FILED

10-459 OCT 4- 2010

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No. 10-_____

IN THE

Supreme Court of the United States

SCHERING CORPORATION,

Petitioner

V.

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, AND SHAWN JONES, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED,

Respondents.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

In this case, the Second Circuit concluded that Schering's pharmaceutical sales representatives fell outside of the FLSA's exemption for "outside salesm[e]n," 29 U.S.C. § 213(a)(1). The court found that the exemption does not apply because pharmaceutical sales representatives are barred by law from making a direct exchange of prescription drugs in return for consideration. The court reached its conclusion by giving controlling deference to the Secretary of Labor's arguments made in an *amicus* brief filed in *In re Novartis Wage & Hour Litigation*, 611 F.3d 141 (2d Cir. 2010), and adopting that analysis in this case. The questions presented are:

1. Whether *Auer* deference should be extended to an agency's interpretation of long-standing regulations when the interpretation causes unfair surprise, imposes extraordinary and unwarranted liabilities against an entire industry, and comes without the opportunity for notice and comment.

2. Whether the Second Circuit committed error in imposing new technical requirements on the outside sales exemption which subvert the purpose and goals of the FLSA and its implementing regulations.

PARTIES TO THE PROCEEDING

All parties are listed in the caption.

RULE 29.6 STATEMENT

Petitioner Schering Corporation is 100% owned by Merck & Co., Inc., a publicly traded company.

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PETITION FOR A WRIT OF CERTIORARI

Schering Corporation ("Schering") 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 court of appeals is available at 2010 WL 2669304 and is reprinted in Appendix ("App.") A. The opinion of the District Court for the District of Connecticut denying petitioner's motion for summary judgment is reported at 604 F. Supp. 2d. 385 and is reprinted in App. B.

JURISDICTION

The judgment of the court of appeals affirming the district court was entered on July 6, 2010. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The statutes and regulations involved are the Fair Labor Standards Act, 29 U.S.C. § 201 *et seq.*, relevant regulations of the Department of Labor ("DOL"), 29 C.F.R. §§ 541.500-541.503, and portions of the Preamble to the final DOL regulations promulgated in 2004. Relevant excerpts from pertinent statutes and regulatory provisions are reproduced in the Appendix, App. D-L.

STATEMENT

The issue in this lawsuit, whether pharmaceutical sales representatives fall within the

FLSA's exemption for outside salespersons, is one of broad practical importance, not only for the pharmaceutical industry but for any business that employs a sales force. By virtue of its appearance in litigation pending before the Second Circuit, the Department of Labor has changed the regulation defining "sales" — and thus changed the definition of the exemption itself — in a manner that imposes substantial and unexpected liabilities on those businesses. The Second Circuit afforded DOL's interpretation "controlling deference" under *Auer v. Robbins*, 519 U.S. 452 (1997), and held that pharmaceutical sales representatives are not exempt outside salespersons.

The question of whether and when controlling deference should be granted to an agency's litigation stance, which has the potential to upend an entire industry with no notice and at enormous cost, is one of fundamental importance that can only be clarified and defined by this Court. The changes to the regulations arising from the deference afforded to DOL's interpretation do nothing to serve the stated goals underlying the FLSA; to the contrary, both the court's ruling and the Secretary's argument undermine the terms and the spirit of the Act while grossly penalizing an industry that employs thousands of sales employees across the country. These factors strongly support the grant of a writ of certiorari.

I. STATUTORY BACKGROUND

Congress enacted the FLSA to serve four goals: (1) to provide workers a minimum living wage; (2) to eliminate exploitative child labor; (3) to minimize the effects of an overworked labor force through

economic disincentives for overtime hours; and (4) to increase employment rates by making it more attractive to hire additional employees rather than to require existing employees to work overtime. *See generally* 29 U.S.C. § 202(a) (App. D at 79a). The Department of Labor has primary responsibility to administer and enforce the Act.

A. Congress carved out certain white-collar positions as exempt from the FLSA's overtime protections

The FLSA imposes various wage and hour requirements on employers, including, in Section 7(a)(1), the requirement that workers receive time-and-a-half overtime pay for work in excess of 40 hours in a workweek. 29 U.S.C. § 207(a)(1) (App. F at 81a). Exempt from these overtime requirements are a number of defined "white-collar" employees. *See id.* § 213(a)(1) (App. G at 83a).

The white-collar exemptions were premised on Congress's belief that employees in those occupations did not need the same level of protection provided to non-exempt employees. White-collar employees typically earned well in excess of the minimum wage and received "other compensatory privileges such as above average fringe benefits and better opportunities for advancement." Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22122, 22124 (Apr. 23, 2004) (App. L at 89a, 93a). Congress also recognized that the work performed by those employees "was difficult to standardize to any time frame." Their work "could not be easily spread to other workers after 40 hours in a week," thereby

"making compliance with the overtime provisions difficult" and "generally precluding the potential job expansion intended by the FLSA's time-and-a-half overtime premium." *Id.*

B. DOL made revisions to the white-collar regulations only after extensive notice-and-comment rulemaking

Since the FLSA's enactment in 1938, any employee employed "in the capacity of outside salesman" has been exempt from the Act's overtime pay requirements. 29 U.S.C. § 213(a)(1) (App. G at 83a). In light of the wide variations in industry practices, Congress did not itself define "outside salesman" but instead entrusted the Secretary of Labor to define and delimit the term through notice-and-comment rulemaking. *Id.* With regard to the white-collar exemptions generally, and the outside sales exemption specifically, the Secretary exercised the responsibility to undertake such rulemaking as recently as 2003. Suggested changes to the regulations had "been the subject of extensive public commentary for two decades." 69 Fed. Reg. at 22124 (App. L at 96a) (citations deleted).

On March 31, 2003, DOL published its Notice of Proposed Rulemaking (68 FR 15560) seeking comments to its proposed revisions to the white-collar exemptions. During the following 90-day comment period, DOL received over 75,000 comments from the public. 69 Fed. Reg. at 22125 (App. L at 92a). After considering those comments and making numerous changes to the regulations, DOL issued its final rule on August 23, 2004.

C. Recognizing that a sale may take place in a variety of ways in the modern workplace, DOL affirmed that an employee is exempt if the employee "in some sense" makes a sale

As explained in the preamble to its final rule, the Department recognized that it had to update its regulations to accommodate the modern workplace. It agreed "that technological changes in how orders are taken and processed should not preclude the [outside sales] exemption for employees who *in some sense* make the sales" and it re-emphasized that "obtaining a commitment to buy" was sufficient to satisfy the exemption. 69 Fed. Reg. at 22162-63 (App. L at 105a) (emphasis supplied).

After taking into consideration the comments made by the public to the proposed rule, DOL defined the outside sales exemption, as it had in the past, by adopting the statutory language provided by Congress in defining the term "sale":

> The term "employee employed in the capacity of outside salesman" in section 13(a)(1) of the [FLSA] shall mean any employee:
>
> (1) Whose primary duty is:
>
> (i) making sales within the meaning of section 3(k) of the [FLSA], or
>
> (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; and

> (2) Who is customarily and regularly engaged away from the employer's place or places of business in performing such primary duty.

29 C.F.R. § 541.500(a) (App. H at 84a). Section 3(k) of the FLSA in turn defined "sale" to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E at 80a).

The most significant change made to the exemption was the elimination of the limitation on the number of hours in which outside sales employees could be engaged in duties not related to sales. Despite concerns expressed by some commenters that employers would take advantage of the change, the restriction was lifted, largely because DOL determined that the outside sales position should be subject to the same primary duty standard applied to other white collar jobs. In support of its decision to apply the primary duty test to the outside sales exemption, the Department cited *Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260, 1267 (10th Cir. 1999), for the proposition that the "determination of an employee's chief duty or primary function must be made in terms of the basic character of the job as a whole." 69 Fed. Reg. at 22161 (App. L at 103a).

II. FACTUAL BACKGROUND

Schering sells branded pharmaceutical products to treat a variety of diseases and disorders, including allergy and respiratory conditions, infectious diseases, cardiovascular disease, high cholesterol, and hepatitis. Schering develops these pharmaceuticals through its research and development efforts, but its corporate success

depends on its ability to sell prescription drugs. To achieve this end, it employs a network of pharmaceutical sales representatives to visit physicians, educate them about the benefits and risks of Schering's products versus those of the competition, and secure their commitment to prescribe Schering's products for their patients when indicated.

A. Federal law governs the manner in which pharmaceutical drugs may be sold

Like other pharmaceutical companies, Schering must conduct its business consistent with the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301 *et seq.*, and the accompanying regulations, 21 C.F.R. Parts 200-299 (the "FDCA"). One requirement imposed by those laws is that certain pharmaceutical products be dispensed by pharmacists pursuant to the "written prescription of a practitioner licensed by law to administer such drug[s]." 21 U.S.C. § 353(b)(1). Thus, under federal law, Schering cannot sell its prescription pharmaceuticals directly to the patients who ultimately consume them.

As a consequence of this legal regime, sales efforts in the pharmaceutical industry are necessarily directed at obtaining commitments from physicians to prescribe the company's products. These commitments cannot be legally binding, however, because physicians are ethically obligated to prescribe a drug only when it is clinically appropriate for the particular patient. *See, e.g., In re Novartis Wage & Hour Litig.*, 593 F. Supp. 2d 637, 650 (S.D.N.Y. 2009).

B. Respondents were experienced salespersons hired to perform sales duties for Schering

Respondents are former employees who worked for Schering during different periods between December 1980 and December 2006. They joined Schering after responding to postings for jobs that they understood to be sales positions requiring prior sales experience, which each Respondent had. They held various titles during their employment terms, all of which identified Respondents as sales representatives, and they were classified by Schering as exempt employees for purposes of the FLSA.

Respondents understood when they were hired, and throughout their employment, that they were expected to (i) create, achieve, and maximize sales objectives; (ii) create daily sales call schedules; (iii) implement plans to achieve sales objectives; (iv) have superior knowledge of the products they were selling; (v) meet with their customers; (vi) listen and respond to their customers' needs; (vii) persist with their customers if they would not commit; and (viii) maintain a positive relationship with their customers.

Schering provided Respondents extensive training on products and disease states as well as sales techniques. They became certified to sell particular drugs after an initial round of training and later participated in advanced training on those drugs. They were required to have complete knowledge of their products in order to sell those products convincingly to their customers — physicians and other healthcare providers.

Although Schering provided a list of targeted physicians in each territory, Respondents themselves determined which physicians to contact and when to do so, and they could call on physicians who were not on the list as well. Respondents analyzed sales data and tailored their sales calls to each physician. Their presentations routinely ended with the Respondent seeking a commitment from the physician to prescribe a particular product when a patient next presented with applicable indications.

C. Respondents obtained commitments from their customers to prescribe Schering's products

By virtue of the nature of the practice of medicine, a physician's commitment does not immediately result in an exchange of goods for cash. Instead, after learning about Schering products, physicians commit to prescribe the products to patients for whom they are appropriate. Respondents tracked their sales by physician to monitor their success and made repeated visits to them to develop an ongoing relationship. Respondents were skilled at building a rapport with the physicians, to whom they referred as their "customers."

D. Schering evaluated and paid Respondents based in large part on their selling skills and ability to grow sales within their assigned territories

Respondents worked independently, with only minimal supervision from their sales managers. They were evaluated based on their ability to satisfy sales objectives. On periodic visits, Respondents'

District Managers completed field coaching reports in which Respondents were rated on their "selling skills," such as proficiency at opening, questioning and probing, and confirming a medical provider's commitment. These field coaching reports tracked the market shares that pharmaceutical sales representatives were able to secure in their geographical areas.

Respondents received incentive pay after they met their sales targets, as measured by the number of Schering products prescribed within their geographical areas. And, their eligibility for merit-based pay increases depended on three criteria: sales results and market share, selling skills, and professional development. Respondents were well-compensated during their employment with Schering and routinely earned close to or more than $100,000 per year, including base salary and incentive compensation awarded as a result of sales success.

III. PROCEEDINGS BELOW

On February 13, 2007, Respondents filed their complaint alleging that they were entitled to overtime wages under the FLSA and seeking to represent themselves and other current and former pharmaceutical sales representatives in an opt-in collective action.

Schering moved for summary judgment on the ground that Respondents were exempt from FLSA overtime requirements under the "outside salesman" exemption. The district court denied the motion, holding that Respondents did not fall within the exemption because they did not make "sales" or obtain binding commitments from physicians. *Schering*, 604 F. Supp. 2d at 393-403 (App. B at 22a-

43a). The court relied heavily on the interpretive canon that exemptions from the FLSA's overtime requirements should be narrowly construed. *Id.* at 393, 395, 397, 398 n.14 (App. B. at 22a, 27a, 31a, 33a n.14).[1]

Notwithstanding its view of the law, the court acknowledged that "several district courts have weighed in differently on what is essentially the identical question." *Kuzinski v. Schering Corp.*, 614 F. Supp. 2d 247, 250 (D. Conn. 2009). The court therefore certified its decision for interlocutory appeal. *Id.* at 249-52.

Schering petitioned the Second Circuit to hear the appeal under 28 U.S.C. § 1292(b). The court granted the petition and directed that the case be heard in tandem with *In re Novartis Wage & Hour Litigation*, No. 09-0437 (2d Cir. 2009), an appeal from a decision of a district court in the Southern District of New York that reached the opposite conclusion on the same issue.

The Secretary of Labor appeared *sua sponte* in the *Novartis* appeal and took the position, for the first time ever, that pharmaceutical sales representatives are not exempt outside salespersons under the FLSA. Brief for the Secretary of Labor as *Amicus Curiae* in Support of Plaintiffs-Appellants, *In re Novartis Wage & Hour Litig.*, No. 09-0437 (2d Cir. Oct. 13, 2009) ("DOL Brief") (App. M at 110a). The Secretary argued that the "outside sales exemption" did not apply because pharmaceutical sales

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[1] Respondents do not dispute that they worked outside the employer's place of business as required by 29 C.F.R. § 541.502, App. J at 86a.

representatives do not consummate transactions or obtain any orders for prescription drugs. DOL Brief at 10 (App. M at 122a).

The Second Circuit afforded "controlling deference" to DOL's argument under this Court's decision in *Auer* and ruled that pharmaceutical sales representatives are not exempt outside salespersons. *In re Novartis Wage & Hour Litig.*, 611 F.3d 141 (2d Cir. 2010) (App. C at 45a). Adopting the reasoning stated in *Novartis*, the court affirmed the trial court's order in *Schering* by summary order. *Kuzinski v. Schering*, 2010 WL 2669304, at *1 (2d Cir. July 6, 2010) (App. A at 3a).

REASONS FOR GRANTING THE PETITION

The appropriateness of the Second Circuit's application of outcome-determinative deference to an interpretation which was a clear departure from the Department's past position is an important question of federal law warranting the granting of the petition. *Auer* requires courts to accord deference to an agency's interpretation of its own regulations in certain, but not all, cases. Without the imposition of appropriate boundaries for *Auer* deference, agencies may use *amicus* briefs to subvert the normal rulemaking processes and avoid formal notice-and-comment procedures which provide accountability and prevent *de facto* rulemaking, unfair surprise, and the attendant potential imposition of massive and unanticipated overtime liability. This Court's guidance is needed to clarify those boundaries.

Moreover, before the filing of DOL's *amicus* brief, it was clear that an employee who promotes a tangible good to customers may properly be classified as an exempt outside salesperson even if that

employee does not engage with the customer in a direct exchange of the good for consideration. It was enough if the customer placed the order himself by calling or ordering the product online after the sales pitch made by the employee.

With its appearance here, DOL ignored its prior acknowledgment that sales may be made in a variety of ways in the modern workplace. Instead, DOL argued — and the Second Circuit deferred to the argument — that employees who applied for sales jobs, were trained in selling skills, were charged with the duty to sell the company's products, were evaluated on their selling skills, were actively involved in developing business plans designed to grow sales in their assigned territories, and were compensated, in part, on their ability to grow sales were not, in fact, salespersons. The exemption did not apply, under DOL's view, merely because those employees are barred by law from delivering prescription drugs to physicians in return for consideration. The writing of the prescription was not enough. Yet, under the realities of the pharmaceutical industry, the only way to obtain a prescription drug is with a prescription. It is the writing of the prescription that makes the transaction equivalent to that of the customer who, after a sales pitch by a door-to-door salesperson, places his order online.

To reach its decision, the Second Circuit committed error by relying on DOL's new and heightened requirement that a direct transaction be consummated between sales representative and customer. It ignored the reality of how prescription drugs are sold and DOL's own guidance that the

"basic character of the job as a whole" should be considered when applying the outside sales exemption. 69 Fed. Reg. at 22161 (App. L at 103a). Because of the extraordinary impact on all sales industries made by the Second Circuit's decision to defer to DOL's litigation argument and the magnitude of the error in construing the outside sales exemption, Schering's petition should be granted.

I. THE COURT'S GUIDANCE IS NEEDED TO CLARIFY THE APPROPRIATE SCOPE OF *AUER* DEFERENCE

In *Auer*, the Court invited DOL's input to interpret regulations related to the salary-basis test under the FLSA. Because the salary-basis test "is a creature of the Secretary's own regulations," the Court concluded that DOL's interpretation should be granted controlling deference, unless the interpretation was "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461 (internal citations omitted). Important to the Court's decision was the conclusion that DOL's interpretation did not pose a threat of "massive and unanticipated overtime liability." *Id.*

Here, despite the threat of massive and unanticipated overtime liability being faced by Schering and the pharmaceutical industry overall with its ruling, the Second Circuit determined that DOL's litigation stance was entitled to controlling deference with little more than a passing reference to *Auer*. No discussion was had of the implications of the change in DOL stance nor did the court address the unfair surprise being faced by the

pharmaceutical industry and the extraordinary impact of the agency's change in position on all businesses employing an outside sales force. The Second Circuit's default to deference, without analysis, in circumstances such as these demonstrates that this Court's guidance is needed.

A. The Court's guidance is needed to clarify the extent to which *Auer* deference should be granted when a change in agency interpretation, without notice and comment, creates massive and unexpected liabilities

Auer deference should not be extended to a case where an agency, uninvited, interprets its regulations in a manner that subjects a company or industry to extraordinary liability without fair notice. The language and purpose of the FLSA's "outside sales" provision, and the Department of Labor's longstanding interpretation of it, all point in the same direction: that pharmaceutical sales representatives are exempt. It would be unjust to allow the Department's unanticipated argument that those sales positions are *not* exempt, announced for the first time in an *amicus* brief, to be the deciding factor in litigation involving virtually all major pharmaceutical companies and thousands of employees. *Cf. Christopher v. SmithKline Beecham Corp.*, No. CV-08-1498-PHX-FJM, 2010 WL 396300, at *2 (D. Ariz. Feb. 1, 2010) (consolidated appeal pending in the Ninth Circuit) (concluding that the DOL Brief was not entitled to deference; "[n]ot only is the DOL's current interpretation inconsistent with

the statutory language and its prior pronouncements, but it also defies common sense").

The Court recently analyzed the potential for disruption and unfair surprise caused by deference to informal agency opinions in *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158 (2007). At issue in *Coke* was DOL's interpretation of two conflicting regulations concerning the treatment under the FLSA of domestic companionship services providers employed by third parties. 551 U.S. at 169. There the Court noted that deference to agency interpretations was only appropriate "as long as interpretative changes create no unfair surprise." *Id.* at 170. In that case, the Court found no such threat because DOL announced its position in a notice-and-comment rulemaking procedure. *Id.* at 170-71. Accordingly, there was no need for the Court to articulate guidelines for applying the "unfair surprise" standard. That need for guidelines, however, exists here. The changes made by DOL — requiring that a salesperson obtain a "binding" commitment or consummate a transaction to be classified as exempt — were not subject to the requisite rulemaking procedures and have created unfair surprise. *Cf. Upton v. S.E.C.*, 75 F.3d 92, 98 (2d Cir. 1996) (explaining that deference should not be extended to an agency's interpretation if it "would penalize [a company that] has not received fair notice of a regulatory violation").

Two of the circuit courts have likewise grappled with the extension of *Auer* and the effect of unfair surprise post-*Coke*, albeit with divergent results. *See Taylor v. Progress Energy, Inc.*, 493 F.3d 454, 461-62 (4th Cir. 2007) (without discussing *Coke*, majority

does not give deference to position advanced in *amicus* brief because it is inconsistent with the statute and accompanying regulations at issue; dissent mentions *Coke* "unfair surprise" standard); *Boose v. Tri-County Metro. Trans. Dist. of Or.*, 587 F.3d 997, 1005 n. 13 (9th Cir. 2009) (finding no unfair surprise under *Coke* because agency attempted to change its position through notice-and-comment rulemaking); *Pub. Citizen v. Nuclear Regulatory Comm'n*, 573 F.3d 916, 923-24 (9th Cir. 2009) (where agency is merely "elaborating on" the interpretation of its own regulation, it is not departing from an "established standard" and there is no unfair surprise).

This Court's guidance on the extension of *Auer* to the DOL Brief, and clarification of *Coke*'s "unfair surprise" standard, is particularly important in a case such as this, one which threatens unfair surprise not only to an individual company and the pharmaceutical industry overall but also other sales organizations who relied on DOL's regulations allowing exempt status for those employees who "in some sense" made a sale.

Before DOL interceded in *Novartis*, employers only had to assure that their sales employees "direct[ed] efforts toward the consummation of a sale" or made a sale "in some sense," even if it was the customer who actually finalized the order. 29 C.F.R. § 541.503(c) (App. K at 87a); 69 Fed. Reg. at 22162 (App. L at 105a). Under DOL's new interpretation of the regulations, an employer must now ask whether its outside sales force actually "consummates" transactions or obtains legally binding commitments in order to classify those

employees as exempt. DOL's interpretation raises questions for all industries where there may be a long sales cycle, requiring salespersons to make multiple visits to customers before a final sale is consummated, or where someone other than the salesperson or customer pushes the button finalizing the order.

The need for guidance is further strengthened in light of DOL's election to engage in the argument only after the great majority of courts to consider the question had concluded, consistent with the Department's previously expressed views, that pharmaceutical sales representatives *are* exempt outside salespersons.[2] Granting this petition will

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[2] *See Christopher*, 2009 WL 4051075, at *5; *Schaefer-LaRose v. Eli Lilly & Co.*, 663 F. Supp. 2d 674, 688 (S.D. Ind. 2009); *Harris v. Auxilium Pharms., Inc.*, 664 F. Supp. 2d 711, 742 (S.D. Tex. 2009); *Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 686 (W.D. Pa. 2009), *aff'd on other grounds,* 372 F. App'x 246 (3d Cir. 2010); *Delgado v. Ortho-McNeil, Inc.*, No. SACV 07-00263-CJC(MLGx), 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-CJC(MLGx), 2009 WL 3326632, at *6 (C.D. Cal. Feb. 6, 2009) (same); *see also Rivera v. Schering Corp.*, No. CV 08-1743-GW(JCx), 2008 WL 6953955, at *9 (C.D. Cal. Aug. 14, 2008) (California law); *Brody v. AstraZenca Pharms. LP*, No. CV 06-6862-ABC(MANx), 2008 WL 6953957, at *9 (C.D. Cal. June 11, 2008) (same); *Menes v. Roche Labs., Inc.*, No. 07 CV 01444-ER-FFMx, 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-JFW(PLAx), 2007 WL 6913682, at *4 (C.D. Cal. Oct. 9, 2007) (same). *But see Jirak v. Abbott Labs., Inc.*, No. 07-C-3626, 2010 WL 2331098, at

allow the Court to prevent an entire industry and other businesses engaged in the making of sales from being penalized for a regulatory violation about which no notice had been given and no opportunity for comment had been allowed.

Extending *Auer* deference in this case, on the other hand, would allow a position articulated for the first time in an *amicus* brief to subvert the normal rulemaking processes. Under the "unfair surprise" analysis described in *Coke*, *Auer* deference is justified only when "an agency's course of action indicates that the interpretation of its own regulation reflects its considered views," as, for example, when the agency has "clearly struggled with the * * * question" for an extended period. *Coke*, 551 U.S. at 171. There is no indication that DOL has *ever* "struggled with" the question whether pharmaceutical sales representatives are outside salespersons. On the contrary, the Department's "course of action" since the FLSA's enactment demonstrates that its current position reflects an abrupt *change* in its views. Granting the petition in this case will allow the Court to define the limits on *Auer* deference and guide DOL and other agencies in the future application of such deference.

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*7 (N.D. Ill. June 10, 2010); *Smith v. Johnson & Johnson*, No. 06-4787 (JLL), 2008 WL 5427802, at *7 (D.N.J. Dec. 30, 2008), *aff'd on other grounds*, 593 F.3d 280 (3d Cir. 2010); *Ruggeri v. Boehringer Ingelheim Pharms., Inc.*, 585 F. Supp. 2d 254, 272 (D. Conn. 2008); *Amendola v. Bristol-Myers Squibb Co.*, 558 F. Supp. 2d 459, 472 (S.D.N.Y. 2008).

B. The Court's guidance is needed to clarify the limitations on *Auer* deference when the regulation mirrors the statutory language

In deciding to extend *Auer* deference to the Secretary's interpretation of whether pharmaceutical representatives make "sales," the Second Circuit considered, and rejected, the argument that deference was not due because the regulation being interpreted merely parrots the statute. *Novartis,* 611 F.3d at 151-52 (App. C at 64a-75a). It did so by looking to regulations not relevant to the question being litigated. The court disregarded *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006), and its instruction that *Auer* deference is not warranted where "the underlying regulation does little more than restate the terms of the statute." This Court's guidance is needed to clarify the extent to which *Gonzales* impacts *Auer* deference.

The question in this case is whether pharmaceutical sales representatives make "sales." To answer that question, DOL interpreted the regulations to conclude that the definition of "sales" requires a binding commitment or a consummated transaction. DOL Brief at 6-13 (App. M at 120a-124a). The regulation defining the word "sale," however, exactly mirrors the words crafted by Congress and nowhere states that commitments must be legally binding or transactions must be consummated.

Congress defined "[s]ale' or 'sell' under section 3(k) of the FLSA to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E

at 80a). The regulations begin with section 541.500, which provides that an employee is exempt if his or her primary duty is "making sales within the meaning of section 3(k) of the Act." 29 C.F.R. § 541.500(a)(1)(i) (App. H at 84a). Going further, section 541.501 of the regulations notes that "Section 541.500 requires that the employee be engaged in * * * [m]aking sales within the meaning of section 3(k) of the Act." It then quotes the definition of sale originally set forth by Congress: "Section 3(k) of the Act states that 'sale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 C.F.R. § 541.501(b) (App. I at 85a).

Nonetheless, the Second Circuit disagreed that the regulations merely parroted the statute. To conclude that the Secretary's interpretations were entitled to controlling deference, the court instead looked to non-definitional regulations explaining that sales are not limited to tangible goods, (29 C.F.R. § 541.501(b) (App. I at 85a)), and addressing the extent to which an outside salesperson may engage in promotional activities (*id.* § 541.503) (App. K at 87a). *Novartis*, 611 F.3d at 152-53 (App. C at 68a-69a). Those regulations upon which the court relied, however, do not answer the question present here of whether an employee in fact makes sales. The court's reliance on those regulations to conclude that controlling deference was warranted demonstrates the need for the Court's guidance in clarifying the interplay between *Auer* and *Gonzales*.

II. THE SECOND CIRCUIT ERRED IN ITS CONSTRUCTION OF THE OUTSIDE SALES EXEMPTION

The position taken by the Second Circuit and DOL in this case is at odds not only with the spirit of the FLSA and the less restrictive approach taken by other courts but also with the position DOL has taken for nearly three quarters of a century. DOL has emphasized, in myriad ways, the breadth and flexibility of the concept of a "sale" under the "outside sales" exemption. As the Department said in 1940, and as it said again in 2004 after extensive notice-and-comment rulemaking, the exemption applies to an employee who "in some sense" makes sales. 69 Fed. Reg. at 22162 (App. L at 105a) (citing U.S. Dep't of Labor, Wage & Hour Div., *"Executive, Administrative, Professional . . . Outside Salesman" Redefined: Report and Recommendations of the Presiding Officer (Harold Stein) at Hearings Preliminary to Redefinition* 45 (Oct. 10, 1940)).

Relying upon DOL's new interpretation, however, the Second Circuit concluded that, because a pharmaceutical sales representative "cannot lawfully transfer ownership of any quantity of the drug in exchange for anything of value, cannot lawfully take an order for its purchase, and cannot lawfully even obtain from the physician a binding commitment to prescribe it," it was not plainly erroneous for DOL to conclude that the employee has not in any sense within the meaning of the statute or

regulations "made a sale." *Novartis*, 611 F.3d at 155 (App. C at 71a-72a). The court's conclusion is error.[3]

A. The court erred in its reliance on DOL's interpretation of the regulations

In interpreting the FLSA's outside sales exemption, the Court starts "as always, with the language of the statute." *Dean v. United States*, 129 S. Ct. 1849, 1853 (2009) (internal quotation marks omitted). At issue in this case is the meaning of the word "sale," which the statute defines to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E at 80a).

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[3] The law prohibiting pharmaceutical sales representatives from engaging in a direct exchange of drugs for consideration, the FDCA and its accompanying regulations, was enacted for the benefit and protection of consumers. That law has nothing to do with the classification of pharmaceutical sales representatives as exempt outside salespersons under the FLSA or whether the duties assigned to pharmaceutical sales representatives are properly classified as exempt. By imposing a new technical requirement under the FLSA that there must be a consummated transaction to constitute a "sale" while relying upon the FDCA to demonstrate there can never be a sale, the Second Circuit and DOL are using the FDCA for purposes it was never intended to serve. Under the Secretary's interpretation, a regulatory scheme which is meant to protect consumers may ultimately result in a major upheaval of how the pharmaceutical industry classifies its employees and conducts its business — certainly an unintended consequence of the consumer protections afforded by the FDCA.

DOL began its argument, not with the language of the statute, but by relying upon the interpretative canon that FLSA exemptions must be construed narrowly. DOL Brief at 7 (App. M at 119a). The FLSA's definition of "sale," however, is not an exemption subject to the narrow construction canon. Rather, it is a statutory definition which is to be construed broadly, *see, e.g., Salyer v. Ohio Bureau of Workers' Comp.*, 83 F.3d 784, 786 (6th Cir. 1996), and which is, on its face, expansive.

Congress's use, for example, of the word "any" demonstrates that the listed examples should be interpreted broadly. *Ali v. Fed. Bureau of Prisons*, 128 S. Ct. 831, 835-36 (2008) ("the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind'") (citations omitted). Beginning the definition with the same word, "sale," shows that the defined term is not restricted to a narrow, technical meaning. That conclusion is buttressed by Congress's election to define the term "sale" to include any "*other disposition*." 29 U.S.C. § 203(k) (App. E at 80a) (emphasis added). This catch-all term forecloses the possibility that Congress intended a restricted meaning of the defined term "sale" by requiring certain unwritten technicalities like a "consummated" transaction.[4]

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[4] The use of the phrase "sale or other disposition" is used in other statutory contexts, such as the Gun Control Act of 1968, 18 U.S.C. § 922(a)(6). This Court, in *Huddleston v. United States*, 415 U.S. 814 (1974), considered whether a felon redeeming a firearm from a pawnshop was "acquiring" the firearm in violation of section 922(a)(6). Huddleston had argued that a redemptive transaction was not a "sale" from the

Contrary to DOL's argument and the Second Circuit's decision, a "binding" commitment or "consummated" transaction is not required to effect a "sale" under the regulations and in fact is contradicted by them. *See* 29 C.F.R. § 541.503(c) (employee makes sales if he or she "obtain[s] a commitment for * * * purchases" or "direct[s] efforts toward the consummation of a sale") (App. K at 87a). In the preamble to the regulations, the Department of Labor confirmed that neither "binding" commitments nor direct transactions need occur between salesperson and customer by explaining that an employee engages in "outside sales" work if "the employee, in some sense, has made sales," and noting that "obtaining a commitment to buy," is sufficient. 69 Fed. Reg. at 22162-63 (App. L at 105a). Directing efforts toward the consummation of a sale and obtaining a commitment for purchases are precisely what pharmaceutical sales representatives do.

The only way in which DOL could conclude that pharmaceutical sales representatives are not exempt outside salespersons was to impose a new and unwarranted requirement that the commitments

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perspective of the pawnbroker, and so could not be an "acquisition" with respect to the person redeeming the firearm. The Court disagreed and interpreted the inclusion of the phrase "other disposition" to mean that Congress intended the statute to encompass more than traditional "sales" which connote transfers of ownership and title. *Id.* at 820-21. The same argument is applicable here: including "other disposition" within the statutory definition of a sale contemplates a disposition separate and distinct from a traditional "sale" resulting in a transfer of ownership or title.

those salespersons obtain must now be legally binding. The Second Circuit's decision deferring to DOL simply ignores the reality present in pharmaceutical sales that physicians are the only customers capable of placing the order for a prescription drug and that the prescription serves as the order for disposition to the patient. The pharmaceutical salesperson directs his or her efforts to consummating a sale not only in "some sense" but also in the "only sense" possible in the pharmaceutical industry. The fact that those sales efforts result not in a direct exchange of a good for consideration but by a physician placing the order does not diminish in any way the conclusion that the employee's primary duty is "making sales".

B. The court erred in its analysis of the outside sales exemption as applied to the pharmaceutical industry

The Second Circuit's conclusion that pharmaceutical sales representatives do not "make sales" as defined under the FLSA is based upon DOL's argument that those employees only "promote" sales made by other persons:

> Novartis sells its drugs to wholesalers; the wholesalers then sell them to pharmacies; and the pharmacies ultimately sell the drugs to patients who have prescriptions for them. The Reps promote the drugs to the physicians; the Reps do not speak to the wholesalers or to the pharmacies or to the patients.

Novartis, 611 F.3d at 153-54 (App. C at 70a.)

That conclusion ignores the reality that the *only* customer who may place an order for pharmaceutical drugs is the physician. The flaw in the court's analysis is that no pharmaceutical company could sell its products to wholesalers or pharmacies or patients if physicians did not write prescriptions. Without the demand from physicians, there is no sale to a wholesaler or pharmacy.

The restrictive approach taken by the Second Circuit cannot be reconciled with that of the Eleventh Circuit in *Gregory v. First Title of America Inc.*, 555 F.3d 1300 (11th Cir. 2009). The *Gregory* court acknowledged it was to narrowly construe the white-collar exemptions, giving "due regard to the plain meaning of the statutory language and the intent of Congress." It was mindful, however, that "[t]o read the FLSA blindly, without appreciation for the social goals Congress sought, would also do violence to the FSLA's spirit." *Id.* at 1307 (internal quotation marks and citations omitted). The Second Circuit's refusal to do the same and to take into account the reality of the sales process in the pharmaceutical industry serves no goal of the FLSA.

In contrast, the Eleventh Circuit took the realities of the sales process in another industry into consideration in *Gregory*. There, the employee, a "marketing director," did not consummate direct transactions with customers of the employer title company. Rather, she was "tasked only with inducing realtors, brokers and lenders to begin referring their customers — the end user — on to First Title for title insurance services." 555 F.3d at 1303. Ultimately, the court concluded that although the marketing director *did not consummate* direct

transactions, she nonetheless qualified as an exempt outside salesperson because she was responsible for obtaining "orders" for title services. *Id.* at 1309-10. Like the employee in *Gregory*, there is "no intervening sales effort" between the efforts of pharmaceutical sales representatives and the "consummation" of the sale. Once the physician writes the prescription, the "selling" is complete. *See id.* at 1310. [5]

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[5] The other cases relied upon by the Second Circuit likewise fail to support its conclusion that pharmaceutical sales representatives do not qualify for the outside sales exemption. *Novartis,* 611 F.3d at 152-53 (App. C at 67a-68a). The civilian military recruiters in the first case, *Clements v. Serco, Inc.*, 530 F.3d 1224 (10th Cir. 2008), did not "sell" anything. *Serco* involved the solicitation of a commitment to *join* the military, *not* the solicitation of a commitment to *buy* goods, a commitment which ultimately characterizes pharmaceutical sales. Moreover, unlike the situation in *Serco* whereby military recruiters had to follow up on the recruitment efforts by civilian employees to "close" the "sale," pharmaceutical sales representatives do not identify prospective purchasers for other employees to approach with a sales pitch.

Wirtz v. Keystone Readers Service, Inc., 418 F.2d 249 (5th Cir. 1969), suffers from the same problem. There, student salespersons who promoted magazine subscriptions to prospective customers were followed by sales managers who actually explained payment plans, executed the contract and collected payment from the customer. 418 F.2d at 252. The student salespersons were found to be non-exempt because they promoted sales made by other employees. *Id.* at 261. The sales process in *Wirtz* simply is not on point; no one follows a pharmaceutical sales representative into physicians' offices to consummate a transaction or obtain a binding commitment.

Before DOL's appearance in the court below, the outside sales exemption did not impose a requirement that sales employees consummate direct transactions with their customers. Indeed, despite DOL's interpretation announced in *Novartis*, the Bureau of Labor Statistics' Occupational Outlook Handbook recently recognized pharmaceutical sales representatives as employees whose duties include "selling products" for wholesalers or manufacturers where technical or scientific knowledge is required. Dep't of Labor, BUREAU OF LABOR STATISTICS' OCCUPATIONAL OUTLOOK HANDBOOK (2010-2011 Edition), *available at* http://data.bls.gov/cgi-bin/print.pl/oco/ocos119.htm ("Handbook"). The Handbook further acknowledges that "sales representatives' primary duties are to make customers interested in their merchandise and to arrange the sale of that merchandise." *Id.*

The narrow and inflexible interpretation of sales taken by the Second Circuit and DOL in this case contradicts the statute, regulations, and established jurisprudence. The unambiguous statutory language, coupled with the nature of the transaction involved in pharmaceutical sales, compels the conclusion that pharmaceutical sales representatives meet the requirements of the FLSA's outside sales exemption. The Court should grant the petition to review the Second Circuit's erroneous decision.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

October 4, 2010

Respectfully submitted,

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