Supreme Court, U.S.
FILED

No. 10-460 OCT 4- 2010

IN THE OFFICE OF THE CLERK

Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner

v.

SIMONA M. LOPES, CATHERINE E. WHITE, *ET AL.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Fair Labor Standards Act ("FLSA") includes various "white-collar" exemptions intended by Congress to distinguish employees who are covered by the statute from those who are not. For seven decades, the pharmaceutical industry has classified its sales representatives as exempt from the FLSA's overtime pay requirement, in reliance on the administrative and outside sales exemptions. The Third Circuit has held that the administrative exemption applies to these employees. The Second Circuit held that neither exemption applies, according "controlling" deference to an amicus brief of the Department of Labor ("DOL"), which advocated that position for the first time. The questions presented are:

1. Whether the Second Circuit's holding that highly-paid pharmaceutical sales representatives are not covered by the FLSA's administrative exemption, in direct conflict with the Third Circuit, or the outside sales exemption, is contrary to the statute's text, purpose and DOL's long-standing regulations.

2. Whether an agency's break with prior interpretations of its regulations, advanced for the first time in an amicus brief, is entitled to heightened deference under *Auer v. Robbins* when it is inconsistent with the statute and its regulations, and causes unfair surprise by upsetting 70 years of settled expectations.

PARTIES TO THE PROCEEDING

Petitioner here and defendant-appellee below is Novartis Pharmaceuticals Corporation ("NPC").

Respondents here and plaintiffs-appellants below are a class of current and former pharmaceutical sales representatives employed by Petitioner in New York, California, and other states, certified by Order entered February 15, 2007 in *In re Novartis Wage and Hour Litigation*, Dkt. No. 18, 06-MD-1794 (PAC) (S.D.N.Y.), an action which consolidated two cases: *Lopes v. Novartis Corporation, et al.*, No. 06-Civ-2268 (S.D.N.Y.), brought by Respondent Simona M. Lopes and Carol Bollinger,[1] and *White v. Novartis Pharmaceuticals Corporation*, No. 06-Civ-02764 (C.D. Cal.), brought by Respondents Catherine E. White and Minel A. Hider Tobertga.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

NPC certifies that Novartis Finance Corporation, Novartis Corporation, Novartis Holding AG and Novartis AG are NPC's parent corporations. Novartis AG is the only publicly held corporation that holds ten percent or more of NPC's stock.

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[1] Carol Bollinger has dismissed all claims against NPC and is not a Respondent to this petition. Joint Stipulation of Partial Dismissal, *Lopes*, Dkt. No. 97 (Apr. 14, 2008).

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Novartis Pharmaceuticals Corporation ("NPC") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

OPINIONS BELOW

The opinion of the Second Circuit Court of Appeals (App. 1a-36a) is reported at 611 F.3d 141 (2d Cir. 2010). The district court's opinion (App. 39a-82a) is reported at 593 F. Supp. 2d 637 (S.D.N.Y. 2009).

JURISDICTION

The judgment of the Second Circuit (App. 37a-38a) was entered on July 6, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant provisions of the Fair Labor Standards Act, 29 U.S.C. §§ 201 *et seq.*, the relevant regulations of the Department of Labor ("DOL") promulgated thereunder, 29 C.F.R. §§ 541.200-541.204, 541.500-541.504, and the relevant portion of the Preamble to the final DOL regulations promulgated in 2004 are set forth in the appendix to this petition (App. 85a-150a).

STATEMENT

This petition concerns the Fair Labor Standards Act ("FLSA") and two of its "white-collar" exemptions—for administrative and outside sales employees—which are critical to American businesses. The Second Circuit's decision has abruptly undone the regime put in place by Congress and enforced by DOL for seven decades, created a split between the circuits and fundamentally altered the legal standards businesses use to determine whether millions of workers are entitled to overtime pay. The court's reinterpretation of these exemptions—reached by deferring to an unsolicited DOL amicus brief—will change the balance between exempt and non-exempt workers under a statute that touches all corners of the U.S. economy. The decision imposes significant and unanticipated costs on American industry by subjecting businesses that utilize administrative and sales employees to substantial retroactive overtime liability. In addition to the broad national interests implicated by these circumstances, there are three specific issues that warrant review.

First, the decision below construes the FLSA's administrative exemption in direct conflict with the Third Circuit, which has held that pharmaceutical sales representatives ("sales reps" or "reps") are covered by the administrative exemption. The Second Circuit's decision also applies a rationale that has been squarely repudiated by both the governing regulations and the D.C. Circuit, in a case applying the same exemption in a different industry.

Second, the decision below recasts the outside sales exemption by imposing a highly technical standard that is contrary to the text and purpose of the statute and its regulations, and is at odds with interpretations by other circuits.

Third, these far-reaching interpretations of the exemptions resulted from the Second Circuit according "controlling deference" under *Auer v. Robbins*, 519 U.S. 452 (1997), to an amicus brief submitted, *sua sponte*, by DOL. The court granted this deference despite the fact that DOL's amicus views represented a sharp break from the agency's long-standing interpretations of these exemptions, as expressed in formal rulemaking. This "regulation by amicus brief" creates unfair surprise by upsetting long-standing expectations and will impose massive retroactive liability and cause fundamental changes in the pharmaceutical industry. The Court should address whether controlling deference under *Auer* is appropriate when an agency's informal interpretation alters the regulatory landscape in a significant and unanticipated fashion.

A. The FLSA and Its White-Collar Exemptions

The FLSA was enacted in 1938 as part of the New Deal to protect American workers from "substandard labor conditions". *Roland Elec. Co. v. Walling*, 326 U.S. 657, 669-70 (1946). Congress sought to "promote economic justice and security for the lowest paid of our wage earners . . . to protect this Nation from . . . wages too low to buy the bare necessities of life and from long hours of work injurious to health". S. Rep. No. 640, 81st Cong., 1st

Sess. (1949). The Act imposes minimum wage and maximum hour protections, including the requirement that employees be paid time-and-a-half when they work more than 40 hours a week. *See* 29 U.S.C. § 207(a)(1).

But "[t]he goal of ameliorating the uglier side of a modern economy did not imply that all workers were equally needful of protection". *Nicholson v. World Bus. Network, Inc.*, 105 F.3d 1361, 1364 (11th Cir. 1997). The FLSA exempts from its overtime requirement "any employee employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of an outside salesman". 29 U.S.C. § 213(a)(1). These white-collar exemptions were central to the statute. As DOL explained in 2004 following notice-and-comment rulemaking:

> The legislative history [of the FLSA] indicates that the [white-collar] exemptions were premised on the belief that the workers exempted typically earned salaries well above the minimum wage, and they were presumed to enjoy other compensatory privileges such as above average fringe benefits and better opportunities for advancement, setting them apart from the nonexempt workers entitled to overtime pay. Further, the type of work they performed was difficult to standardize to any time frame and could not be easily spread to other workers after 40 hours in a week[.]

Dep't of Labor, Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22122, 22123-24 (Apr. 23, 2004) ("Final Rule").

1. DOL's 1940 Regulations

Early efforts to amend the FLSA to exclude all white-collar employees ceased with the general understanding that the "duties" test for these workers—one of the issues here—would be relaxed in the implementing regulations. Marc Linder, *Time and a Half's the American Way: A History of the Exclusion of White-Collar Workers from Overtime Regulation, 1868-2004*, 513-21, 678 (2004). Thus, the regulations adopted in 1940 defined an "administrative" employee expansively, covering any employee who "is compensated . . . at a rate of not less than $200 per month" and "whose work involves the execution under only general supervision of special non-manual assignments and tasks directly related to management policies or general business operations involving the exercise of discretion and independent judgment". 29 C.F.R. § 541.2 (1940). A 1940 DOL report that issued along with the new regulations made clear that the exemption should cover broad categories of office workers and require the exercise of only minimal discretion. Dep't of Labor, Wage & Hour & Pub. Contracts Div., Report and Recommendations of the Presiding Officer (Harold Stein) on Proposed Revisions of Regulations, Part 541 ("Stein Report"), at 26-27 (Oct. 10, 1940). For example, the report explained that an executive secretary's ability "to distinguish between callers at the office" constituted the kind of "exercise of

discretion and independent judgment" that qualifies for the administrative exemption. *Id.* at 27.

Critically, DOL provided that where it was "difficult" to determine whether the "discretion and independent judgment" requirement has been met, "inclusion or exclusion should be determinable by reference to a completely objective requirement" which was to be "the payment of a stated salary". *Id.* at 26. This "salary criterion" was viewed as the "best and most easily applied test" for the exemption. *Id.*[2]

Further, the 1940 regulations defined an "outside salesman" as one "who is customarily and regularly engaged away from his employer's place or places of business in making sales within the meaning of section 3(k) of the Act". 29 C.F.R. § 541.5 (1940). The FLSA's broad definition of "sale", expressly incorporated by DOL in its regulations interpreting the outside sales exemption, "includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition". 29 U.S.C. § 203(k). The 1940 Stein Report explained that what was required was that the employee "in some sense make a sale". Stein Report at 46.

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[2] The $200/month salary set forth in the 1940 regulations, and described in this report as the line above which employees should qualify for the administrative exemption, is an amount equivalent to a current annual salary of approximately $37,000. *Dollar Times*, www.dollartimes.com/calculators/inflation.htm (last visited Sept. 23, 2010). NPC's sales reps earn an average annual salary of $91,500, two-to-three times that amount. *See infra* p. 10.

2. DOL's 2004 Final Rule

With the exception of periodic changes to the pay threshold, the relevant regulations remained largely unchanged for many years. Beginning in the mid-1980s, DOL undertook a review of the white-collar exemptions, which culminated in a 2004 notice-and-comment rulemaking. These revised regulations were "the subject of extensive public commentary for two decades", congressional oversight hearings and a 1999 General Accounting Office report, which recommended that DOL streamline and clarify the white-collar exemptions to better accommodate the modern workplace. Final Rule at 22124-25. Addressing a concern that the administrative exemption was "confusing and applied inconsistently" by DOL, *id.*, the agency simplified the test to focus on a non-exclusive list of factors to determine whether employees exercise "discretion and independent judgment", *id.* at 22143-44. This minimal test eliminated an earlier requirement that the exempt employee "customarily and regularly" exercise discretion. *Id.* In rejecting this requirement, DOL made clear that it was adopting "the definition of discretion and independent judgment to reflect existing federal case law," which required only that the employee's "primary duty . . . '*include*' the exercise of discretion and independent judgment". *Id.* at 22142-43 (emphasis added).[3] DOL stated its intent "to

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[3] DOL cited, as relevant case law, *O'Dell v. Alyeska Pipeline Service Co.*, which held that an inspector who exercised "*some* discretion and independent judgment during the course of his job . . . was [exempt]", 856 F.2d 1452, 1454 (9th Cir. 1988) (emphasis added), and *Dymond v. U.S. Postal Service*, which

eliminate outdated and confusing language from existing guidelines" and noted that "[f]ederal courts generally find that employees who meet at least two or three of these factors are exercising discretion and independent judgment, although a case-by-case analysis is required". *Id.* at 22142-43.

The Final Rule also confirmed the breadth and flexibility of the outside sales exemption. The changes made to the regulations were minor, including a new "primary duty" test to determine whether an employee's duties were primarily outside sales. *See, e.g., id.* at 22160, 22161. The Preamble reaffirmed DOL's long-standing position that the outside sales exemption requires only that an employee "*in some sense*, has made sales". *Id.* at 22162 (citing Stein Report).

B. The Critical Role of Sales Reps in the Sale of Prescription Medications

Pharmaceutical companies must sell their products in accordance with the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and its accompanying regulations, 21 C.F.R. Pts. 200-299, which prohibit these companies from transferring title to their prescription medicines directly to doctors or patients. *See* 21 U.S.C. § 353(b)(1). Instead, pharmaceutical companies utilize their sales reps to generate sales of medicines by persuading physicians to make the determination,

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held that the administrative exemption is met when the "employee's primary duty simply *includes* work requiring the exercise of discretion and independent judgment", 670 F.2d 93, 95 (8th Cir. 1982) (internal quotation marks and citations omitted) (emphasis added). *See* Final Rule at 22143.

in conjunction with their patients, to write prescriptions for the company's products. Sales reps visit physicians, educate them about particular medications, address concerns they have and ultimately close the sale by obtaining the physicians' commitment to prescribe those medications for appropriate patients. App. 42a; *Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 671-72, 677-79 (W.D. Pa. 2009), *aff'd*, 2010 WL 1063935 (3d Cir. 2010).[4] Sales reps are often the only point of contact between doctors and pharmaceutical companies.

To gain physicians' commitments to prescribe, sales reps must develop a rapport with them, understand their questions and demonstrate how certain medications can serve the physicians' patients. To ensure compliance with Food and Drug Administration ("FDA") regulations, sales reps use detailed materials provided by the company for their presentations, but it is still up to the sales reps to "tailor their presentations to each individual physician based on such variables as the amount of time the physician allocates to meeting with the [sales rep]; the physician's patient base and prescribing habits and the [sales rep's] assessment of the physician's personality". App. 43a. "[Sales reps] are capable of mounting an impressively sophisticated and intense marketing pitch." *IMS Health, Inc.*, 550 F.3d at 46. Sales reps also have discretion to allocate a budget for appropriate meals

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[4] The function of sales reps is generally the same across the pharmaceutical industry. *See, e.g., IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 46-47 (1st Cir. 2008); *Baum*, 605 F. Supp. 2d at 687; *Schaefer-LaRose v. Eli Lilly & Co.*, 663 F. Supp. 2d 674, 694 n.14 (S.D. Ind. 2009).

and educational seminars for physicians and their staffs, and to distribute free samples of medications in a strategic way to physicians. App. 43a.

That sales reps "succeed[] in inducing physicians to prescribe large quantities of brand-name drugs seems clear (even if the exact magnitude of that effect is not)". *IMS Health, Inc.*, 550 F.3d at 56. "Not only do visits from sales rep[s] increase drug sales, but they do so more than advertisements directed to physicians in professional journals or advertisements directed to consumers". David Orentlicher, *Prescription Data Mining and the Protection of Patients' Interests,* 38 *J.L. Med. & Ethics* 74, 76 (Spring 2010).

Sales reps work outside of NPC's offices. App. 44a, 67a-68a. They develop their own business plans and set their own schedules. App. 43a. Sales reps determine how often to visit particular physicians, but are expected to make a total number of sales calls each day. App. 44a. Their supervisors usually communicate with them electronically. App. 44a, 67a-68a. To fill sales rep positions, NPC seeks individuals who are college-educated, self-motivated and have the ability to work independently. App. 41a. When hired, sales reps are told that they are part of NPC's sales force and that they will be engaged in selling NPC products. *Id.* NPC provides sales reps with extensive training in sales techniques and other subjects relevant to NPC products. *Id.*

Sales reps are well-paid and their compensation is tied to sales of their products in their assigned territory. App. 44a. At NPC, sales reps average $91,500 in salary and commission and are eligible for

other performance-based rewards such as all-expenses-paid vacations. *Id.* The industry-wide median is more than $93,000.[5] Commissions represent 15-25 percent of a sales rep's salary at NPC. App. 41a, 44a. The position is considered one of the most desirable American jobs.[6]

Sales reps compose a significant part of the pharmaceutical industry's workforce. At NPC there are 6,000 sales reps out of 13,000 total employees. App. 41a. Overall, the American pharmaceutical industry employs approximately 100,000 reps.[7] NPC annually spends over $500 million on sales reps. App. 67a. Pharmaceutical companies spend billions of dollars on marketing directed at physicians—sales reps representing the vast majority of those expenditures. *IMS Health, Inc.*, 550 F.3d at 70 n.17 (Lipez, J., concurring and dissenting).

Comparing themselves to assembly line workers, Respondents claim that regulatory limitations make them nothing more than robots. App. 78a. But, as one court explained, "[n]o one can honestly say that a

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[5] Jennifer Merritt, Carolyn Bigda & Donna Rosato, *Young and Restless—top 20 jobs, Money Magazine* (2007), *available at* http://money.cnn.com/galleries/2007/moneymag/0703/gallery.bestjobs_young.moneymag/16.html.

[6] *See supra* note 5; *see also* Linda Wang, *Chemical & Engineering News, Employment Outlook—Prescription for Success in Sales*, Feb. 19, 2007, at 43-46, *available at* http://pubs.acs.org/cen/employment/85/8508employment.html ("With the good pay, flexible hours, and the strong business foundation it provides, it is no wonder that pharmaceutical sales is a popular job.").

[7] *See supra* note 6.

salesperson is effective simply by spitting out a memorized script; no one can imagine a company that would require rote adherence to planned words in any situation". *Baum*, 605 F. Supp. 2d at 685. Or, as the district court here noted, such assertions "do not begin to answer why or how a robot or an automaton could or should earn an average salary of $91,500 per year". App. 78a.

C. Historic Treatment of Sales Reps Under the FLSA

For decades it has been the universal "practice throughout the pharmaceuticals industry" to classify sales reps as exempt employees under the FLSA and thus not subject to overtime requirements. App. 10a. There is ample historic justification for this practice.

In 1945, DOL issued an opinion letter stating that a pharmaceutical company's "medical detailists" (as sales reps are also referred to), whose work was "aimed at increasing the use of [the company's] product in hospitals and through physicians' recommendations", and who maintained relations with doctors, were exempt administrative employees. Applicability of exemption for administrative employees to medical detailists, May 19, 1945, 2 Lab. L. Rep. (CCH) ¶ 33,093 (3d ed. 1946). In making its determination, DOL noted that the detailists worked "virtually without supervision", were paid more than the statutory minimum, did work "directly related to general business operations", used "their discretion and independent judgment" and had "skills or knowledge acquired through special training or experience". *Id.*

During the ensuing decades, DOL never repudiated its 1945 opinion or suggested that sales reps' job responsibilities had changed in a way that warranted reclassification. The first challenge to the sales reps' exemption came in 1982, in a private lawsuit. A federal district court held that, notwithstanding restrictions placed on the sales rep by her employer, the plaintiff's exercise of discretion and independent judgment qualified her for the administrative exemption. *See Cote v. Burroughs Wellcome Co.*, 558 F. Supp. 883, 886-87 (E.D. Pa. 1982). The court relied in part on DOL's 1945 opinion. *Id.* at 886 n.2. Until the present case, DOL had not expressed disagreement with *Cote* or with the industry's treatment of sales reps as exempt.

Recently, a handful of pharmaceutical sales reps have brought several suits challenging their exempt status. Just this year, the Third Circuit upheld the applicability of the administrative exemption, concluding that a sales rep's exercise of at least some independent judgment and discretion with respect to matters of significance satisfies the minimal test adopted by DOL in the 2004 rulemaking. *Smith v. Johnson & Johnson*, 593 F.3d 280, 285 (3d Cir. 2010). And a clear majority of the federal district courts to consider the issue have held that sales reps are covered by the administrative exemption as a matter of law or that the question was a triable issue of fact.[8] Similarly, the majority of federal courts

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[8] *See Jackson v. Alpharma Inc.*, No. 07-3250, 2010 WL 2869530 (D.N.J. July 19, 2010); *Baum*, 605 F. Supp. 2d at 686-87, *aff'd*, 2010 WL 1063935; *Schaefer-LaRose*, 663 F. Supp. 2d at 694; *Ruggeri v. Boehringer Ingelheim Pharms., Inc.*, 585 F. Supp. 2d 254, 277 (D. Conn. 2008); *Amendola v. Bristol-Myers*

have held that sales reps qualify for the outside sales exemption.[9]

D. Proceedings Below

Respondents are a class of current and former NPC sales reps, who brought two lawsuits in 2006 claiming that the FLSA and state law mandate the payment of overtime wages. The suits were consolidated in the Southern District of New York.

Squibb Co., 558 F. Supp. 2d 459, 477 (S.D.N.Y. 2008); *Cote*, 558 F. Supp. at 887. *But see Harris v. Auxilium Pharms.*, No. 07-cv-03938, slip op. at 5 (S.D. Tex. Sept. 28, 2010); *Jirak v. Abbott Labs., Inc.*, No. 07 C 3626, 2010 WL 2331098, at *4 (N.D. Ill. June 10, 2010).

[9] *See Christopher v. SmithKline Beecham Corp.*, No. CV-08-1498, 2009 WL 4051075, at *5 (D. Ariz. Nov. 20, 2009) (consolidated appeal pending in the Ninth Circuit); *Schaefer-LaRose*, 663 F. Supp. 2d at 688; *Baum*, 605 F. Supp. 2d at 686, *aff'd on other grounds*, 2010 WL 1063935; *Delgado v. Ortho-McNeil, Inc.*, No. SACV 07-00263, 2009 WL 2781525, at *5 (C.D. Cal. Feb. 6, 2009) (consolidated appeal pending in the Ninth Circuit); *Yacoubian v. Ortho-McNeil Pharm., Inc.*, No. SACV 07-00127, 2009 WL 3326632, at *6 (C.D. Cal. Feb. 6, 2009) (same); *Rivera v. Schering Corp.*, No. CV 08-1743, 2008 WL 6953955, at *3 (C.D. Cal. Aug. 14, 2008) (California law); *Brody v. AstraZeneca Pharms.*, No. CV 06-6862, 2008 WL 6953957, at *9 (C.D. Cal. June 11, 2008) (same); *Menes v. Roche Labs., Inc.*, No. 07 CV 01444, 2008 WL 6600518, at *2 (C.D. Cal. Jan. 7, 2008) (same); *Barnick v. Wyeth*, 522 F. Supp. 2d 1257, 1265 (C.D. Cal. 2007) (same); *D'Este v. Bayer Corp.*, No. CV 07-3206, 2007 WL 6913682, at *4 (C.D. Cal. Oct. 9, 2007) (same). *But see Harris*, No. 07-cv-03938, slip op. at 5; *Jirak*, 2010 WL 2331098, at *4; *Kuzinski v. Schering Corp.*, 604 F. Supp. 2d 385, 402-03 (D. Conn. 2009), *aff'd*, No. 09-1945-cv, 2010 WL 2669304 (2d Cir. July 6, 2010); *Smith v. Johnson & Johnson*, No. 06-4787, 2008 WL 5427802, at *7 (D.N.J. Dec. 30, 2008), *aff'd on other grounds*, 593 F.3d 280 (2010); *Ruggeri*, 585 F. Supp. 2d at 272; *Amendola*, 558 F. Supp. 2d at 472.

App. 39a. The jurisdiction of the district court was properly invoked pursuant to 28 U.S.C. §§ 1331 and 1367. Respondents seek back pay for overtime allegedly worked by the sales reps. After discovery, NPC moved for summary judgment, claiming that the sales reps were covered by both the outside sales and administrative exemptions. Respondents cross-moved for summary judgment.

Granting summary judgment for NPC, the district court held that both exemptions applied. App. 40a. Finding *Cote* "directly applicable", the court held that sales reps "engaged in many of the same discretionary activities", and thus "meet each of the administrative exemption's requirements". App. 78a-79a. The court rejected the characterization of sales reps as "mere 'robots'", explaining that "employees may exercise discretion and independent judgment even when they carry out their duties within the confines of a highly regulated industry". App. 79a. The district court also held that the outside sales exemption applied because sales reps "make sales in the sense that sales are made in the pharmaceutical industry . . . by obtaining commitments to prescribe NPC drugs from physicians. They are credited with those sales and compensated accordingly by means of incentive payments." App. 62a, 68a-69a.

The Second Circuit reversed. Giving "controlling deference" to an amicus brief filed by DOL, App. 17a, the court rejected the application of both exemptions as a matter of law. With regard to the administrative exemption, the court acknowledged that the reps exercised discretion and independent judgment in performing their job duties,

but deferred to DOL's newly articulated position that the reps are not "*sufficiently* allowed to exercise either discretion or independent judgment in the performance of their primary duties" and that "for the administrative exemption to apply to the [sales reps], the regulations require a showing of a *greater* degree of discretion, and *more* authority to use independent judgment in matters of significance, than NPC allows the Reps". App. 33a, 35a (emphases added). With regard to the outside sales exemption, the Second Circuit again deferred to DOL's reassessment of the exemption, and held that because the sales reps "cannot transfer ownership" of drugs and do not obtain a legally binding commitment from physicians, they do not make "sales", even within the broad meaning of the FLSA. App. 27a-29a. Following its decision, the Second Circuit granted NPC's motion to stay the mandate.

REASONS FOR GRANTING THE PETITION

I. Review Is Warranted Because the Second Circuit's New Standards Will Become the National Default Rule, Undermining the Congressionally Created Balance Between Exempt and Non-Exempt Employees and Disrupting a Major American Industry

The Second Circuit's erroneous decision warrants, and is ripe for, the Court's review because it will have immediate disruptive effects on American employers and will become the national standard if uncorrected by the Court.

1. Although Congress passed the FLSA to protect American workers from oppressive working

conditions, *see Nicholson*, 105 F.3d at 1363, "its application is not unlimited". *Cleveland v. City of Elmendorf*, 388 F.3d 522, 526 (5th Cir. 2004). Congress designed the white-collar exemptions to exempt from the FLSA well-paid employees working in positions that were difficult to standardize based on hours worked. *See* Final Rule at 22123-24.

In 1940, DOL revised its regulations governing the white-collar exemptions to ensure their broad sweep. *See supra* pp. 5-6. DOL did this to address employers' concerns about the burdens of the FLSA and to ward off legislative threats to exempt white-collar workers altogether. *Id.* As a result, the administrative exemption became "[o]ne of the broadest and most . . . flexible[] exemptions contained in the [FLSA]", 1 Les A. Schneider & J. Larry Stein, *Wage and Hour Law: Compliance and Practice* § 5:24 (2010). DOL's 2004 Final Rule was designed to reaffirm that the white-collar exemptions were to be applied in a straightforward and expansive manner. Final Rule at 22124-27; *see supra* pp. 6-8.

2. The Second Circuit's decision destroys the balance between exempt and non-exempt employees created by Congress and DOL. The court of appeals has added a new, subjective "greater degree of" discretion and "more" independent judgment test to the administrative exemption—a test that is not found in the FLSA or its regulations. It also has rewritten the outside sales exemption to impose a new "transfer of title" requirement that is contrary to the language and purpose of the FLSA. These new tests narrow the exemptions, contrary to Congress's original intent, and create the exact mischief that

Congress and DOL, prior to the filing of its amicus brief, sought to avoid.

These new requirements are not limited to the pharmaceutical industry or to sales reps. On the contrary, the Second Circuit's unprecedented interpretations of the administrative and outside sales exemptions risk a change in the treatment of nearly one-quarter of the American workforce, *see* U.S. General Accounting Office, *Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place*, 2 (1999) (in 1998, 20-27 percent of the full-time workforce in the United States—19 to 26 million workers—was covered by the white-collar exemptions), and subjects employers across all industries to suit by multiple employees seeking back pay and other damages.

The decision also calls into question a number of existing courts of appeals' interpretations of the FLSA in other industries. *See, e.g., Gieg v. DDR, Inc.*, 407 F.3d 1038, 1047-48 (9th Cir. 2005) (definition of sales in the automobile industry); *Renfro v. Mich. Power Co.*, 370 F.3d 512, 517-19 (6th Cir. 2004) (utility construction planners); *Cowart v. Ingalls Shipbldg., Inc.*, 213 F.3d 261, 267 (5th Cir. 2000) (shipbuilding); *Robinson-Smith v. Gov't Emps. Ins. Co.*, 590 F.3d 886, 892-96 (D.C. Cir. 2010) (insurance adjusters); *Reich v. John Alden Life Ins. Co.*, 126 F.3d 1, 13 (1st Cir. 1997) (insurance salespersons).

3. In particular, the Second Circuit's decision will have an immediate and deleterious effect on the pharmaceutical industry. Potential litigants across the country will flock to courts in the Second Circuit

to take advantage of the new regime there, leaving all pharmaceutical companies virtually defenseless because of the similarities in their sales forces. Precedent and earlier victories outside the Second Circuit, most notably in the Third Circuit, will provide no protection against relitigating the exemptions' applicability under the new rule in the Second Circuit: virtually all of those cases were individual lawsuits or opt-in collective actions in which the trial court granted summary judgment before addressing the propriety of class certification. Because, in this context, "[a] single positive trumps all the negatives", *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 333 F.3d 763, 766-67 (7th Cir. 2003) (Easterbrook, J.), all pharmaceutical companies, even those that have prevailed to date in other courts, will soon be faced with massive retroactive liability.[10]

A lasting effect of the Second Circuit's decision will be a fundamental alteration in the way in which the pharmaceutical industry has marketed prescription drugs for decades. Converting sales reps—who are central to the way pharmaceutical companies sell their products—from salaried to

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[10] Nor will the impact of the Second Circuit's decision be limited to newly-filed cases—the decision will have ramifications even in individual cases in other jurisdictions in which pharmaceutical companies have previously prevailed. Indeed, on September 28, 2010, the United States District Court for the Southern District of Texas granted plaintiffs' motion for reconsideration in *Harris*, "adopt[ing] the reasoning of the Second Circuit"—including paying controlling deference to DOL's amicus brief—and reversed its earlier holding that sales reps were exempt under both the administrative and outside sales exemptions. *Harris*, No. 07-cv-03938, slip op. at 5.

hourly workers will necessarily lead to a fundamental change in how these companies operate. By tying compensation to hours worked, rather than sales performance, sales reps will lose their incentive to generate profits for their employer. And as hourly workers, sales reps will also lose the flexibility to spend as much time as they feel appropriate to make a sale, thereby reducing opportunities for increased compensation. *See* Steven Blackburn, *In re Novartis Wage and Hour Litigation, in Top 20 Food and Drug Cases, 2009 & Cases to Watch, 2010*, 159, 168 (John B. Reiss ed., 2010). By stripping the sales rep position of these defining qualities, the decision will also make it difficult for pharmaceutical companies to recruit and retain sales reps who prize flexibility, work requiring self-motivation and initiative and opportunities for incentive compensation—the very people who have been successful in this position. *See id.* at 168-69.

II. The Second Circuit's Interpretation of the Administrative Exemption Is Erroneous and Conflicts with Decisions of the Third and D.C. Circuits and DOL Regulations

The FLSA regulations state that the exercise of discretion and independent judgment "involves the comparison and the evaluation of possible courses of conduct, and acting or making a decision after the various possibilities have been considered". 29 C.F.R. § 541.202(a). An illustrative "non-exclusive" list of factors is used to determine "whether an employee exercises discretion and independent judgment with respect to matters of significance", including, *inter alia*, whether the employee "performs work that affects business

operations to a substantial degree", "has authority to commit the employer in matters that have significant financial impact" and "is involved in planning long- or short-term business objectives". 29 C.F.R. § 541.202(b).

1. The Second Circuit agreed that sales reps evaluate various courses of conduct, make on-the-spot decisions in executing their sales strategies, decide how to allocate their budgets, commit NPC financially by entering into various contracts which may cost NPC thousands of dollars and make judgments about the allocation of samples to physicians—all without direct supervision. App. 32a-35a. Thus, the sales reps met several Section 202(b) factors, which DOL, in the past, has said is enough for the exemption to apply. Final Rule at 22143.

Nonetheless, the court concluded that sales reps are not "*sufficiently* allowed to exercise either discretion or independent judgment in the performance of their primary duties", according controlling deference to DOL's argument that, while sales reps exercised some discretion, "the regulations require a showing of a *greater degree* of discretion and *more* authority to use independent judgment in matters of significance, than [NPC] allows the Reps". App. 33a, 35a (emphases added). Not only was such deference to DOL improper (*see infra* Part IV), but concluding that a "greater degree of" discretion and "more" independent judgment are required to qualify for the exemption is erroneous, flatly contrary to DOL's 2004 Final Rule, *see supra* pp. 6-7, and in conflict with the Third and D.C. Circuits.

2. Though aware of DOL's brief in this case, the Third Circuit in *Smith* concluded that a Johnson & Johnson ("J&J") sales rep was an administrative employee because she "executed nearly all of her duties without direct oversight" and "described herself as the manager of her own business who could run her territory as she saw fit". *Smith*, 593 F.3d at 285. This was so even though she "worked off of a prepared 'message' that J&J provided her" and "J&J gave her pre-approved visual aids and did not permit her to use other aids". *Id.* at 282. In *Baum*, the Third Circuit held that, under a Pennsylvania state law modeled on the FLSA, an AstraZeneca sales rep whose duties were "very similar" to those of the J&J sales rep in *Smith* was covered by the administrative exemption. 2010 WL 1063935, at *9-10. There is no material difference between the job description of NPC's sales reps and the duties and responsibilities of any of the sales reps held exempt in these cases. *See supra* pp. 8-11.

The Second Circuit's decision also conflicts with the D.C. Circuit's application of the liberal standard embodied in DOL's 2004 regulations. In *Robinson-Smith*, the D.C. Circuit reversed a decision which had concluded that although auto damage adjusters exercised "some discretion", the discretion "exercised was not sufficient" to meet the standards of the administrative exemption. 590 F.3d at 890. The D.C. Circuit concluded that while "the parties disagree on how much discretion the adjuster exercises, no one disputes that he exercises 'some'",

and thus the employees were covered by the administrative exemption. *Id.* at 893-95.[11]

3. Although the FLSA's exemptions "are to be narrowly construed against the employers seeking to assert them and their applications limited to those [] plainly and unmistakably within their terms and spirit", *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960), this canon does not trump common sense. "To read the FLSA blindly, without appreciation for the social goals Congress sought, would also do violence to the FLSA's spirit." *See Gregory v. First Title of Am., Inc.*, 555 F.3d 1300, 1307 (11th Cir. 2009) (quoting *Nicholson*, 105 F.3d at 1364). When the statutory language and intent of Congress are clear, this canon of construction does not apply. *Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 508 (7th Cir. 2007) (*citing A.H. Phillips, Inc. v. Walling*, 324 U.S. 490, 493 (1945)); *Mechmet v. Four Seasons Hotel, Ltd.*, 825 F.2d 1173, 1177-78 (7th Cir. 1987) (canon is at best a tie-breaker if regulations or statute do not answer the issue).

The Second Circuit's new rules do "violence to the FLSA's spirit". It is undisputed that NPC's sales reps earn compensation well above the statutory

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[11] DOL and the Second Circuit cite Section 202(e) of the regulations, which deals with employees who follow rote applications of "well-established techniques, procedures or specific standards described in manuals or other sources". 29 C.F.R. § 541.202(e). *Robinson-Smith* and other circuit court decisions have rejected the view that Section 202(e)'s predecessor (29 C.F.R. § 541.207(b) (2004)) barred application of the administrative exemption to employees who exercise only "some" discretion and independent judgment. 590 F.3d at 893-94 (citing cases).

minimum for this exemption and engage in daily work outside the office, free from supervision. They do not track their time, and the nature of their job would make it difficult to monitor any effort to do so. It is also undisputed that the reps' compensation structure rewards them based on their efforts in increasing sales in their territories. Their work directly affects NPC's primary business operation—the sale of pharmaceutical products. They are precisely the type of worker contemplated by the white-collar exemptions. *See Nicholson*, 105 F.3d at 1364.

III. The Second Circuit's Rejection of the Outside Sales Exemption Conflicts with the FLSA and DOL's Own Regulations and Is At Odds with Decisions from Other Circuit Courts

DOL broadly defines an outside sales employee as one whose primary duty is: "(i) making sales within the meaning of section 3(k) of the Act, or (ii) obtaining orders". 29 C.F.R. § 541.500(a). Under Section 3(k) of the statute, "'[s]ale' or 'sell' *includes any* sale, exchange, contract to sell, consignment for sale, shipment for sale, or *other disposition*". 29 U.S.C. § 203(k) (emphases added). This definition of sales applies throughout the FLSA. *See* 29 U.S.C. § 203. The Second Circuit erred in concluding that sales reps do not come within the scope of the exemption.

1. The plain meaning and purpose of the statute clearly supports the application of the outside sales exemption here. The statutory language is expansive. The word "includes" is a term of

enlargement, therefore the definition is illustrative, not all-inclusive. *See Samantar v. Yousuf*, 130 S. Ct. 2278, 2287 & n.10 (2010). Moreover, the term "other disposition", the Second Circuit agreed, "is a catch-all that could have an expansive interpretation". App. 26a. The exemption is premised on the idea that the individual nature and quality of an outside salesperson's work, and entitlement to commission-based incentive compensation, does not warrant the protection of overtime wages:

> Such salesman . . . works individually . . . . In lieu of overtime, he ordinarily receives commissions as extra compensation. He works away from his employer's place of business, is not subject to the personal supervision of his employer, and his employer has no way of knowing the number of hours he works per day.

Jewel Tea Co. v. Williams, 118 F.2d 202, 207-08 (10th Cir. 1941). Petitioner's sales reps clearly meet these criteria.

2. The court of appeals' narrow interpretation that sales require a transfer of ownership takes the FDCA's requirement of a physician's prescription for drug sales—intended to protect patients from the use of inappropriate or unsafe drugs[12]—and turns it on

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[12] *See* Krista Hessler Carver, *A Global View of the First Amendment Constraints on FDA*, 63 *Food & Drug L. J.* 151, 211 n.540 (2008) (21 U.S.C. § 353(b)(1) "rel[ies] on physician's

its head to require the reclassification of thousands of employees. This overly technical construction is at odds with the decisions of other circuits, which reject an overly formalistic approach in favor of one that accounts for the economic realities of the industries at issue and the expansive language of the exemption itself. The Ninth and Tenth Circuits have held that leases are sales under the FLSA, even though no transfer of title is involved. *See Gieg*, 407 F.3d at 1047-49; *Brennan v. Dillon*, 483 F.2d 1334, 1337 (10th Cir. 1973). The Eleventh Circuit has held, based on economic realities and the plaintiff's receipt of commissions, that obtaining orders and referring customers to the employer insurance company without consummating the insurance contract is selling under the outside sales exemption. *Gregory*, 555 F.3d at 1303, 1308-10. Here, the sales reps make sales as they are made in the pharmaceutical industry, and they earn incentive compensation tied to sales within their territories, even if they cannot legally transfer title under the governing FDA regulations. *Cf. Medtronic, Inc. v. Benda*, 689 F.2d 645, 648, 653 (7th Cir. 1982), *cert. denied*, 459 U.S. 1106 (1983) (medical device sales reps sold to physicians because physicians were the "real" purchasers).

3. The Second Circuit's and DOL's interpretation of the exemption is inconsistent with the position DOL has taken for almost 70 years. As DOL explained in 2004, outside salesmen are exempt because they have "salaries well above the minimum wage", "above average fringe benefits and better

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supervision to render safe the use of drugs that would otherwise be unsafe").

opportunities for advancement", their jobs are "difficult to standardize to any time frame" and cannot "be easily spread to other workers after 40 hours in a week". Final Rule at 22123. In its 1940 report, DOL also articulated a list of factors to be considered in determining whether an employee qualifies as an "outside salesperson", which include whether the employer advertised the position as a sales job, the "qualifications [set by the employer] for hiring, [the employee's] sales training [and] the method of payment" of the employee. Stein Report at 51-52. Indeed, as recently as February 2010, DOL's Bureau of Labor Statistics specifically classified pharmaceutical sales reps as employees who "*sell* goods" for wholesalers or manufacturers where technical or scientific knowledge is required. U.S. Bureau of Labor Statistics, *Standard Occupational Classification Definitions* 41-4011 (2010) (emphasis added).[13]

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[13] DOL's position is at odds with the Department of Justice's view, in enforcing the off-label marketing provisions of the FDCA, that sales reps "sell" drugs. *See, e.g.*, Dep't of Justice, Press Release, Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008) (company "structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted *and sold* the drugs for off-label uses") (emphasis added).

IV. The Court Should Grant the Petition To Clarify the Application of *Auer* Where an Agency's Position, Advanced Without Notice-and-Comment Procedures, Reinterprets Unambiguous Regulations, Thereby Causing Unfair Surprise

1. The Second Circuit's analysis as to why DOL's newly-minted views were entitled to controlling deference began and ended with its citation to *Auer*. *See* App. 17a. That the court would conclude that an agency's informal expression of its position was entitled to dispositive deference on such a cursory basis—in a case involving significant economic effects and long-standing policies advanced after notice-and-comment rulemaking—demonstrates that this Court's guidance is needed. *Auer* deference certainly has a place in the Court's administrative law jurisprudence. However, it requires appropriate bounds to ensure that the use of amicus briefs does not improperly substitute for rulemaking and other formal agency processes that assure notice to regulated parties, the opportunity for public participation and political accountability. *Auer* cannot be a rubber stamp. This case presents a needed opportunity for the Court to make clear that there are limitations on *Auer* deference and to give guidance as to the application of those limits.

This is an important and recurring issue—important because the views of administrative agencies have a significant impact on American industries, and recurring because of the prevalence of agency interpretations advanced in amicus briefs and through other informal means. Indeed, DOL's amicus brief below stems from a program it

announced in 2004 to intervene in private FLSA litigations expressly because it expected that federal courts will defer to those interpretations. 13 No. 6 *FLSA Emp. Exemption Handbook News*, 16 (June 2008).

2. In *Auer*, an FLSA case involving the interpretation of the salary-basis test for calculating whether employees come within the scope of a white-collar exemption, the Court requested an amicus brief from DOL to address the appropriate scope of that rule. "Because the salary-basis test is a creature of the Secretary's own regulations", the Court reasoned that DOL's interpretation of it "is controlling unless 'plainly erroneous or inconsistent with the regulation'". *Auer*, 519 U.S. at 461. The Court has held that such deference is warranted only when the agency interprets its own ambiguous regulations. *See id.* at 461; *see also Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000) ("*Auer* deference is warranted only when the language of the regulation is ambiguous.").[14] That DOL's interpretation took the form of an amicus brief, rather than legally binding rulemaking, did not "in the circumstances of [that] case, make it unworthy of deference". *Auer*, 519 U.S. at 462. Critically, the Court determined that DOL's position was reasonable, in part, because it "avoids the imposition of massive and unanticipated overtime liability". *Id.* at 461.

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[14] The Court has also held that an agency's interpretation does not warrant *Auer* deference where the relevant regulations mirror the statutory language and "give[] little or no instruction on a central issue in th[e] case". *Gonzales v. Oregon*, 546 U.S. 243, 256-57 (2006).

Recently, in *Long Island Care at Home, Ltd. v. Coke*, the Court revisited the scope of deference to informal agency interpretations that could cause such disruption. In *Coke*, DOL had issued conflicting regulations and interpretations concerning the treatment under the FLSA of employees paid by third parties to provide home health care—a large and growing industry in this country. 551 U.S. 158, 162 (2007). The Court deferred to DOL's most recent position adopting one interpretation of two conflicting regulations, but importantly noted that deference to such agency interpretations would be appropriate only "as long as interpretative changes create no unfair surprise". *Id.* at 170. The Court did not give guidance on how to apply this standard, although it noted that the standard was met in that case because DOL announced its latest position in a notice-and-comment rulemaking procedure. *Id.* at 170-171; *see also Christensen*, 529 U.S. at 588 (cautioning that courts should be wary of informal agency interpretations that create "*de facto* a new regulation" by ignoring clear pre-existing regulatory language).

Prior to *Coke*, a leading academic commentator urged the Court to articulate a "fair notice" limitation on *Auer*. *See* Richard J. Pierce, Jr., *Democratizing the Administrative State*, 48 *Wm. & Mary L. Rev.* 559, 607-08 (2006); *see also* Thomas L. Casey, III, *Towards Function and Fair Notice*, 2008 *Mich. St. L. Rev.* 725, 737-48 (2008) (concluding that *Coke* adopted a fair notice limitation).[15] Since *Coke*,

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[15] Other academic commentators have gone further and urged the Court to abrogate *Auer* entirely. *See, e.g.*, William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference:*

two circuit courts have discussed the impact of "unfair surprise" on *Auer* deference—with diverse results. *See Taylor v. Progress Energy, Inc.*, 493 F.3d 454, 461-62 (4th Cir. 2007) (no deference for DOL's interpretation of Family Medical Leave Act advanced in an amicus brief because it was inconsistent with preamble accompanying regulations at issue; no discussion of *Coke*); *id.* at 464 (Duncan, J. dissenting) (applying *Coke* and claiming no unfair surprise because agency issued notice, after oral argument in the appeal, that it was considering changing its position); *Boose v. Tri-Cnty. Metro. Trans. Dist. of Or.*, 587 F.3d 997, 1005 n.13 (9th Cir. 2009) (no unfair surprise under *Coke* because agency attempted to change its position through notice and comment rulemaking); *Pub. Citizen v. NRC*, 573 F.3d 916, 923-24 (9th Cir. 2009) (no unfair surprise because agency is merely "elaborating on" interpretations of its regulations). Other circuits have also expressed doubts about the extent of *Auer*'s reach. *See Keys v. Barnhart*, 347 F.3d 990, 993-94 (7th Cir. 2003) (questioning rationale of *Auer*); *Mich. Bell Tel. Co. v. Covad Commc'ns Co.*, 597 F.3d 370, 375 n.6 (6th Cir. 2010) (same).

3. This case presents substantial problems of fair notice and economic disruption. In 1945, DOL

The Supreme Court Treatment of Agency Statutory Interpretations from Chevron *to* Hamdan, 96 *Geo. L. J.* 1083, 1184 (Apr. 2008) (Court should abrogate *Seminole Rock* and its progeny); Kristen E. Hickman & Matthew D. Krueger, *In Search of the Modern* Skidmore *Standard*, 107 *Colum. L. Rev.* 1235, 1294 (Oct. 2007) (*Skidmore* deference more appropriate for informal agency interpretations of regulations); Thomas W. Merrill & Kristen E. Hickman, Chevron's *Domain*, 89 *Geo. L. J.* 833, 900 (Apr. 2001) (same).

issued an opinion letter concluding that sales reps were exempt. In the intervening 64 years, the agency never issued a contrary pronouncement, never brought an enforcement action concerning sales reps, and never issued audit findings challenging the industry's treatment of these employees—even after the issue became the subject of litigation in 1982 and the exemptions were revisited and revised in 2003-2004. There is little question that it was an "unfair surprise" upsetting settled expectations when DOL, without notice, intervened here and reversed this history. While it "is possible for an entire industry to be in violation of the Fair Labor Standards Act for a long time without the Labor Department noticing . . . a more plausible hypothesis is that the . . . industry has been left alone because the character of its compensation system" does not violate the FLSA. *Yi,* 480 F.3d at 510-11. Nor can there be doubt that the effect of the Second Circuit's decision on the pharmaceutical industry will be substantial: it will impose massive retroactive liability—the precise opposite effect of the DOL position deferred to in *Auer*—and significantly change the defining characteristics of its sales force. *See supra* Part I.3. Such disruption is a relevant factor in assessing the extent of deference owed to an agency's informal interpretation. *Cf. Singh v. City of New York*, 524 F.3d 361, 369-70 (2d Cir. 2008) (Sotomayor, C.J.) (noting that the "wide-ranging impact" on businesses was a relevant factor in rejecting plaintiffs' proffered interpretation of the Portal-to-Portal Act, where such interpretation would "suddenly impos[e] upon businesses across the country a liability to compensate employees" that no court had imposed in 60 years).

DOL also created unfair surprise by abandoning its positions in the 2004 Final Rule, where it clearly stated that employees came within the scope of the administrative exemption if their work satisfies at least two or three of the factors identified in 29 C.F.R. § 541.202(b), and codified the holdings of federal cases to simplify the application of the exemption. Final Rule at 22142-44. Instead of adhering to those views here, DOL grafted a new, subjective "greater degree of" discretion and "more" independent judgment test onto the administrative exemption that has no basis in the regulations. Similarly, DOL's brief reinterprets the outside sales exemption to impose a specific "consummated transaction" test that is at odds with the regulations. In doing so, DOL ignored the 2004 Final Rule's definitive statement that the outside sales exemption only required that a sale "in some sense" take place. Final Rule at 22162 (reiterating DOL's statements in the 1940 Stein Report). Thus, through the informal means of an amicus brief, DOL has written "de facto a new regulation", *Christensen*, 529 U.S. at 588, that imposes "unfair surprise", *Coke*, 551 U.S. at 159, 170-71, on the regulated community. *See also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (deference inappropriate if alternative reading is compelled by "other indications of the Secretary's intent at the time of the regulation's promulgation") (internal quotations and citation omitted); *Caruso v. Blockbuster-Sony Music Entm't Ctr.*, 193 F.3d 730, 737 (3d Cir. 1999) (Alito, C.J.) ("An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning") (citation omitted).

According *Auer* deference when an agency brief advances a new reading of a critical feature of a major regulatory regime strikes at fundamental principles of fairness. Strong deference to such critical changes is inappropriate absent notice-and-comment procedures. *See KPMG, LLP v. SEC*, 289 F.3d 109, 116-17 (D.C. Cir. 2002) (explaining in *dictum* that the court could not defer to SEC's interpretation of its regulations if doing so would impose a penalty on an individual without fair notice) (citation omitted). As the Seventh Circuit noted in *Doe v. Mutual of Omaha Insurance Co.*, when an agency advances a "radically expansive" and "far-reaching" interpretation of its regulations that threatens a sea change in an entire industry, courts are "justif[ied] . . . in requiring the Department to invite deference by a more deliberative, public, and systematic procedure than the filing of an amicus brief". 179 F.3d 557, 561, 563 (7th Cir. 1999).

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

October 4, 2010

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