UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CENTER FOR FOOD SAFETY and ENVIRONMENTAL DEFENSE FUND, Plaintiffs, v. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORMAN E. SHARPLESS, ACTING COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION;[1] and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	No. 17 Civ. 3833 (VSB) (BCM)

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT

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[1] Pursuant to Federal Rule of Civil Procedure 25(d), Acting Commissioner Sharpless has been automatically substituted in place of former Commissioner Gottlieb.

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Once again, Plaintiffs ask this Court to construe the Federal Food, Drug, and Cosmetic Act to require manufacturers to (1) notify the agency whenever manufacturers determine that a substance is generally recognized as safe for a particular use ("GRAS"), and (2) keep records supporting GRAS conclusions. But these requirements are not in the text of the FDCA, are not "implied" in the statutory scheme, and have not been imposed by FDA or any court in the six decades since the Food Additives Amendment was enacted. Because the Act is silent on these matters, FDA's reasonable decision to adopt voluntary notification and recordkeeping is entitled to deference under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

Contrary to Plaintiffs' suggestion, FDA was justified in considering efficiency and its enforcement priorities when enacting the Rule. Congress expressly gave the agency power to promulgate regulations "for the efficient enforcement" of the FDCA. 21 U.S.C. § 371(a). Because the GRAS exception applies only to substances that are, by definition, generally recognized as safe, FDA's decision to adopt a voluntary notice regime with respect to these substances—allowing the agency some flexibility to deploy its limited staff, time, and funds to higher enforcement priorities—is reasonable and entitled to deference. The current rule also comports with a sixty-plus year history of agency, industry, and Congressional practice.

And contrary to plaintiffs' arguments, Pl. Opp. 6-11, the Rule is neither "unconstitutional" nor a "subdelegation." The GRAS Rule does not "subdelegate" any authority to manufacturers: the GRAS Rule does not give any conclusive legal effect—or, indeed, ascribe any legal significance whatsoever—to a manufacturer's GRAS conclusion. The Rule does not give manufacturers any power they would not have without the Rule.

Finally, the GRAS Rule's criteria governing GRAS conclusions are consistent with the FDCA and are neither arbitrary nor capricious. Each of Plaintiffs' arguments to the contrary rests

on at least one of two false assumptions: (1) that manufacturers' GRAS conclusions are binding determinations of whether substances are GRAS, or (2) that FDA is obliged to impose requirements beyond those in the FDCA or to provide specific answers to any question on which the statute is silent. Because those predicates are incorrect, Plaintiffs' challenges have no merit.

I. THE FDCA DOES NOT MANDATE NOTIFICATION OR RECORDKEEPING.

Plaintiffs' opposition largely repeats their prior arguments that mandatory notification and recordkeeping are required under the FDCA under *Chevron* step one or, alternatively, under *Chevron* step two. Those arguments should be rejected.

A. *Chevron* Step One

As the government's opening brief explained, the FDCA's text defines GRAS substances, but is wholly silent on the procedures that manufacturers or the FDA must use for identifying them. *See* Gov. Br. 10-12. Plaintiffs nonetheless argue that the FDCA unambiguously *implies* a requirement of mandatory notification and recordkeeping in "at least three" provisions not directly related to GRAS substances. Pl. Opp. at 13. But even considering the overall structure and purpose of the FDCA, *see* Pl. Opp. 12 (citing *King v. Burwell*, 135 S. Ct. 2480 (2015)), the general, broadly-worded statutory sections plaintiffs identify do not "directly [speak] to the precise question at issue" and demand the procedures Plaintiffs seek. *Chevron*, 467 U.S. at 842-43.

First, the statute setting forth FDA's basic mission does not establish an unambiguous requirement of mandatory notification and recordkeeping. It provides that FDA "shall . . . protect the public health by ensuring that . . . foods are, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). This language does not specify what *means* FDA shall employ to accomplish those ends. In other words, the language "does not compel the agency to use any

particular method to attain" those goals. *NRDC v. FDA*, 760 F.3d 151, 178 (2d Cir. 2014). It certainly does not unambiguously require the specific procedures Plaintiffs propose, as would be required for Plaintiffs to prevail at *Chevron* step one.

Plaintiffs accuse FDA of "disregarding" § 393(b) "for efficiency's sake." Pl. Opp. at 13. But the government argues only that FDA may consider efficiency in deciding how best to pursue § 393(b)'s broadly worded mandate—which Congress has expressly permitted. *See* 21 U.S.C. § 371(a) (authorizing FDA to promulgate regulations "for the efficient enforcement" of the FDCA). As the Second Circuit recently noted, "'no legislation pursues its purposes at all costs … and it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law.'" *NRDC*, 760 F.3d at 178 (quoting *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987)). Indeed, it is a fundamental principle of administrative law that an agency normally may consider cost, efficiency, and priorities in deciding how to regulate. *See Michigan v. EPA*, 135 S. Ct. 2699, 2707-08 (2015).[2]

Second, the GRAS Rule's system of voluntary notification and recordkeeping does not conflict with mandatory premarket review of "food additives." *See* Pl. Opp. 14-15. The FDCA provides that a "food additive" is not safe unless, among other things, FDA finds that it is safe under prescribed conditions of use. 21 U.S.C. §§ 348(a), (c). But this provision is inapplicable to GRAS substances, which are, by definition, not "food additives." *Id.* § 321(s). It thus does not address whether manufacturers must notify FDA and keep records of GRAS conclusions.

[2] Plaintiffs also dispute the agency's determination that voluntary notification would be more efficient than mandatory notification. That policy argument is irrelevant to *Chevron* step one. *See, e.g., Loving v. IRS*, 917 F. Supp.2d 67, 79 (D.D.C. 2013). Defendants address it in the context of *Chevron* step two, *infra* I.B.

Plaintiffs seek to avoid this clear reading by characterizing the GRAS Rule as "introducing a system in which FDA cannot independently evaluate whether a substance is GRAS or a food additive." Pl. Opp. at 15. But, as Plaintiffs admit, FDA's approval is not a prerequisite to obtaining GRAS status. *See* 21 U.S.C. § 321(s) (GRAS status is determined by the opinion of "experts qualified by scientific training and experience to evaluate" a substance's safety); Pl. Opp. at 2 (disclaiming any argument that FDA approval is required for GRAS status). In any event, the administrative record refutes the contention that FDA "cannot" independently assess GRAS status of substances under the GRAS Rule. Not only can FDA review the GRAS notices it receives, but it has—on multiple occasions—contested the GRAS status of substances for which no GRAS notice was submitted. AR 8649-56, 8662-66; Gov. Br. at 15 & n.11.[3]

Third, Plaintiffs' "cumulative effect" citation, Pl. Opp. 15-17, does not support their argument. The FDCA provides that, in considering whether to approve a "food additive," FDA must consider "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically- or pharmacologically-related substance or substances in such diet." 21 U.S.C. § 348(c)(5)(B). But the question is not, as Plaintiffs would have it, whether FDA should "track new, science-based GRAS determinations." Pl. Opp. at 16. FDA does become aware of and track new GRAS conclusions, including through the voluntary GRAS notification process. The question is instead whether Congress has directed that, in pursuit of that task, FDA must

[3] Plaintiffs dismiss these examples on the ground that enforcement came after the unapproved food additives were introduced into food. Pl. Opp. at 20. But since Plaintiffs do not contend that FDA is required to evaluate GRAS conclusions before manufacturers market substances, it is difficult to see how this distinction supports their argument. It is necessarily true that FDA cannot enforce the Act against violations that it does not know about, but that would be equally true under a system of mandatory notification: FDA would be unable to enforce the Act if it did not learn of a violation of the notification requirement or otherwise learn about an improper invocation of the GRAS exemption.

impose mandatory notification and recordkeeping requirements on manufacturers who invoke the GRAS exemption. Congress has plainly not done so.

Plaintiffs argue that FDA's obligation to "tak[e] into account" related substances means notification of GRAS is mandatory. Pl. Opp. at 15-17. But that interpretation would be impose boundless duties on FDA, since it is not limited to information provided by manufacturers claiming the GRAS exemption. It would mean that if any information might be relevant to the cumulative effects analysis, FDA is not merely authorized but statutorily obligated to require anyone in possession of that information—whatever its nature, volume, source, or value—to provide it to FDA. By requiring FDA to "take into account" related substances, Congress did not impose such a significant information-sharing burden on the public. "Congress does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 489 (2001).

B. *Chevron* Step Two

As the government explained in its opening brief, FDA reasonably exercised its rulemaking authority to fill the gap Congress left with a voluntary, rather than mandatory, system of notification and recordkeeping. Gov. Br. at 12-17. Plaintiffs' arguments to the contrary are without merit.

First, as the statutory requirement for premarket approval of "food additives" shows, Congress knows how to require premarket FDA engagement when it so intends. The lack of any similar provision requiring premarket notification for GRAS substances indicates that Congress imposed no such requirement. *Russello v. United States*, 464 U.S. 16, 23 (1983); Gov. Br. at 12-13. Plaintiffs miss the point when they emphasize that they urge only premarket notification, not premarket review. Pl. Opp. at 18. Whatever the specific premarket FDA engagement Plaintiffs

demand, it was reasonable for FDA to infer that Congress did not intend to require premarket engagement through silence in the GRAS context when it expressly required FDA premarket engagement in the "food additives" context.

Second, FDA reasonably determined that voluntary notification was a more efficient way to enforce the FDCA than either the pre-existing affirmation petition process or mandatory notification for two reasons. Voluntary GRAS notices would improve upon the existing (also voluntary) GRAS affirmation process by simplifying the process and incentivizing manufacturers to provide information to FDA—a finding supported by the fact that GRAS notices increased after FDA instituted the interim policy; and additionally, mandatory submissions would increase the volume of submissions FDA would need to review, consuming resources that could be better directed toward evaluating higher-priority substances. 81 Fed. Reg. 54,960, at 54, 964, 54,979; Gov. Br. at 13. Plaintiffs' responses are unpersuasive. They argue that FDA would receive more information through mandatory notices, but their only response to FDA's concern about the burden of reviewing that increased amount of information is to say that "threats to public health certainly must trump efficiency." Pl. Opp. at 19. But FDA's point is that the inefficiency of having to review increased submissions would hinder the protection of public health by diverting agency resources from higher public health priorities. The decision about how to structure enforcement priorities is entitled to great deference, *see NRDC*, 760 F.3d at 170-71, and Plaintiffs offer no reason and point to no evidence in the administrative record to justify setting aside the agency's judgment.

Third, under the GRAS Rule, FDA can and does enforce the FDCA against manufacturers who improperly claim the GRAS exemption. Gov. Br. at 15 & n.11; *id*. at 23 (citing examples). Plaintiffs contend that it is "impermissible" to construe the FDCA to allow

FDA to rely on such enforcement rather than mandatory notice, because the FDCA purportedly requires premarket approval for food additives to address problems inherent in post-violation enforcement. *Id.* at 19-20. But, as explained above, Congress expressly carved GRAS substances out of the premarket FDA notice and approval regime that applies to "food additives." FDA's decision not to create a parallel premarket regime for GRAS substances out of whole cloth when Congress declined to direct that action cannot be an unreasonable reading of the statute.

Fourth, in filling the statutory gap with a voluntary, rather than mandatory, system, the GRAS Rule is consistent with past practice dating back to the enactment of the Food Additives Amendment—a practice Congress has never changed. Plaintiffs do not dispute that FDA has never imposed mandatory notification and recordkeeping requirements. Nor do they deny that Congress has never directed the agency to change its longstanding practice. Instead, they dismiss this history on the ground that Congress has never even considered directing the agency to require notification and recordkeeping. Pl. Opp. at 21. But this hardly rebuts FDA's argument. In *Chevron* itself, the Court found that an agency's longstanding view that a statutory term was flexible was permissible, in part because "Congress has never indicated any disapproval" of the agency's longstanding view. 467 U.S. at 864. Congress's silence certainly cannot be taken as *disapproval* of FDA's longstanding practice, which would be the only relevant consideration at *Chevron*'s second step. Given the statutory silence and FDA's consistent practice over sixty years of not requiring notification and recordkeeping, Plaintiffs have failed to show that FDA's gap-filling is unreasonable.

II. ALLOWING VOLUNTARY NOTIFICATION DOES NOT SUBDELEGATE FDA'S AUTHORITY TO MANUFACTURERS.

As Defendants explained in their opening brief, Plaintiffs' purportedly constitutional challenge to voluntary notification as unauthorized subdelegation fails both because it is not a

constitutional claim, and because the GRAS Rule does not give any authority to private manufacturers. Gov. Br. at 17-20. Plaintiffs' opposition fails to show otherwise.

Plaintiffs' "unconstitutional subdelegation" claim boils down to a contention that the agency has acted outside of its statutory authority by allegedly subdelegating authority to private manufacturers. *See* Pl. Opp. at 6 (admitting that Congress can authorize subdelegation but arguing it has not done so here). But a claim of *ultra vires* agency action does not itself establish a constitutional violation. *Dalton v. Specter*, 511 U.S. 462, 472 (1994).

Indeed, the Second Circuit has uniformly treated subdelegation claims as statutory rather than constitutional issues. Gov. Br. at 18. In response, Plaintiffs point to *R.H. Johnson & Co. v. SEC*, 198 F.2d 690 (2d Cir. 1952). But that case addressed a claim not of agency subdelegation of statutory authority, but Congress' delegation of its legislative authority. *Id.* at 695 (holding that Congress's enactment of the Securities Exchange Act of 1934 did not "unconstitutionally delegate[] power to" a private organization). Plaintiffs, however, do not invoke the Article I nondelegation doctrine in this case, nor is it plausibly applicable. *See* Gov. Br. at 17. The Court should address Plaintiffs' subdelegation claim as *Fund for Animals v. Kempthorne*, 538 F.3d 124 (2d Cir. 2008) and *Cooling Water Intake Structure Coalition v. EPA*, 905 F.3d 49 (2d Cir. 2018), did—as a question of Congress's intent.[4]

But regardless of how it is framed, Plaintiffs' subdelegation claim fails for a basic reason: the GRAS Rule does not subdelegate agency authority. Nothing in the GRAS Rule gives private parties the power to decide for FDA, the courts, or anyone else whether a substance is GRAS for

[4] Plaintiffs also cite generally to a section of the Corpus Juris Secondum that relies entirely on inapposite state-court cases that do not address the federal Constitution. Pl. Opp. at 10 (citing 16 C.J.S. Constitutional Law § 449). Whatever the rule in various states, a claim that a federal agency has done something Congress has not authorized it to do is distinct from a claim that the agency has violated the Constitution. *See Dalton*, 511 U.S. at 472.

a particular use. If FDA had promulgated no rule at all, manufacturers would have the same option they have now: to act without notifying FDA and assume the risk of enforcement if FDA later determines that they violated the law. The Rule provides them no additional authority.

Plaintiffs cite no case holding that such an arrangement constitutes a "subdelegation" of authority. *Fund for Animals* does not, as they suggest, stand for the proposition that an agency "subdelegates" its authority to "police the boundary" between what is legal and what is illegal whenever it relies on post-violation enforcement, rather than mandatory pre-violation notification, to address violations. *See* Pl. Opp. 8 (arguing that FDA subdelegated "'almost the entire determination' of whether a substance is safe to add to food" because "any enforcement necessarily would come after a violation has occurred"). Neither the Second Circuit nor any other court has adopted that wholly implausible and unsupported rule. If accepted, it would undermine hundreds if not thousands of regulatory enforcement schemes, including in the areas of health and safety, that rely upon the imposition of penalties or other sanctions following the violation of a regulatory requirement.[5]

III. THE GRAS CRITERIA SHOULD BE UPHELD.

As the government previously explained, Plaintiffs can prevail on their challenge to the Final Rule's GRAS criteria only if they show that the FDCA precludes those criteria or that the criteria embody an unreasonable or impermissible interpretation of the FDCA. Gov. Br. at 20.

[5] On pages 8 and 9, Plaintiffs quote a sentence from a case that *Fund for Animals* cited, *Nat'l Park & Conservation Ass'n v. Stanton*, 54 F. Supp. 2d 7 (D.D.C. 1999), that reads in full: "The relevant inquiry in this case therefore becomes whether, in delegating its responsibility to the Council to administer the Niobrara, NPS retained sufficient final reviewing authority over Council actions to prevent a violation of the unlawful delegation doctrine." *Id.* at 19. But in the phrase "to prevent a violation," which Plaintiffs italicize, the "violation" that was being "prevented" was the agency's potential violation of the legal delegation doctrine, not a private party's violating the underlying law. In any event, the Second Circuit did not quote that sentence from *Stanton*, a non-binding decision of another district court.

Plaintiffs fail to make either showing. Instead, for each challenged criterion, Plaintiffs either misinterpret the criterion as authorizing manufacturers to violate the FDCA, assume incorrectly that FDA is required to supplement the FDCA's GRAS exemption with additional requirements or specificity, or both.

First, Plaintiffs argue that the GRAS Rule's lack of a blanket prohibition on the use of unpublished materials to support GRAS conclusions is "inconsistent with FDA's own conclusion that published material is more likely to be objective, credible, and generally known." Pl. Opp. at 23. But the FDCA contains no blanket prohibition on the use of unpublished material. Rather, it requires general recognition of safety, 21 U.S.C. § 321(s), which FDA reasonably interpreted to require (1) common knowledge throughout the scientific community, (2) reliance on "generally available and accepted" data, and (3) the same "quantity and quality" of scientific evidence as is required for "food additives." 21 C.F.R. § 170.30(a), (b). FDA's decision not to impose an extra-statutory, absolute prohibition on the use of unpublished material is not "inconsistent" with its view that published material is "more likely" to meet these standards. That published material is "more likely" to meet these standards does not mean that unpublished material can never meet them. In addition, the GRAS rule does not affirm the GRAS status of a substance merely because a manufacturer relying on unpublished evidence has claimed it. If a manufacturer relies on inadequate evidence—whether published or unpublished—to support a GRAS conclusion, that manufacturer is subject to enforcement.

Second, the GRAS Rule is not arbitrary and capricious for "failure to protect" against conflicts of interest. Pl. Opp. at 23. The GRAS Rule is consistent with the FDCA, which is silent on this question. The Rule requires general recognition of safety "throughout the scientific community," not merely among a select group of experts. Plaintiffs respond that this "does not

require manufacturers to consult unbiased experts before reaching safety conclusions." Pl. Opp. at 23 (emphasis omitted). But this response assumes that the GRAS Rule somehow ratifies such biased safety conclusions. It does not. If a manufacturer consults only biased experts, then those experts' opinions likely will not be shared "throughout the scientific community." And if the manufacturer utilized the GRAS exemption for substances that are not generally recognized as safe "throughout the scientific community," it will have violated the law and will be subject to enforcement action.

Third, contrary to Plaintiffs' argument, there is no "loophole" allowing manufacturers "to determine a substance to be 'generally recognized as safe' after FDA raises safety concerns about that substance. Pl. Opp. at 24. Plaintiffs apparently refer to the fact that the GRAS Rule permits a manufacturer to withdraw a GRAS notice before FDA has finished evaluating it. 81 Fed. Reg. at 55,015. It does not follow from this that the manufacturer can lawfully treat the substance as GRAS, regardless of whether it is. If a manufacturer withdraws a GRAS notice and proceeds to treat the substance as GRAS, FDA may enforce the statute against that manufacturer or product if it determines that the substance is not GRAS. *See* Gov. Br. at 23.

Fourth, Plaintiffs argue that the GRAS Rule "fails to constrain manufacturers from issuing GRAS determinations under circumstances that *FDA itself* would consider inappropriate." Pl. Opp. at 24. Once again, this argument assumes—without any support in the FDCA or GRAS Rule—that a manufacturer's conclusion that a substance is GRAS means that the substance *is* GRAS. It does not. As FDA explained in promulgating the Final Rule, a novel or newly synthesized substance typically will not be generally recognized as safe. 81 Fed. Reg. at 54,976. As with reliance on unpublished material, it does not follow that FDA was required to replace the "generally recognized as safe" standard with a blanket "no novel or newly

synthesized substances" standard. To repeat: If FDA determines that a manufacturer has utilized the exemption for a novel or newly synthesized substance that is not actually GRAS, then it can bring an enforcement action.

Fifth, the GRAS Rule does not conflict with the FDCA on the subject of carcinogenic substances. Like the FDCA itself, the Rule does not expressly say anything about whether carcinogenic substances can be GRAS. The GRAS Rule's silence on this issue does not somehow put it into conflict with the FDCA's equal silence. As there is no requirement in the FDCA that FDA address this issue through rulemaking, the GRAS Rule's silence on carcinogenic substances is not a basis for setting it aside.

CONCLUSION

For the reasons set forth above and in Defendants' Opposition and Cross-Motion for Summary Judgment, this Court should grant Defendants' Cross-Motion for Summary Judgment and deny Plaintiffs' Motion.

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Respectfully submitted,

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