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THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA
SACRAMENTO DIVISION

MARK BAKER,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

No. 2:24-cv-02558-DC-SCR

REPLY IN SUPPORT OF MOTION TO DISMISS

Hearing Date: February 6, 2025
Time: 10:00 a.m.
Location: 501 I Street Sacramento, CA 95814
Courtroom 27, 8th Fl., Hon. Sean C. Riordan

INTRODUCTION

Plaintiff's Response to Defendants' Motion to Dismiss (ECF No. 11) ("Opp.") confirms that Plaintiff's claims should both be dismissed. First, Plaintiff still has not plausibly explained why a liaison between the U.S. Food and Drug Administration ("FDA") and the National Highway Traffic Safety Administration ("NHTSA") about light emitting diode ("LED") headlamps, or why more activity by the Technical Electronic Products Radiation Safety Standards Committee ("Standards Committee" or "Committee"), would reduce his exposure to such headlamps. Therefore, he cannot establish Article III traceability or redressability. But even if Plaintiff had standing, his claims under 5 U.S.C. § 706(1) fail because he does not identify a discrete agency action that Defendants were legally required to take but did not. Defendants' Motion to Dismiss should therefore be granted.

DISCUSSION

I. Plaintiff Lacks Standing Because He Has Not Explained Why An Interagency Liaison Or More Active Standards Committee Would Reduce His LED Headlamp Exposure.

In their Motion to Dismiss, Defendants argued that Plaintiff's Complaint fails to establish standing because it does not plausibly allege that his alleged injuries were caused by Defendants' failure to liaise about LED headlamps or FDA's alleged dissolution of the Standards Committee. Mot. to Dismiss (ECF No. 9) ("MTD") at 8-11. Regarding the failure to liaise (Count I), Plaintiff argues that his alleged injuries—which include a "psychological reaction" based on "exposure to LED headlamps," Opp. 3—are traceable to FDA and NHTSA because they "did not establish a liaison to test and evaluate LED vehicle headlamp technology," and therefore did not "take any collaborative action" like adopting LED-specific "performance standards," Opp. 4. But Plaintiff still "does not explain how or why LED-specific communications between the agencies, standing alone, would lead either [agency]" to adopt such standards or take any other action that could reduce his exposure to LED headlamps. MTD 9. And he ignores facts that make it particularly implausible that a liaison would lead to his desired result. *Id.* at 9 (noting "FDA and [NHTSA] have independently expressed skepticism of Plaintiff's views").

Plaintiff also maintains that his injuries would be redressed by a favorable ruling on Count I because "a ruling by this [C]ourt directing the FDA and NHTSA to comply with 21 U.S.C.

360ii(a)(6)(A)" would "result in performance standards for LED vehicle headlamps." Opp. 5. But "conclusory allegations" like these are "insufficient to establish standing." *Carrico v. City & Cnty. of San Francisco*, 656 F.3d 1002, 1006 (9th Cir. 2011) (citation omitted). And they are particularly inadequate here, where Defendants have explained why recent statements by both agencies make it unlikely that merely liaising would cause either agency to change its views. *See* MTD 9-10, 12. It therefore remains, at best, "'speculative' whether liaising would lead either agency to take action that prevents third-parties . . . from exposing Plaintiff to LED headlamps." MTD 12 (quoting *Lujan v. Def. of Wildlife*, 504 U.S. 555, 561 (1992)).

Plaintiff's discussion of standing (Opp. 3-5) offers no direct response to Defendants' arguments about traceability and redressability with respect to the Standards Committee (Count II). *See* MTD 10-11, 12. For example, he does not address Defendants' argument that the Committee's alleged unavailability "has not prevented FDA from taking the action Plaintiff seeks . . . because FDA could ensure that the Committee is available if and when the agency prepares to propose or adopt a new performance standard" concerning LED products. MTD 10. Nor does Plaintiff respond to Defendants' argument that he "offer[ed] no reason to expect that a more active Committee," if ordered by the Court, "would even consult with FDA about the agency's views on the scientific research surrounding LED products," let alone change FDA's mind about whether to adopt LED-specific performance standards. MTD 12. Instead, Plaintiff offers another conclusory assertion that an order directing FDA "to comply with . . . 21 U.S.C. 360kk(f)(1)(A) would likely result in performance standards for [the] LED vehicle headlamps" that are "causing Plaintiff's injuries." Opp. 5. Not only is this assertion unsupported, but it is also premised on a misunderstanding of the Standards Committee's statutory role, which is to advise FDA when the agency is contemplating *prescribing* a performance standard. 21 U.S.C. § 360kk(f)(1)(A). Thus, Plaintiff's "fail[ure] to oppose many arguments in [Defendants'] motion to dismiss" about his standing to pursue Count II means that "the Court may treat such non-opposition as implicit consent to the merits of the arguments asserted." *Lopez v. Cnty. of Los Angeles*, No. 15-cv-3804, 2016 WL 54123, at *2 (N.D. Cal. Jan. 5, 2016); *see also Ramirez v. Ghilotti Bros. Inc.*, 941 F. Supp. 2d 1197, 1210 n.7 (N.D. Cal. 2013) (collecting cases for the proposition that a "failure to address"

arguments raised in a motion constitutes "abandonment" of those issues by the opponent). Plaintiff's Complaint should therefore be dismissed because he lacks standing.

II. Even If Plaintiff Has Standing, Counts I And II Fail To State A Claim.

A. Count I Should Be Dismissed Because Plaintiff Has Not Identified Any Discrete Legal Requirement That FDA and NHTSA Liaise About LED Headlamps.

Defendants' Motion to Dismiss argues that 21 U.S.C. § 360ii(a)(6)(A) does not require FDA and NHTSA to liaise about LED headlamps, and therefore Count I should be dismissed under *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004) and its progeny. MTD 14-16. In response, Plaintiff first asserts that under the statute, "FDA shall (meaning 'must') both consult and maintain liaison with federal agencies." Opp. 6. But this statutory language is not in dispute. *See* MTD 14 (observing that § 360ii(a)(6)(A) sets forth "a broad, generalized requirement" for FDA to "consult" with "appropriate" agencies).

By contrast, Plaintiff's next contention—that this statutory requirement also "includes NHTSA" and "includes LED vehicle headlamps," Opp. 6—goes beyond the statute, which does not reference NHTSA or LED headlamps. *See* 21 U.S.C. § 360ii(a)(6)(A). Moreover, Plaintiff did not rebut Defendants' argument that such a requirement cannot be inferred from the statutory language. *See* MTD 14-16; *see also Lopez*, No. 15-cv-3804, 2016 WL 54123, at *2 (a failure to respond implies "consent to the merits of the arguments asserted"). Therefore, Plaintiff ignores that although the statute directs FDA to fulfill the "broad objective" of consulting with other agencies to further the agency's Radiation Control Program, it "leaves [FDA] a great deal of discretion in deciding how to achieve these objectives" rather than requiring the specific action Plaintiff seeks. *Gardner v. U.S. Bureau of Land Mgmt.*, 638 F.3d 1217, 1222 (9th Cir. 2011) (cleaned up).

Plaintiff also argues that FDA and NHTSA must employ "reasoned decision making" and "cannot act arbitrarily or capriciously" in "claim[ing] that a liaison between the FDA and NHTSA is not necessary." Opp. 7; *see also* Opp. 2, 10, 11 (similar). But under *Norton* and its progeny, it is *Plaintiff's* burden to support his claim under 5 U.S.C. § 706(1) by identifying "a discrete agency action that" the agencies are legally "required to take" but did not. 542 U.S. at 64. In the absence of such a requirement,

Defendants bear no burden to justify the absence of Plaintiff's desired action. Plaintiff's argument about reasoned decision making also confuses the prerequisite for pursuing a claim under § 706(1)—which forms the basis for Count I, *see* Compl., (ECF No. 1) ¶ 67—with the standard for reviewing agency action under 5 U.S.C. § 706(2), which does not. Although a "failure to act" is defined as a type of "agency action" that can be challenged under the APA, a claim seeking to challenge a failure to act must be pursued under § 706(1) (and must identify an action the agency is legally required to take). *Norton*, 542 U.S. at 62, 64. By contrast, the § 706(2) standard—which permits a court to set aside "agency action" that is "arbitrary, capricious, an abuse of discretion"—applies only to "*final* agency action" that the agency has *already taken*. *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (emphasis added). Here, Plaintiff is challenging agency *inaction* which, as Plaintiff recognizes, is properly considered under § 706(1). *See* Compl. ¶¶ 67, 71, 75 (alleging Defendants failed to liaise on LED headlamps and seeking an order compelling such liaison under § 706(1)).[1]

Plaintiff further acknowledges that § 360ii(a)(6)(A) only directs FDA to liaise with "appropriate" federal departments and agencies without referring to NHTSA specifically. Opp. 12. But he contends that "the term 'appropriate' in this case is non-discretionary . . . unless the FDA can provide a strong and convincing argument that an agency such as NHTSA is not an appropriate agency to maintain a liaison with." *Id*. Here again, however, Plaintiff seeks to improperly transfer to Defendants his burden of satisfying *Norton's* requirement. Plaintiff also argues that the term "appropriate" must be "inclusive of all" federal agencies "[d]ue to the ubiquity of LED technology." Opp. 10-11. But the mere fact that other agencies may be "somehow involved with LED technology," *id.*, falls far short of a "specific legislative command" that FDA liaise with all federal agencies about such products, particularly considering that

[1] To the extent Plaintiff also seeks to assert a claim alleging arbitrary and capricious decision making under 5 U.S.C. § 706(2), that claim is not properly before the Court because it is not in the Complaint. *See, e.g.*, *Sears v. City of Oroville*, No. 2:22-cv-1624-KJM-KJN, 2023 WL 2958004, at *2 (E.D. Cal. April 14, 2023) ("Statements in an opposition brief do not amend the complaint."). Yet even if it were, the claim would fail because Plaintiff has not identified any "final agency action." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (defining "final agency action," which is a prerequisite to a claim under § 706(2)); *see also ONRC Action v. Bureau of Land Mgmt.*, 150 F.3d 1132 (9th Cir. 1998) (refusing to infer final agency action from an agency's mere "failure to implement" a policy).

§ 360ii(a)(6)(A) does not contain a discrete requirement for FDA to liaise with *any* agency about such products. *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010).

Plaintiff's additional arguments about the absence of a liaison are immaterial because none purport to identify a discrete legal requirement that Defendants liaise about LED headlamps. Those arguments also fail for other reasons. For example, Plaintiff's contention that NHTSA "completely defers to the FDA for ensuring that LED vehicle headlamps are biologically safe" in the absence of an interagency liaison, Opp. 7, misconstrues NHTSA's statement. In responding to Plaintiff's inquiry, NHTSA "recognize[d] that separate expertise resides in sister agencies that are health-focused, such as the Food and Drug Administration." NHTSA, Interpretation 571.108-NCC-230201-001, LED Headlights (Feb. 13, 2024).[2] However, NHTSA also explained that the agency's Motor Vehicle Safety Standard No. 108 "specifies performance requirements for headlamps," and that many of Plaintiff's concerns about such headlamps are already "indirectly regulated through the headlamp performance requirements." *Id.* Thus, while NHTSA "recognized, and deferred to, [FDA's] distinct area of expertise and authority," MTD 12, it also asserted its own expertise and authority.

Plaintiff also contends that FDA "ignored the issue of LED vehicle headlamps" when denying his citizen petitions requesting action on LED products. Opp. 9. But this is belied by FDA's response, which acknowledged and discussed Plaintiff's requests and arguments about LED headlamps in detail. *See, e.g.*., Ex. 1 (ECF No. 9-2) at 2 (summarizing Plaintiff's requests about "LED Vehicle Lights"); 16-17 (offering a science-based response to Plaintiff's request that FDA "regulate . . . LED products used on vehicles"); 7-19 (addressing all of Plaintiff's contentions about LED products generally).[3]

For all of these reasons, Count I fails to state a claim and should be dismissed.

[2] https://perma.cc/M757-7UHF.

[3] The Court may recall that, in his prior lawsuit, Plaintiff criticized FDA's petition response at length. *See Baker v. FDA, et al.*, No. 2:24-cv-278-KJM-SCR ("*Baker I*"), ECF No. 15, at 3, 8, 14-17, 18, 20, 22, 28. The government addressed those arguments in its reply. *See Baker I*, ECF No. 17 at 6-9. Plaintiff then voluntarily dismissed that lawsuit, *Baker I*, ECF No. 22, and he declined to challenge FDA's petition response in his pending Complaint, placing the issue outside the scope of this lawsuit.

B. Count II Should Be Dismissed Because Plaintiff Has Not Identified Any Discrete Legal Requirement That The Standards Committee Meet More Frequently.

In requesting dismissal of Count II, Defendants argued that judicially noticeable facts rebut Plaintiff's allegation that FDA dissolved the Standards Committee. MTD 17. They further argued that, while Plaintiff seeks to compel greater frequency in the Committee's meetings, Plaintiff has identified no discrete legal requirement that the Committee meet with a particular schedule, nor does it require that they meet even when FDA is *not* preparing to prescribe any performance standards. MTD 18-19.

In response, Plaintiff rejects FDA's assertion that the Standards Committee will continue to have a role in "advising [the agency] regarding proposed performance standards" because the Committee "has met just once in the past 21 years." Opp. 12. But Plaintiff ignores that FDA has also *proposed* a performance standard "just once in the past 21 years." *Id.* Nor has Plaintiff identified any occasion when FDA has prescribed a performance standard under 21 U.S.C. § 360kk(a) without first consulting the Committee. He therefore cannot establish that FDA has failed to comply with 21 U.S.C. § 360kk(f)(1)(A)'s requirement that FDA "consult" the Standards Committee "before prescribing any standard under this section."

All of this suggests a straightforward answer to Plaintiff's rhetorical question about why the Standards Committee has not met more "regularly," Opp. 12. Specifically, 21 U.S.C. § 360kk(f)(1)(A) only directs FDA to consult the Committee "before prescribing any [performance] standard," and § 360kk(a) grants the agency broad discretion to propose such standards only when it "determines" they are "necessary," so there may be sustained periods of time in which consulting the Committee is not required. Plaintiff may object to the fact that FDA has found it unnecessary to propose any performance standards—and therefore, consult the Committee—regarding "LED vehicle headlamps, LED flashing lights on emergency vehicles, LED streetlights, LED general service lamps, and LED indicator lights." Opp. 12. But his personal views on that issue fall far short of a "specific legislative command" that FDA consult the Standards Committee more often than it has. *Hells Canyon Pres. Council*, 593 F.3d at 932.

Plaintiff acknowledges that § 360kk(f)(1)(A) only requires FDA to consult the Standards Committee "before prescribing any standard under this section," but he argues this requires consultation

"at all times up to and including" the prescription of such a standard, Opp. 13. This ignores that "if Congress wanted to mandate that" FDA consult with the Standards Committee at all times, "Congress knew how to write such a law," but it "did not do so in this statute." *Marietta Mem'l Hosp. Emp. Health Benefit Plan v. DaVita Inc.*, 596 U.S. 880, 887 (2022). Indeed, the statute "does not dictate any particular" number or frequency of consultations that must occur before a standard is prescribed. *Id.* FDA can therefore discharge its statutory obligation by consulting the Committee just once prior to the prescription of any standard, as it has in the past. *See, e.g.*, Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products, 88 Fed. Reg. 3638-01, 3641 (Jan. 20, 2023) (noting "FDA consulted with the . . . Standards Committee . . . [o]n October 26, 2016").[4]

Plaintiff also complains that FDA has not offered any "reasoned decision making[]" justifying the absence of more recent meetings. Opp. 12. But this fails for the same reason as Plaintiff's identical argument in support of Count I (*see supra* pp. 3-4): namely, it seeks to shift a burden that, under *Norton* and its progeny, Plaintiff must satisfy to support his claim under 5 U.S.C. § 706(1). And this argument again conflates the prerequisite of a § 706(1) claim with the standard of review under § 706(2).[5]

Plaintiff next suggests that FDA violated § 360kk(f)(1)(A) by "outsourc[ing] the petitions" Plaintiff submitted "to a secret organization" instead of "asking the members of [the Standards Committee] to review" them. Opp. 13. Plaintiff is apparently referring to FDA's choice, in reviewing his petitions and the evidence he submitted, to "engage[] an independent, third-party organization to conduct a comprehensive literature search to identify the current state of knowledge with regard to adverse health effects of LED light." MTD 9 (quoting Ex. 1 (ECF No. 9-2) at 19). But as Defendants have explained—and Plaintiff has failed to rebut—nothing in § 360kk(f)(1)(A) "requires FDA to consult

[4] Moreover, Plaintiff also offers no authority stating that "before" means "at all times," Opp. 13, and standard dictionary definitions suggest otherwise, *see* Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/before (last accessed Jan. 5, 2025) (defining "before" to simply mean "in advance; ahead" of an event).

[5] And as discussed above (*supra* p. 4 n. 1), to the extent Plaintiff seeks to raise a new claim under 5 U.S.C. § 706(2), that claim is not properly before the Court, and it would nonetheless fail because Plaintiff has not identified any final agency action.

the [Standards] Committee when the agency is *refraining* from prescribing" a performance standard, as the agency did in denying Plaintiff's citizen petitions. MTD 10.[6]

For all of these reasons, Count II fails to state a claim and should be dismissed.

III. Plaintiff's Other Arguments Misconstrue Defendants' Motion And Fail To Establish His Standing Or Satisfy *Norton*'s Requirement.

To the extent the Court construes any of the arguments in Plaintiff's Petition for Writ of Mandate (ECF No. 11) ("Pet.") as responding to Defendants' Motion to Dismiss, those arguments also fail.

For example, Plaintiff alleges that Defendants' Motion to Dismiss "withheld evidence [and] thus denie[d] the Court the ability to engage in a judicial review of the full administrative record." *Id.* at 4. But this misconstrues both the nature of Defendants' motion and the procedural posture of this case. As Defendants explained in responding to Plaintiff's Petition, Defendants currently have no obligation to produce the administrative record under the general schedule set forth in Local Rule 261, and the administrative record is not needed to resolve the legal issues presented in the motion to dismiss. *See* Opp. to Plf. Pet. for Writ of Mandate (ECF No. 12) ("Pet. Opp.") at 3-4. Defendants are also not obligated to support a motion to dismiss under Rule 12 with evidence. Instead, "[t]he purpose of [Rule] 12(b)(6) is to enable defendants to challenge the legal sufficiency of complaints without subjecting themselves to discovery." *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987). The "focus" of such a motion is therefore "the complaint" itself, *Schneider v. California Dep't of Corr.*, 151 F.3d 1194, 1197 n.1 (9th Cir.1998), not evidence placed before the Court. And here, Plaintiff's Complaint must contain "well-pleaded facts, not legal conclusions . . . that plausibly give rise to an entitlement to relief" as a matter of law, *Whitaker v. Tesla Motors, Inc.*, 985 F.3d 1173, 1176 (9th Cir.

[6] Although immaterial, Plaintiff's assertion that this organization is a "secret" one that FDA has "decline[d] to name," Opp. 13, is also incorrect. Indeed, counsel for Defendants referred to the organization's name, which is ECRI (formerly the "Emergency Care Research Institute," *see* https://home.ecri.org/), during the Court's hearing on FDA's motion to dismiss Plaintiff's prior lawsuit. *See Baker v. FDA, et al.*, No. 2:24-cv-278-KJM-SCR ("*Baker I*") ECF No. 20. Plaintiff's unawareness of the organization's identity also suggests he could not have any plausible basis for speculating that it may have a "conflict of interest." Opp. 14.

2021) (citation omitted). It must also contain allegations that support the Court's subject matter jurisdiction, including Plaintiff's standing. *See* Fed. R. Civ. P. 12(b)(1).

In any event, none of the categories of "evidence" Plaintiff references, Pet. 4, would help establish his standing or satisfy the requirement of *Norton*. For example, Plaintiff refers to the publicly available transcript of a 2016 meeting of the Standards Committee indicating that the Committee discussed LED products, among other topics. Pet. 6. According to Plaintiff, this "proves that the FDA is considering performance standards for LED products," and therefore must consult the Committee. *Id.* This argument is premised on several mistakes, however: first, the Standards Committee and FDA are not the same, so a discussion by the former cannot be imputed to the latter. *See* 21 U.S.C. § 360kk(f)(1)(A) (stating FDA "shall establish" the Committee, not that the Committee will be part of FDA). Second, nothing in the statute suggests *the Committee's* discussion of a topic obligates *FDA* to then consult *the Committee* on that same topic. *See id.* Third, even if FDA were "considering performance standards for LED products" in 2016, Pet. 6, that alone would not legally require consultation with the Committee, because FDA need only do so "before *prescribing* any standard," 21 U.S.C. § 360kk(f)(1)(A). And fourth, FDA made clear, in its 2023 response to Plaintiff's citizen petitions, that the agency has decided against proposing any performance standards for LED products at this time. *See generally* Ex. 1 to MTD. Therefore, while Plaintiff has not established that FDA violated § 360kk(f)(1)(A) in 2016, he provides even less reason to find that it is doing so *now*, and therefore cannot justify the prospective injunctive relief he seeks. *See, e.g.*, *City of Los Angeles v. Lyons*, 461 U.S 95, 108 (1983) ("Past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief.") (cleaned up).

Plaintiff also points (Pet. 6-7) to the Standards Committee's charter which, in a section entitled "estimated number and frequency of meetings," states that the Committee will meet "approximately once every other year." Ex. B to Pet. at 2. As a threshold matter, Plaintiff's new claim that this document requires the Committee to meet more frequently is not in his Complaint, and therefore, not properly before the Court. *See* Compl. ¶ 69, 73 (alleging that FDA has failed to comply with 21 U.S.C. § 360kk(f)(l)(A), not the charter); *Sears*, 2023 WL 2958004 at *2 ("Statements in an opposition brief do

not amend the complaint."). But this new claim also fails. That is because "[t]he [Supreme] Court [has] explained that even discrete agency action cannot be compelled under § 706(1) unless that action is 'demanded *by law*.'" *San Luis Unit Food Producers v. U.S.*, 709 F.3d 798, 803 (9th Cir. 2013) (quoting *Norton*, 542 U.S. at 65) (emphasis added). Therefore, a "legislative command," *Hells Canyon Pres. Council*, 593 F.3d at 932, or a promulgated "agency regulation[] that [has] the force of law," *Norton*, 542 U.S. at 65, can give rise to a *legally* required agency action. The statement Plaintiff quotes from the Standards Committee's charter is neither. But even if it had the force of law, the document's statement about the "estimated" and "approximate[]" frequency of the Committee's meetings (Ex. B to Pet. at 2) would still not be "a specific, unequivocal command . . . about which [FDA] had *no discretion whatever*." *Norton*, 542 U.S. at 63 (emphasis added). The estimated number of meetings identified in that statement therefore cannot be "compelled under the APA." *Id.*

In short, even if the Court considers the arguments in Plaintiff's Petition, they do not support his claims, let alone establish his standing.[7]

CONCLUSION

For the foregoing reasons, Plaintiff's Complaint should be dismissed.

DATED: January 14, 2025

Respectfully Submitted,

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[7] Plaintiff also does not explain why his allegations about "Headlightgate" (Pet. 4-5) or his references to 49 U.S.C § 30118(c)(1) (Pet. 5) could establish his standing or satisfy *Norton's* requirement.

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CERTIFICATE OF SERVICE

I hereby certify that this document, which was filed through the CM/ECF system, will be sent via e-mail on January 14, 2025 to Plaintiff Mark Baker's email address at mbaker@softlights.com. This document will also be sent by U.S. mail to Mr. Baker's address on file with the Court:

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January 14, 2025

/s/ *Scott P. Kennedy*
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