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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

MEMORANDUM OF POINTS AND AUTHORITIES 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

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INTRODUCTION

Plaintiff—an advocate for more stringent regulation of light emitting diode ("LED") products—brought this lawsuit to compel the United States Food and Drug Administration ("FDA") and the National Highway Traffic Safety Administration ("NHTSA") to liaise with one another about headlamps that use LEDs. Specifically, he wants the agencies to mutually address his assertion that LED headlamps pose serious hazards to human health and safety, even though both have already considered his assertion and reasonably declined to act on it. Plaintiff also seeks to compel FDA to reconstitute the Technical Electronic Product Radiation Safety Standards Committee ("Standards Committee" or "Committee"), which he alleges was unlawfully dissolved in 2016.

However, Plaintiff's claims are subject to dismissal under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) for several reasons: First, Plaintiff lacks standing. While he alleges that exposure to LED headlamps is harming his health and wellbeing, he has not plausibly established that this injury results from Defendants' failure to liaise or from FDA's alleged dissolution of the Standards Committee. Nor has he established that the relief he seeks—which includes a compulsory interagency liaison and quarterly meetings of the Standards Committee—would redress his injury.

Second, even if Plaintiff had standing, his claims fail as a matter of law. While he alleges in Count I that FDA and NHTSA are obliged to liaise with one another about LED headlamps, he identifies no statutory provision requiring this discrete action, as he must to compel agency action under the Administrative Procedure Act ("APA"). Moreover, while Plaintiff claims in Count II that FDA unlawfully dissolved the Standards Committee, his underlying factual allegations—and publicly available facts subject to judicial notice—establish only that the Committee has vacancies and has not met for several years. And Plaintiff identifies no statutory provision requiring that the Committee maintain full membership at all times or that it meet with specified frequency. For all these reasons, Plaintiff's Complaint should be dismissed.

BACKGROUND

I. Statutory and Regulatory Background

A. FDA's Regulation of Radiation-Emitting Electronic Products

FDA is responsible for regulating radiation-emitting electronic products through the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act, which were originally enacted as the Radiation Control for Health and Safety Act of 1968, Pub. L. 90-602, 82 Stat. 1173 (Oct. 18, 1968) ("Radiation Control Act"). These provisions apply to any "electronic product," which is defined to include "any manufactured or assembled product" that "emits . . . electronic product radiation." 21 U.S.C. § 360hh(2). In practical terms, this broad definition encompasses nearly any product that is powered by electricity, because all such devices can emit an electromagnetic field. *See* 21 C.F.R. § 1000.15 (listing "[e]xamples of electronic products subject to the Radiation Control" Act).

FDA has implemented the Radiation Control Act by "establish[ing]" an "electronic product radiation control program." 21 U.S.C. § 360ii(a); *see* 21 C.F.R. Subchapter J (illustrating various aspects of the program). As part of that program, FDA has developed performance standards for electronic products. The agency issues such standards only when it "determines that [they] are necessary for the protection of the public health and safety." *Id.* § 360kk(a)(1); *see also* § 360ii(a)(1). To date, FDA has promulgated performance standards for a variety of electronic products, including, for example, diagnostic x-ray systems, microwave ovens, and sunlamp products. 21 C.F.R. §§ 1020.30, 1030.10, 1040.20. However, FDA generally does not consider it necessary to issue specific performance standards for every type of electronic product because most such products do not pose a risk to public health, among other reasons. Final Response Letter from FDA to Soft Lights Foundation, Ex. 1 at 6-7.[1]

[1] The Court may take judicial notice of a "matter[] of public record," such as FDA's attached response to Plaintiff's citizen petitions, "without converting [the] motion to dismiss into a motion for summary judgment." *Khoja v. Orexigen Therapeutics*, Inc, 899 F.3d 988, 999 (9th Cir. 2018). Moreover, courts "routinely take judicial notice of . . . information on government websites," *Applied Underwriters, Inc. v. Lara*, 530 F. Supp. 3d 914, 923-24 (E.D. Cal. 2021), and the same petition response is available on a government website, *see* https://www.regulations.gov/document/FDA-2022-P-1151-0215.

Another aspect of FDA's radiation control program involves the agency's "consult[ations]" with other "[f]ederal departments and agencies" on "performance standards" and methods to "evaluat[e] electronic product radiation." 21 U.S.C. § 360ii(a)(6). To list just one illustrative example, FDA has consulted with the Federal Communications Commission on standards related to "wireless power transfer" devices as "new technologies such as 5G [cellular networks] are introduced."[2] The Radiation Control Act does not require FDA to consult with any particular agency at any specific time; rather, it leaves FDA flexibility to determine which agencies are "appropriate" for such consultation, and when. 21 U.S.C. § 360ii(a)(6).

FDA has also implemented the Radiation Control Act by establishing the Standards Committee, which FDA "consult[s] before prescribing any" performance standards for radiation emitting products. 21 U.S.C. § 360kk(f)(1)(A). FDA most recently renewed the Standards Committee's charter in January of 2023. Notice; Renewal of Federal Advisory Committee, 88 Fed. Reg. 4190 (Jan. 24, 2023). In so doing, the agency reiterated that the Committee "provides advice and consultation" to FDA "on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products." *Id.*; *see also* 21 C.F.R. § 14.100(d)(3) (similar).

Like many other everyday devices, LED products fall within the Radiation Control Act's definition of "electronic product." *See* 21 C.F.R. § 1000.15(b) (noting "devices" that emit "[w]hite light" are subject to the Act). However, FDA has not found performance standards for LED products to be necessary in part because of their long history of safety. Ex. 1 at 7. This does not mean, however, that LED products are wholly unregulated. For example, LED product manufacturers are responsible for compliance with all applicable regulations regarding radiological health and safety. *See, e.g.*, 21 C.F.R. § 1002.20 ("accidental radiation occurrence reports"); 21 C.F.R. Part 1003 ("notification of defects"); 21 C.F.R. Part 1004 ("repurchase, repairs, or replacement of electronic products"). And as discussed below (*infra* p. 4), LED products used in certain applications—such as vehicle headlamps—may be required to comply with regulations specific to those applications. LED manufacturers are also influenced by

[2] Letter from Jeffrey Shuren, Director, FDA Center for Devices and Radiological Research, to Julius Knapp, Chief, FCC Office of Engineering and Technology (Apr. 21, 2019), https://www.fda.gov/media/135022/download.

internationally accepted consensus standards concerning light-emitting devices, which help promote and maintain product safety even in the absence of government regulations. Ex. 1 at 9 (listing examples).

B. NHTSA's Regulation of Vehicle Headlamps

The National Traffic and Motor Vehicle Safety Act authorizes NHTSA to promulgate "motor vehicle safety standards" to "reduce traffic accidents and deaths and injuries resulting from traffic accidents." 49 U.S.C. § 30101. Before promulgating such a standard, NHTSA "consider[s] whether a proposed standard is reasonable, practicable, and appropriate for the particular type of motor vehicle or motor vehicle equipment for which it is prescribed," among other things. *Id.* § 30111(b)(3). And in developing such standards, NHTSA "may advise, assist, and cooperate with" other federal "departments [and] agencies," among others. *Id.* § 30111(c).

NHTSA promulgated Standard No. 108 to promote vehicle safety by "specif[ying] requirements for original and replacement lamps, reflective devices, and associated equipment" used in automobiles. 49 C.F.R. § 571.108, ¶¶ S1-S2. This standard regulates the performance of motor vehicle headlamps regardless of whether they use LEDs or other light-emitting technologies. *See id.*; *see also* NHSTA, Interpretation 571.108-NCC-230201-001, LED Headlights (Feb. 13, 2024)[3] (asserting that "LEDs are allowed to be used as a light source in integral beam headlamps as long as the headlamp conforms to all applicable headlamp requirements in" Standard No. 108). For example, vehicle headlamps—including those that use LEDs—must comply with Standard No. 108's photometric requirements, which specify minimum and maximum brightness levels to help prevent glare while promoting adequate visibility. *Id.* § 571.108, Tables XVIII and XIX. They must also comply with Standard No. 108's chromaticity requirements, which set permissible color characteristics. *Id.* ¶ S14.4, Tables I-a. Similarly, they must comply with the Standard's requirement that headlamps be "steady burning," meaning that the light they produce "is essentially unvarying in intensity." Interpretation 571.108-NCC-230201-001; *see also* 49 C.F.R. § 571.108, Table I-a.

[3] https://perma.cc/M757-7UHF. The statements in this document are subject to judicial notice without conversion to a motion for summary judgment. *Supra* n.1.

II. Factual Background

A. Plaintiff's Advocacy Concerning LED Products

Plaintiff Mark Baker, through the non-party Soft Lights Foundation, advocates for the regulation of LED products. *See* Compl. ¶¶ 26, 28, 49-57. Among other things, Plaintiff maintains that "LED vehicle headlamps," which he describes as "blinding," are causing "serious harm and injury to the public." *Id.* ¶ 36. He also maintains that he "has suffered eye pain, neurological and psychological trauma, and is at imminent risk of injury or death" from his exposure to LED headlamps. *Id.* ¶ 19. For these reasons, Plaintiff's organization has submitted numerous petitions to FDA and NHTSA requesting a range of regulatory actions concerning LED products. *See id.* ¶¶ 26, 28, 49-57. Among other things, he has asked FDA to promulgate "performance standards for LED vehicle lights." *Id.* ¶ 49. He has also asked NHTSA to "issue a notice of non-compliance to" various car manufacturers "for selling vehicles with [allegedly] unauthorized LED vehicle headlamps," and has asked the agency to "issue regulations requiring that vehicle headlamps emit spatially uniform light," among other things. *Id.* ¶¶ 51, 52.

B. Plaintiff's Past and Present Litigation

Plaintiff previously sued FDA in a lawsuit filed on January 22, 2024. *Baker v. FDA, et al.*, No. 2:24-cv-278-KJM-SCR ("*Baker I*"), Dkt. No. 1. In that lawsuit, Plaintiff claimed that FDA had "failed to comply with the requirements of 21 U.S.C. [§] 360ii(a)(1), (2), (3), (4), (5), or (6)," and "failed to protect the public" from LED products "in violation of 21 U.S.C. [§§] 360hh – 360ss." *Id.* ¶¶ 71-72. He also claimed that FDA had violated the Equal Protection Clause. *Id.* ¶¶ 74-78.

The government moved to dismiss *Baker I* on July 29, 2024. *Baker I*, Dkt. No. 13. On September 19, 2024, this Court heard oral argument on the motion to dismiss. *Baker I*, Dkt. No. 19. A week later, and before the Court ruled on the motion to dismiss, Plaintiff moved to voluntarily dismiss *Baker I* under Federal Rule of Civil Procedure 41(a)(2). *Baker I*, Dkt. No. 22-1. In so moving, Plaintiff stated an intention to pursue "more narrowly focused" claims—including a claim about the Standards Committee and one about "whether the FDA and NHTSA must maintain a liaison"—in a new lawsuit. *Id.* at 3. Plaintiff suggested that "after a ruling" on those new claims, the issues presented in *Baker I* could "be more easily answered." *Id.* On October 31, 2024, the Court issued Findings and Recommendations,

which recommended that the motion for voluntary dismissal be granted. *Baker I*, Dkt. No. 25. Neither party filed objections to the recommendation, which therefore became final. *See id.*

Plaintiff filed the present lawsuit on September 23, 2024. *See* Compl., Dkt. No. 1. In Count I, Plaintiff claims that FDA and NHTSA have "failed to establish and maintain a liaison on . . . LED vehicle headlamps to ensure the health and safety of the public, in violation of 21 U.S.C. [§] 360ii(a)(6)(A)." *Id.* ¶ 71. In Count II, Plaintiff claims that "FDA has unlawfully dissolved [the Standards Committee] in violation of 21 U.S.C. [§] 360kk(f)(l)(A)." *Id.* ¶ 73. On October 30, 2024, the Court issued an Order Relating and Reassigning Case, which found that the instant case is related to *Baker I* within the meaning of Local Rule 123(a) and reassigned it accordingly. Dkt. No. 5. Defendants now move to dismiss.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(1), a complaint must be dismissed if a court lacks subject matter jurisdiction over the plaintiff's claims. Federal courts are "presume[d]" to lack subject matter jurisdiction, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006), and it is the plaintiff's burden to establish it, *Kokkonen v. Guardian Life. Ins. Co.*, 511 U.S. 375, 377 (1994). To establish jurisdiction, a plaintiff "must allege facts, not mere legal conclusions." *Leite v. Crane Co.*, 749 F.3d 1117, 1121 (9th Cir. 2014); *see Ashcroft v. Iqbal*, 556 U.S. 662, 677–79 (2009). Jurisdiction must be "established as a threshold matter" and, where it is not established, "the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998).

A defendant "may challenge the plaintiff's jurisdictional allegations in one of two ways." *Leite*, 749 F.3d at 1121. A facial attack "accepts the truth of the plaintiff's allegations but asserts that they are insufficient on their face to invoke federal jurisdiction." *Id.* (quotations omitted). "The district court resolves a facial attack as it would a motion to dismiss under Rule 12(b)(6): Accepting the plaintiff's allegations as true and drawing all reasonable inferences in the plaintiff's favor, the court determines whether the allegations are sufficient as a legal matter to invoke the court's jurisdiction." *Id.*

By contrast, a factual attack "contests the truth of the plaintiff's factual allegations." *Leite*, 749 F.3d at 1121. In a factual attack, the court "may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment." *Am. Diabetes Ass'n v. U.S. Dep't of the Army*, 938 F.3d 1147, 1151 (9th Cir. 2019) (quotations omitted). The plaintiff "must support [his] jurisdictional allegations with competent proof," *Leite*, 749 F.3d at 1121 (quotations omitted), and "[n]o presumptive truthfulness attaches to plaintiff's allegations," *Thornhill Pub. Co. v. Gen. Tel. & Elecs. Corp.*, 594 F.2d 730, 733 (9th Cir. 1979) (quotations omitted). The plaintiff "bears the burden of proving by a preponderance of the evidence that each of the requirements for subject matter jurisdiction has been met." *Leite*, 749 F.3d at 1121.

Under Rule 12(b)(6), a complaint must "state[] a plausible claim for relief [to] survive[] a motion to dismiss." *Iqbal*, 556 U.S. at 679. In deciding such a motion, a court need not "accept as true" mere "legal conclusions" that are cast as allegations, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. "[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. In other words, a motion under Rule 12(b)(6) tests whether the Complaint contains "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. 2021) (citation omitted). While *pro se* complaints are interpreted more liberally than those drafted by attorneys, "vague and conclusory allegations" in such a complaint still do not satisfy Rule 12(b)(6) because courts "may not supply essential elements of the claim that were not initially pled." *Litmon v. Harris*, 768 F.3d 1237, 1241 (9th Cir. 2014).

DISCUSSION

I. Plaintiff Lacks Standing Because He Cannot Establish That His Injuries Are Traceable To Defendants' Conduct Or That They Will Be Redressed By Success On His Claims.

Standing is a threshold jurisdictional inquiry, and the burden of establishing it therefore falls on the party invoking the court's subject matter jurisdiction. *See Lujan v. Def. of Wildlife*, 504 U.S. 555, 561 (1992). To establish standing, Plaintiff must demonstrate that he has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant[s], and (3) that it is likely to be

redressed by a favorable decision." *Spokeo v. Robbins*, 578 U.S. 330, 338 (2016). A plaintiff must establish standing "for each claim" and "each form of relief" sought. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006).

Plaintiff's alleged injuries consist of "eye pain, neurological and psychological trauma," and "imminent risk of injury or death." Compl. ¶ 19. Plaintiff attributes these injuries to his "expos[ure] to LED vehicle headlamps." Compl. ¶ 19. However, Plaintiff does not assert that the government exposed him to such headlamps—rather, he contends that the government, through inaction, has failed to prevent others from doing so. *See id.* For the reasons discussed below, Plaintiff has not satisfied his burden of demonstrating that these injuries are traceable to, or redressable by, the governmental conduct challenged in either of his two claims.

A. Plaintiff's Injuries Are Not Traceable To Defendants' Conduct Because Neither The Agencies' Failure To Liaise, Nor FDA's Alleged Dissolution Of The Standards Committee, Caused Plaintiff's Exposure To LED Headlamps.

Fair traceability—also referred to as the causation requirement—"is central to Article III standing" because it "screens out plaintiffs who were not injured *by* the defendant's action" or inaction. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024) (emphasis added, citation and quotation marks omitted). The requirement therefore prevents courts from becoming "virtually continuing monitors of the wisdom and soundness of government" conduct. *Id.* at 384. Moreover, where a plaintiff is not the direct object of the government's conduct—but instead "challenges the government's unlawful regulation (or lack of regulation) of *someone else*" (here, Plaintiff alleges inadequate regulation of those exposing him to LED headlamps)—traceability is "substantially more difficult to establish." *Id.* at 382. In such cases, courts carefully scrutinize whether "the line of causation between the [allegedly] illegal conduct and injury" is "too speculative or too attenuated" to support standing. *Id.* at 369 (cleaned up).

With respect to Count I, Plaintiff asserts that Defendants' alleged "failure to comply with 21 U.S.C. [§] 360ii(a)(6)(A)" by liaising on LED products has "a causal connection" to "Plaintiff's injuries." *Id*; *see also id.* ¶ 36 (similar). But this conclusory assertion of Article III causation is facially insufficient to establish jurisdiction. *Leite*, 749 F.3d at 1121. That is because Plaintiff does not plausibly

explain how a liaison on LED headlamps between FDA and NHTSA would have reduced his exposure to those products. For example, Plaintiff speculates that a better "liaison between the FDA and NHTSA" could lead "staff for both agencies" to agree with his view that "LED vehicle headlamps are triggering non-epileptic and epileptic seizures, migraines, thoughts of suicide, eye pain, and impaired vision and cognitive functioning." Compl. ¶ 42. But Plaintiff does not explain how or why LED-specific communications between the agencies, standing alone, would lead either agency to this conclusion.[4] Thus, the Complaint's assertion of traceability for Count I is facially inadequate because it is premised on the highly speculative assumption that, simply by liaising on LED products, FDA and NHTSA would take some action that would remedy Plaintiff's alleged injuries.

Moreover, facts drawn from outside the Complaint—which can be considered in a factual attack on standing, *Am. Diabetes Ass'n.*, 938 F.3d at 1151—render Plaintiff's theory of traceability even more implausible. That is because both FDA and NHSTA have independently expressed skepticism of Plaintiff's views concerning LED products, making it unlikely either would change its views simply by liaising on the issue. For example, in denying Plaintiff's citizen petitions, FDA reviewed all of Plaintiff's submissions and concluded that he provided "[i]nsufficient [e]vidence" to support the adoption of LED-specific performance standards. Ex. 1 at 7-18. FDA also "engaged 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 on humans." *Id.* at 19. That search concluded that "the overall quality of evidence in the literature for any health effects was low," and that "the literature either did not report severe adverse health effects when using LED lighting, or the results were inconclusive/inconsistent." *Id.* Plaintiff does not plausibly explain whether or why FDA would adopt a *different* view of the scientific research than the one described in this response simply by liaising with NHTSA.

[4] Plaintiff also alleges that "neither the FDA nor NHTSA know how to accurately measure the intensity of LED vehicle headlamps." *Id.* ¶ 43. But he does not plausibly explain how they could better accomplish this by liaising, nor does he explain why better methods of measurement—even if discovered—would lead either agency to regulate LED headlamps more stringently.

Similarly, NHTSA responded to an inquiry from Plaintiff asking "whether LEDs are legal as a light source in motor vehicle headlamps" and requesting "NHTSA's position on the safety of LED light sources in headlamps." Interpretation 571.108-NCC-230201-001. The agency explained the ways in which LED headlamps are already subject to the safety requirements set forth in Standard No. 108. *Id.* It otherwise referred Plaintiff to FDA for his broader "health-focused" concerns about LED products, which go beyond NHTSA's purview of promoting automotive safety. *Id.* Plaintiff does not plausibly explain how or why NHTSA would significantly alter the approach to headlamps set forth in Standard No. 108 simply by liaising with FDA on that subject. For these reasons, Plaintiff has failed to carry his burden of establishing Article III traceability with respect to Count I.

With respect to Count II, Plaintiff similarly asserts that Defendants' "failure to comply with . . . 21 U.S.C. [§] 360kk(f)(l)(A)" by allegedly dissolving the Standards Committee has "a causal connection" to "Plaintiff's injuries." Compl. ¶ 19. But Plaintiff's assertion of traceability for Count II is facially inadequate because the Complaint fails to explain how the Committee's status prevented FDA from reducing Plaintiff's exposure to LED headlamps.

Instead, Plaintiff observes that FDA would be "required to first consult with" the Committee before promulgating any standard that could reduce his exposure to LED headlamps. Compl. ¶ 32. However, while Plaintiff is correct that FDA is obliged to consult the Committee "before *prescribing* any" performance standard, 21 U.S.C. § 360kk(f)(1)(A) (emphasis added), he overlooks that nothing requires FDA to consult the Committee when the agency is *refraining* from prescribing one. In other words, because FDA need not consult the Committee to maintain the status quo, the Committee's status cannot be a cause of FDA's failure to regulate LED headlamps. And even assuming, as Plaintiff alleges, that the Committee "is not available" at present, Compl. ¶ 31, this has not prevented FDA from taking the action Plaintiff seeks. That is because FDA could ensure that the Committee is available if and when the agency prepares to propose or adopt a new performance standard, as it has in the past. *See, e.g.*, Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products, 88 Fed. Reg. 3638-01, 3641 (Jan. 20, 2023) (noting that "FDA consulted with the . .

.Standards Committee (TEPRSSC) . . . [o]n October 26, 2016").[5] Thus, the Complaint's assertion of traceability for Count II is facially inadequate because the Complaint does not explain how the Committee's status has prevented—or even discouraged—FDA from taking action on Plaintiff's concerns. For these reasons, Plaintiff has failed to carry his burden of establishing Article III traceability with respect to Count II.

B. Redressability Is Absent Because Plaintiff Has Not Established That Compelling A Liaison, Or Compelling FDA To Reconstitute The Standards Committee, Would Reduce His Exposure To LED Headlamps.

Plaintiff also bears the burden of showing that it is "likely, as opposed to merely speculative, that [his] injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561 (citation and quotation marks omitted). "To determine whether an injury is redressable, a court will consider the relationship between the judicial relief requested and the injury suffered." *California v. Texas*, 141 S. Ct. 2104, 2115 (2021) (citation and quotations marks omitted). And as with traceability, redressability is "substantially more difficult to establish" when a plaintiff "challenges the government's unlawful regulation (or lack of regulation) of *someone else*." *All. for Hippocratic Med.*, 602 U.S. at 382. For the same reasons discussed above with respect to traceability,[6] Plaintiff cannot establish that success on his claims would redress his alleged injuries.

Plaintiff alleges that a favorable decision on Count I would "cause Defendants FDA and NHTSA to establish and maintain a liaison to address the health and safety impacts of LED vehicle headlamps." Compl. ¶ 19; *see also id.* ¶ 75 (requesting that the Court "[o]rder[] the FDA and NHTSA to . . . establish and maintain a liaison on . . . LED vehicle headlamps"). But for the reasons discussed above (*supra* pp.

[5] Moreover, while the Committee "may propose" performance standards to FDA for its "consideration," 21 U.S.C. § 360kk(f)(1)(B), Plaintiff does not allege that the Committee would recommend the type of standard he desires (nor could he without speculating). And even if the Committee were to recommend such a standard, Plaintiff offers no reason to expect that FDA would then adopt it, particularly given that it so recently decided against doing so. *See* Compl. ¶ 49.

[6] In many cases, the causation and redressability requirements "are two sides of the same coin," such that the analysis of each is largely the same. *Ctr. for Biological Diversity v. Exp.-Imp. Bank of the U.S.*, 894 F.3d 1005, 1012 n.2 (9th Cir. 2018).

8-11), the Complaint offers no plausible reason to expect that such a liaison would mitigate his injuries. In other words, it is "speculative" whether liaising would lead either agency to take action that prevents third-parties, such as car owners and manufacturers, from exposing Plaintiff to LED headlamps, *Lujan*, 504 U.S. at 561. This deficiency in the Complaint renders its assertion of redressability for Count I facially inadequate.

Additionally, facts drawn from outside the Complaint render Plaintiff's theory of redressability for Count I even more implausible. As discussed above, both FDA and NHSTA have considered Plaintiff's assertions about LED headlamps but nonetheless have not taken steps to revise their existing regulations. *Supra* pp. 9, 10. Each agency has also recognized, and deferred to, the other's distinct area of expertise and authority. *Id.*; *see also* Compl. ¶ 30. Plaintiff offers no plausible reason to expect any change should the agencies liaise with one another on the same subject.

Plaintiff similarly alleges that a favorable decision on Count II would "cause Defendant FDA to reconstitute" the Standards Committee. Compl. ¶ 19; *see also id.* ¶ 76 (requesting that the Court order "FDA to reconstitute" the Committee and direct it to meet "at least quarterly"). But as discussed above, *supra* pp. 10-11, Plaintiff offers no reason to expect that a more active Committee would even consult with FDA about the agency's views on the scientific research surrounding LED products. That is because the agency and Committee would only be required to consult on LED products if and when FDA were to prescribe a performance standard for such products—and FDA has already decided against doing so. Therefore, Plaintiff has not carried his burden of establishing redressability with respect to Count II.

C. The Procedural Rights Exception To Standing's Usual Requirements Does Not Apply Because the Statute At Issue Affords Plaintiff No Procedural Rights.

Finally, this case is unlike those in which the "normal" requirements of standing are relaxed so the plaintiff may vindicate "violations of [his] procedural rights." *Ctr. for Biological Diversity v. Exp.-Imp. Bank of the U.S.*, 894 F.3d 1005, 1012 (9th Cir. 2018). That is because the statutory provisions at issue in Counts I and II—specifically, 21 U.S.C. §§ 360ii(a)(6)(A) and 360kk(f)(l)(A)—do not "accord[]

[Plaintiff] a procedural right to protect [his] concrete interests." *Douglas Cnty. v. Babbitt*, 48 F.3d 1495, 1500 (9th Cir. 1995). Nor were his interests "threatened by" the government's conduct. *Id.*

First, neither § 360ii(a)(6)(A) nor § 360kk(f)(l)(A) provides Plaintiff any procedural right under these circumstances. Even if § 360ii(a)(6)(A) required FDA and NHTSA to liaise with one another, nothing in that provision affords members of the public a right to enforce that requirement to protect their interests—much less Plaintiff a right to compel a liaison merely to vindicate his dissatisfaction with the regulatory status quo. Similarly, even assuming § 360kk(f)(1)(A) affords some litigants the right to enforce its requirements—for example, a manufacturer claiming FDA failed to "consult" the Standards Committee "before prescribing" a new performance standard, *id.*—it affords no procedural right to Plaintiff here. That is because, as discussed above, § 360kk(f)(1)(A) does not require FDA to consult the Committee when it *refrains* from prescribing a performance standard.

Second, Plaintiff's interests are not "threatened by" Defendants' conduct because it is not "reasonably probable" that Defendants' alleged violation of §§ 360ii(a)(6)(A) and 360kk(f)(l)(A) will "cause the [] harm[s]" that Plaintiff alleges. *Douglas*, 48 F.3d at 1501 & n.6; *see also R.J. Reynolds Tobacco Co. v. FDA*, 810 F.3d 827, 829-31 (D.C. Cir. 2016) (explaining that even when a plaintiff sues to vindicate a procedural right, he or she must show that the alleged violation of that right poses a "distinct risk to [his] particularized interest[s]" that is "probable or imminent" rather than "speculative"). Indeed, as discussed above, *supra* pp. 8-11, it is highly speculative whether Defendants' alleged failure to comply with §§ 360ii(a)(6)(A) and 360kk(f)(l)(A) contributed to Plaintiff's alleged injuries.

Because the procedural injury exception does not apply here, Plaintiff must fully satisfy the traditional elements of standing. And for the reasons discussed above, he cannot satisfy the traceability and redressability requirements. Plaintiff's claims should therefore be dismissed under Rule 12(b)(1).

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

A. Count I Fails Because § 360ii(a)(6)(A) Does Not Require FDA And NHTSA To Liaise About LED Headlamps.

Count I alleges that FDA and NHTSA violated 21 U.S.C. § 360ii(a)(6)(A), Compl. ¶ 71, but this claim fails because it is based upon a fundamental misreading of the statute. Plaintiff bases his claim on

the statute's requirement that FDA "consult and maintain liaison with . . . appropriate Federal departments and agencies" on issues related to "electronic product radiation." Compl. ¶ 60 (quoting § 360ii(a)(6)(A)). Plaintiff reasons that because LED headlamps "emit electromagnetic radiation," *id.* ¶ 62, the statute effectively requires FDA to "maintain [a] liaison" with NHTSA specifically "for LED vehicle headlamps," *id.* ¶ 66. In other words, Plaintiff contends that FDA and NHTSA must consult and liaise on LED headlamps simply because those products "emit electromagnetic radiation." *Id.* ¶ 62. Plaintiff therefore concludes that the agencies' failure to liaise on this subject constitutes "agency action unlawfully withheld or unreasonably delayed" under 5 U.S.C. § 706(1).

A claim under § 706(1) can only proceed if the agency "failed to take a discrete agency action that it is required to take." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). Put another way, the APA "carefully circumscribed" judicial review of agency inaction "to situations where an agency has ignored a specific legislative command." *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 923, 932 (9th Cir. 2010). This requirement "protect[s] agencies from undue judicial interference with their lawful discretion" and "avoid[s] judicial entanglement in abstract policy disagreements which courts lack the expertise and information to resolve." *Norton*, 542 U.S. at 55–56.

Count I should be dismissed under Rule 12(b)(1), or alternatively, Rule 12(b)(6),[7] because that claim does not identify a discrete action that Defendants were statutorily required, yet failed, to take. Contrary to Plaintiff's reading, 21 U.S.C. § 360ii(a)(6)(A) does not contain a discrete, mandatory directive for FDA to act with respect to a specific type of radiation-emitting product, such as LED headlamps. Instead, § 360ii(a)(6)(A) contains only a broad, generalized requirement that FDA "shall . . . consult and maintain liaison with . . . appropriate Federal departments and agencies on techniques, equipment, and programs for testing and evaluating electronic product radiation." *Id.* FDA has repeatedly satisfied that requirement over time by, for example, consulting with the Federal

[7] The Ninth Circuit has described the requirement of *Norton* as being a jurisdictional one, such that it is properly analyzed under Rule 12(b)(1). *See, e.g.*, *San Luis Unit Food Producers v. U.S.*, 709 F.3d 798, 803–04 (9th Cir. 2013). Other courts in the Ninth Circuit have questioned this. *See, e.g.*, *Al Otro Lado, Inc. v. Nielsen*, 327 F. Supp. 3d 1284, 1318 n.15 (S.D. Cal. 2018). Regardless of whether the requirement is jurisdictional or not, the analysis of Count I's shortcomings is the same.

Communications Commission on standards related to "wireless power transfer" devices.[8] Thus, while Plaintiff is correct that the statute contains a "non-discretionary" requirement, Compl. ¶ 62, he is mistaken about the nature and scope of that requirement.

Indeed, the breadth of § 360ii(a)(6)(A) is significant because "if Congress wanted to mandate that" FDA take product-specific action on LED products, "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); *see also City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion."). Nor can the Court "assume that Congress has omitted from its adopted text [a] requirement" to take certain actions with respect to LED products "that [Congress] nonetheless intends to apply." *Jama v. Imm. & Customs Enf't*, 543 U.S. 335, 341 (2005). This is particularly true because "Congress has shown elsewhere in the same statute that it knows how to make such a [product-specific] requirement manifest." *Id.* For example, in 21 U.S.C. § 360jj(a)(1)(C), Congress directed FDA to specifically study "the need for controlling the sale of . . . antiquated X-ray equipment . . . ." Why would Congress have failed to similarly specify in § 360ii(a)(6)(A)—either in the original statute, or in the years since LED product use entered the mainstream—that it was requiring FDA to liaise with other agencies about LED products specifically? The most "straightforward" interpretation—and therefore, the "best" one—is that Congress never intended such a requirement. *Jones v. Hendrix*, 599 U.S. 465, 480 (2023).

Plaintiff's argument is even more implausible when considered within the "context" of the "overall statutory scheme." *Turkiye Halk Bankasi A.S. v. U.S.*, 598 U.S. 264, 275 (2023). The logic behind Plaintiff's reading of § 360ii(a)(6)(A)—which posits that FDA and NHTSA must liaise on LED headlamps because those products emit electronic product radiation, *see* Compl. ¶¶ 62, 64—would also require FDA to take every single action described in § 360ii(a)(1)-(6) for each of the products that emit such radiation, a class that includes virtually every electronic product available. In other words,

[8] Letter from Jeffrey Shuren, Director, FDA Center for Devices and Radiological Research, to Julius Knapp, Chief, FCC Office of Engineering and Technology (Apr. 24, 2019), https://www.fda.gov/media/135022/download.

Plaintiff's interpretation would leave the agency no discretion to determine which electronic products require the agency's attention and which do not. That interpretation is therefore irreconcilable with 21 U.S.C. § 360kk(a), which gives FDA discretion to promulgate performance standards for electronic products only "if [it] determines" them to be necessary. It is also irreconcilable with § 360ii(a)(2), which requires the agency to use its judgment by "plan[ning] . . . operational activities" to minimize "unnecessary electronic product radiation," not *all* such radiation. Plaintiff's construction of the Act therefore fails because "[b]asic principles of statutory interpretation require that" § 360kk(a) and the subparts of § 360ii(a) be construed "in harmony with one another, not set [] at cross-purposes." *Jones v. Hendrix*, 599 U.S. 465, 478 (2023).

Count I also fails for another reason: even if Plaintiff were correct that § 360ii(a)(6)(A) requires FDA to liaise with other agencies about LED products, such as headlamps, the statute nonetheless vests FDA with discretion to determine *which* agencies are the "appropriate" ones with which to liaise. *Id.* Indeed, as Plaintiff acknowledges (Compl. ¶ 63), the statute makes no mention of NHTSA. Plaintiff's conclusory assertion that NHTSA is nonetheless an "appropriate Federal [] agenc[y]" for consultation introduces a discrete requirement that the statute lacks. Nor, for that matter, does the statute require NHTSA to do anything at all, except perhaps respond if and when FDA determines that a consultation would be "appropriate."

For these reasons, Plaintiff has not stated—and cannot state—a viable claim that the statute requires FDA to take the discrete action of liaising with NHTSA on LED headlamps. Count I therefore fails to identify any violation of the statute, or any action the Court could properly compel under 5 U.S.C. § 706(1).

B. Count II Fails Because FDA Has Not Dissolved The Standards Committee, And Nothing Requires The Committee To Meet Quarterly Or Prevent Vacancies In Its Membership.

Count II alleges that "FDA has unlawfully dissolved [the Standards Committee] in violation of 21 U.S.C. [§] 360kk(f)(l)(A)." Compl. ¶ 73. In support of this claim, Plaintiff cites government websites indicating that the Committee currently has 11 vacancies and last met in 2016. *Id.* ¶¶ 31-32. On this

basis, Plaintiff alleges that "FDA disbanded [the Committee] in 2016." *Id.* ¶ 31. Plaintiff concludes that the Court should "compel the FDA to reconstitute" the Standards Committee under 5 U.S.C. § 706(1), Compl. ¶ 69, and order that the body meet "at least quarterly," *id.* ¶ 76. Count II is therefore properly analyzed under *Norton* which, as discussed above, requires Plaintiff to identify "a discrete agency action that [FDA] is required to take" yet did not. 542 U.S. at 64; *see supra* p. 14 (discussing the standard in greater detail).

Count II fails for several reasons. First, judicially noticeable facts from government websites—which are eligible for consideration on a motion to dismiss, *Khoja*, 899 F.3d at 999; *Applied Underwriters*, 530 F. Supp. 3d. at 923-24—contradict Plaintiff's allegation that FDA dissolved the Standards Committee in 2016. *See Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) (Courts need not "accept as true allegations that contradict" facts that are "properly subject to judicial notice"). The Federal Register shows that FDA renewed the Committee's charter in 2023. Notice; Renewal of Federal Advisory Committee, 88 Fed. Reg. 4190 (Jan. 24, 2023). And FDA's website states that it has "established" the Committee, which continues to have a role in "advis[ing] FDA regarding proposed performance standards," among other things. FDA, Technical Electronic Product Radiation Safety Standards Committee[9] (current as of Jan. 13, 2023). The website also provides instructions for "nominat[ing] technically qualified individuals interested in serving on this committee"—something it would not do if the Committee were defunct. *Id.*; *see also* Request for Nominations for Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee, 87 Fed. Reg. 73769-01 (Dec. 1, 2022) (seeking "[n]ominations" for "current and upcoming vacancies" in the Committee). Thus, assuming that 21 U.S.C. § 360kk(f)(1)(A) imposed a discrete requirement by directing FDA to "establish a Technical Electronic Product Radiation Safety Standards Committee," FDA has satisfied it.

At most, Plaintiff's allegations can establish only that the Standards Committee has vacancies and has not met in several years. *See* Compl. ¶¶ 31-32. But these facts do not support Plaintiff's claim

[9] https://www.fda.gov/advisory-committees/radiation-emitting-products/technical-electronic-product-radiation-safety-standards-committee.

under § 706(1), because there is no discrete requirement in § 360kk(f)(1)(A) that precludes the Committee from having vacancies in its membership, nor does the statute require the Committee to meet with a particular frequency. To the contrary, the statute requires FDA to ensure that the Committee is prepared for consultation only when the agency is contemplating "prescribing a [performance] standard under" § 360kk. *Id.* § 360kk(f)(1)(A). Nor can Plaintiff establish a violation of any other aspect of § 360kk(f)(1)(A). For example, while the statute specifies that the Committee must be "composed of fifteen members" with specific qualifications and backgrounds, *id.*, FDA satisfied this by establishing a Committee with 15 positions, *see* 88 Fed. Reg. 4190, which the agency has sought to fill, *see, e.g.*, 87 Fed. Reg. 73769-01. But nothing in the statute obligates FDA to prevent vacancies in these positions at all times, particularly not when FDA is *declining* to propose any performance standard. And while the statute also provides that the Committee "may propose electronic product radiation safety standards," *id.* § 360kk(f)(1)(B), this suggests, at most, a permissive authorization for the Committee to make such recommendations from time to time—not a discrete, continual requirement that FDA immediately fill vacancies.

Plaintiff's reading of § 360kk(f)(1)(A) is also difficult to reconcile with the remainder of § 360kk, which only requires FDA to prescribe a performance standard "*if* [the agency] determines that such standards are necessary. . . ." *Id.* § 360kk(a)(1) (emphasis added). That provision makes clear that FDA is not under a continual duty to prescribe performance standards; it has discretion to prescribe them only if—and *when*—it finds them necessary. This renders Plaintiff's theory that the Committee must meet "at least quarterly," Compl. ¶ 76, all the more implausible. Indeed, Plaintiff overlooks that FDA can discharge its duty under § 360kk(f)(1)(A) by ensuring that the Committee stands prepared to consult on a performance standard whenever FDA is prepared to propose one, just as FDA has done in the past. *See, e.g.*, 88 Fed. Reg. at 3641.

For all of these reasons, Plaintiff's interpretation of § 360kk(f)(1)(A) also violates each of the interpretive canons Defendants levied against his interpretation of § 360ii(a)(6)(A). *See supra* pp. 15-16. For example, "[i]f Congress wanted to mandate that" FDA must convene the Standards Committee quarterly and ensure against vacancies 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*, 596 U.S. at 887. And courts should not "assume that Congress has omitted from its adopted text [a] requirement" about the frequency of the Committee's meetings "that [Congress] nonetheless intends to apply." *Jama*, 543 U.S. at 341. Moreover, while § 360kk(f)(1)(A) must be read "in harmony" with the discretion afforded to FDA under § 360kk(a)(1), *Jones*, 599 U.S. at 478, under Plaintiff's reading, it cannot be.

In short, because FDA has established—not dissolved—the Standards Committee, and because § 360kk(f)(1)(A) contains no discrete requirement that the Committee should meet quarterly or keep its membership positions filled at all times, Plaintiff cannot establish that FDA has violated this provision. Count II should therefore be dismissed.

CONCLUSION

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

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Respectfully Submitted,

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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 December 3, 2024 to Plaintiff Mark Baker's email address at mbaker@softlights. This document will also be sent by U.S. mail to Mr. Baker's address on file with the Court:

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