to maintain the efficiency and accessibility that Congress sought to create in the civil tort system in this area of litigation.³²

Vance v. Ball State University,
133 S. Ct. 2434 (2013)

Synopsis:

Petitioner Maetta Vance brought a Title VII action against her employer, respondent Ball State University (BSU), claiming BSU was vicariously liable for a fellow employee’s creation of a racially hostile work environment.³³ Under Title VII, an employer’s liability for such harassment depends on whether the harasser is a “supervisor.”³⁴ Where the supervisor’s harassment is characterized

²⁸ *Id.*

²⁹ *See id.*

³⁰ *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (holding where Congress’s intent is clear, the court and the agency are required to follow Congress’s unambiguously expressed intent).

³¹ *Sebelius*, 133 S. Ct. at 1890.

³² *See id.* (stating that the system was “designed to work faster and with greater ease than the civil tort system”).

³³ *Vance v. Ball State Univ.*, 133 S. Ct. 2434, 2439–40 (2013).

³⁴ *Id.* at 2439.

as “tangible employment actions,” the employer is strictly liable for the harasser’s actions.³⁵ Where a non-supervisory employee commits the harassment, the accuser has the additional burden of proving that the employer was “negligent in controlling working conditions” before vicarious liability may attach to the employer.³⁶ In their 2006 pleadings filed with the U.S. District Court for the Southern District of Indiana, Vance and BSU disputed the issue of whether or not Vance’s harasser was her supervisor for purposes of Title VII.³⁷ The district court held in BSU’s favor, finding Vance’s harasser was not a supervisor under the Seventh Circuit’s definition, which requires supervisors to possess “the power to hire, fire, demote, promote, transfer, or discipline an employee.”³⁸ The Seventh Circuit affirmed, holding steady to its established precedent that was in conflict with the Equal Employment Opportunity Commission’s (EEOC) standard.³⁹ The U.S. Supreme Court granted certiorari to provide guidance for lower courts.⁴⁰

Facts, Analysis, Ruling:

Vance, an African-American woman, worked as a full-time catering assistant at a division of BSU’s dining services.⁴¹ In late 2005 and early 2006, Vance filed internal complaints and charges with the EEOC against BSU.⁴² Among her complaints and charges of racial harassment and retaliation, many pertained to a Caucasian female employee, Saundra Davis, who served as a catering specialist

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 2440.

³⁸ *Id.* (quoting *Hall v. Bodine Elec. Co.*, 276 F.3d 345, 335 (7th Cir. 2002)).

³⁹ *Id.* at 2443. The Second and Fourth Circuits follow the EEOC’s standard, while the First, Seventh, and Eighth Circuits have advocated for the bright-line rule of defining a supervisor as one who has “the power to hire, fire, demote, promote, transfer, or discipline the victim.” *Id.*

⁴⁰ *Id.* The Court was notably concerned about providing “reasonably clear jury instructions in employment discrimination cases,” citing the opinions of courts and commentators. *Id.* at 2451; *see also id.* at 2451 n.13 (citing cases and law articles that discuss the necessity of simplified, straightforward jury instructions in employment discrimination cases).

⁴¹ *Id.* at 2439.

⁴² *Id.*

in Vance's division.⁴³ BSU attempted to address the problem but was unsuccessful in resolving the grievances and Vance filed suit in federal district court in 2006.⁴⁴ Her complaint alleged that Davis was her supervisor and BSU was vicariously liable for the racially hostile work environment that Davis created.⁴⁵ The district court found against Vance in summary judgment, holding that BSU was not vicariously liable because Davis was not Vance's supervisor under the "hire, fire, demote, promote, transfer, or discipline" standard of the Seventh Circuit; and moreover, BSU was not liable in negligence "because it responded reasonably to the incidents of which it was aware."⁴⁶ The Seventh Circuit affirmed the ruling.⁴⁷

At the U.S. Supreme Court, Vance argued that the general and legal usage of "supervisor" supported her claim that Davis was her supervisor.⁴⁸ As the Court noted, a dictionary entry defines the term as "one who inspects and directs the work of others."⁴⁹ Vance pointed out that Davis's job description gave her leadership responsibilities, and there was evidence that Vance and other kitchen employees were "at times led or directed" by Davis.⁵⁰ However, the Court was able to show that varying uses of the word in other dictionaries and legal authority existed so as to arrive at the conclusion that Vance's argument was not compelling.⁵¹

The Court then discussed at length its previously-established framework of when an employer can be vicariously liable,⁵²

⁴³ *Id.*

⁴⁴ *Id.* at 2440.

⁴⁵ *Id.*

⁴⁶ *Id.* (citing *Vance v. Ball State Univ.*, 2008 WL 4247836, at *15–16 (S.D. Ind. Sept. 8, 2010)).

⁴⁷ *Id.*

⁴⁸ *Id.* at 2444.

⁴⁹ *Id.* (quoting 17 OXFORD ENGLISH DICTIONARY 245 (2d ed. 1989)).

⁵⁰ *Id.* at 2449.

⁵¹ *Id.* at 2444–46.

⁵² The framework was laid out in *Burlington Industries, Inc. v. Ellerth*, 524 U.S. 742 (1998), and *Faragher v. City of Boca Raton*, 524 U.S. 775 (1998). In *Ellerth*, the employer hired his victim and promoted her, but subjected her to sexual harassment. 524 U.S. at 742. The Court held that an employee who does not suffer tangible job consequences as a result of actionable discrimination may nonetheless hold the employer strictly liable, but the employer may raise an affirmative defense. *Id.* The Seventh Circuit did not have any trouble characterizing the harasser in *Ellerth* as the victim's supervisor. *Vance*, 133 S. Ct. at 2446.

concluding that the “defining characteristic” of a supervisor is the ability to “cause ‘direct economic harm’ by taking a tangible employment action.”⁵³ Thus, under the existing framework, it was appropriate to adopt the Seventh Circuit’s bright-line rule that a showing of a tangible employment action against the victim—i.e., “a significant change in employment status, such as hiring, firing, failing to promote, reassignment with significantly different responsibilities, or a decision causing a significant change in benefits”⁵⁴—is required before vicarious liability can attach.⁵⁵

The Court bolstered its adoption of the bright-line rule with a policy discussion that emphasized the reasons it rejected the EEOC’s definition,⁵⁶ which the Court called “a study in ambiguity.”⁵⁷ The Court pointed to the EEOC’s position elaborated in both the Government’s Brief for United States as *Amicus Curiae* (U.S. Brief),⁵⁸ as well as the EEOC’s publication,⁵⁹ entitled *Enforcement Guidance: Vicarious Employer Liability for Unlawful Harassment by Supervisors*.⁶⁰ The EEOC defined “supervisor” as one who “has authority to undertake or recommend tangible employment decisions

In *Faragher*, the victim was a female lifeguard who sued the city of Boca Raton for sexual harassment based on the theory of vicarious liability. 524 U.S. at 775. The Court held that there is strict liability if the supervisor is the harasser, but the employer may present an affirmative defense. *Id.* As in *Ellerth*, it was not disputed that the harassers were the victim’s supervisors. *Vance*, 133 S. Ct. at 2447.

⁵³ *Vance*, 133 S. Ct. at 2448 (quoting *Ellerth*, 524 U.S. at 762).

⁵⁴ *Id.* at 2442 (quoting *Ellerth*, 524 U.S. at 761).

⁵⁵ *Id.* at 2454. In essence, the Court believes that vicarious liability is justified where there are tangible employment actions, as those “are the means by which the supervisor brings the official power of the enterprise to bear on subordinates.” *Id.* at 2448 (quoting *Ellerth*, 524 U.S. at 762).

⁵⁶ *Id.* at 2450.

⁵⁷ *Id.* at 2449.

⁵⁸ Brief for United States as Amicus Curiae in Support of Neither Party at 9, *Vance v. Ball State Univ.*, 133 S. Ct. 2434 (2012) (No. 11-556).

⁵⁹ *Enforcement Guidance: Vicarious Employer Liability for Unlawful Harassment by Supervisors*, EEOC (June 18, 1999), <http://www.eeoc.gov/policy/docs/harassment.html> [hereinafter EEOC Guidance].

⁶⁰ *Vance*, 133 S. Ct. at 2449. As with Title VII claims generally, the EEOC’s definition of “supervisor” in the context of an actionable harassment requires an inquiry in the “surrounding circumstances, expectations, and relationships.” *Id.* at 2463 (Ginsberg, J., dissenting) (quoting *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 81–82 (1998)).

affecting the employee,” *or* one who “has authority to direct the employee’s daily work activities.”⁶¹ Additionally, a supervisor’s authority must be “of sufficient magnitude so as to assist the harasser explicitly or implicitly in carrying out the harassment.”⁶² The Court was especially concerned that this definition was “ill-defined” and the vagueness of this standard would complicate harassment cases.⁶³ Thus, in adopting the Seventh Circuit’s bright-line rule, the Court was assured that it had simplified an important issue in employment discrimination cases.⁶⁴ With this rule, the issue of vicarious liability can easily “be resolved as a matter of law before trial”;⁶⁵ and even where supervisorial status is disputed as a matter of fact—i.e., the parties have a genuine dispute about whether the alleged harasser a supervisor or not for purposes of Title VII—it is a “relatively straightforward” preliminary question that can be easily presented to the jurors.⁶⁶

Impact:

In the majority opinion by Justice Alito, there was notably a lack of discussion about how much weight the Court should give to the EEOC’s definition.⁶⁷ In her dissent, Justice Ginsberg noted that the Court, as a general rule, affords *Skidmore* deference to the EEOC’s guidelines, which respects the agency’s definition to the extent that it is persuasive.⁶⁸ The dissent pointed out that the EEOC

⁶¹ EEOC Guidance, *supra* note 59.

⁶² *Vance*, 133 S. Ct. at 2449 (quoting U.S. Brief at 27; EEOC Guidance).

⁶³ *Id.* at 2449–50. Specifically, the Court feared that “[a]pplying these standards would present daunting problems for the lower federal courts and for juries.” *Id.* at 2450.

⁶⁴ *Id.* at 2450.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *See id.* at 2449–50. The Court analyzed the merits of the EEOC definition without considering the EEOC’s expertise in relevant areas of the law and without considering how the EEOC arrived at its definition. *Id.* at 2461–62 (Ginsberg, J., dissenting).

⁶⁸ *Id.* at 2461. The Court in *Skidmore* recognizes an administrative agency’s persuasive power:

We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the

had the “informed judgment” and “body of experience” in enforcing Title VII, and that it had adhered to its definition of “supervisor” for fourteen years based on the Court’s guidance provided in *Ellerth* and *Faragher*.⁶⁹ Furthermore, the EEOC’s formulation of the rule reasonably ensured that ordinary employees would not be treated as supervisors for the purposes of ascertaining the liability of the employer.⁷⁰ The dissent deemed the majority’s chosen definition as one that “undermine[s] Title VII’s capacity to prevent workplace harassment,”⁷¹ and questioned the “workability” of the Court’s definition.⁷² Specifically, the dissent argued that the majority’s definition was so limiting that it does not reflect the reality of workplace: that “[s]upervisors, like the workplaces they manage, come in all shapes and sizes.”⁷³ Thus, those supervisors that have the ability to assign unpleasant tasks or alter the work environment of a fellow employee in objectionable ways may be able to escape liability simply because the supervisor lacks the authority to take tangible employment actions.⁷⁴

With the concerns of the dissent in mind, the impact of the case is two-fold: not only has the Court created precedent that diverges from *Skidmore*’s mandate, affecting the ability of administrative agencies to enforce their regulatory policies, the Court has also simplified some of the complexity in adjudicating

courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

⁶⁹ *Vance*, 133 S. Ct. at 2461 (Ginsberg, J., dissenting).

⁷⁰ *See id.* at 2461–62 (discussing how the EEOC’s standard applies).

⁷¹ *Id.* at 2463.

⁷² *Id.* at 2463 n.6.

⁷³ *Id.*

⁷⁴ *Id.* at 2451 (majority opinion). If the harasser is not deemed a supervisor of the victim; the plaintiff-victim will not be able to argue strict liability but instead must prove negligence.

employment harassment cases—and perhaps, in the interest of efficiency, weakened the mandate of Title VII.⁷⁵

Mutual Pharmaceutical Co. v. Bartlett,
133 S. Ct. 2466 (2013)

Synopsis:

Respondent Karen Bartlett suffered significant injuries resulting from her use of an inflammatory pain reliever manufactured by the generic drug manufacturer, petitioner Mutual Pharmaceutical (Mutual).⁷⁶ Bartlett alleged that New Hampshire's design-defect cause of action required Mutual to change the drug's labeling to provide stronger warnings, which Mutual failed to do.⁷⁷ The jury in federal district court awarded Bartlett \$21.06 million in compensatory damages on a design-defect claim under New Hampshire tort law,⁷⁸ a ruling that was upheld by the U.S. Court of Appeals for the First Circuit.⁷⁹ The U.S. Supreme Court reversed the judgment, holding that New Hampshire's design-defect claim was directly in conflict with the Federal Food, Drug, and Cosmetic Act (FDCA),⁸⁰ which, by operation of preemption, prohibited Mutual from providing a stronger label warning.⁸¹

⁷⁵ See *id.* at 2466 (Ginsberg, J., dissenting) (voicing the hope that Congress will “restore the robust protections against workplace harassment the Court weakens” with the *Vance* ruling).

⁷⁶ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013).

⁷⁷ *Id.* at 2470.

⁷⁸ *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220 (D.N.H. 2011), *aff'd*, 678 F.3d 30 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013).

⁷⁹ *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013).

⁸⁰ The FDCA requires drug manufacturers to “gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce.” *Bartlett*, 133 S. Ct. at 2470.

⁸¹ *Id.*

Facts, Analysis, Ruling:

In December 2004, Bartlett took a generic form of sulindac manufactured by Mutual to address her shoulder pain.⁸² In response to the drug, Bartlett soon developed toxic epidermal necrolysis, which deteriorated sixty-five percent of her skin and resulted in severe disfigurement, physical disabilities, and near-blindness.⁸³ Bartlett filed suit in state court, alleging claims for failure-to-warn and design-defect.⁸⁴ Mutual removed the suit to federal court, where the jury awarded damages to Bartlett based on her design-defect claim.⁸⁵ Mutual appealed, arguing that New Hampshire's tort law was preempted by the FDCA, the Hatch–Waxman Act, and the FDCA's regulations.⁸⁶

Specifically, New Hampshire law imposes a duty on manufacturers not to sell “any product in a defective condition unreasonably dangerous to the user or consumer.”⁸⁷ It is a strict liability law that the state supreme court has held “can be satisfied either by changing a drug's design or by changing its labeling.”⁸⁸ The FDCA similarly requires all drugs to be “safe for use,” which has been interpreted to require any drug's “probable therapeutic benefits” to “outweigh its risk of harm.”⁸⁹ The Hatch–Waxman Act, on the other hand, seeks to usher generic drugs into the market at an expedited pace, and thus allows generic drugs to be approved without facing the same level of scrutiny as their identical (in several key respects) brand-name counterparts that have already been approved by the FDA.⁹⁰ The stipulation is that once a drug is approved, the

⁸² *Id.* at 2472.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 36 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013).

⁸⁷ *Bartlett*, 133 S. Ct. at 2473 (quoting RESTATEMENT (SECOND) OF TORTS § 402A (1965)).

⁸⁸ *Id.* at 2474.

⁸⁹ *Id.* at 2470–71 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)).

⁹⁰ *Id.* at 2471. The Hatch–Waxman Act is the popular name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat.

generic drug manufacturer can neither make any major changes to the drug's composition, nor unilaterally change a drug's label.⁹¹ Mutual argued that these federal laws conflicted with state law because Mutual could not simultaneously comply with both sets of laws, pointing out that: (a) Mutual could not change the drug's design as required under federal law, and (b) Mutual could only satisfy New Hampshire law by changing its label, which was likewise an unavailable option under federal law.⁹²

The First Circuit Court of Appeals disagreed with Mutual's argument, finding that Congress had demonstrated no intent for federal law to preempt state tort claims.⁹³ Additionally, the First Circuit reasoned that Mutual had a third option: to stop selling the product in New Hampshire.⁹⁴ Accordingly, it affirmed the district court's ruling and jury award.⁹⁵

The U.S. Supreme Court arrived at the opposite conclusion, finding that federal law preempted New Hampshire's tort law.⁹⁶ The Court rejected the First Circuit's rationale for failing to find preemption, stating, "Even in the absence of an express pre-emption provision,"⁹⁷ state law may be preempted where a party finds it "impossible . . . to comply with both state and federal requirements."⁹⁸ The Court agreed with the First Circuit that Mutual could not redesign the drug or independently strengthen the label, but rejected the First Circuit's suggestion that Mutual had a third option of "choos[ing] not to make [sulindac] at all."⁹⁹ Therefore, because Mutual could not satisfy both federal and state law at the same time,

1585 (1984) (codified as 21 U.S.C. § 355(j)(2)(A) (2012)). *Id.* The Hatch-Waxman Act is a supplement to the FDCA. *Id.* at 2494 (Sotomayor, J., dissenting).

⁹¹ *Id.* at 2471 (majority opinion).

⁹² *Id.* at 2474.

⁹³ *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 36 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013).

⁹⁴ *Id.* at 38.

⁹⁵ *Id.* at 43, 44.

⁹⁶ *Bartlett*, 133 S. Ct. at 2470.

⁹⁷ *Id.* at 2473.

⁹⁸ *Id.* (quoting *English v. Gen. Electric Co.*, 496 U.S. 72, 79, 110 (1990)).

⁹⁹ *Id.* at 2477. The Court then discussed at length that the First Circuit's "stop-selling" rationale was incompatible with "the vast majority—if not all" of the impossibility preemption cases that the Supreme Court had decided. *Id.* at 2478.

the Supremacy Clause rendered New Hampshire's conflicting law ineffective.¹⁰⁰

Impact:

Bartlett's two dissents respectively raised an interesting administrative law issue that the majority opinion skirted in its discussion: the role of the FDA in determining whether federal preemption applied.¹⁰¹ The FDA conceded that federal preemption of state law design-defect claims was a "difficult and close" call, but the agency sustained the position that the FDCA's misbranding prohibition preempts state law because "permitting juries to balance the health risks and benefits of an FDA-approved drug would undermine" the FDA's role in maintaining drug safety.¹⁰² Justice Breyer's dissent questioned the prudence of affording *Skidmore* deference to the FDA's interpretation,¹⁰³ which the majority seemed to have taken for granted in its wholesale adoption of the rationale set forth in *PLIVA*.¹⁰⁴ Justice Breyer's dissent recognized that the FDA

¹⁰⁰ *Id.* at 2472–73.

¹⁰¹ *Id.* at 2481 (Breyer, J., dissenting); *see also id.* at 2494 (Sotomayor, J., dissenting).

¹⁰² *Id.* at 2494 (Sotomayor, J., dissenting).

¹⁰³ *Id.* at 2481 (Breyer, J., dissenting). In *Skidmore v. Swift & Co.*, the Supreme Court established its standard of deferring to an agency's authority:

We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

323 U.S. 134, 140 (1944).

¹⁰⁴ The Court extended its ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)—i.e., the adoption of the FDA's interpretation—"that failure-to-warn claims against generic manufacturers are preempted by the FDCA's prohibition on changes to generic drug labels," to apply to design-defect claims as well without weighing the strength of the FDA's interpretation in the present case. *Bartlett*, 133 S. Ct. at 2476–78.

generally had expertise in administering drug-related federal statutes, but rejected giving “special weight to the FDA’s views” here.¹⁰⁵ Not only did the agency fail to “develop an informed position on the preemption question” by receiving and evaluating the views of interested parties (it did not communicate its interpretation through regulations or the like), but instead offered conflicting views on the matter in its briefs.¹⁰⁶ Justice Sotomayor’s dissent independently raised this concern as well, stating that the majority, by “defe[rring] to an agency’s *conclusion* that state law is pre-empted,”¹⁰⁷ “replace[d] careful assessment of regulatory structure with an *ipse dixit* . . . [that] treat[s] the FDA as the sole guardian of drug safety.”¹⁰⁸

Bartlett serves as an interesting judicial representation of the scholastic discussion “of the proper role of agencies and the extent to which courts owe them deference in preemption cases.”¹⁰⁹ The majority clearly chose to defer to agency views. On one hand, this decision exemplifies the Court’s recognition that the agency is better suited than the courts to interpret how state rules impact federal statutory purposes.¹¹⁰ On the other hand, the dissent represents the view that Congress’s intent should hold sway with respect to the interpretation of federal statutes.¹¹¹ The holdings in *PLIVA* and *Bartlett* have strong implications for societal health and drug safety, as the decisions have broadened the FDA’s scope of regulatory power, and have established strong precedent that gives weight to the agency’s ability to dictate the application of federal preemption in the area of drug regulation.

¹⁰⁵ *Id.* at 2481 (Breyer, J., dissenting).

¹⁰⁶ *Id.* (stating that “the FDA has set forth conflicting views on this general matter in different briefs filed at different times”).

¹⁰⁷ *Id.* at 2494 (Sotomayor, J., dissenting).

¹⁰⁸ *Id.* at 2493.

¹⁰⁹ Daniel J. Meltzer, *Preemption and Textualism*, 112 MICH. L. REV. 1, 44 (2013).

¹¹⁰ *Id.*

¹¹¹ *See id.* at 45 n.282.

UNITED STATES COURTS OF APPEALS

Ketchikan Drywall Services, Inc. v.
Immigration & Customs Enforcement,
725 F.3d 1103 (9th Cir. 2013)

Synopsis:

Appellant Ketchikan Drywall Services, Inc. (KDS) sought review of decisions issued by the Immigration and Customs Enforcement (ICE) and the Office of the Chief Administrative Hearing Officer.¹¹² ICE determined that KDS committed 271 violations of section 274A(b) of the Immigration and Nationality Act.¹¹³ Subsequently, an administrative law judge (ALJ) found in favor of ICE on 225 of those claims, affirming that KDS was liable for a civil penalty of \$173,250.¹¹⁴ The Ninth Circuit applied *Skidmore* deference to the Virtue Memorandum¹¹⁵ and denied KDS's petition for review.¹¹⁶

Facts, Analysis, Ruling:

Section 274A(b) of the Immigration and Nationality Act requires employers to verify their employees are legally authorized to work in the United States by filing the Employment Eligibility Verification Form (I-9 Form).¹¹⁷ Employers must retain these forms and provide them for inspection at the request of federal officials.¹¹⁸

¹¹² Ketchikan Drywall Servs., Inc. v. Immigration & Customs Enforcement, 725 F.3d 1103, 1108 (9th Cir. 2013).

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ See *infra* note 135.

¹¹⁶ Ketchikan Drywall, 725 F.3d at 1108.

¹¹⁷ *Id.*; see 8 U.S.C. § 1324a(b) (2012). The “employment verification system” requires employers to (1) attest under penalty of perjury that the employer has examined the employee’s documents; (2) attest under the penalty of perjury that the employee is eligible for employment in the United States; and (3) retain a copy of the form and “make it available for inspection by officers” of relevant federal enforcement agencies. *Id.*

¹¹⁸ Ketchikan Drywall, 725 F.3d at 1108; see 8 C.F.R. § 274a.2(b)(2)(ii) (2013) (“Any person or entity required to retain Forms I-9 in accordance with this section

KDS, a drywall installation company, employed four full-time employees and twenty part-time employees.¹¹⁹ In March 2008, KDS received a Notice of Inspection and administrative subpoena requesting its I-9 Forms for employees working from January 1, 2005, to March 25, 2008.¹²⁰ KDS responded on April 2, 2008, by producing some I-9 Forms and other employee verification documents.¹²¹ In April 2009, KDS received a Notice of Intent to Fine from ICE.¹²² KDS made further production of documents, which ICE accepted and reviewed.¹²³ An amended Notice of Intent to Fine was served on KDS in October 2009, containing 271 total violations of 8 U.S.C. § 1324a(b) and 8 C.F.R. § 274a.2(b) for failure to provide I-9 Forms for some of the employees, and for incomplete I-9 Forms for others.¹²⁴ KDS was ordered to pay a civil penalty of \$286,624.25.¹²⁵

KDS requested a hearing and “produced for the first time more copies of identification and employment authorization documents” to the ALJ, who denied consideration of these documents.¹²⁶ The ALJ granted ICE’s motion for summary decision for 225 violations and granted KDS’s motion for summary decision on the remaining violations.¹²⁷

Upon review before the Ninth Circuit, KDS contended that many of the 225 violations that the ALJ found were not violations.¹²⁸ First, KDS argued that in cases where ICE alleged no I-9 Forms were provided, KDS complied by presenting them, for the first time, to the ALJ.¹²⁹ Second, KDS insisted that its alleged omissions “were

shall be provided with at least three business days notice prior to an inspection of Forms I-9 by officers of an authorized agency of the United States.”).

¹¹⁹ *Ketchikan Drywall*, 725 F.3d at 1108.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at 1108–09.

¹²⁵ *Id.* at 1109.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

either minor or could be filled in by reference to the copied documents” that KDS retained.¹³⁰

Based on a plain reading of the text, the Ninth Circuit rejected KDS’s argument that section 1324a(b)(4) unambiguously allowed KDS to comply with the employer verification requirements simply by copying and retaining the documents.¹³¹ Additionally, the court pointed out that 8 C.F.R. § 274a.2(b)(3) spells out the requirement: “The copying . . . and retention of the copy or electronic image does not relieve the employer from the requirement to fully complete section 2 of the Form I–9.”¹³²

KDS made the alternative argument that, despite its omissions, it should be treated as in compliance due to the “good faith” compliance provision, which states that an entity is considered in compliance “notwithstanding a technical or procedural failure to meet such requirement if there was a good faith attempt to comply with the requirement.”¹³³ To address the merit of this argument, the court had to define “technical or procedural” violations and thus looked to Immigration and Naturalization Service’s (INS) interim guidelines on the “good faith” compliance provision.¹³⁴

The interim guidelines, or the “Virtue Memorandum,”¹³⁵ were promulgated informally in anticipation of formal regulations, and thus the court found that *Chevron* deference was improper.¹³⁶ Instead, *Skidmore* deference was proper for a number of reasons.¹³⁷ First, judging by the detailed treatment of the provision, the agency appeared to have considered the issue thoroughly.¹³⁸ Moreover, it defined and distinguished “substantive” violations versus “technical

¹³⁰ *Id.*

¹³¹ *Id.* at 1110–11.

¹³² *Id.* at 1111 (quoting 8 C.F.R. § 274a.2(b)(3) (2013)).

¹³³ *Id.* at 1111 n.7 (quoting 8 U.S.C. § 1324a(b)(6)(A) (2012)).

¹³⁴ *Id.* at 1112.

¹³⁵ See Memorandum from Paul S. Virtue, INS Acting Exec. Comm’r of Programs, Interim Guidelines: Section 274A(b)(6) of the Immigration and Nationality Act Added by Section 411 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (Mar. 6, 1997).

¹³⁶ *Ketchikan Drywall*, 725 F.3d at 1112. As the court quoted, interpretations that “lack the force of law—do not warrant *Chevron*-style deference.” *Id.* (quoting *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000)).

¹³⁷ *Id.* at 1112.

¹³⁸ *Id.*

or procedural” violations in a reasonable manner.¹³⁹ Additionally, the agency itself relied on the Virtue Memorandum in enforcing the employment verification statute for over a decade.¹⁴⁰ Finally, the agency had relative expertise in determining what constitutes substantive omissions for I-9 Forms.¹⁴¹

Relying on the Virtue Memorandum, the court found that KDS’s violations were “substantive deficiencies” that could not be excused under the “good faith” compliance provision.¹⁴² KDS’s failure to check appropriate boxes, despite having available copies of the relevant documents, constituted substantive violations.¹⁴³ Additionally, the untimely offering of relevant documents also constituted substantive violations, as the Virtue Memorandum provided that certain substantive deficiencies in the I-9 Forms could be excused only where the information was presented in the form of a legible copy at the I-9 inspection along with the I-9 Form itself.¹⁴⁴ Thus, the court held it was proper for the ALJ to refuse to admit the untimely-produced documents.¹⁴⁵

Impact:

Ketchikan Drywall provides an instance where the agency exercised its delegated authority to promulgate the law, but not through a more formal procedure that complies with the Administrative Procedure Act. As demonstrated by the Ninth Circuit’s analysis, such informal pronouncements of the law will not be afforded *Chevron* deference, but may still compel the court to accord *Skidmore* deference in the particular case based on the agency and the particular interpretation’s combined power of persuasion.¹⁴⁶

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 1112–13.

¹⁴¹ *Id.* at 1113. Under *Skidmore*, a court may defer to an agency’s interpretation, in a particular case, depending on its “power to persuade,” which “depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements.” *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

¹⁴² *Ketchikan Drywall*, 725 F.3d at 1113–15.

¹⁴³ *Id.* at 1113.

¹⁴⁴ *Id.* at 1115.

¹⁴⁵ *Id.*

¹⁴⁶ See *supra* notes 136–141.

Gentiva Healthcare Corp. v. Sebelius,
723 F.3d 292 (D.C. Cir. 2013)

Synopsis:

Medicare provider Gentiva Healthcare Corp. (Gentiva) brought an action against the Secretary of the Department of Health and Human Services (HHS) for violating the Medicare Integrity Program statute.¹⁴⁷ The D.C. Circuit affirmed the district court's award of summary judgment in favor of the Secretary, holding that (1) the Secretary "may delegate the 'sustained or high level of payment error' determination to another HHS official" in calculating overpayment claims, and (2) the merits of the determination were not subject to judicial review.¹⁴⁸

Facts, Analysis, Ruling:

In 2007, Medicare contractor Cahaba Safeguard Administrators (Cahaba) initiated a review of reimbursement claims filed by Gentiva for healthcare services provided between July 1, 2005, and November 30, 2006.¹⁴⁹ Cahaba's two key findings led it to believe that Gentiva's claims "exhibited a 'sustained or high level of payment error'": first, Cahaba found that fifty-eight percent of Gentiva's claims under review had been at least partially denied on the basis of noncompliance with the requirements for Medicare coverage;¹⁵⁰ and second, Gentiva received a higher payment as compared to other providers in its region for each beneficiary served.¹⁵¹

Cahaba then drew a sample of thirty of Gentiva's claims and determined that eighty-seven percent of the sampled claims were overpaid.¹⁵² Cahaba extrapolated this error rate over all claims and

¹⁴⁷ Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292, 294 (D.C. Cir. 2013).

¹⁴⁸ *Id.* at 296.

¹⁴⁹ *Id.* at 294.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

determined that Gentiva owed Medicare \$4,242,452.10 in overpayment.¹⁵³ Gentiva challenged the payment determination before an HHS Administrative Law Judge (ALJ) and argued that the sampling and extrapolation method was invalid, which was rejected by the ALJ.¹⁵⁴

The Medicare Appeals Council of HHS's Departmental Appeals Board (Council) subsequently reviewed Gentiva's appeal of the ALJ's approval of Cahaba's use of extrapolation.¹⁵⁵ The language of the Medicare Integrity Program¹⁵⁶ statute is written as follows:

(3) Limitation on use of extrapolation

A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.¹⁵⁷

Gentiva argued that, under this statute, the Secretary was required to personally make a determination of a sustained or high level of

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ The Medicare Integrity Program was created by the Deficit Reduction Act of 2005 under § 1936 of the Social Security Act. *Medicaid Integrity Program—General Information*, CMS.GOV, <http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/index.html?redirect=/medicaidintegrityprogram> (last updated Aug. 30, 2013). The purpose of the program is to “prevent and reduce provider fraud, waste, and abuse in the \$300 billion per year Medicare program.” *Id.*

¹⁵⁷ 42 U.S.C. § 1395ddd(f)(3) (2006).

payment error before extrapolation could be used.¹⁵⁸ The Council rejected this reading as “unduly narrow,” as § 1395kk(a) had given the Secretary “broad authority” to contract her administrative duties for the Medicare program.¹⁵⁹ Additionally, the Council found that the determination was valid.¹⁶⁰

Gentiva appealed the decision in federal district court, where the court applied the *Chevron* analysis and granted summary judgment for the Secretary.¹⁶¹ Applying the first step of *Chevron* to the issue of whether the Secretary could legally subdelegate her authority to determine if extrapolation was warranted, the court found that there was no “explicit indication” that the Secretary’s “sustained or high level of payment error” determination could not be delegated to contractors.¹⁶² Applying the second step of *Chevron*, it was reasonable for the Secretary to interpret § 1395ddd(f)(3) as permitting her to subdelegate that determination function, and thus the agency’s position was warranted deference.¹⁶³ Finally, the court held that it did not have jurisdiction to hear Gentiva’s challenge of the determination based on § 1395ddd(f)(3)’s language: “There shall be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors.”¹⁶⁴

Gentiva appealed the district court’s findings and the D.C. Circuit reviewed the issues de novo.¹⁶⁵ The circuit court agreed with the lower court that the Secretary’s construction of § 1395ddd(f)(3) should be deferred to because the statute was ambiguous and the

¹⁵⁸ *Gentiva*, 723 F.3d at 294.

¹⁵⁹ *Id.*; see 42 U.S.C. § 1395kk(a) (“The Secretary may perform any of his functions under this subchapter directly, or by contract providing for payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.”).

¹⁶⁰ *Gentiva*, 723 F.3d at 294.

¹⁶¹ *Id.* at 294–95. Under *Chevron*, the court asks two questions: first, “whether Congress has directly spoken to the precise question at issue”; and second, “if the statute is silent or ambiguous” as to the issue, “whether the agency’s answer is based on a permissible construction of the statute.” *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

¹⁶² *Gentiva*, 723 F.3d at 295.

¹⁶³ *Id.*

¹⁶⁴ *Id.* (quoting 42 U.S.C. § 1395ddd(f)(3)) (internal quotation marks omitted).

¹⁶⁵ *Id.*

Secretary's interpretation was reasonable.¹⁶⁶ The circuit court rejected Gentiva's argument that the statute unambiguously required the Secretary herself to make the "sustained or high level of payment error" determination because the statute provided that "[a] medicare contractor . . . may use extrapolation" and, in the same sentence, stated that "the Secretary" makes the determination of whether extrapolation may be used.¹⁶⁷ Instead, the court stated, "'Secretary' does not always means 'Secretary'" because she may delegate the determination to another HHS official, and, under § 1395kk(a), she may even delegate to non-government actors by contract.¹⁶⁸ Thus, the court held that the statute did not unambiguously require the Secretary to make the determination herself; it was reasonable for the Secretary to construe the statute as permissive towards her delegation of this duty.¹⁶⁹

Finally, the D.C. Circuit agreed with the district court that the jurisdictional limits provided in the statute—that "[t]here shall be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors"—barred the court's review of the merits of the "sustained or high level of payment error" determination.¹⁷⁰ The court, reiterating its holding that the Secretary may delegate the job of making such determinations to contractors, rejected Gentiva's argument that the review limitation applies only when the Secretary makes the determination.¹⁷¹ The district court's summary judgment for the Secretary was affirmed.¹⁷²

Impact:

This case reaffirmed the Secretary's power to subdelegate her Medicare functions and contractor's authority to carry out overpayment determinations and use those calculations to extrapolate the amount of overpayment. In the decision, the court explained that

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 295–96.

¹⁶⁸ *Id.* at 296.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 297; 42 U.S.C. § 1395ddd(f)(3) (2006).

¹⁷¹ *Gentiva*, 723 F.3d at 297.

¹⁷² *Id.*

“although [the court] believe[d] Gentiva may have the better reading of § 1395ddd(f)(3),” the court must defer to the Secretary because the statute was ambiguous and the Secretary’s reading was reasonable.¹⁷³ Additionally, the court found that it did not have jurisdiction to review the determinations, even where the duty of making the determination had been delegated to another entity.¹⁷⁴ This was a straightforward application of *Chevron*,¹⁷⁵ and perhaps a suitable one. As then Judge Breyer of the First Circuit explained,

[T]he more closely related to the everyday administration of the statute and to the agency's (rather than the court's) administrative or substantive expertise, the less likely it is that Congress (would have) “wished” or “expected” the courts to remain indifferent to the agency's views.¹⁷⁶

This case appears to be highly consistent with Justice Breyer’s guidance. The Secretary’s duty of determining a “sustained or high level of payment error” was precisely prescribed by Congress and closely related to the Secretary’s mandate to administer the Medicare Integrity Program, which is within the HHS’s administrative expertise. As such, it was reasonable and proper for the court to defer to the agency’s interpretation of the relevant statute.

Mortgage Bankers Ass’n v. Harris,
720 F.3d 966 (D.C. Cir. 2013)

Synopsis:

Appellant Mortgage Bankers Association (MBA) brought suit against the Secretary of the Department of Labor (DOL) for violating the Administrative Procedure Act’s (APA) notice and comment

¹⁷³ *Id.* at 296.

¹⁷⁴ *Id.* at 297.

¹⁷⁵ *See supra* note 161.

¹⁷⁶ *Mayburg v. Sec’y of Health & Human Servs.*, 740 F.2d 100, 106 (1st Cir. 1984).

rulemaking procedure.¹⁷⁷ The DOL had issued an agency interpretation by way of an opinion letter posted in response to the MBA's inquiry in 2006, and later reversed its interpretation in 2010 by issuing an Administrator's Interpretation.¹⁷⁸ The new rule provided that mortgage loan officers were not exempt from federal overtime laws.¹⁷⁹ The district court granted summary judgment against MBA, holding that MBA failed to demonstrate the APA procedure had been triggered by MBA's "substantial and justified reliance" on the new regulation.¹⁸⁰ The D.C. Circuit reversed the summary judgment, holding that such reliance was not a separate and independent element of the circuit's two-part analysis.¹⁸¹

Facts, Analysis, Ruling:

The Fair Labor Standards Act (FLSA) was enacted in 1938 by Congress to ensure that employees who work more than forty hours per week are paid overtime wages, unless they are covered by an exemption provided in the Act.¹⁸² Section 213(a)(1) provides that employees who are "employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary)" are considered exempt from the overtime pay requirement.¹⁸³ FLSA is administered by the Wage and Hour Division of the DOL, which is also responsible for promulgating regulations that define and interpret the scope of FLSA's exemptions.¹⁸⁴ As a matter of practice, the DOL issues opinion letters through its website and electronic legal research databases¹⁸⁵ to announce its interpretation of FLSA.¹⁸⁶ Opinion

¹⁷⁷ *Mortg. Bankers Ass'n v. Harris*, 720 F.3d 966, 968 (D.C. Cir. 2013).

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 969.

¹⁸¹ *Id.* at 972.

¹⁸² *Mortgage Bankers Ass'n v. Solis*, 864 F. Supp. 2d 193, 195–96 (D.D.C. 2012), *rev'd and remanded sub nom.* *Mortg. Bankers Ass'n v. Harris*, 720 F.3d 966 (D.C. Cir. 2013).

¹⁸³ *Id.* at 196 (quoting 29 U.S.C. § 213(a)(1) (2012)).

¹⁸⁴ *Id.*

¹⁸⁵ See *Wage and Hour Division (WHD) Rulings and Interpretations*, U.S. DEP'T OF LABOR, <http://www.dol.gov/whd/opinion/opinion.htm> (last visited Mar.

letters are typically in response “to inquiries from private parties seeking guidance about the application of the FLSA to their business activities.”¹⁸⁷

In 2006, the DOL issued an opinion letter (2006 Opinion Letter) responding to MBA’s inquiry regarding whether or not its 2200 member companies were required to pay their mortgage loan officers overtime.¹⁸⁸ Mortgage loan officers “typically assist prospective borrowers in identifying and then applying for various mortgage offerings.”¹⁸⁹ MBA had asked the DOL whether such employees who “spent less than fifty percent of their working time on ‘customer-specific persuasive sales activity’” were considered exempt.¹⁹⁰ In the 2006 Opinion Letter, the DOL relied on its 2004 regulations¹⁹¹ in declaring that mortgage loan officers, based on the facts presented by MBA,¹⁹² satisfied the elements of the administrative exemption.¹⁹³ Addressing the second prong of the 2004 regulations codified under 29 C.F.R. part 541, the DOL clarified in the 2006 Opinion Letter that “work directly related to the management or general business operations of their employer or their employer’s customers” was *different* from “working on a

11, 2014). The website offers updates of the WHD Administrator’s interpretations and rulings as well as withdrawals of previous interpretations and rulings made on the basis of new statutes, regulations, and case law. *Id.* “Note that rulings and interpretations may be affected by changes to the applicable statute or regulations.” *Id.*

¹⁸⁶ *Solis*, 864 F. Supp. 2d at 197.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 198.

¹⁸⁹ *Harris*, 720 F.3d at 968.

¹⁹⁰ *Solis*, 864 F. Supp. 2d at 198.

¹⁹¹ See Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22,122 (Apr. 23, 2004) (codified at 29 C.F.R. pt. 541). The administrative exemption of FLSA applies to an employee: (1) compensated on a salary or fee basis at a rate of not less than \$455 per week; (2) whose primary duty is the performance of office or non-manual work directly related to the management or general business operations of the employer or the employer’s customers; and (3) whose primary duty includes the exercise of discretion and independent judgment with respect to matters of significance. *Id.*

¹⁹² *Solis*, 864 F. Supp. 2d at 199. The letter specifically stated that its opinion was “based exclusively on the facts and circumstances” presented in MBA’s request. *Id.*

¹⁹³ *Id.*

manufacturing production line or selling a product in a retail or service establishment.”¹⁹⁴ The mortgage loan officers satisfied this prong because they had primary duties “other than sales,” which required them to collect and analyze financial information to provide specially-tailored advice to customers about mortgage loans and the risks and benefits of each mortgage loan alternative for the particular customer.¹⁹⁵ The 2006 Opinion Letter additionally stated, the fact that mortgage loan officers used software programs or tools in providing such services, did not disqualify them under the third prong of the test—the requirement that the exempt employee exercise discretion and independent judgment as part of the employee’s primary duties.¹⁹⁶ MBA’s members allegedly relied on this letter and classified their mortgage loan officers as exempt from FLSA’s overtime law.¹⁹⁷

In March 2010, the Acting Administrator of the Wage and Hour Division issued an Administrator Interpretation *sua sponte* (2010 Administrator Interpretation),¹⁹⁸ without implementing the APA’s notice and comment process.¹⁹⁹ The 2010 Administrator Interpretation specifically addressed whether a typical mortgage loan officer’s duties fit the second prong of the test, i.e., the primary duty of “office or non-manual work directly related to the management or general business operations of their employer or their employer’s customers.”²⁰⁰ It defined the second prong to include work that services the business itself, including “accounting, budgeting, quality control, purchasing, advertising, research, human resources, labor relations, and similar areas.”²⁰¹ As such, where mortgage loan officers’ primary duties were to “sell[] loans directly to individual

¹⁹⁴ *Id.* at 198, 199.

¹⁹⁵ *Id.* at 199.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.* Administrator Interpretations are issued at the Administrator’s discretion when the WHD wishes to “set forth a general interpretation of the law and regulations, applicable across-the-board,” as it is a more “efficient and productive” way of providing guidance than issuing fact-specific opinion letters, “where a slight difference in the assumed facts may result in a different outcome.” *WHD Rulings and Interpretations*, *supra* note 185.

¹⁹⁹ *Solis*, 864 F. Supp. 2d at 201.

²⁰⁰ *Id.* at 199.

²⁰¹ *Id.*

customers, one loan at a time,” the administrative exemption did not apply to them.²⁰²

MBA filed suit in federal district court in January 2011 against the DOL for violating the APA’s notice and comment rulemaking requirement through its issue of the 2010 Administrator Interpretation.²⁰³ MBA sought to have the 2010 Administrator Interpretation “vacat[ed] and set aside” and to have the DOL enjoined from enforcing it.²⁰⁴ Under D.C. Circuit law, an agency is “required to use notice and comment procedures” if the interpretation of a regulation “itself carries the force and effect of law.”²⁰⁵ This procedure is triggered when two elements are met: where the agency has made “definitive interpretations” and in doing so, made “a significant change” to its rule.²⁰⁶ However, the district court agreed with the DOL that MBA’s alleged reliance on the 2006 Opinion Letter was not “substantial and justifiable reliance on a well-established agency interpretation” and found for the DOL on summary judgment.²⁰⁷

The particular issue in contention between MBA and the DOL that came before the D.C. Circuit’s three-judge panel was whether D.C. case law had added another element to the analysis.²⁰⁸ The DOL argued that MBA had to meet a third element of “substantial and justified reliance” to trigger the requirement of the notice and comment procedure.²⁰⁹ The D.C. Circuit disagreed with the DOL’s reading of the cases and held that “reliance” was merely

²⁰² *Id.* at 200 (citing *Casas v. Conseco Fin. Corp.*, No. Civ. 00–1512, 2002 WL 507059 (D. Minn. Mar. 31, 2002)). The 2010 Administrator Interpretation cited other cases in support of this conclusion that mortgage loan officers are non-exempt employees. See Nancy J. Leppink, *Administrator’s Interpretation No. 2010–1*, U.S. DEP’T OF LABOR WHD (Mar. 24, 2010), http://www.dol.gov/WHD/opinion/adminIntrprtn/FLSA/2010/FLSAAI2010_1.pdf.

²⁰³ *Solis*, 864 F. Supp. 2d at 201.

²⁰⁴ *Id.*

²⁰⁵ *Id.* at 204.

²⁰⁶ *Harris*, 720 F.3d at 969. The test originated from *Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579 (D.C. Cir. 1997).

²⁰⁷ *Solis*, 864 F. Supp. 2d at 208. The court noted that the only type of reliance that MBA had cited was that between 2006 and 2010 mortgage loan officers had “become accustomed to the freedom to control their own hours and breaks” under their status as exempt employees. *Id.*

²⁰⁸ *Harris*, 720 F.3d at 967–68.

²⁰⁹ *Id.* at 968–69.

part of the first element inquiry of whether there was a definitive interpretation.²¹⁰ In oral argument, the DOL conceded that the first and second elements of the analysis had already been met—namely, there were two definitive and conflicting agency interpretations.²¹¹ Having fulfilled the two elements of the analysis, the D.C. Circuit ordered the district court to vacate the DOL’s 2010 Administrator Interpretation.²¹²

Impact:

When formulating regulations, agencies are required to follow the APA’s notice and comment procedure, which applies to “repeals” and “amendments” of those regulations.²¹³ The D.C. Circuit is perhaps unique in adding “change an interpretation of a regulation” to that list.²¹⁴ *Paralyzed Veterans of America* and its progeny in the D.C. Circuit have established that where an agency makes a significant revision to an earlier “definitive interpretation,” the agency has “in effect amended its rule,” which requires notice and comment.²¹⁵ The D.C. Circuit approach reflects a pushback against the familiar practice of deferring to agency interpretation following the Supreme Court’s decisions in *Chevron U.S.A. v. Natural Resources Defense Council, Inc.* and *Bowles v. Seminole Rock & Sand Co.*²¹⁶ In reaffirming its strict two-element test for evaluating

²¹⁰ *Id.* at 971 (“[W]e have always considered it as part of the first element.”).

²¹¹ *Id.* at 968.

²¹² *Id.* at 972.

²¹³ *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997).

²¹⁴ Scott H. Angstreich, *Shoring Up Chevron: A Defense of Seminole Rock Deference to Agency Regulatory Interpretations*, 34 U.C. DAVIS L. REV. 49, 79 (2000).

²¹⁵ Michael Asimow & Robert A. Anthony, *A Second Opinion? Inconsistent Interpretive Rules*, 25 ADMIN. & REG. L. NEWS 16 (Winter 2000). Some commentators, such as Asimow and Anthony, are highly critical of the D.C. Circuit’s approach, believing it violates APA § 553(b)(A)’s exemption for interpretive rules. *Id.* The relevant provision states that the notice and comment procedure does not apply “to interpretive rules, general statements of policy, or rules of agency organization, procedure or practice.” 5 U.S.C. § 553(b)(3)(A) (2012).

²¹⁶ See *Paralyzed Veterans*, 117 F.3d at 584–85 (discussing concerns that such deference “arguably creates perverse incentives for an agency to draft vague

changes in agency interpretations, the D.C. Circuit advances its purported goal of encouraging greater accountability in the interpretation of regulations.²¹⁷ What remains to be seen is the impact on venue selection for agencies and regulated entities alike.²¹⁸

regulations that give inadequate guidance” in order to circumvent the notice and comment process required by the APA). For the two Supreme Court cases, see *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945).

²¹⁷ See *id.* at 584 (“[The Court] is certainly not open to an agency to promulgate mush and then give it concrete form only through subsequent less formal ‘interpretations.’”).

²¹⁸ See Angstreich, *supra* note 214, at 121. Angstreich explains that agencies try to avoid amending regulations by bringing enforcement actions in circuits that agree with their interpretations. *Id.* However, as “regulatory statutes permit appeal to the D.C. Circuit in addition to the circuit or circuits in which the party seeking review transacts business,” litigants challenging the interpretations are more likely to appeal to the D.C. Circuit, as that circuit’s analysis makes a finding of “amendment” more accessible. *Id.* at 122.