United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 7, 2017 Decided March 20, 2018

No. 16-1299

ORTON MOTOR, INC., D/B/A ORTON'S BAGLEY,
PETITIONER

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
RESPONDENT

On Petition for Review of an Order
of the Departmental Appeals Board of the
United States Department of Health and Human Services

Johanna Dennehy argued the cause for petitioner. With her on the briefs were *Michael J. Baratz* and *Molly Bruder Fox*.

Megan Barbero, Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief were *Mark B. Stern* and *Alisa B. Klein*, Attorneys, and *AnnaMarie Kempic*, Deputy Chief Counsel for Litigation, United States Food & Drug Administration.

Before: TATEL, GRIFFITH and WILKINS, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* WILKINS.

WILKINS, *Circuit Judge*: Orton Motor, Inc. d/b/a Orton's Bagley ("Orton") is a gas station and convenience store in Bagley, Minnesota, that sells cigarettes and tobacco products, among other sundries. The Food and Drug Administration ("FDA") levied civil money penalties in the amount of $500 against Orton following two inspections in which Orton sold cigarettes to a minor without first checking identification to verify age. As a policy, if a retailer fails an inspection for the first time, the FDA's Center for Tobacco Products (the "Center") charges all violations observed during that inspection as a single violation. However, the Center charges each separate violation of a regulation as a discrete violation during subsequent failed inspections. Accordingly, the FDA counted both the sale to a minor and the failure to verify age as two separate violations on Orton's second failed inspection and assessed the maximum penalty of $500 for three violations within a 24-month period under the civil money penalty schedule.

Orton challenges this determination on two principal grounds: that the Tobacco Control Act precludes the FDA's methodology of charging multiple violations in a single inspection, and that the FDA violates the law by failing to provide a process for retailers to challenge first violations before the issuance of a warning letter. We find no merit in either contention, and accordingly, we deny Orton's petition.

I.

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act ("TCA"), which "g[ave] the FDA broad regulatory authority over tobacco products, including, for instance, authority to impose restrictions on their sale, and on the advertising and promotion of such products . . . ." *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891, 898 (D.C.

Cir. 2010) (citations omitted). The FDA previously attempted to regulate tobacco products under the Food, Drug, and Cosmetic Act ("FDCA") in 1996, but the Supreme Court concluded in *Food & Drug Administration v. Brown & Williamson Tobacco Corp.* that it lacked the authority to do so based on "the FDCA's overall regulatory scheme and [] the tobacco-specific legislation that [Congress] ha[d] enacted subsequent to the FDCA." 529 U.S. 120, 125-26 (2000). Congress passed the TCA to fill this gap, finding that "Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products" and determining that "[i]t is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products." 21 U.S.C. § 387 Note, Findings (7) & (12); Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009). The TCA incorporated this authority to regulate tobacco into the existing regulatory structure of the FDCA. *Sottera*, 627 F.3d at 894-95.

Relevant to this case, the TCA prohibits the "misbranding of any . . . tobacco product . . . in interstate commerce," 21 U.S.C. § 331(b), as well as "the doing of any [] act . . . [that] results in [a tobacco product] being . . . misbranded." *Id.* § 331(k). A tobacco product is "deemed to be misbranded" if "it is sold or distributed in violation of regulations prescribed under section 387f(d)," *id.* § 387c(a)(7)(B), which in turn authorizes the Secretary of Health and Human Services to "require restrictions on the sale and distribution of a tobacco product" by regulation, as "appropriate for the protection of the public health." *Id.* § 387f(d). The regulations promulgated pursuant to this section provide that:

> (1) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;
> (2) (i) Except [through mail-order and in locations admitting only adults], each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;
> (ii) No such verification is required for any person over the age of 26;
> (3) Except as otherwise provided in [regulations about self service], a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);
> (4) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes [or a quantity of cigarettes or smokeless tobacco smaller than that contained in a manufacturer-distributed package];
> (5) Each retailer must [bring into compliance] all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment.

21 C.F.R. § 1140.14(a). Neither the statute nor the regulations explicitly states how violations are to be counted.

The TCA created civil monetary penalties for violations related to tobacco. Section 333 provides for civil money penalties "in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding," with enhanced penalties available for intentional violations. 21 U.S.C. § 333(f)(9). Other provisions specify the penalty schedule applicable to

violations of the retailer-specific regulations. For a retailer with an approved training program, the maximum penalties are:

> (I) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;
> (II) in the case of a second violation within a 12-month period, $250;
> (III) in the case of a third violation within a 24-month period, $500;
> (IV) in the case of a fourth violation within a 24-month period, $2,000;
> (V) in the case of a fifth violation within a 36-month period, $5,000; and
> (VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

21 U.S.C. § 333 Note; Pub. L. No. 111-31, 123 Stat. 1776, 1839 (June 22, 2009).

The TCA requires the Secretary of Health and Human Services to issue guidance regarding a variety of topics and procedures for the assessment of violations and civil money penalties. Codified at 21 U.S.C. § 333, these provisions direct that the Secretary issue guidance:

> (B) providing for timely and effective notice . . . to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check . . . .;
> (C) providing for a hearing pursuant to the procedures established through regulations of the

> Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;
> (D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;
> (E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to [the penalty schedule] within the time periods provided for in such [schedule].

TCA § 103(q)(1); Pub. Law No. 111-31, 123 Stat. 1776, 1838-39 (June 22, 2009).

The Center published two guidance documents explaining its approach to enforcement of the tobacco retail regulations. One was entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" and the other offered "Responses to FAQs" about the same. *See* Ctr. for Tobacco Prods., Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers: Guidance for Industry* ("*CMP Guidance*") (rev. Dec. 2016), *available at* www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm (last visited Mar. 19, 2018); *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions* ("*FAQs*") (rev. Dec. 2016), *available at* www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm252810.htm (last visited Mar. 19, 2018). The guidance documents bear a banner announcing

that they are "not binding on FDA or the public." *See CMP Guidance* at 1; *FAQs* at 1. Substantively, the guidance sets forth the Center's approach to actions for civil money penalties. The CMP Guidance provides significant detail about the Center's enforcement approach, including follow-up visits to inspect retailers after violations. The Center's "FAQ" document explains the Center's enforcement position of counting multiple regulation violations on subsequent visits, while "count[ing] only one regulation violation from the first inspection." *See FAQs*, Question 43 at 13 ("[The Center] counts only one regulation violation from the first inspection at a retail outlet, regardless of the number of regulation violations that were noted and included in a Warning Letter. For any subsequent inspections, [the Center] may count any or all violations and its general policy is to count all of them individually.").

II.

The parties do not disagree about the facts underlying this dispute. On July 10, 2013, an FDA inspector visited Orton and observed that a minor was permitted to purchase cigarettes, in violation of then-current 21 C.F.R. § 1140.14(a) (2010), and that no one checked the minor's identification before the tobacco sale, in violation of 21 C.F.R. § 1140.14(b)(1) (2010). The FDA issued a "Warning Letter" on August 15, 2013, documenting these violations and concluding that they "cause [Orton's] cigarettes to be 'misbranded'" under 21 U.S.C. § 387(c). *See* Letter from Ann Simoneau, Office of Compliance and Enforcement, Center for Tobacco Products (Aug. 15, 2013); Joint Appendix ("J.A.") 1-3. Orton did not challenge the issuance of the Warning Letter at that time.

On May 16, 2015, the FDA again inspected Orton and documented the same violations for a second time: the sale of

tobacco products to a minor and that the minor's purchase took place without Orton checking the minor's identification to verify age. The Center brought an administrative complaint against Orton on October 1, 2015, seeking civil money penalties of $500. *See* Admin. Compl. For Civ. Money Penalties, *Ctr. for Tobacco Prods. v. Orton Motor, Inc. d/b/a Orton's Bagley*, FDA Docket No. FDA-2015-H-3414 (Oct. 1, 2015); J.A. 4-8. This amount derives from the FDA's regulations at 21 C.F.R. § 17.2 (2014), which provided at the time for a $500 maximum civil money penalty for "3 [Violations] within a 24 month period." *Id.* at 2. Orton answered the Complaint with a defense that the statute and regulations "do not authorize [the agency] to impose multiple violations as a result of one inspection" or "one transaction." *See* Answer to Admin. Compl., *Ctr. for Tobacco Prods. v. Orton Motor, Inc. d/b/a Orton's Bagley*, FDA Docket No. FDA-2015-H-3414 at 3 (Oct. 30, 2015); J.A. 11-14. Orton accordingly argued that the $500 penalty was impermissible "because two violations were cited during one inspection" or "one transaction." *Id.* Orton sought a hearing before an administrative law judge ("ALJ"). *Id.* at 1.

After a prehearing conference and cross-motions for summary decision, ALJ Lewis Booker issued a Decision and Order concluding that Orton "misbranded a tobacco product on May 16, 2015, and will be sanctioned by a civil monetary penalty of $0 and a judicial Warning Letter." FDA Office of Admin. Law Judges, Initial Decision and Order, *Ctr. for Tobacco Prods. v. Orton Motor, Inc. d/b/a Orton's Bagley*, FDA Docket No. FDA-2015-H-3414 (Feb. 8, 2016); J.A. 26-35. In short, ALJ Booker concluded that both the sale to a minor and the failure to check identification resulted in "misbranding" under a single statutory provision, and, as such, constituted a single violation supporting civil money penalties. ALJ Booker held that the July 10, 2013, and May 16, 2015,

incidents each constituted misbranding but, because they were 22 months apart, they triggered a $0 penalty. *Id.* at 5-6. The ALJ issued his own Warning Letter based on the later violation. *Id.* at 7.

The Center appealed to the Departmental Appeals Board (the "Board"). In a decision on June 30, 2016, the Board reversed the ALJ's decision and reinstated the $500 penalty. *See* Final Decision on Review of Administrative Law Judge Decision, *Ctr. for Tobacco Prods. v. Orton Motor, Inc. d/b/a Orton's Bagley*, Docket No. A-16-56 (June 30, 2016); J.A. 40-65. The Board reasoned that the agency was interpreting its own regulations, justifying deference unless the agency's interpretation was contrary to the regulations' unambiguous meaning. Other portions of the statute demonstrated that Congress "knew how to limit the number of violations for multiple acts in the course of one transaction" as well as to limit "how penalties may be applied," including by imposing caps where multiple violations are "adjudicated in a single proceeding." *Id.* at 11-12. The FDA's guidance demonstrated its approach to "distinct" violations, including that the FDA would not count multiple violations in the first inspection, but would do so in subsequent visits. *Id.* at 13-15, 20. The Board further reasoned that the Center's enforcement policy gave effect to the statute's notice provisions, including through its guidance and the availability of hearings when civil money penalties are imposed on the basis of prior enforcement. *Id.* at 18-19. The Board re-imposed the $500 penalty as authorized under the schedule. *Id.* at 26. Orton petitioned for review.

III.

Orton argues that the $500 penalty imposed by the Board should be set aside under the Administrate Procedure Act as "not in accordance with law." 5 U.S.C. § 706(2)(A). In

particular, Orton contends that the TCA does not permit the Center's practice of charging multiple violations arising from a single inspection or transaction or the issuance of a warning letter for a first violation, without a hearing. Orton's petition thus implicates the consistency between the FDA's practices and the TCA.

The deference afforded to an agency interpretation of a statute "var[ies] with circumstances." *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001). An interpretation reached through a formal process, including adjudication, will ordinarily be reviewed under *Chevron*. *See id.* at 230-31. In this case, however, the interpretation that we now review did not originally arise through an FDA adjudication: instead, the Center expressed its position in guidance documents, upon which the Board in turn relied during the civil money penalty proceedings. Such "interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law [] do not warrant *Chevron*-style deference," and instead "are 'entitled to respect' . . . but only to the extent that those interpretations have the 'power to persuade.'" *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Orton purports to challenge both the Board decision and the guidance documents themselves, but we need not determine which form of the agency's interpretation is Orton's primary target: it makes no difference in the result here, since our conclusion does not require the valence of *Chevron* deference.

Under *Skidmore*, the weight a court affords to an agency interpretation "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."

Skidmore, 323 U.S. at 140. Ultimately, a court will uphold an agency determination under *Skidmore* if it is persuasive. *Christensen*, 529 U.S. at 587. Evaluating the statute "in this old-fashioned way," *Fed. Election Comm'n v. Craig for U.S. Senate*, 816 F.3d 829, 839 (D.C. Cir. 2016) (quotation marks omitted), assessing its text and structure, we conclude that the FDA's interpretation is persuasive. "[W]e need not reach the question of *Chevron* deference if the [agency] interpretation satisfies the requirements for *Skidmore* deference." *Union Neighbors United, Inc. v. Jewell*, 831 F.3d 564, 580 (D.C. Cir. 2016) (citing *Brown v. United States*, 327 F.3d 1198, 1205 (D.C. Cir. 2003) (quotation marks omitted).

A.

Orton posits that the TCA precludes the charging of multiple violations at one time based on certain procedural aspects of the statute as well as the broader legislative context. But the statute and the regulatory scheme support the agency's contrary conclusion, which has consistently informed its enforcement practices.

As an initial matter, the statute provides plainly for the imposition of civil penalties for violations of the tobacco requirements. *See* 21 U.S.C. § 333(f)(9). Although the statute does not expressly permit the charging of multiple violations from a single inspection or transaction, the law provides the FDA with the authority to impose civil penalties for *any* violations committed, absent such a restriction. The FDA's position that its enforcement authority permits it to impose penalties for each violation of the tobacco sale restrictions arising during a single inspection or transaction is a persuasive interpretation of the plain terms of the statute.

Orton argues that three procedural provisions combine to curtail the FDA's enforcement authority: the requirement of "timely and effective notice . . . to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check," that the FDA enact regulations establishing a hearing process and an "expedited procedure for the administrative appeal of an alleged violation," and that "a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet." *See* TCA § 103(q). But these provisions hardly demand the interpretation that Orton advocates. Notice before a "followup compliance check" refers to subsequent inspections – by the plain meaning of the words, "compliance check" is an event of inspection, not the incident of a violation. And "notice . . . of all previous violations" does not mean that the Center may not charge multiple violations, where the regulations support overlapping as well as discrete-but-concurrent violations and where the statute expressly contemplates the adjudication of multiple violations in a single proceeding, as discussed below. Instead, "all previous violations" must mean all violations previous to those charged. This conclusion preserves the integrity of the statutory scheme and reconciles the provisions within it. *See James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1093 (D.C. Cir. 1996) (noting the Court's "obligation to interpret the statute's provisions in harmony with each other"); *Nat'l Corn Growers Ass'n v. EPA*, 613 F.3d 266, 272 (D.C. Cir. 2010) (citing *Brown & Williamson Tobacco Corp.* for the proposition that a "statute must be interpreted as a 'coherent regulatory scheme' with 'all parts fit into a harmonious whole'").

The structure of the regulations promulgated under Section 387f(d), as directed by 21 U.S.C. § 387c(a)(7)(B), also cuts against Orton's proposed interpretation. First, Orton's position would render regulations superfluous with respect to retailer

conduct toward underage tobacco purchasers. Generally speaking, a retailer who sells a tobacco product to a minor, in violation of 21 C.F.R. § 1140.14(a)(1), likely only would do so without checking identification first, in violation of 21 C.F.R. § 1140.14(a)(2). Understanding these regulations as restricting separate conduct and supporting separate violations gives meaning to both age-related regulations in such circumstances. The distinction between the groups of tobacco purchasers to which the regulations relate further suggests that each of these regulations has independent significance: the requirement that a retailer verify age applies with respect to prospective tobacco purchasers up to 26 years old, while the sales restriction relates only to would-be purchasers under the age of 18. Accordingly, the regulations punish violations of the age-verification requirements for any purchaser under age 26, but the punishment becomes more severe when the violation also results in a minor being permitted to purchase tobacco – the concern at the core of the age-related regulations. Moreover, setting aside the overlap at issue here, it requires little imagination to envision an inspection revealing multiple violations of other sale restrictions. Perhaps a retailer sells a loose cigarette to a 25-year-old, without checking identification, violating 21 C.F.R. § 1140.14(a)(4) and (2). Or maybe a store offers loose cigarettes in a self-service vending machine, despite having no age restrictions on entry to that location, violating 21 C.F.R. § 1140.14(a)(4) and (3). If the statute counted single and multiple violations identically for purposes of the civil money penalties that may attach, the incentive for retailers to comply with each of the regulations would diminish.

When examining the varied, potentially overlapping conduct covered by these regulations, it merits note that the regulations themselves have a special history. Ordinarily, reliance on regulations to interpret the authorizing statute

would be misplaced. *See Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 609 (2013) ("[R]egulations, in order to be valid, must be consistent with the statute under which they are promulgated." (quoting *United States v. Larionoff*, 431 U.S. 864, 873 (1977)). But the regulations at issue here are unique because Congress in the TCA directed the agency to promulgate "identical" regulations to those promulgated by the Secretary of Health and Human Services in 1996, which were part of the prior regulatory regime that the Supreme Court struck down in *Brown & Williamson*. *See* 21 U.S.C. § 387a-1(a)(2). *Cf. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,396-01, § 897.14 (Aug. 28, 1996). Evidently, Congress legislated with these restrictions in mind. *See Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Curran*, 456 U.S. 353, 381-82 & n.66 (1982) ("re-enact[ing] a statute without change" or "incorporating sections of a prior law" demonstrate congressional intent to "le[ave] intact" contemporary interpretations); *cf. Pub. Citizen, Inc. v. U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 669 (D.C. Cir. 2003) (declining to rely on congressional ratification canon of interpretation where "no formal regulation addressed the question"). With these regulations in place at the direction of Congress, the statute is easily understood to permit multiple violations where multiple regulations were breached.

Structural characteristics of the statute confirm the strength of the FDA's interpretation and provide further reason to find it persuasive. The TCA recognizes the adjudication of multiple violations within a single proceeding where it caps civil money penalty liability for tobacco control "for all such violations adjudicated in a single proceeding." 21 U.S.C. § 333(f)(9). The reference to "violations" in the plural form demonstrates that a single proceeding may involve the simultaneous adjudication of more than one violation.

Orton asserts that the inclusion of this language in the section governing tobacco civil money penalties generally, but not within the provisions setting forth the specific procedures for retailers, indicates Congress's intention that multiple violations be adjudicated in discrete proceedings in the latter. Pet'r's Br. 31-32. However, as Orton concedes in the Reply, § 333(f)(9) by its plain terms applies to retailers as well as to any other entity doing business regulated by the TCA. Pet'r's Reply Br. 10. Moreover, there is no conflict between § 333(f)(9) and the specific procedures for civil money penalties against retailers – as noted above, the statute is otherwise silent as to whether multiple violations may be charged at once. It makes little sense that Congress would provide generally for the adjudication of multiple tobacco control violations in a single proceeding, but carve out retailers from that provision implicitly through a series of other procedures – without ever stating such an intention expressly. Nothing in the retailer provisions demands such a reading of the statute taken as a whole.

In contrast to the contorted exception that Orton would have us imply with respect to tobacco retailers, Congress clearly precluded the agency from finding multiple violations in a single transaction in other portions of the FDCA. In particular, the FDCA provides that "multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation" for the purpose of calculating civil money penalties with respect to violations of certain prescription drug sampling restrictions. 21 U.S.C. § 333(b)(2). The absence of such a limitation in the provisions governing tobacco violations suggests that multiple violations can arise from a single inspection or transaction, based on the presumption that "[w]here Congress includes particular

language in one section of a statute but omits it in another section of the same Act . . . Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted).

This principle holds true despite the enactment of the FDCA provisions at different times. Courts presume that Congress legislates against the backdrop of existing statutes. *See, e.g.*, *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) (courts "presume that Congress is knowledgeable about existing law pertinent to the legislation it enacts"); *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA*, 559 U.S. 573, 590 (2010). While that presumption "may be overcome by specific language that is a reliable indicator of congressional intent," *Arkansas Dairy Co-op Ass'n, Inc. v. U.S. Dep't of Agr.*, 573 F.3d 815, 829 (D.C. Cir. 2009) (citation omitted), the TCA included no such clear language distinguishing the new tobacco provisions from the rest of the FDCA into which they were incorporated. Assuming, as we must, that Congress understood the statutory framework into which it legislated the TCA, the explicit preclusion of multiple violations based on a single event of improper prescription drug sampling provides further persuasive force in favor of the FDA's position that the tobacco restrictions contain no such charging limitation.

We finally note that the *Skidmore* inquiry "consider[s] whether the agency has applied its position with consistency" as a factor in persuasion. *Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 399 (2008). While not dispositive, variation in an agency's interpretation will "count against" its persuasiveness. *See Landmark Legal Found. v. IRS*, 267 F.3d 1132, 1137 (D.C. Cir. 2001). Here, the Center's position shows no irregularity. To the contrary, the FDA guidance documents upon which the Board relied have been operative since 2013, without change to the Center's violation-counting

methodology. That the FDA has interpreted the statute consistently buttresses our determination that its reading merits our respect.

Accordingly, we deny Orton's petition with respect to its first argument that the FDA's methodology of counting violations is improper.

B.

We now turn to Orton's argument that the FDA violated the TCA by not providing a process to challenge an alleged first violation prior to issuance of a warning letter. As described above, the TCA directed the Secretary to issue guidance "providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties." TCA § 103(q)(1)(C). The FDA's regulations detail extensive procedures governing such hearings. However, the FDA treats first violations as falling outside of these civil money penalty procedures, as the penalty is $0.00 and a warning letter. Orton argues that this omission violates the TCA and Orton's procedural due process rights.

We disagree. The consequences from a first violation alone do not trigger notice and hearing requirements, either under the TCA or principles of procedural due process. The TCA requires such procedures only for the assessment of civil money penalties, and no such penalty attaches to a first violation. TCA § 103(q)(1)(C). While the notice requirement attaches to any alleged violation, *see id.* § 103(q)(1)(B), it is undisputed that Orton received a warning letter providing notice of the violations found during the first inspection. Orton does not explain why the warning letter itself is not sufficient notice.

Moreover, this Court has rejected the idea that an FDA warning letter itself is a consequence subject to judicial review. In *Holistic Candlers & Consumers Association v. Food & Drug Administration*, we explained that FDA warning letters, while potentially significant as bases for later enforcement, are not subject to review where "no legal consequences flow from the agency's conduct to [that point]." 664 F.3d 940, 944-45 (D.C. Cir. 2012) (citation omitted). The lack of legal consequences distinguishes an FDA warning letter in this context from an agency letter representing final agency action. *Cf. Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1030 (D.C. Cir. 2016) (warning letter carries legal consequences where its issuance is "dispositive" of notice and establishes "willfulness" in a later proceeding); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436-37 (D.C. Cir. 1986) (concluding that an EPA letter constituted reviewable agency action where it stated agency policy that certain products would be considered misbranded and the company would face cancellation of its registration). Because the warning letter issued to Orton does not determine Orton's rights or obligations or carry other legal consequences, the FDA's lack of a hearing procedure by which Orton could challenge the first violation is not unlawful.

As for Orton's constitutional claims, due process is required only where government action threatens a deprivation of life, liberty, or property. But Orton has failed to show that the mere issuance of a warning letter, absent further enforcement action, effects any such deprivation. "[R]eputation alone, apart from some more tangible interests such as employment, is [n]either 'liberty' [n]or 'property' by itself sufficient to invoke the procedural protection of the Due Process Clause." *Paul v. Davis*, 424 U.S. 693, 701 (1976); *see Trifax Corp. v. Dist. of Columbia* 314 F.3d 641, 643-44 (D.C. Cir. 2003). Orton has not alleged any such tangible effect here. *See Trifax*, 314 F.3d at 644.

Critically, a retailer has an opportunity to challenge the issuance of a first violation upon the later assessment of civil money penalties. During oral argument, counsel for the FDA clarified that a retailer can challenge the facts underlying a first violation during the adjudication of a subsequent violation: if a first violation is disproved, it will not be counted against a retailer. Oral Arg. at 24:17-28; 31:51-32:07. This is important because a first violation becomes legally significant when civil money penalties are assessed for violations identified during a subsequent failed inspection. At that point, the amount of penalty assessed moves up the civil money penalty schedule, based on the foundation of the first violation. As the first violation affects the amount of penalty assessed later, the concrete consequence of the first violation arises at that point. The FDA adjudication of the subsequent violation thus provides a meaningful opportunity for a retailer to be heard regarding the underlying first violation, at the time that the first violation carries legally significant effects. Due process requires nothing more, and for this reason, we reject Orton's second basis for its petition.

* * *

For the foregoing reasons, we deny Orton's petition.