UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACETAMINOPHEN – ASD-ADHD PRODUCTS LIABILITY LITIGATION	Case No. 1:22-md-03043-DLC
This Document Relates to:	**WALMART INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR RECONSIDERATION AND REQUEST FOR CERTIFICATION UNDER 28 U.S.C. § 1292(b)**
Robin Hatfield, et al. v. Wal-Mart Stores, Inc.; Case No. 1:22-cv-09011	
Lisa Roberts, et al. v. Wal-Mart Stores, Inc.; Case No. 1:22-cv-09012	

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INTRODUCTION

Separate from the tentative final monograph, a codified FDA regulation specifies a particular pregnancy warning: "If pregnant or breast-feeding, ask a health professional before use." 21 C.F.R. § 201.63. No one disputes that FDA lawfully promulgated this regulation through notice-and-comment rulemaking. *See* Dkt. 32 at 23; Dkt. 133-1 at 2. And no one doubts that this regulation preempts conflicting state warning requirements. Dkt. 32 at 23-24 (acknowledging that Walmart could not "unilaterally change or contradict the language of the general pregnancy warning"). The only point of disagreement is whether a state can require additional pregnancy warnings on top of the one that FDA determined was appropriate.

FDA directly addressed this question when it promulgated § 201.63 and explained that the answer is no: "Manufacturers marketing their products in States with differing requirements will be able to use the new FDA labeling ***without also being required to use the pregnancy-nursing warning labeling required by any State***." *Pregnant or Nursing Women*, 47 Fed. Reg. 54750, 54757 (Dec. 3, 1982) (emphasis added). FDA reached this conclusion after notice and comment *specifically* on the federally prescribed warning's preemptive effect. *Id.*; *see also Over-the-Counter Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded*, 47 Fed. Reg. 39470 (Sept. 7, 1982) (proposing the rule). And FDA has never changed its interpretation of its regulation as prescribing an exclusive, verbatim federal warning.

Plaintiffs ignored FDA's explanation of § 201.63's exclusivity and preemptive effect in their opposition, redirecting the Court to the tentative final monograph instead. Perhaps as a result, the Court's November 14 opinion does not address the critical language from FDA's 1982 rulemaking and interprets § 201.63 contrary to FDA's explicit contemporaneous interpretation. Walmart respectfully asks the Court to reconsider its conclusion that "FDA has not 'determined' that state law failure to warn claims are preempted" when they are based on the failure to give

additional pregnancy warnings. Dkt. 145 at 25. That is exactly what FDA determined in promulgating § 201.63, and there is no basis to disregard FDA's explanation of what its regulation means.

In the alternative, Walmart asks that the Court certify its order for immediate appeal. Whether § 201.63 preempts additional state pregnancy warning requirements is ideally suited for interlocutory appeal. That question is a pure question of law, and its answer could dispose of these cases in their entirety; accordingly, it is a "controlling question of law." 28 U.S.C. § 1292(b). There are, at the very least, "substantial ground[s] for difference of opinion," *id.*; the Court's holding that § 201.63 does not preempt additional state pregnancy warnings directly conflicts with FDA's explanation for why it promulgated the regulation: to mandate a verbatim federal warning that would preempt additional warnings, even if required by states. And immediate appellate resolution would "materially advance the ultimate termination of the litigation." *Id.* Before this MDL gets too far along, with the resulting massive resource expenditure by the Court and by the parties, all would benefit from the Second Circuit's clarification of this key element of the federal regulatory regime. The standard for immediate review under § 1292(b) is satisfied.

Walmart does not seek reconsideration or certification on a different question: assuming, contrary to Walmart's belief, that federal law permitted Walmart to unilaterally add an additional pregnancy warning, whether FDA nonetheless would have rejected the warning that Plaintiffs contend should have been given. *See* Dkt. 131 at 10. This latter question, unlike the preemptive effect of § 201.63, is not a pure question of law. It also remains a moving target because Plaintiffs have been unwilling to identify a warning that should have been added. Nov. 17 Tr. at 75 ("we're not in a position yet to get specific about what that warning should say"). And, as previewed at the November 17 hearing, Defendants expect FDA to release materials that will show that FDA

carefully considered the very claims and concerns underlying Plaintiffs' liability theory, found them unsubstantiated, decided that the § 201.63 warning remains adequate, and concluded that additional warnings should not be given. *Id.* at 12–14. That issue should be litigated, if necessary, once such information has become available.[1]

ARGUMENT

I. Reconsideration of the November 14 Order's Interpretation of § 201.63 Is Warranted to Address FDA's Contrary Interpretation.

The Court should reconsider its determination that § 201.63 does not preempt additional pregnancy warnings because the Court "overlooked" FDA's explanation when it promulgated § 201.63 that it intended the federal pregnancy warning to be exclusive and preemptive. *See* L. Civ. R. 6.3. As this Court has explained, the argument "that the Court erred in its interpretation of a regulation . . . is a proper basis for a motion for reconsideration." *Cruz v. Barnhart*, 2006 WL 547681, at *2 (S.D.N.Y. Mar. 7, 2006) (Cote, J.). Interpreting § 201.63 to mean the opposite of what FDA said it meant would be unusual enough; doing so without addressing FDA's interpretation warrants reconsideration.

A. FDA emphasized, in notice-and-comment rulemaking, that the § 201.63 warning is exclusive and preempts additional pregnancy warnings.

The Court concluded that states may require additional pregnancy warnings because, it determined, § 201.63 does not foreclose such additional warnings. Dkt. 145 at 18. For reasons that Walmart will not reargue in this motion, Walmart believes that the text and structure of § 201.63

[1] Walmart likewise does not raise in this motion any issue relating to whether Walmart is a manufacturer. Walmart maintains that it is not a manufacturer. *See* 21 C.F.R. § 201.1(b) (defining manufacturer as "the person who performs all of the following operations that are required to produce the product: (1) mixing, (2) granulating, (3) milling, (4) molding," etc.). But Walmart understands that the Court accepted Plaintiffs' contrary allegations for purposes of Walmart's motion to dismiss. Dkt. 145 at 28. Walmart (and presumably other defendants) will raise issues relating to their respective roles in the distribution chain, including the impact of such a role on certain preemption issues, on a more developed factual record later in this litigation.

itself, even without regard to the rulemaking that created it, show that the mandatory federal pregnancy warning set forth in § 201.63 is exclusive. Dkt. 133 at 3-4. The Court disagreed. Dkt. 145 at 20-23. What the Court overlooked, however, is that when FDA created that regulation in 1982, FDA stated in its final rule that the new federal pregnancy warning was exclusive. The Court did not address this clear language in the 1982 rulemaking, apparently because the Court believed that FDA treated the issue of preemption as "largely 'academic.'" Dkt. 145 at 24 (quoting 47 Fed. Reg. 54750, 54756 (Dec. 3, 1982)). With respect, that was mistaken. The very purpose for the rulemaking was California's adoption of a pregnancy warning and FDA's belief that consumers needed a single, national uniform warning. It is no exaggeration to say that prescribing an exclusive, verbatim federal warning and preempting different state warnings was the whole point of the rulemaking.

FDA's proposed rule repeatedly underscored that its proposed pregnancy warning would be exclusive and preempt any additional state pregnancy warnings—including even state warnings that were similar to FDA's warning. *Over-the-Counter Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded*, 47 Fed. Reg. 39470, 39471 (Sept. 7, 1982). Specifically, the proposed pregnancy warning would "preempt any differing State requirements and [would] allow manufacturers first marketing in States with differing requirements to use only the new FDA labeling." *Id.* FDA was explicit about what triggered the rulemaking: California had enacted legislation requiring a pregnancy warning that was set to go into effect on November 18, 1982. *Id.* at 39470. For this reason, FDA proposed its own national pregnancy warning and invited "comments on the preemptive effect the warning required by this proposal [would] have on State OTC drug labeling requirements such as California's and those under consideration by other States." *Id.* at 39471. FDA noted that its proposed warning was similar to California's and that a

company might satisfy California law—which required a warning "substantially similar" to California's text—by giving FDA's warning rather than California's. *Id.* But not vice-versa: FDA proposed requiring a verbatim federal warning, so a company that gave California's slightly different warning would *not* comply with federal law. That was because "one of the express purposes of the proposed regulation is to establish a national pregnancy/nursing warning requirement with a specified text." *Id.*

Far from treating preemption as academic, FDA stated that because of the importance of having a single, specified warning, "a State labeling requirement that specified wording for an OTC drug pregnancy/nursing warning that was different from the wording proposed here would prevent the accomplishment and execution of the full purpose and objectives of the agency in issuing the regulation." *Id.* Accordingly, "*in the opinion of FDA, such a State requirement would be preempted*." *Id.* (emphasis added). FDA's proposal with respect to preemption addressed only FDA's new proposed pregnancy warning and did not extend "to other aspects of OTC drug labeling" or address "whether State requirements should be *generally* preempted," beyond the specific case of additional warnings related to pregnancy. *Id.* (emphasis added).

Further confirming the central role that establishing a uniform national warning and preempting state warnings played in the rulemaking, FDA invoked good cause to shorten the "usual 60-day comment period" because "[t]he California requirement will take effect on November 18, 1982, unless preempted by FDA regulations." *Id.* FDA thus provided only a "30-day comment period" and determined that "any final rule" would "become effective 30 days following publication of the final rule." *Id.* "This early effective date will preempt any differing

State requirements and will allow manufacturers first marketing in States with differing requirements to use ***only the new FDA labeling***." *Id.* (emphasis added).[2]

On December 3, 1982, FDA issued its final rule. Again, FDA emphasized why the rule was necessary (and why it had been expedited): "[B]ecause the State of California requirement for a pregnancy-nursing warning for OTC drugs was to become effective on November 18, 1982, FDA concluded that a 30-day comment period was necessary to minimize confusion concerning manufacturers' obligations under State and Federal law." 47 Fed. Reg. at 54750. FDA noted that "[s]everal comments . . . were submitted in response to the agency's invitation for comments on the preemptive effect the FDA warning would have on the California and other similar State OTC drug labeling requirements." *Id.* at 54756. FDA also restated its position set forth in the proposed rule that its new warning would be uniform and exclusive because of the importance of ensuring "clear" and "consistent" warnings for consumers:

> ***[A] single national pregnancy-nursing warning with a specified text is necessary*** to ensure that OTC drugs are used safely and for their intended purposes. A single national warning will help ensure that consumers receive clear, unambiguous, and consistent information on the labeling of OTC drugs concerning use by pregnant or nursing women. Differing State requirements could conflict with the Federal warning, cause confusion to consumers, and otherwise weaken the Federal warning.

Id. at 54756 (emphasis added). And FDA explained that, given the exclusive, uniform nature of the new federal warning, state requirements to give different warnings are preempted:

> FDA believes that differing State OTC drug-pregnancy nursing warning requirements would prevent accomplishment of the full purpose and objectives of the agency in issuing

[2] FDA did, however, propose to allow some time for companies to come into compliance with the new exclusive federal warning requirement, acknowledging that some manufacturers may have already started "revising their labeling in anticipation of the effective date of the California law." *Id*. "Therefore, although the regulation [would] become effective 30 days after publication of the final rule, manufacturers will be permitted to defer labeling changes until present supplies of labels are exhausted, or until one year after publication of the final rule." *Id*. After that time, covered OTC drugs had to comply with the new federal labeling requirements, meaning that the drugs would bear "only the new FDA labeling." *Id*.

> the regulation and that, under the doctrine of implied preemption, ***these State requirements are preempted by the regulation as a matter of law***.

Id. (emphasis added). Underscoring the comprehensive nature of the regulation, FDA included a specific avenue of recourse if a person believed that FDA's warning was inadequate or inappropriate: petition FDA for an exemption. 21 C.F.R. § 201.63(d).

FDA's decision to require a uniform, exclusive warning makes eminent sense. As this MDL shows, there are many OTC acetaminophen products, all of which, under the monograph system, are supposed to be substantially identical and interchangeable from the consumer's perspective. That heightens the importance of a "single national warning" to ensure that consumers receive "clear, unambiguous, and consistent information." 47 Fed. Reg. at 54756. If Plaintiffs were correct that § 201.63 merely represented a "floor" and companies were free to adopt additional pregnancy warnings, then Equate 500 mg acetaminophen tablets could bear a different pregnancy warning from Tylenol 500 mg acetaminophen tablets, with CVS's store brand bearing yet a third warning, Target's a fourth, and so on. That would be a recipe for confusion that would serve no one's interest. Indeed, different warnings on interchangeable products could even "inaccurately imply a therapeutic difference . . . and thus could be impermissibly 'misleading.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011) (making this point about different labeling between brand and generic drugs, which are supposed to be bioequivalent).

This Court acknowledged that "Walmart's concern is not insignificant as a policy matter," but stated that "that concern does not control the conflict preemption analysis." Dkt. 145 at 16. The concern, however, is not Walmart's—it is FDA's, as expressly stated in the rulemaking that created § 201.63. And while policy arguments about the relative virtues of simple, uniform labeling of OTC products versus allowing states to require additional warnings do not control the preemption analysis, the federal regulatory regime does. *Mensing*, 564 U.S. at 626 ("different

federal statutes and regulations may, as here, lead to different pre-emption results"). Here, exercising its authority to ensure that OTC drugs are appropriately labeled, FDA acted within its power by promulgating a regulation requiring an exclusive, verbatim federal warning (while simultaneously creating a safety valve in § 201.63(d) by providing for petitions for exemptions from the requirement to give only that verbatim warning). That regulation would preempt state pregnancy warning requirements even if FDA had never uttered the word "preemption"; barring states from requiring different warnings is part and parcel of requiring "a single national pregnancy-nursing warning with a specified text." 47 Fed. Reg. at 54756. But FDA eliminated any possible doubt by explicitly stating that § 201.63 preempted additional state warning requirements.

The Court overlooked FDA's explicit preemption determination by saying that "FDA noted that the issue of preemption was largely 'academic.'" Dkt. 145 at 24. Respectfully, the Court misunderstood the 1982 rulemaking. When FDA used the word "academic," it was not characterizing the preemptive effect of the rule as a non-issue. Rather, it was referring specifically to the regulation's effect on California's requirement, given that California allowed manufacturers to use a different pregnancy warning if substantially similar to California's text. 47 Fed. Reg. at 54756. Because companies that "use the FDA warning would also be in compliance with the California requirement," given that the two warnings were substantially similar, it was academic to such companies whether California's requirement was invalid under the Supremacy Clause; if it was valid, it would be satisfied by giving the federal warning. *Id.* But FDA specifically rejected the converse proposition: Companies could not give the California warning and be in compliance with § 201.63. *Id*. at 54753. Even though California's warning was "substantially similar" to FDA's warning, FDA believed that national uniformity was too critical to permit differences in wording—let alone differences in meaning as advocated by Plaintiffs here:

> The agency believes that a standard warning appearing on OTC drug products covered by the regulation would insure that the intended message is conveyed uniformly to all women and would prevent consumer confusion. Therefore, the final rule will not provide for the use of substantially similar language ***or for the voluntary addition of words to the warning***.

Id. (emphasis added); *accord id*. at 54754 ("Alternative language will not be accepted.").

FDA thus made clear that it "regard[ed] the California requirement as preempted as of the date of publication of this regulation." *Id.* at 54757. And, beyond California's specific situation, FDA made equally clear that § 201.63's warning was exclusive: "Manufacturers marketing their products in States with differing requirements will be able to use the new FDA labeling *without also being required to use the pregnancy-nursing warning labeling required by any State*." *Id.* (emphasis added). Finally, FDA made its final rule effective "immediately upon publication" because the rule "preempt[s] any State requirements" and California's was already in effect. *Id.*

In short, FDA could not have been clearer about the exclusive nature and preemptive effect of its pregnancy warning rule: § 201.63 displaced all other pregnancy warning requirements, making it so companies must give the federal warning verbatim and forgo other pregnancy warnings, even if mandated by a state.

B. FDA's interpretation of its regulation is entitled to deference.

Plaintiffs do not dispute that FDA had authority to promulgate § 201.63. Nor do they dispute that if a valid FDA regulation prohibited additional pregnancy warnings, their state-law claims would be preempted. The question, then, is whether § 201.63 prohibited Walmart from giving additional pregnancy warnings. As shown in the preceding section, FDA emphatically explained that the answer is yes. Courts routinely defer to agencies' interpretations of their own

regulations, and there is no basis here to interpret § 201.63 contrary to FDA's explicit contemporaneous explanation of what its regulation means.

As "[t]he agency that wrote the regulation," FDA has "direct insight into what the rule was intended to mean." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2412 (2019) (plurality op.). Here, all the hallmarks of *Kisor/Auer* deference apply. *First*, "the text, structure, history, and purpose" of § 201.63 either establish that the regulation forecloses additional pregnancy warnings or, at the very least, are ambiguous about whether additional pregnancy warnings are allowed. *Id.* at 2414 (opinion of the Court). Indeed, even if § 201.63's "text," viewed in isolation, is ambiguous in this respect, the "history" and "purpose" of § 201.63 leave no doubt that the federal pregnancy warning was intended to be exclusive; as discussed above, that was the whole point of the rulemaking that created the regulation. *Second*, FDA's interpretation is "reasonable"; it explains why FDA formulated its mandatory, verbatim warning the way it did, and why the federal warning would be most effective by precluding additional warnings on the same subject. *Id. Third*, "the character and context of the agency interpretation entitles it to controlling weight." *Id.* at 2416. FDA's interpretation is "authoritative"—it was set out in the final rule that promulgated the regulation, after notice and comment specifically on the new federal warning's preemptive effect. *Id.* Likewise, far from representing a post-hoc effort to address an issue that "the agency failed to anticipate . . . in crafting [the] rule," *id*. at 2412, FDA's decision to foreclose "the voluntary addition of words to the warning" was front and center in the rulemaking, decades before this litigation began. 47 Fed. Reg. at 54754. The interpretation also implicates FDA's substantive expertise: it is uniquely well-positioned to evaluate when additional drug warnings will be helpful to consumers and to weigh any benefits of allowing additional warnings against the value of simplicity and uniformity. *Kisor*, 139 S. Ct. at 2417. And FDA's reading "reflect[s] fair and

considered judgment." *Id*. Again, FDA announced its interpretation of § 201.63 in the very rule that adopted that regulation, after notice and comment on the rule's preemptive effect. This is the antithesis of an agency announcing a "new interpretation" of a preexisting regulation in a way that causes "unfair surprise"; FDA told the world in perfectly clear terms that § 201.63 set forth the only pregnancy warning permitted by federal law when it adopted that regulation. *Id.*

For all these reasons, there is no basis to interpret § 201.63 to permit "the voluntary addition of words to the warning" when FDA explained that it crafted § 201.63, and decided to adopt it, to accomplish precisely the opposite result. "To the extent there is any ambiguity," FDA's "interpretation is reasonable and not plainly erroneous or inconsistent with the regulation." *SEC v. Alpine Securities Corp.*, 982 F.3d 68, 77 n.34 (2d Cir. 2020). Indeed, FDA's interpretation cannot be separated from the regulation: FDA meant what it said when it promulgated § 201.63. *See Kisor*, 139 S. Ct. at 2412 (plurality op.) ("Want to know what a rule means? Ask its author."). As the Second Circuit has explained, it "does not make sense to interpret the text of a regulation independently from its preamble." *Halo v. Yale Health Plan, Director of Benefits & Records Yale Univ.*, 819 F.3d 42, 52 (2d Cir. 2016) (quotation omitted).

In their proposed surreply, Plaintiffs accused Walmart of "pivot[ing] to obstacle preemption" rather than impossibility preemption and argued that *Wyeth v. Levine* demonstrates that obstacle preemption does not apply here. Dkt. 133-1 at 2. There was no pivot: Walmart relied (and still relies) on impossibility preemption. As Plaintiffs point out, *FDA* used some terminology associated with obstacle preemption in the 1982 rulemaking, explaining that "FDA believes that differing State OTC drug pregnancy-nursing warning requirements would prevent accomplishment of the full purpose and objectives of the agency in issuing the regulation." 47 Fed. Reg. at 54756. But FDA did so in the context of explaining why it chose to adopt an exclusive

federal warning that, as such, made it *impossible* for companies to add different pregnancy warnings to their labeling. Because FDA believed that "a single national pregnancy-nursing warning with a specified text is necessary," *id*., FDA promulgated § 201.63, opting to preclude "the voluntary addition of words to the warning" and admonishing that "[a]lternative language will not be accepted." *Id*. at 54753-54.[3] What matters for preemption is that FDA made it impossible for Walmart to unilaterally add the warning that Plaintiffs now contend state law required; that FDA did so because an alternative approach would undermine the goals of federal law shows that FDA had good reason to do so. And Plaintiffs in any event do not dispute that FDA had authority to adopt an exclusive federal pregnancy warning that preempts 50+ different state warning requirements.

More broadly, Plaintiffs err in suggesting that *Wyeth* requires the Court to ignore FDA's interpretation of § 201.63 as preemptive. Dkt. 133-1 at 1-2. *First*, the Supreme Court in *Wyeth* found the preemption policy it analyzed there to be "inherently suspect" because it suffered from a "procedural failure," namely, it never went through notice-and-comment rulemaking. *Wyeth v. Levine*, 555 U.S. 555, 578 (2009). In fact, the proposed rule at issue in *Wyeth* had stated that it "would *not* contain policies that have federalism implications or preempt State law." *Id*. (emphasis added). Here, in contrast, § 201.63 underwent notice-and-comment rulemaking as an exclusive, preemptive rule; the 1982 rulemaking centered on preemption and was expedited specifically so

[3] Plaintiffs' representation to the Court that "FDA *never* suggested that inclusion of additional warnings would be impossible under federal law," Dkt. 133-1 at 1 (emphasis in original), is flatly inconsistent with the language of the rulemaking.

that § 201.63 could displace California's pregnancy warning, along with any other state pregnancy warning that might be adopted in the future. *See* 47 Fed. Reg. at 39470-71; *supra* at 4-9.[4]

Second, the preemption policy in *Wyeth* was just that—a policy, disconnected from any actual regulation. The Court thus "ha[d] no occasion . . . to consider the pre-emptive effect of a specific agency regulation bearing the force of law." *Wyeth*, 555 U.S. at 580. Here, there is no dispute that § 201.63 "is a specific agency regulation bearing the force of law."

And *third*, the sweeping preemption policy in *Wyeth* was based on generic principles that the Court found inconsistent with FDA's longstanding views and the FDCA itself. *Id.* at 577. In contrast, FDA in 1982 carefully evaluated whether to make a *single* type of warning—a pregnancy warning—exclusive and concluded that it was necessary to do so. Plaintiffs have never argued that the FDCA prohibits FDA from requiring an exclusive pregnancy warning. And far from a departure from the agency's past views, FDA's understanding that § 201.63 is exclusive and thus preempts additional pregnancy warnings was clearly set out when the regulation was first promulgated; indeed, it was the *reason why* FDA promulgated the regulation. Again, it is Plaintiffs' contrary interpretation that would "represent[] a dramatic change in position." *Id.* at 579.

As the Supreme Court reaffirmed this year, preambles should not be ignored. *See Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1943 n.4 (2022) ("courts regularly consult preambles and recitals even in statutes and contracts"). Courts have long held that "the preamble of the key

[4] Plaintiffs' interpretation would implicate a procedural failure, as FDA has never undertaken notice-and-comment rulemaking to establish that § 201.63 is *not* exclusive and preemptive. Were FDA to claim that its regulation means the opposite of what FDA said it meant when it promulgated the regulation, FDA's reversal would receive no deference. *Kisor*, 139 S. Ct. at 2417–2418 ("a court may not defer to a new interpretation, whether or not introduced in litigation, that creates 'unfair surprise' to regulated parties).

regulation can be used to explain the regulation." *St. Helena Clear Lake Hospital v. Becerra*, 30 F.4th 301, 304 (D.C. Cir. 2022); *see also Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 158 n.13 (1982) (looking to the preamble "for the administrative construction of the regulation, to which deference is . . . clearly in order"). Indeed, the Second Circuit has instructed courts to "begin with the regulation's text and its preamble." *Halo*, 819 F.3d at 53. Here, the preamble is clear: "Manufacturers marketing their products in States with differing requirements will be able to use the new FDA labeling without also being required to use the pregnancy-nursing warning labeling required by any State." 47 Fed. Reg. at 54756. As in *de la Cuesta*, "[a]ny ambiguity in § [201.63]'s language is dispelled by the preamble accompanying and explaining the regulation. The preamble unequivocally expresses the [agency's] determination to displace state law." 458 U.S. at 158. Section 201.63's warning is exclusive and preemptive.

C. FDA has never rescinded its contemporaneous explanation of what § 201.63 means.

FDA has never reversed its determination that the pregnancy warning in § 201.63 is exclusive and preemptive. This Court did not assert otherwise in its opinion; the Court dismissed the 1982 rulemaking on the ground that FDA treated the issue of preemption as "academic" and focused instead on FDA's final rule issued in 1999, regarding which the Court stated that "the agency addressed the issue of preemption head on." Dkt. 145 at 24. For the reasons already discussed, Walmart submits that the Court erred by downplaying the 1982 rulemaking. Once it is understood that FDA in 1982 squarely and consciously adopted § 201.63 to impose an exclusive federal warning, the question becomes whether FDA has undertaken notice-and-comment rulemaking to revoke that regulation or to—somehow—reinterpret it to mean the opposite of what FDA said it meant when FDA wrote it. Not even Plaintiffs contend as much. As a result, the 1999 rulemaking is largely beside the point.

Walmart respectfully submits that when the Court stated that FDA "addressed the issue of preemption head on" in the 1999 rulemaking, the Court overlooked the distinction between two different issues of preemption. The first question—and the only one at issue here—is limited to the pregnancy warning specified by § 201.63: is that federal warning exclusive such that state requirements to give different pregnancy warnings are preempted? FDA's 1982 rule adopting that regulation addressed that question head-on and answered it "yes." The second question is whether *all* state OTC labeling requirements—not just state pregnancy warning requirements—are preempted. The Court is correct that the 1999 rulemaking addressed this latter question head-on, but this far broader question is not presented by this case.

In the 1982 rulemaking, FDA distinguished between these two questions. While making clear that it intended to prescribe an exclusive pregnancy warning, FDA made equally clear that it was *not* asserting that "all State OTC drug labeling requirements of any type" were preempted. 47 Fed. Reg. at 54756. FDA stated that it "share[d] the concerns" expressed by some commenters "that States may elect to regulate aspects of OTC drug labeling other than pregnancy-nursing warnings." *Id*. FDA explained that "a proliferation of such State requirements may weaken FDA's efforts to develop comprehensive national labeling and other requirements for OTC drugs." *Id*. But FDA stopped short of comprehensively preempting state OTC drug labeling requirements. Instead, because "[t]he current regulation" was limited to the pregnancy-nursing warning, FDA explained that its preemption determination "is intended to apply only to one aspect of OTC drug labeling requirements: pregnancy-nursing warnings." *Id*. As to state requirements beyond the specific context of pregnancy-nursing warnings, FDA promised to "monitor future State labeling requirements to determine whether future action is necessary." *Id.*

Fulfilling that promise, FDA in 1997 proposed to take the broader step it had declined to take in 1982: preempting *all* state OTC drug labeling requirements. *Over-The-Counter Human Drugs; Proposed Labeling Requirements*, 62 Fed. Reg. 9024, 9052 (Feb. 27, 1997). But after Congress enacted an express preemption provision, FDA decided not to move forward by regulation to make all of its OTC labeling requirements exclusive and to preempt the states from imposing any OTC labeling requirements whatsoever. *See* Dkt. 145 at 25; *Over-The-Counter Human Drugs; Labeling Requirements*, 64 Fed. Reg. 13254, 13272 (Mar. 17, 1999). In pulling back from its 1997 proposal to comprehensively preempt all state OTC labeling requirements, however, FDA never indicated that it intended to change the meaning of § 201.63.

Nor does the express preemption provision, 21 U.S.C. § 379r, affect this case. That provision first prohibits states from establishing certain requirements for OTC drugs, *id*. § 379r(a), and then limits the effect of that new prohibition: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." *Id*. § 379r(e). As a result, nothing in § 379r "affect[s]" this case—not the prohibition on state regulation in subsection (a), and not the provision in subsection (e) limiting the effect of that prohibition. The plain text of § 379r thus leaves the pregnancy-warning-preemption issue where it was before § 379r's enactment, namely, governed by § 201.63. *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 321 n.19 (D. Conn. 2016) (§ 379r(e) "only limits the scope of the express preemption clause in § 379r(a)" and "does not purport to limit the preemptive effect of other sources of federal law, *including FDA regulations*, that conflict with state law requirements") (emphasis added); *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 151 (2017) (§ 379r(e) " does not foreclose the possibility that conflict preemption may arise from federal sources other than 21 U.S.C. § 379r").

In short, FDA squarely determined in 1982 that § 201.63 forecloses other pregnancy warnings, even if they are mandated by a state. In the past 40 years, FDA has never wavered from that determination; the 1999 rulemaking did not address this specific preemption question. Walmart is unaware of any other authority finding § 201.63 to be non-exclusive and state pregnancy warnings for OTC drugs to be non-preempted, and commentators consistently identify § 201.63 as an example of FDA establishing an exclusive and preemptive warning.[5] Because the Court overlooked FDA's clear statements that the federal warning mandated by § 201.63 is exclusive, the Court should grant reconsideration.

II. Section 1292(b) Certification is Warranted.

In the alternative, Walmart asks this Court to certify its November 14 order for immediate appeal. Congress enacted 28 U.S.C. § 1292(b) "to assure the prompt resolution of knotty legal problems." *Weber v. U.S.*, 484 F.3d 154, 159 (2d Cir. 2007). To achieve this objective, § 1292(b) authorizes immediate appeal of a non-final order where the order "(1) involves a controlling question of law about which (2) there is substantial ground for difference of opinion and (3) an

[5] *See Preemption under specific regulatory schemes—Food, drugs, and cosmetics*, 2 Owen & Davis on Prod. Liab. § 15:19 (4th ed.) (May 2022 update) (identifying "FDA's requirement of a pregnancy warning on a broad range of OTC drug products" as an example of an FDA regulation that "preempt[s] all state regulations"); M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 Pace L. Rev. 103, 142 (2000) (noting that "FDA maintains that its requirement of a pregnancy warning on a broad range of drug products" is preemptive); Lars Noah, *The Imperative to Warn: Disentangling the 'Right to Know' From the 'Need to Know' About Consumer Product Hazards*, 11 Yale J. Reg. 293, 322 n.123 (1994) ("In pursuit of assuring such uniformity, FDA explained that its [pregnancy warning] regulation would preempt state requirements."); Mark B. Gelbert, *State Statutes Affecting the Labeling of OTC Drugs: Constitutionality Based on Commerce Clause and Federal Preemption Theories*, 46 Food Drug Cosm. L. J. 629, 640 (Sept. 1991) (explaining that FDA "determined that a single national pregnancy-nursing warning with a specified text was necessary to ensure that OTC drugs are used safely and for their intended purpose"); George M. Burditt, *Federal Preemption and the Curl Suit*, 44 Food Drug Cosm. L. J. 199, 201 (May 1989) (identifying FDA's "regulation on Pregnancy Warnings" along with FDA's "Tamper Resistant Packaging regulation" and "its regulation of Reye's Syndrome" as examples of FDA preempting state requirements).

immediate appeal from the order may materially advance the ultimate termination of the litigation." *Hymes v. Bank of America, N.A.*, 2020 WL 9174972, at *3 (E.D.N.Y. Sept. 29, 2020) (quotation marks omitted). "When a ruling satisfies these criteria and 'involves a new legal question or is of special consequence,' then the district court 'should not hesitate to certify an interlocutory appeal.'" *Balintulo v. Daimler AG*, 727 F.3d 174, 186 (2d Cir. 2013) (quoting *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 111 (2009)). Section 1292(b), moreover, was "[a]dopted with complex litigation in mind" and "provides a mechanism for obtaining early review of crucial orders where an appellate ruling may simplify or shorten the litigation," such as orders involving "pivotal claims or defenses." Manual for Complex Litig. (Fourth) at 209. Whether § 201.63 preempts Plaintiffs' claims is a perfect candidate for § 1292(b) certification.

A. Section 1292(b)'s prerequisites are satisfied.

1. Whether additional pregnancy warnings are preempted is a controlling question of law.

The preemption question here is a quintessential controlling question of law because it presents a pure question of law on which this litigation turns. To determine "whether a controlling question of law exists, the district court should consider whether: reversal of the district court's opinion could result in dismissal of the action; reversal of the district court's opinion, even though not resulting in dismissal, could significantly affect the conduct of the action; or, the certified issue has precedential value for a large number of cases." *In re A2P SMS Antitrust Litig.*, 2015 WL 876456, at *3 (S.D.N.Y. Mar. 2, 2015) (quotation marks omitted). In addition, the court should evaluate whether the "question of law certified on interlocutory appeal . . . refer[s] to a pure

question of law that the reviewing court could decide quickly and cleanly without having to study the record." *Id.* (quotation marks omitted).

Reversal of the Court's holding that § 201.63's federal pregnancy warning is non-exclusive would result in dismissal of these two actions. If the Second Circuit applied FDA's interpretation that § 201.63 allows companies "marketing their products in States with differing requirements [to] be able to use the new FDA labeling *without also being required to use the pregnancy-nursing warning labeling required by any State*," then Plaintiffs' actions would be dismissed. 47 Fed. Reg. at 54756-57 (emphasis added). Plaintiffs have acknowledged that a determination of preemption would be dispositive of this litigation. Pl. Ltr. (Dkt. 3) at 2. Indeed, even beyond these two actions, such a decision by the Second Circuit would resolve an important legal question that would have precedential value for (and likely result in the dismissal of) *every action* in the MDL. And importantly, whether § 201.63 preempts state requirements to give different pregnancy warnings is a pure question of law; § 201.63 means what it means, regardless of what information becomes available concerning FDA's review of acetaminophen-specific information or studies. *See supra* at 2-3 (noting that Walmart does not seek reconsideration or certification on whether FDA would have rejected the warning that Plaintiffs contend should have been added to the label); *Hymes*, 2020 WL 9174972, at *4 (granting certification where the "preemption issue" was "dispositive of the cases at bar and . . . a pure question of law").

2. FDA's understanding of § 201.63 establishes that there are substantial grounds for difference of opinion.

The second prong of the certification test "is met when (1) there is conflicting authority on the issue, or (2) the issue is particularly difficult and of first impression for the Second Circuit." *Capitol Records, LLC v. Vimeo, LL*, 972 F. Supp. 2d 537, 551 (S.D.N.Y. 2013). Whether the pregnancy warning set forth in § 201.63 is exclusive is a question of first impression, not only for

the Second Circuit, but for *all* courts. *See* Dkt. 145 at 16 ("Neither the Supreme Court nor any circuit court has addressed preemption in the context of drugs regulated under the monograph system."). In novel cases like this one, courts can find a substantial ground for difference of opinion "principally[] because precedent bearing on the matter is relatively thin." *Baron & Budd, P.C. v. Unsecured Asbestos Claimants Comm.*, 321 B.R. 147, 157 (D.N.J. 2005).

The fact that FDA explicitly stated that § 201.63 preempted state pregnancy warning requirements shows that there is, at the very least, a substantial basis for Walmart's position. FDA explained contemporaneously that it was adopting § 201.63 because it believed that "a single national pregnancy-nursing warning with a specified text is necessary," 47 Fed. Reg. at 54756, that "[a]lternative language will not be accepted," *id*. at 54754, and that companies henceforth "will be able to use the new FDA labeling without also being required to use the pregnancy-nursing warning labeling required by any State," *id*. at 54757. And FDA has never repudiated its contemporaneous explanation of how this regulation works and why it was adopted. Against this backdrop, it would be extraordinary to hold that FDA was wrong about what its regulation meant. That is more than enough to show substantial grounds for difference of opinion. *See Muniz v. Winn*, 462 F. Supp. 2d 175, 183-84 (D. Mass. 2006) (interlocutory appeal is warranted where court reaches a decision that conflicts with the views of "the relevant administrative agency"), *rev'd on other grounds sub nom. Muniz v. Sabol*, 517 F.3d 29 (1st Cir. 2008).

3. An immediate appeal will materially advance the litigation.

An interlocutory appeal on the preemptive effect of § 201.63 will materially advance this litigation. *See Mei Xing Yu v. Hasaki Rest., Inc.*, 874 F.3d 94, 98 (2d Cir. 2017) (granting petition for § 1292(b) appeal); *In re The Duplan Corp.*, 591 F.2d 139, 148 n.11 (2d Cir. 1978) (§ 1292(b) appeal warranted where issue "may importantly affect the conduct of [the] action"). If the Second Circuit were to determine that § 201.63 preempts Plaintiffs' claims, that would end their actions.

See Hymes, 2020 WL 9174972, at *6. Not only that, but such a decision would likely dispose of *every* action filed in the MDL. As a result, it is an understatement to say that "certifying an interlocutory appeal on the preemption issue would materially advance the ultimate disposition of this litigation." *Id.*

B. The Court should exercise its discretion to certify its order for appeal because it resolves a new legal question of special consequence.

The Court's decision below upends a longstanding status quo. In the forty years since FDA promulgated § 201.63, no other court has ever held that § 201.63 allows for additional pregnancy warnings. Indeed, no court has even addressed this question, likely because FDA had already given a clear answer. *See also* Dkt. 145 at 16 ("Neither the Supreme Court nor any circuit court has addressed preemption in the context of drugs regulated under the monograph system."). The novelty of this legal question favors certification.

Moreover, certification is imperative here because the legal question is highly significant. If federal law really permits companies to add pregnancy warnings on top of the federal warning required by § 201.63, then consumers may be faced with differing, and even arguably conflicting, messages on products that are supposed to be interchangeable. The potential for confusion is why FDA, after notice and comment specifically on this question, decided that the benefits of simplicity and uniformity outweighed any benefits of allowing companies to give additional pregnancy warnings. *See supra* at 6-8. Overwarning is a serious risk as well: pregnant women need options to treat fever and pain, as those conditions can be dangerous to mother and child alike. *See* Dkt. 131 at 4–5.

Apart from the significance of this legal question in itself, its resolution is extremely important for this MDL. As the Court knows, the ubiquity of acetaminophen means that this MDL could become massive in size and scope. Before everyone—the Court as well as all parties—

devotes extensive resources to this litigation, it would be in everyone's interest to secure the Second Circuit's answer to this fundamental preemption question. This situation is tailor-made for interlocutory appeal, just as the Manual for Complex Litigation anticipated. *See* Manual for Complex Litig. (Fourth) at 209. *Hymes* is instructive. The district court there decided to certify a preemption question for appeal because "there would be system-wide benefits to granting an interlocutory appeal." 2020 WL 9174972, at *7. The court noted that "there are at least three other cases pending before district courts in this Circuit which raise the same preemption question at issue here." *Id.* Here, there are hundreds of cases pending that involve the same preemption question, making it all the more important to obtain the Second Circuit's review now, before "system-wide" costs accumulate. And in *Hymes*, the district court's decision to certify was sound: the Second Circuit granted leave to appeal and reversed the district court's denial of dismissal for failure to state a claim, holding that the National Banking Act preempted New York law. *Cantero v. Bank of America, N.A.*, 49 F.4th 121, 130 (2d Cir. 2022). The Second Circuit may do the same here.

CONCLUSION

For the foregoing reasons, the Court should reconsider its November 14, 2022 Opinion and Order and dismiss Plaintiffs' claims against Walmart on the ground that 21 C.F.R. § 201.63 made it impossible for Walmart to unilaterally give the warning that Plaintiffs say state law required. In the alternative, the Court should certify its order under § 1292(b).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2022, a copy of **WALMART INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR RECONSIDERATION AND REQUEST FOR CERTIFICATION UNDER 28 U.S.C. § 1292(b)** was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all registered users.

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