NO. 11-204

In the
Supreme Court of the United States

MICHAEL SHANE CHRISTOPHER ET AL.,
PETITIONERS,

v.

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE,
RESPONDENT.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. PhRMA closely monitors legal issues that impact the pharmaceutical industry and has frequently participated in cases before this Court.

PhRMA has a particular interest in this case because whether pharmaceutical sales representatives ("PSRs") are exempt from overtime pay under the "outside sales" exemption of the Fair Labor Standards Act of 1938 ("FLSA" or "the Act"), 29 U.S.C. §§ 201 *et seq.*, is of critical importance to the pharmaceutical industry and the tens of thousands of PSRs it employs across the nation. Throughout the 70 years since the enactment of the FLSA, the settled understanding has been that PSRs, who are highly skilled, well-compensated sales professionals, are exempt from overtime pay. A ruling that PSRs are not exempt would expose PhRMA's members to the risk of staggering retrospective liability and could require them to restructure their sales operations in ways that would

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[1] The parties have consented to the filing of this brief. No counsel for any party authored this brief in whole or in part, and no person or entity, other than PhRMA and its counsel, made a monetary contribution to the preparation or submission of this brief.

adversely affect not only PhRMA's members, but also the tens of thousands of PSRs they employ, the vast majority of whom who have never asked to be—and do not want to be—treated as hourly workers.

SUMMARY OF ARGUMENT

I. This case turns on whether the job performed by PSRs comes within the FLSA's definition of "[s]ale" or "sell" in 29 U.S.C. § 203(k). That definition is explicitly broad and inclusive: "'Sale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." By providing examples of what a "sale" "includes," and by using examples that do not involve a transfer of title and extend beyond the term "sale" itself, Congress made clear that the definition was intended to be flexible and non-technical so that it could be applied across the spectrum of industries to myriad specific methods by which sales occur.

This statutory definition plainly encompasses PSRs throughout the pharmaceutical industry, whose job is to obtain the maximum allowable commitment from physicians to prescribe the PSRs' assigned products. Given the applicable legal and ethical constraints, a sale of a prescription drug involves different mechanics than sales in other industries, but the key customer is the physician, and that is why pharmaceutical companies hire large outside sales forces of PSRs to sell to physicians. Recognizing this reality is not a call for special treatment for the pharmaceutical industry, but rather for the common sense that Congress

intended in fashioning § 203(k)'s explicitly practical definition.

II. PSRs' exempt status is of enormous practical importance to both pharmaceutical companies and PSRs themselves. Treating PSRs as non-exempt would require a major restructuring of the PSR position that would benefit no one. Like other outside salespersons, PSRs work with little direct supervision, manage their own flexible schedules, and generally receive substantial performance-based incentive compensation. These aspects of the position make the PSR job much sought-after and facilitate the recruitment of highly qualified candidates, but the same aspects are fundamentally incompatible with classification as an hourly employee. The FLSA's broad definition of sales clearly demonstrates that Congress would not have wanted technicalities about how sales occur in the pharmaceutical industry—due to regulatory and ethical requirements that are far afield from the worker-protection purposes of the FLSA—to make it impossible for the PSR position as we know it to exist, thereby hurting both pharmaceutical companies and PSRs.

III. A. Petitioners and the United States seek to avoid having this Court interpret § 203(k) for itself on the rationale that the Court should defer to the Department of Labor's regulations. Deferring to those regulations, however, does not advance the analysis, because the regulations simply incorporate the statutory definition and do not narrow it or purport to offer a different definition. The regulations relied on by the United States merely refer back to, and thus confirm, § 203(k)'s broad

definition. If there were any doubt, 29 C.F.R. § 779.241 builds on the statute's flexible approach by emphasizing that "selling" includes any work that "in a practical sense is an essential part of consummating" a transaction. None of the regulations supports the Secretary's newly-minted rigid position that making sales requires a fully consummated transfer of title.

B. Nor can the Court resolve this case by extending "controlling" deference under *Auer v. Robbins*, 519 U.S. 452 (1997), to the Secretary's *amicus*-brief pronouncement that PSRs do not make sales. Because the regulations merely parrot the statutory definition of sales, the Secretary's view about the proper result in this case cannot be understood as a genuine interpretation of the regulations. To the contrary, if the Secretary is interpreting anything, it is the *statutory* definition that the regulation expressly incorporates. But when an agency proffers a statutory interpretation in an *amicus* brief, without going through notice-and-comment rulemaking, it is not entitled to deference under either *Chevron* or *Auer*. In all events, even if the Secretary's *amicus*-brief view were regarded as an interpretation of the regulations, it still would not merit controlling deference because it upsets settled expectations by departing abruptly and without explanation from the Department's long-established flexible definition of sales.

ARGUMENT

I. THROUGHOUT THE PHARMACEUTICAL INDUSTRY, PSRs MAKE SALES WITHIN THE MEANING OF THE FLSA.

Congress provided in the FLSA that employees who are employed "in the capacity of outside salesman" are exempt from the Act's overtime requirements, and it authorized the Department of Labor to "define[] and delimit[]" the term "outside salesman." 29 U.S.C. § 213. Congress also included in the Act a definition of "[s]ale" or "sell" that is broad and inclusive: "'Sale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k).

Pursuant to its delegated authority from Congress to implement the outside-sales exemption, the Department promulgated a regulation that ties the definition of "outside salesman" to the Act's definition of "sale" by providing that to be eligible for the exemption, an employee must make "sales within the meaning of" § 203(k). 29 C.F.R. § 541.500 (a)(1). To determine whether petitioners are covered by that exemption, this Court therefore must construe the statutory definition of "sale." The statutory definition plainly encompasses what PSRs do.

PSRs are the pharmaceutical industry's "90,000-person sales force." Pet. App. 26a. Their sales efforts are directed toward physicians because a patient, the "ultimate user" of a prescription drug, cannot purchase that drug "without first obtaining a physician's authorization," *id.* at 3a, and so it is the

physician who "selects the medication" that is purchased by or for the patient, *id.* at 26a. The PSR's goal is therefore to obtain a "non-binding commitment from the physician to prescribe the PSR's assigned product when medically appropriate." *Id.* at 27a. Regulations and ethical guidelines make this "the absolute maximum commitment" that a PSR can obtain from a physician. *Id.* In the context of the highly regulated pharmaceutical industry, physicians are the customers and PSRs' efforts to obtain these commitments from them constitute "making sales" within the meaning of the FLSA.

Congress crafted the FLSA to be flexible so that it could be sensibly applied in a wide variety of circumstances across diverse industries. *Cf. Walling v. A.H. Belo Corp.*, 316 U.S. 624, 634–35 (1942) (Congress eschewed "rigid definition[s]" in the FLSA "because the employment relationships to which the Act would apply were so various and unpredictable"). In keeping with that overarching goal, Congress provided a definition of "sale" or "sell" that is broad and explicitly open-ended. That statutory definition, which is expressly incorporated in the regulations defining the scope of the outside-sales exemption, easily encompasses the work of PSRs.

Congress provided that for purposes of the FLSA, "'[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). "Includes" is a "term of enlargement, and not of limitation," *Burgess v. United States*, 553 U.S. 124, 131 n.3 (2008) (quotation omitted). This is particularly true where,

as in § 203, some definitional provisions use the word "mean" while others use "include," which makes it crystal clear in context that the former "enumerate and restrict" while the latter "enlarge and extend." *Am. Sur. Co. of N.Y. v. Marotta*, 287 U.S. 513, 517 (1933); *see Helvering v. Morgan's, Inc.*, 293 U.S. 121, 125 n.1 (1934).

Moreover, by including "any sale" as just one of several types of transactions that fall within the definition, Congress clearly signaled that the Act's broad concept of sales is not limited by any narrower meaning the term "sale" might have in other contexts. This is confirmed by the strikingly open-ended phrase "or other disposition." *See* Pet. App. 28a. Petitioners contend that a "disposition" necessitates a transfer of title, Br. 25–26, but in fact, the meaning of "disposition" is far broader and encompasses diverse "arrangement[s]." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 361 (11th ed. 2008); *see* Steven I. Locke, *The Fair Labor Standards Act Exemptions and the Pharmaceuticals Industry: Are Sales Representatives Entitled to Overtime?*, 13 BARRY L. REV. 1, 25–26 (2009) (canvassing dictionary definitions).

The language of § 203(k) clearly reflects Congress's intent to adopt a definition of sales that was sufficiently flexible to accommodate the various ways in which sales are made in different industries. This broad and explicitly inclusive definition is the

antithesis of the Department's narrow focus on a consummated transfer of title.[2]

PSRs make sales within this flexible, functional definition because they work to obtain the maximum legally and ethically permissible commitment from physicians to prescribe the PSRs' assigned products. The purchase and sale of a prescription drug is a complex transaction involving multiple parties, including the physician who prescribes the drug, the pharmacist who dispenses it, the insurance company that often pays for all or part of it, and the patient who consumes it. It is the physician, however, whose knowledge, training, and ethical responsibilities make him or her the "gatekeeper" whose decision whether to prescribe a particular drug, or not, is the key to determining whether the transaction will occur. *Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 678 (W.D. Pa. 2009), *aff'd on other grounds*, 372 F. App'x 246 (3d Cir.), *cert. denied*, 131 S. Ct. 332 (2010); *see* Med. Prof'ls Br. 2 ("the prescribing decision requires a number of

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[2] The Court should not, as one *amicus* brief suggests, "presume that Congress … incorporated" any supposed common-law definition of "sales" or "salesman." NELA Br. 4–6. Rather, the Court "must follow" the "explicit definition" of "sale" that Congress provided in the statute, "even if it varies from … ordinary meaning." *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000). Further, because the Department defined the exemption for "outside salesmen" by incorporating the statutorily defined term "sale" into that regulation, it is *Congress's* definition of that term that determines the scope of the exemption.

sophisticated, independent judgment calls that are left to the discretion of each individual physician").[3]

It is for this reason that PSRs' sales efforts are focused on one-on-one discussions with the physician, the critical decisionmaker and thus the effective "buyer" in the prescription drug market. "Without physicians, no drugs would ever be sold to patients. While physicians are not a formal link in the drug-company-to-patient supply or distribution chain, they are, in fact, the l[i]nchpins." *Yacoubian v. Ortho-McNeil Pharm., Inc.*, No. 07-127, 2009 WL 3326632, at *5 (C.D. Cal. Feb. 6, 2009), *appeal docketed*, No. 09-55229 (9th Cir. Feb. 13, 2009). And PSRs do not seek merely to persuade physicians of the benefits of their assigned products in a general way, but rather seek specifically to obtain the maximum possible commitment from the physicians to prescribe those products when medically appropriate. In the context of the highly regulated

[3] In their *amicus* brief, Drs. Brody and Curfman contend that the exchange between a PSR and a physician should not be viewed as a sale because the physician uses his or her "best professional judgment when making a prescribing decision." Med. Prof'ls Br. 1. PhRMA agrees with this description of the role and responsibility of the physician, but the *amici* doctors' conclusion that the physician's exercise of professional judgment means that the exchange cannot be a "sale" is a non-sequitur. Many goods and services are sold to sophisticated buyers who, like physicians, critically evaluate the information provided by salespersons. That PSRs are not "heavy-handed," but rather provide "value" primarily in their "information dispensing capacity," *id.* at 3, 7, does not mean that PSRs are not salespeople; it means that PSRs' sales techniques are appropriately adapted to the unique context of prescription medicines.

pharmaceutical industry, there is no doubt that this is making sales and that PSRs are employed "in the capacity of outside salesm[e]n." 29 U.S.C. § 213(a)(1); *see* Pet. App. 26a.

PSRs' status as the pharmaceutical industry's sales force is confirmed by the fact that, like petitioners in this case, PSRs throughout the industry bear many traditional indicia of salespersons. For example, pharmaceutical companies typically "advertise[] openings for [PSRs] as sales positions," *In re Novartis Wage & Hour Litig.*, 611 F.3d 141, 144 (2d Cir. 2010)*, cert. denied*, 131 S. Ct. 1568 (2011), and "recruit[] applicants who have prior sales experience" to fill those positions. Pet. App. 5a; *see Kuzinski v. Schering Corp.*, 604 F. Supp. 2d 385, 390 (D. Conn. 2009) ("advertisements [for PSR jobs] seek individuals with sales skills and experience"), *aff'd*, 384 F. App'x 17 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1567 (2011).

Once hired, PSRs receive extensive, ongoing training on "selling techniques." *Jirak v. Abbott Labs., Inc.*, 716 F. Supp. 2d 740, 742 (N.D. Ill. 2010), *appeal docketed*, No. 11-1980 (7th Cir. Apr. 28, 2011). Sales training programs for PSRs are similar to such programs in other industries, including such elements as "building interpersonal skills," Pet. App. 6a, and "role-playing to simulate future interactions with physicians," *Baum*, 605 F. Supp. 2d at 671. PSR training also focuses on the classic salesperson's art of "closing," which in the heavily regulated prescription drug market means "ask[ing] for a commitment from a physician to prescribe" the PSR's assigned products when appropriate. Pet. App. 6a; *see Schaefer-LaRose v. Eli Lilly & Co.*, 663

F. Supp. 2d 674, 678, 688 (S.D. Ind. 2009) (describing how Lilly trains PSRs "to ask for business on every call and to ask the physician to commit to prescribe Lilly products" (internal quotation marks omitted)), *appeal docketed*, No. 10-3855 (7th Cir. Dec. 14, 2010). PSRs throughout the pharmaceutical industry are "trained specifically in the art of conducting these delicate closing efforts." *Baum*, 605 F. Supp. 2d at 683.

Finally, pharmaceutical companies evaluate and compensate PSRs based on factors including their sales ability and results. *See, e.g.*, *Schaefer-LaRose*, 663 F. Supp. 2d at 687 (noting that plaintiff's "efforts were neither incidental to sales made by others nor performed only for the purpose of increasing Lilly's sales in general"); *In re Novartis Wage & Hour Litig.*, 593 F. Supp. 2d 637, 652 (S.D.N.Y. 2009) ("To the extent physicians write prescriptions for [Novartis] drugs, it is the [PSRs]—and not other [Novartis] employees—who obtain these prescriptions and who receive credit for them by means of incentive payments."), *rev'd*, 611 F.3d 141 (2d Cir. 2010); *Delgado v. Ortho-McNeil, Inc.*, No. 07-263, 2009 WL 2781525, at *5 (C.D. Cal. Feb. 6, 2009), *appeal docketed*, No. 09-55225 (9th Cir. Feb. 11, 2009). In all these respects, PSRs' jobs are indistinguishable from those of sales professionals in other industries.[4]

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[4] Contrary to petitioners' assertions, nothing in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), casts any doubt on PSRs' status as salespersons. Petitioners contend that *Sorrell* held that "the role of detailers is not to enter into a commercial

Moreover, many pharmaceutical companies use PSRs not only to sell prescription drugs that the patient obtains through a pharmacy, but also to sell physician-administered prescription drugs (such as vaccines and other injectable pharmaceuticals) or over-the-counter drugs. Because these products are not dispensed by a pharmacy, physicians may place orders with or take delivery from the PSRs. These activities would likely be considered "sales" even under petitioners' and the United States' narrow conception of that term, which simply highlights how artificially rigid that conception is. A PSR's job description does not change depending on which type of product he or she is assigned to sell, and indeed, some PSRs are assigned both types of products. It is impossible to imagine that Congress intended PSRs'

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transaction but *instead* to provide information about particular products." Pet'rs Br. 11 (emphasis added). But *Sorrell* held no such thing; petitioners' dichotomy between being a salesperson and providing scientific information is of their own making. Rather, this Court held that a state law restricting PSRs' use of data regarding a physician's prescribing history was unconstitutional even assuming that the burdened speech was properly deemed commercial. 131 S. Ct. at 2667, 2672. And PhRMA expressly acknowledged that the prohibited speech, while scientific and educational in nature, was designed to promote a commercial transaction and "undertaken with a commercial motive." PhRMA Br. 25, *Sorrell*, 131 S. Ct. 2652 (No. 10-779). More fundamentally, petitioners' dichotomy is false, as speech may be *both* entitled to full First Amendment protection *and* intended to induce sales. *See Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 795–96 (1988); *see also Sorrell*, 131 S. Ct. at 2665 ("While the burdened speech results from an economic motive, so too does a great deal of vital expression.").

status as salespersons to depend on which type of product they are selling at any given moment.

The United States mistakenly suggests that the FLSA cannot take account of "industry-by-industry variations" in how sales are made. U.S. Br. 21; *see also* Pet'rs Br. 28. To the contrary, Congress made the definitions in the FLSA broad and flexible enough to account for the practical reality that the "precise contours of a 'sale' naturally differ across industries, markets, and even cultures." *Baum*, 605 F. Supp. 2d at 677. If Congress had wanted the FLSA to be applied robotically with no regard for real-world context, it would have drafted a very different statute and, in particular, a very different definition of "sale" or "sell." Contrary to the suggestion of petitioners and their *amici*, the pharmaceutical industry is not asking for special treatment, but rather for "common sense in applying [the] broad statutory language [of the FLSA] to a specific case and controversy." *Id.* The Act requires no less.[5]

As a last resort, petitioners assert that "exemptions from overtime must be construed

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[5] Recognizing that the FLSA's common-sense definition includes PSRs' efforts would not, as one *amicus* brief suggests, necessitate treating as exempt every employee who "promot[es] products or services with the end goal of increasing sales." NELA Br. 18. NELA greatly exaggerates the slipperiness of this particular slope, as the employees it discusses, unlike PSRs, generally do not obtain "the absolute maximum commitment" that they can legally and ethically obtain from the key customers in their industry. Pet. App. 27a; *see* NELA Br. 18–21.

narrowly." Pet'rs Br. 11 (citing *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960); *A.H. Phillips, Inc. v. Walling*, 324 U.S. 490, 493 (1945)). Even if this supposed canon of construction were well-founded, it would not apply here, as the Department's decision to define the scope of the outside-sales exemption by reference to the statutory definition of sales means that the provision that must be construed is § 203(k). That provision is not an exemption, but a general definitional provision that applies in many contexts within the FLSA—including the Act's coverage provisions, which the United States says must be *broadly* construed, U.S. Br. 26. Section 203(k), however, is one provision with one meaning; it cannot mean one thing when incorporated into an exemption and another thing when incorporated into a coverage provision. *See Clark v. Martinez*, 543 U.S. 371, 378 (2005); *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) ("we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context").[6]

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[6] In any event, the foundations of this supposed canon are highly questionable. *See Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 508 (7th Cir. 2007) (Posner, J.) (the canon's "underlying principle is mysterious," as it does not explain why "one provision in a statute [should] take precedence over another").

II. REQUIRING COMPANIES TO PAY PSRs OVERTIME WOULD HAVE SEVERE ADVERSE CONSEQUENCES FOR THE INDUSTRY AND PSRs THEMSELVES.

Pharmaceutical companies have structured their sales operations in reliance on their uniform understanding that PSRs are exempt from the FLSA's overtime requirements. If PSRs are not exempt, companies would also be forced to undertake major restructuring that would be difficult and costly both for the industry and for PSRs themselves, whose jobs may be rendered far less attractive.

A. If pharmaceutical companies are required to pay PSRs overtime, the reclassification of the PSR position will be costly and disruptive, because key aspects of PSRs' jobs as they are currently structured are fundamentally incompatible with treating PSRs as hourly employees.

First, PSRs operate with little direct supervision. As one court explained, PSRs "spend the great majority of their time out of the office. They are not generally subject to direct supervision while they go about their business. They do not report to work first thing in the morning and clock in. They have a large degree of autonomy, which would make it more difficult to make them accountable for every minute of their day." *Delgado*, 2009 WL 2781525, at *5. Pharmaceutical companies ordinarily give PSRs wide freedom to structure their schedules as they see fit, which includes identifying the best time and place to meet with a particular doctor. This was exemplified by one plaintiff who "worked without direct hour-to-hour, day-by-day

supervision" and was never "told … how many hours she should work in any given week." *Schaefer-LaRose*, 663 F. Supp. 2d at 679, 688.

Second, most PSRs are eligible to receive substantial performance-based incentive compensation. As noted, many pharmaceutical companies establish sales goals, track the number of prescriptions issued by physicians, and use sales figures as a factor in determining PSRs' incentive compensation. *See id.* at 686–88. Thus, "[t]he object of [PSRs'] harder work" is not "to garner overtime," but rather "to generate sales." *Delgado*, 2009 WL 2781525, at *3. Thanks in part to their ability to earn incentive compensation, many, if not most, PSRs are extremely well-compensated.

The fundamental incompatibility of the outside salesperson's job with the FLSA's overtime pay requirement means that reclassifying PSRs would require radically transforming their jobs. Simply put, "[i]t is impractical to make [PSRs] hourly employees due to the lack of supervision and structure in their jobs, and because they generate additional incentive income … instead of overtime." *Yacoubian*, 2009 WL 3326632, at *4; *see Baum*, 605 F. Supp. 2d at 686 (PSRs "are professionals whose absence from the office makes it impossible … to carefully supervise their hours" and who "have sufficient leverage to negotiate excellent pay packages"). There is no reason to think that Congress would have wanted technicalities about how sales occur in the pharmaceutical industry, due to regulatory and ethical requirements having nothing to do with the worker-protection purposes of

the FLSA, to make it impossible for the PSR position as we know it to exist.[7]

B. Not only would reclassifying PSRs impose major costs on pharmaceutical companies, it would also have a severe impact on the lives of tens of thousands of PSRs nationwide. The vast majority of PSRs have never asked to be classified as hourly workers under the FLSA, and for good reason: Most PSRs enjoy the benefits associated with their exempt classification. It is telling in this respect that so many of the named plaintiffs in FLSA actions against pharmaceutical companies are *former*, not current, PSRs. *See* Knight & Marks, *Overtime Exemption Litigation Targets the Pharmaceutical Industry*, at 1, 8 (noting that "the opt-in rate for

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[7] If PSRs must be reclassified as hourly employees, the cost and disruption associated with overhauling pharmaceutical companies' PSR-centered sales operations prospectively would be on top of the staggering retrospective liability the industry would face. In the past six years, "plaintiffs' lawyers have filed nearly 100 collective and class action lawsuits" against pharmaceutical companies under the FLSA and analogous state laws. Brent D. Knight & Michelle G. Marks, *Overtime Exemption Litigation Targets the Pharmaceutical Industry*, CLASS ACTION WATCH, Sept. 2011, at 1, 6. If PSRs are not subject to the outside-sales exemption, the industry faces billions of dollars of potential liability from suits like these. Like respondent, PhRMA believes that if PSRs are not outside salespersons, they are nonetheless covered by the "administrative" or other exemptions, *see* Resp. Br. 60 n.24; *see, e.g., Smith v. Johnson & Johnson*, 593 F.3d 280, 285 (3d Cir. 2010), but at a minimum, holding that PSRs are not subject to the outside-sales exemption would guarantee years of costly litigation that would divert resources from the industry's core mission of developing new medicines.

pharmaceutical collective actions under the FLSA has been low—typically in the range of 4–6%" and "typically fewer than 10% of those who join these cases are actively employed by the company they sue").

There is no doubt that most PSRs appreciate the ability to operate with minimal day-to-day supervision, set their own schedules, and manage their territories. Declarations submitted by PSRs in similar cases in support of pharmaceutical companies' classification of them as exempt employees attest to this fact and demonstrate that many PSRs regard this aspect of their job as critical to their success. *See, e.g.*, Decl. of Julie Montagne at ¶16, *Evancho v. Sanofi-Aventis U.S., Inc.*, No. 3:07-2266 (D.N.J. Sept. 7, 2007), ECF No. 161-2 ("I believe that if Sales Professionals were hourly employees, then we would lack the freedom necessary to make independent decisions; our success in sales and career growth would be very limited."); Decl. of Jamie Demboski at ¶ 11, *Evancho*, No. 3:07-2266 (D.N.J. Sept. 7, 2007), ECF No. 161-11 ("It would be extremely difficult and impractical for me to keep track of the hours I work and I do not think that I would be successful as a sales person if I was relegated to a schedule or required to keep a time card."). Yet the autonomy and flexibility prized by many current PSRs will have to be curtailed significantly if pharmaceutical companies must treat PSRs as non-exempt and pay them as hourly employees.

Likewise, many PSRs value the industry's traditional, incentive-based compensation structure. Not only does this compensation regime enable many

successful PSRs to earn highly competitive salaries, often reaching six figures; it also enhances their well-being by contributing to their sense of ownership and investment in their work. *See, e.g.*, Decl. of Judy Kennedy at ¶5, *Evancho*, No. 3:07-2266 (D.N.J. June 18, 2007), ECF No. 127-27 ("I like to think that I 'own my territory.' … The harder I work, and the more calls I make, the more profitable my business is and the greater my compensation. … Like other sales jobs, the chance to get out of the business what I put into it is what motivates me."); Decl. of Marta Villahermosa at ¶12, *Brody v. AstraZeneca Pharm., LP*, No. 2:06-6862 (C.D. Cal. Apr. 25, 2008), ECF No. 119 ("I believe that treating my territory as my own business has made me successful. … In my territory, I am the CEO …."). However, if pharmaceutical companies are forced to reclassify PSRs and pay them overtime, this incentive-based compensation structure will have to give way to a more rigid, hours-based system.

It is doubtful that current PSRs—especially skilled and motivated ones—would be better off. Current PSRs are rightly disturbed by these efforts by a relative handful of mostly former employees to upend a compensation system that continues to work well for tens of thousands of PSRs. *See, e.g.*, Decl. of Jane Mandel at ¶10, *Evancho*, No. 3:07-2266 (D.N.J. June 18, 2007), ECF No. 127-23 ("The concept of receiving overtime in our jobs is absurd. I don't see

how any of us will gain anything if we move to this format. It is all very upsetting to me.").[8]

This case ultimately turns on Congress' intent, and it cannot plausibly be argued that PSRs are the type of workers whom Congress sought to protect. PSRs are well-educated, highly trained individuals with jobs that most would envy for their attractive features and high pay. The FLSA, in contrast, was intended to protect "the most vulnerable workers, who lacked the bargaining power to negotiate a fair wage or reasonable work hours with their employers." 73 Fed. Reg. 67,934, 67,987 (Nov. 17, 2008). The simple reality is that petitioners are seeking to use a strained reading of a statute that was never intended to apply to their positions to obtain a windfall at the expense of the pharmaceutical industry and tens of thousands of current and prospective PSRs. As one court has noted, "[n]either semantics nor overly narrow statutory constructions should be allowed to devalue [PSRs] by forcing upon them uniform and limiting labor protections" that were never intended to apply to their positions. *Baum*, 605 F. Supp. 2d at 686.

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[8] Moreover, PSRs play an important role in disseminating scientific information to physicians, and changing the PSR job from one involving a high degree of flexibility with rewards for individual motivation to one with rigid working hours and fixed compensation could make it harder for PhRMA's members to attract high-quality applicants for these important jobs.

III. PETITIONERS' AND THE UNITED STATES' ARGUMENTS FOR IGNORING THE FLSA'S BROAD DEFINITION LACK MERIT.

Petitioners and the United States assert that the Court is compelled for two reasons to accept the Secretary of Labor's view that PSRs are not covered, instead of the Court being free—indeed compelled—to interpret the statutory definition of "sale" for itself.

First, petitioners and the United States argue that the Court should defer to regulations that, they assert, unambiguously demonstrate that PSRs do not make sales. That argument fails because the regulations do not support the Secretary's narrow interpretation, but rather simply refer back to—and confirm the breadth of—the statutory definition. The Department has never promulgated a regulation that purports to give "sale" a different or narrower meaning for purposes of the outside-sales exemption than the meaning given that term by Congress in § 203(k). Thus, the regulations do not alter the need for the Court to determine whether PSRs make sales within the meaning of the statute.

Second, if *Chevron* deference to the Department's regulations will not work, petitioners and the United States fall back to seeking *Auer* deference to the Secretary's view, announced for the first time in an *ad hoc* 2009 *amicus* brief, that a sale requires a consummated transfer of title. The premise of *Auer* deference is absent here, however, because the Secretary's view cannot plausibly be described as an interpretation of the Department's regulations. As already explained, the regulations

merely incorporate and refer back to the statutory definition of "sale." Repeating that statutory definition in a regulation does not empower the Department to dictate its desired bottom-line result in pending private litigation via an *amicus* brief—especially an *amicus* brief that unexpectedly breaks with the Department's longstanding flexible view of the statutory definition of "sale."

A. The Regulations Confirm that PSRs Make Sales Within the Act's Broad Definition.

Petitioners and the United States argue that regulations promulgated by the Department of Labor radically constrict the Act's broad, flexible definition of sales and mandate the Secretary's newly-minted focus on the transfer of title. This notion that the plain language of the regulations dictates the result desired by petitioners and the United States does not bear the slightest scrutiny. To the contrary, the regulations confirm and incorporate the practical approach dictated by the statute. Petitioners' and the United States' plea for *Chevron* deference to the regulations gets them nowhere because the regulations do not purport to answer the question presented with any more specificity or in any different way than the statute itself does.

1. Petitioners and the United States rely on several regulations, but the Department has never issued any regulation that purports to limit "sales" as used in the outside-salesman exemption in a way that could support its position in this case. Instead, the regulations at issue all refer back to the broad statutory definition of "sale" in § 203(k), which they incorporate either expressly or by reference. None of

these regulations narrows the statutory definition in any way that would exclude PSRs.

First, the general "outside salesman" regulation, 29 C.F.R. § 541.500 (a)(1), states only that an employee whose "primary duty" consists of "making sales within the meaning of [§ 203(k)]" is an exempt outside salesperson. This is a prototypical parroting regulation, as it explicitly refers back to the statute's definition of sales and does not attempt to elaborate on or clarify that definition. *See Gonzales v. Oregon*, 546 U.S. 243, 257 (2006). This cross-reference back to § 203(k) in the very section defining the scope of the "outside salesman" exemption sets the theme for the regulations that follow, all of which similarly refer back, explicitly or implicitly, to the statutory definition.

Second, the making-sales regulation, 29 C.F.R. § 541.501(b), states only that "[s]ales within the meaning of section 3(k) of the Act *include* the transfer of title to tangible property and, in certain cases, of tangible and valuable evidences of intangible property" (emphasis added). By its plain terms, this regulation provides *examples* of "sales" but does not define or delimit that term. *See Burgess*, 553 U.S. at 131 n.3. If there were any doubt about whether this first sentence of § 541.501(b) limits the Act's definition, the second sentence confirms that it does not by reciting the full text of § 203(k) verbatim. This deliberate parroting makes it obvious that this regulation was intended to adopt, and not to narrow or vary, the statutory definition. The United States is thus simply mistaken when it tells the Court that § 541.501(b) provides "that an employee sells goods *only* if he

transfers title to those goods to the buyer." U.S. Br. 14 (emphasis added).

Third, petitioners and the United States rely heavily on the promotion-work regulation, 29 C.F.R. § 541.503, but it does not purport to define "sale" either. It states only that whether an employee's "promotional work" is covered by the outside-sales exemption depends on whether that work is "incidental to and in conjunction with the employee's own outside sales." The regulation does not offer any guidance about what constitutes "the employee's own outside sales," and it does not draw a bright line between promotion and sales. Instead, it requires that one refer back to § 203(k)'s definition of sales in order to understand the boundaries of exempt sales work and non-exempt promotional work.

In all events, it is clear as a historical matter that the promotion-work regulation was not intended to exclude employees who, like PSRs, are the only sales force in their industry. The discussion of promotional work in the Department's 1940 report focused on the idea that "promotion men" were not covered because they merely "pav[ed] the way for salesmen." *Stein Report*, *supra*, at 46. This is echoed in the regulations' emphasis on the need for an exempt employee to make his or her "own sales." 29 C.F.R. § 541.503(b); *see id.* § 541.500(b). It therefore bears emphasis that PSRs do not "pave the way" for anyone. They are, as the Ninth Circuit recognized, "pharmaceutical manufacturers['] … 90,000-person sales force." Pet. App. 26a.

The United States contends that "GSK has a [separate] sales force that takes and processes orders

from retailers," U.S. Br. 15, but it conspicuously fails to cite any support for that statement. In reality, while pharmaceutical companies have systems in place to maintain the inventories of wholesalers and retailers of prescription drugs (consisting mainly of periodic restocking pursuant to a general contract), these systems are largely ministerial and require only a few employees to administer them. For example, one of PhRMA's members employs more than 2,000 PSRs but fewer than ten employees who are responsible for processing orders from retailers and wholesalers, a ratio that is typical of how the industry is structured. These employees are not hired for sales experience and are not trained in sales techniques.

The United States fails entirely to justify its counter-intuitive position that these few employees who restock inventory pursuant to existing contracts are the salespeople, rather than the industry's far more numerous "sales representatives" who use their sales experience and training to persuade physicians to write prescriptions authorizing the purchase of a drug. Petitioners' and the United States' narrow focus on the transfer of title ignores the essence of what it means to make a sale in this industry. The transfer of title is not the key; a pharmaceutical company's contract with a wholesaler may specify that title transfers at the point of delivery, but that does not make the delivery-truck driver a salesperson. Instead, the real sales in the pharmaceutical industry result from the interaction between PSRs and the key customers, the physicians who must be persuaded to prescribe the company's drug when appropriate and

thus authorize its purchase. The notion that tens of thousands of PSRs are not salespersons because they are "paving the way" for the minuscule number of employees who, without any sales training, take and process restocking orders is self-refuting.

2. Were there any doubt that the regulations confirm the broad statutory definition and do not adopt the Secretary's new inflexible approach, that doubt would be resolved by 29 C.F.R. § 779.241. Petitioners and the United States try to sweep this provision under the rug, but it clearly refutes their position by providing that an employee "will be considered to be 'selling'" if the employee "performs any work that, *in a practical sense* is an *essential part* of consummating the 'sale'" (emphases added). With its explicit focus on the "practical sense" in which the employee's work contributes to a consummated sale and its explicit provision that an employee may be engaged in "selling" even if he or she does not directly consummate the sale, § 779.241 plainly belies the United States' position that PSRs do not "sell" because they do not transfer title.

Petitioners do not even mention § 779.241, and the United States dismisses it on the ground that it interprets the statute's enterprise-coverage provision, not the outside-sales exemption. U.S. Br. 26–27; *see* 29 U.S.C. §§ 203(s), 207(a)(1) (FLSA covers, *inter alia*, an enterprise "that has employees … selling … goods or materials" in commerce). The United States' argument ignores the fact that § 779.241 interprets § 203(k), the very statutory provision at issue here, and § 203(k) defines "sale" or "sell" for purposes of *both* the enterprise-coverage provisions *and* the outside-sales exemption. The text

of § 779.241 confirms this by cross-referencing "[t]he statutory definition of the term 'sale' or 'sell'" as quoted in 29 C.F.R. § 779.15, which in turn both quotes and explicitly refers to § 203(k).

Because it interprets § 203(k), § 779.241 is directly relevant to this case, and the United States cannot escape the fact that § 779.241 refutes the Department's new rigid view. Section 779.241 is also consistent with the Department's longstanding interpretation, dating back to 1940, that the outside-sales exemption covers employees who "*in some sense* make a sale." 69 Fed. Reg. 22,122, 22,162 (Apr. 23, 2004) (quoting U.S. Dep't of Labor, Wage & Hour Div., *"Executive, Administrative, Professional … Outside Salesman" Redefined: Report and Recommendations of the Presiding Officer at Hearings Preliminary to Redefinition* at 46 (Oct. 10, 1940) (hereinafter "*Stein Report*")) (emphasis added).[9]

In sum, the regulations relied on by petitioners and the United States do not contradict, but rather incorporate and confirm, the flexible, practical definition of sales that is dictated by § 203(k). The regulations provide no support whatsoever for petitioners' and the United States' position that sales within the meaning of the outside-sales

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[9] As explained above, *see supra* at 14, the United States' attempt to dismiss § 779.241 is fundamentally misguided because it seeks to create two competing versions of § 203(k)'s definition of "sale" or "sell." To give § 203(k) different meanings when incorporated in different contexts "would be to invent a statute rather than interpret one." *Clark*, 543 U.S. at 378.

exemption are narrowly limited to transactions that consummate a transfer of title. The Court should therefore reject the untenable contention that the regulations "unambiguously resolve this case in petitioners' favor." Pet'rs Br. 31.

B. The Secretary's Newly-Minted Interpretation Is Not Entitled to *Auer* Deference.

The Court should also reject petitioners' fallback request for deference to the Secretary's *amicus*-brief pronouncement that PSRs do not make sales within the meaning of the FLSA. When an agency interprets an ambiguous statute not through notice-and-comment rulemaking, but in an *ad hoc* amicus brief, the agency's interpretation is not entitled to *Chevron* deference. *See United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001); *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000). Petitioners do not disagree, but assert that the Secretary's view is nonetheless entitled to "controlling" deference under *Auer* because it interprets the Department's own regulations defining the scope of the outside-sales exemption. That assertion is wrong for at least two reasons.

1. This Court has held that *Auer* deference does not apply when the regulation that the agency claims to be interpreting "does little more than restate," "summarize," "paraphrase," or otherwise "parrot[]" statutory language. *Gonzales*, 546 U.S. at 257. As the Court explained, *Auer* deference comes into play only when an agency offers its views on the meaning of regulatory language that *the agency itself* selected "using its expertise and experience." *Id.* When regulatory language parrots statutory

language, the agency is not genuinely interpreting its own words; "the question … is not the meaning of the regulation but the meaning of the statute." *Id.* And an agency's interpretation of a statute, of course, carries no "special authority" when it is announced in an *amicus* brief, *id.*; rather, an agency must employ notice-and-comment rulemaking or comparable procedures to be eligible for *Chevron* deference for its statutory interpretations. *See Christensen*, 529 U.S. at 587.

As explained above, the regulations on which the United States relies are prototypical parroting regulations. Section 541.500(a)(1) refers to "sales within the meaning of" the statute; § 541.501(b) quotes the statutory language verbatim and gives examples of what it "includes"; and § 541.503 describes non-exempt promotion work by reference to "sales" without further defining that statutory term. Because all these regulations fall back on the statutory definition, the Secretary's view regarding whether PSRs make sales is, at best, her view of what the *statute* means.

The Secretary may be able to obtain deference—under *Chevron*, not *Auer*—to her view of what the statute means, but only if she goes through notice-and-comment rulemaking and announces her view in a form that carries the force of law. *See Christensen*, 529 U.S. at 587. But the Secretary's interpretation of the *statute* is obviously not eligible for *Auer* deference. Because Congress, not the Secretary, wrote the words at issue, the Secretary can claim no special insight into what the author of those words meant. Equally fundamentally, the Secretary cannot insist on deference to her policy

judgments where she has avoided the process required to trigger deference to such judgments under *Chevron*. It would be perverse to afford "controlling deference" under *Auer* to a view announced in an *amicus* brief that unquestionably would not be eligible for deference under *Chevron* where the regulation that the agency purports to interpret does little more than track the statutory language.

2. The Secretary's new position that a sale requires a consummated transaction was announced for the first time in an *amicus* brief in 2009. As the Ninth Circuit recognized, that position "transform[ed] what since [the early days of the FLSA had] been recognized as a multi-factor review of an employee's functions into a single, stagnant inquiry." Pet. App. 35a. Even if one indulges the fiction that that position meaningfully constitutes an interpretation of regulatory language written by the Department—as opposed to an interpretation of statutory language that, as such, is by definition not eligible for *Auer* deference—the Secretary's new position is an about-face from the flexible, functional understanding of sales that the Department has espoused for decades. This new position upsets the reasonable expectations of the pharmaceutical industry, which has structured its sales operations in reliance on the Department's practical, non-technical approach. For that reason as well, the Secretary's interpretation does not merit controlling *Auer* deference.

This Court has stated on many occasions that "an agency's interpretation of a … regulation that conflicts with a prior interpretation is entitled to

considerably less deference than a consistently held agency view." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994) (quoting *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987)) (internal quotation marks omitted); *see also Mead*, 533 U.S. at 228; *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993); *Watt v. Alaska*, 451 U.S. 259, 273 (1981). Likewise, the Court has warned that a new interpretation does not merit any deference when it results in "unfair surprise." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170–71 (2007). And in recent decisions, the Court has continued to treat consistency as an important factor in the decision whether to afford *Auer* deference. *See Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2263–65 (2011); *Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 881 (2011).

Consistency is important for at least two reasons. For one, an unexplained departure from an agency's longstanding interpretation of its regulation "is likely to reflect the agency's reassessment of wise policy rather than a reassessment of what the agency itself originally meant," *Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666, 682 (6th Cir. 2005), and an agency's naked policy preferences do not merit controlling *Auer* deference.[10] Moreover, regulated entities structure their affairs on the

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[10] The Department has made no secret of its intent to use uninvited *amicus* briefs to advance its current assessment of wise policy. Its website solicits requests for *amicus* briefs in order to provide "stronger overtime protection for America's workers." Overtime Security *Amicus* Program, http://www.dol.gov/sol/541amicus.htm.

assumption that an agency will not suddenly and without explanation abandon its long-held views. An agency may not "under the guise of interpreting a regulation, … create *de facto* a new regulation" and thereby circumvent the required notice and public participation. *Christensen*, 529 U.S. at 588.

Here, the Secretary's new interpretation of sales, announced not through notice-and-comment rulemaking but by lobbing an unsolicited *amicus* brief into a private lawsuit, upends decades of settled expectations for the entire pharmaceutical industry and tens of thousands of PSRs and threatens the industry with massive retrospective liability. The Secretary did not even acknowledge, much less successfully explain away, the conflict between her current position and the Department's longstanding view that an employee will be deemed to "make sales" if the employee makes a sale "in some sense," 69 Fed. Reg. at 22,162 (quoting *Stein Report* at 46), "in any way participates in the sale," or "performs any work that, in a practical sense is an essential part of consummating the 'sale,'" 29 C.F.R. § 779.241. As the Ninth Circuit properly recognized, courts should not afford any deference—let alone "controlling" deference—to such an "about-face regulation, expressed only in ad hoc *amicus* filings," that departs from "decades of DOL nonfeasance and the consistent message to employers that a salesman is someone who 'in some sense' sells." Pet. App. 35a.[11]

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[11] One *amicus* brief attempts to cast doubt on whether the pharmaceutical industry was unfairly surprised by the

As Justice Scalia pointed out in urging the Court to revisit *Auer*, extending *Auer* deference uncritically risks "promot[ing] arbitrary government" by "encourag[ing] the agency to enact vague rules which give it the power … to do what it pleases." *Talk Am.*, 131 S. Ct. at 2266 (concurring opinion). This case exemplifies the dangerous incentives that can be created by misapplying *Auer*. If an agency can get "controlling deference" to its desired position by simply repeating statutory language in a regulation and then announcing a surprising new interpretation of that "regulatory" language in the midst of pending private litigation, agencies can hardly be expected to resist the temptation to proceed in that manner. But regulations that do little more than repeat statutory language do not provide the clarity and predictability that regulations are supposed to provide; the APA's rulemaking requirement is

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Secretary's new position by suggesting that the PSR position has changed since its inception. *See* Pharm. Rep. Br. 3 (suggesting that the Secretary "analyzed these changed duties, not the PSRs of long ago"). Tellingly, however, the *amici* do not assert that any relevant changes were at all recent and focus instead on changes that took place between the 1930s and 1960s. *See id.* at 14–20; *see also id.* at 19 ("the modern drug industry came into being after World War II"). Pharmaceutical companies reasonably expected that the Secretary would afford notice and opportunity for comment before announcing a new interpretation of "sales" that went against a half-century's worth of settled expectations. Indeed, "no pharmaceutical company has ever requested an interpretation on [this] issue from DOL" (*id.* at 9 n.7) precisely because until a few short years ago, the exempt status of PSRs was regarded as obvious by all concerned.

intended to force agencies to promulgate meaningful rules, not parroting regulations that merely set the stage for the agency to announce—and dictate—its desired outcome in the context of a private lawsuit. *See Thomas Jefferson Univ.*, 512 U.S. at 525 (Thomas, J., dissenting) ("agency rules should be clear and definite so that affected parties will have adequate notice concerning the agency's understanding of the law"). The Court should not encourage agencies to avoid or minimize the rulemaking process in favor of an ambush-by-*amicus*-brief approach to regulation.[12]

Indeed, the United States' brief in this case demonstrates the dangers that follow when agencies bypass notice-and-comment rulemaking and instead attempt to use *amicus* briefs to dictate outcomes in individual cases. While the United States at times suggests that its position amounts to a bright-line rule requiring a consummated transfer of title, it muddies the waters with qualifying statements. Thus, the United States asserts that "the Department has interpreted" the requirement that an outside salesperson make sales "in some sense" "flexibly to encompass the various ways in which salespeople can obtain a commitment to buy," U.S. Br. 20–21, and it claims sensitivity to "the modern

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[12] If the Court concludes that *Auer* requires deference under the circumstances of this case, PhRMA joins respondent in urging the Court to overrule *Auer* to the extent it requires deference to agency interpretations announced in *amicus* briefs in private litigation. *See* Resp. Br. 51–57. The Court need not reach that question, however, as the Secretary's position does not merit *Auer* deference under existing precedent.

reality that salesmen may make sales without executing written contracts or orders," *id.* at 33. Yet the Secretary's position in this case reflects no such sensitivity. It is evident that what the United States really wants is for the Secretary to be able to insist on a rigid consummated-transfer-of-title requirement *for PSRs*, while retaining the freedom to adopt a different and more "flexibl[e]" approach in other cases. But allowing an agency to pick winners and losers on a case-by-case basis is anathema to the purposes for which Congress enacted the APA.[13]

For all these reasons, the Court should not afford *Auer* deference to the Secretary's *amicus* brief. The Court's task is to decide whether the FLSA's definition of sales is sufficiently broad to encompass PSRs. The Secretary's *amicus*-brief view has no legitimate claim to bind the Court or to tip the scales; it merits consideration "only to the extent it is persuasive," *Gonzales*, 546 U.S. at 269, and it is not.

CONCLUSION

The Court should affirm the judgment below.

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[13] This muddying of the waters also belies the United States' contention that its approach has the virtue of being clear and easily administrable. *See* U.S. Br. 18–22.

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