No. 10-459

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Schering Corporation ("Schering") has petitioned the Court to review the ruling by the Second Circuit that pharmaceutical sales representatives are not exempt outside salespersons under the Fair Labor Standards Act. An important question of federal law is raised by the ruling—namely, whether *Auer* deference should be extended to an agency's interpretation of statutory language stated for the first time in an unsolicited *amicus* brief when that interpretation causes unfair surprise and imposes substantial liability on not only the pharmaceutical industry, but also any industry that employs outside sales representatives.[1] As shown below, Respondents' attempts to challenge the bases for certiorari fall short and the Court's review is warranted.

A. This Case Involves An Important Question of Federal Law.

The Second Circuit's decision has far-reaching consequences for the pharmaceutical industry, including the potential for enormous retroactive

[1] Schering's appeal was heard in tandem with *In re Novartis Wage & Hour Litigation*, 611 F.3d 141 (2d Cir. 2010) (App. C at 45a) ("*Novartis*"). The Department of Labor ("DOL") appeared *sua sponte* in *Novartis* on behalf of the plaintiffs. (App. M at 110a) In an opinion that dictated the result in Schering's appeal, the Second Circuit in *Novartis* deferred to DOL's interpretation of the outside sales and administrative exemptions and ruled that the plaintiffs were not exempt employees. Novartis filed its petition for writ of certiorari on October 4, 2010. (No. 10-460).

liability for back overtime pay and the upheaval associated with a major restructuring of the sales forces of all pharmaceutical companies — all because of an abrupt and unexpected change in DOL's interpretation of its regulations announced for the first time in an *amicus* brief. Brief of Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amicus Curiae* in Support of Petitioner at 23-25, *Novartis Pharms. Corp. v. Lopes*, No. 10-460 ("PhRMA Brief"); *see also* Pet. 2, 14-19. Nor will the impact be limited to the pharmaceutical industry. The Second Circuit's decision upsets decades of settled law on the meaning of the word "sale," creating uncertainty for employers in nearly every sector of the American economy." Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioner at 22, *Novartis Pharms. Corp. v. Lopes*, No. 10-460 ("Chamber Brief"). Respondents do not dispute this far-reaching impact, nor can they.

Instead, Respondents argue the interpretation of the outside sales exemption "urged" by Schering will "swallow the rule." Opp. 15. Schering, however, does not advocate an interpretation which would "include all employees engaged in activities designed to increase demand for their employer's goods or services" as Respondents suggest, nor one which would cover employees "wearing sandwich boards on the sidewalk." *Id.* Such suggestions, as well as Respondents' comparison of pharmaceutical sales representatives (who play an integral role in the provision of healthcare to patients) with a cereal company's popular mascot, are merely meant to distract the Court from the widespread and deleterious consequences of the Second Circuit's ruling, affecting

substantially more employees and industries than Respondents admit. Pet. 2, 14-19; PhRMA Brief, at 23-25; Chamber Brief, at 22.

B. The Court's Guidance Is Needed To Clarify *Auer* Deference.

Respondents argue that the scope of deference to be afforded an agency's interpretation of its own regulations is "plain and unambiguous" under *Auer v. Robbins*, 519 U.S. 452 (1997), and that the Court's guidance is not needed to clarify *Auer*'s limits in the circumstances present here. Opp. 21-22. Respondents' conclusory arguments aside, application of *Auer* deference in this case is far from "plain and unambiguous."

As a threshold matter, *Auer* requires that the regulation at issue be ambiguous. 519 U.S. at 463. Neither DOL nor the Second Circuit identified an ambiguity in the regulations, and the court made no reference to that requirement in its ruling. The failure to address this threshold issue only serves to underscore the need for clarification of when *Auer* deference should apply.

Nor is it clear that the court's analysis is consistent with the limits on *Auer* deference established under *Gonzales v. Oregon*, 546 U.S. 243 (2006). The question of whether any of the millions of sales representatives employed in the United States are properly classified as exempt outside salespersons turns on the meaning of "sale." Rather than delegating the matter to DOL, Congress itself defined the word "sale" in expansive terms, 29 U.S.C. § 203, and DOL expressly adopted that definition in its implementing regulations, 29 C.F.R. § 541.500. Under *Gonzales*, courts should not defer to an agency's

interpretation of language that merely paraphrases the statute. 546 U.S. at 257. On its face, therefore, deference to DOL's interpretation of "sale" appears unwarranted, and the court's conclusion to the contrary by relying on non-definitional regulations separate from the definition of "sale" creates uncertainty as to the interplay between *Gonzales* and *Auer*. Pet. at 20-21.

Most importantly, this case presents the unsettled issue of *Auer*'s role where an agency's informal interpretation, here in an unsolicited *amicus* brief, creates unfair surprise and the potential for massive and unanticipated liability. Pet. 15-19. *Long Island Care at Home, Ltd. v. Coke* suggests that courts should not accord "controlling" deference to an agency's interpretation in such circumstances. 551 U.S. 159, 171 (2007). *Coke,* however, had no cause to elaborate on this dictum because DOL's change in interpretation there came about after only notice-and-comment rulemaking. *Id.* The Second Circuit's failure to address the unfair surprise and unanticipated liability arising from DOL's interpretation in *Novartis* underscores the uncertainty that remains after *Auer* and the need for the Court's guidance.

C. DOL's New Interpretation Creates Unfair Surprise.

In their effort to show that there was no unfair surprise here, Respondents contend that "no one" could have read the agency's regulations and concluded that pharmaceutical sales representatives are exempt outside salespersons. Opp. 20. They reach that conclusion despite the expansive definition of the word "sale" and DOL's consistent instruction for 70 years that a sales employee only

had to make sales "in some sense" to be exempt. The notion that the industry should have known better is belied by numerous lower court rulings that applied DOL's pre-*Novartis* guidance and found that pharmaceutical sales representatives make sales under both the FLSA and state laws that look to the FLSA for guidance, the existence of which caused the trial court to certify interlocutory appeal in this matter. Pet. 18, n.2.

DOL has long acknowledged that an employee engages in "sales" as defined by § 203(k) of the FLSA whenever the employer can demonstrate "that the employee, in some sense, has made sales." 69 Fed. Reg. 22122, 22162 (Apr. 23, 2004) (citing 1940 Stein Report at 46) (App. L at 104a-105a)). Before the filing of DOL's *amicus* brief in *Novartis*, there was no requirement that the employee engage with the customer in a direct exchange of goods for consideration, as long as the employee "in some sense" made sales. With its *amicus* brief, however, DOL abandoned the flexible understanding of the meaning of a "sale" and imposed a new requirement that a direct exchange of a good for consideration occur between the employee and customer. Because of the regulatory constraints that prohibit a direct exchange of pharmaceutical drugs to be made between a pharmaceutical sales representative and a physician's patients, that interpretation makes it impossible for pharmaceutical companies to classify *any* employees as outside salespersons, even when those employees perform every other traditional function of the job. It no longer is enough that those employees make sales in the only sense in which sales can be made in the pharmaceutical industry.

Despite this shift, Respondents assert that "[t]here has been no change" from DOL's past position, and thus no unfair surprise, as to what constitutes a "sale" for the purposes of the outside sales exemption. Opp. 16-20. To support this proposition, Respondents cite to inapplicable precedent and selectively cite (and in some instances, misquote) regulatory language.

1. Respondents' authority fails to rebut the unfair surprise caused by DOL's new interpretation.

Respondents continue to ignore the nature of the pharmaceutical industry, including the reality of what a "sale" is in that context. Their authority misses the mark because pharmaceutical sales representatives do not merely pave the way for others to complete the transaction and do not sell a theoretical concept.

Two cases relied upon by Respondents were cited in *Novartis* and were already distinguished in Schering's Petition. Pet. 28, n.5. These cases both involved employees who paved the way for "sales" to be "closed" by other employees, a business model which differs materially from that of the pharmaceutical industry. *See Clements v. Serco, Inc.*, 530 F.3d 1224 (10th Cir. 2008) (civilian recruiters were not exempt where they "merely cultivated 'a list of persons who seem[ed] receptive to the idea' of joining the Army" and others evaluated and enlisted the accepted candidates); *Wirtz v. Keystone Readers Serv., Inc.*, 418 F.2d 249 (5th Cir. 1969) ("student salesmen" who were employed to make the first contact with potential customers were not exempt;

they were engaged in activities incidental to sales made by managers).[2]

Respondents' reliance on certain DOL Opinion Letters is similarly misplaced. Pharmaceutical sales representatives are not like college enrollment advisors who only meet with prospective students "selling them on attendance at school." WH Opinion Letter FLSA, 1998 DOLWH LEXIS 17 (Feb. 19, 1998) (Opp. 5, n.3). Nor are they remotely comparable to solicitors of charitable donations or liaisons between organ donors and non-profit foundations. Those employees' duties are akin to those of outside buyers, the opposite of outside salespersons. *See* WH Opinion Letter FLSA 2006-16, 2006 DOLWH LEXIS 65 (May 22, 2006) (selling the concept of donating to a charity did not qualify as sales); WH Opinion Letter FLSA, 1994 DOLWH LEXIS 65 (Aug. 19, 1994) (selling the concept of tissue donation did not qualify for the outside sales exemption). Schering's pharmaceutical sales representatives do not sell a theoretical concept. Rather, they work to secure a physician's commitment to prescribe a specific product for appropriate patients, and the physician

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[2] The comparison of pharmaceutical sales representatives to the manufacturer's representative who does preliminary work, such as encouraging a retailer to buy the manufacturer's products, likewise fails. In the case of the manufacturer's representative, a distributor's salesperson actually follows the representative to the retailer and takes the retailer's order. Opp. 18-19. There is no one like the distributor's salesperson in the sale of prescription drugs; no one from a pharmaceutical wholesaler follows a pharmaceutical sales representative into a doctor's office to "take the order" from the physician.

places the order for the product by writing the prescription.[3]

2. To create the false impression that DOL's new interpretation does not represent a change in position, Respondents misquote the regulations.

Respondents cite "instructive examples" in the regulations which allegedly support DOL's interpretation of the exemption. Opp. 4-5. Analogizing pharmaceutical sales representatives to a company's representative who visits chain stores to monitor inventory, for example, Respondents state "[b]ecause the employee in this instance does not *consummate the sale* . . . the work is not exempt outside sales work." Opp. 5 (citing 29 C.F.R. § 541.503 (c) (emphasis supplied by Respondents)). The words omitted by the use of ellipses, however, prove the fallacy of the argument. The regulation actually states the following: "Because the employee in this instance does not consummate the sale *nor direct efforts toward the consummation of a sale*, the work is not exempt outside sales work." 29 C.F.R. § 541.503 (c) (emphasis supplied). Even if pharmaceutical sales representatives cannot "consummate" a sale in the technical sense now required by the

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[3] The Opinion Letters do not mandate that the employee consummate a direct sale to be classified as an outside salesperson. The 1994 Opinion Letter analyzing the position of tissue recovery coordinators, for example, explained that exempt work "includes the sale of commodities" but did not require that the sale occur by a direct exchange between the salesperson and customer. 1994 DOLWH LEXIS 65.

Second Circuit and DOL, they unquestionably direct their efforts towards the consummation of a sale.

In further support of their contention that DOL's interpretation is nothing new, Respondents misstate another key regulatory term. Elaborating upon the statutory requirement of a "sale" under Section 3(k) of the FLSA, Respondents allege that the "regulations further specify that sales under the act *involve* the 'transfer of title to tangible property, and in certain cases tangible and valuable evidence of intangible property.'" Opp. 4 (emphasis added). The regulation actually provides that sales within the meaning of the FLSA "*include* the transfer of title to tangible property." 29 C.F.R. § 541.501(b) (emphasis added). Respondents' use of the word "involve" suggests that the following reference to a transfer of title is mandatory. The word "include" shows that the regulation's reference to the transfer of title is not mandated. Respondents' reliance on selective excerpts and misstatement of relevant regulations serve only to confirm that DOL's new interpretation materially changes the outside sales exemption.

CONCLUSION

After *Auer*, *Coke*, and *Gonzales*, questions remain as to the deference afforded to an agency interpretation. *Coke* instructs that there is no unfair surprise when an interpretation is advanced through notice-and-comment rulemaking (which also suggests that the agency has exercised its considered judgment in advancing the interpretation), but that is not the case here. In the Second Circuit, an uninvited brief, which adds a new twist to established regulations and threatens massive and unanticipated liability sufficient to upend an entire

industry, does not establish unfair surprise. The Court's guidance is needed to clarify the standard required to show unfair surprise, the proof a party must muster to show that an interpretation was not the result of the considered judgment of the agency, and the extent to which a court may look beyond the terms being interpreted to determine whether the agency's interpretation warrants deference. For the foregoing reasons and those stated in the Petition, Schering Corporation's Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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