Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Kathy and Johnny, Inc., d/b/a Conoco at Brighton Boulevard/Shell
Docket No. A-16-139
Decision No. 2775
March 6, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) appeals the Order of Default Judgment entered against Respondent Kathy and Johnny, Inc. by an Administrative Law Judge (ALJ). *Kathy and Johnny, Inc., d/b/a Conoco at Brighton Boulevard/Shell*, Docket No. FDA-2015-H-3524 (2016) (ALJ Decision). CTP sought to assess an $11,000 civil monetary penalty (CMP) on Respondent for six violations within a 48-month period of the FDA tobacco regulations promulgated under the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq*. One of the violations alleged by CTP was Respondent's use of a self-service display of tobacco products in a facility accessible to people under the age of eighteen (minors), which CTP alleged is prohibited under 21 C.F.R. § 1140.16(c). The ALJ raised the question, sua sponte, whether a transfer of a tobacco product to a consumer is necessary to establish a violation of section 1140.16(c). The ALJ concluded that unambiguous language in the statute and regulations "requires *a sale or distribution* as an element to violate 21 C.F.R. § 1140.16(c)." ALJ Decision at 6 (emphasis in original). The ALJ then determined that CTP had not established a violation of section 1140.16(c) because it had not alleged or demonstrated that a minor obtained a tobacco product from the self-service display in Respondent's facility. Consequently, the ALJ concluded that Respondent committed only five violations and reduced the CMP to $5,000.

For the reasons discussed below, we conclude that the ALJ's determination that Respondent's use of a self-service display of tobacco products did not violate section 1140.16(c) is legally erroneous. We conclude that the unambiguous language of the statute and regulations does not require a sale or transfer of a tobacco product to a person to establish a violation of 21 C.F.R. § 1140.16(c). We further explain that even if we were to find ambiguity in the wording of the Act and regulations, we would uphold CTP's interpretation because it is reasonable, consistent with the purposes of the Act and regulations, and longstanding. We therefore reverse the ALJ Decision in part, conclude that Respondent committed six violations within a 48-month period, and reinstate a CMP of $11,000.

Legal Background

Section 906(d)(1) of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1796 (2009) (TCA), amended the Act to authorize the Secretary of the Department of Health and Human Services to promulgate regulations that establish "restrictions on the sale and distribution of" tobacco products, "including restrictions on the access to" tobacco products "if the Secretary determines that such regulation would be appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). In addition, the Act prohibits doing any act to a tobacco product that results in the product being "misbranded." *Id.* § 331(k). A tobacco product is "deemed to be misbranded … if, in the case of any tobacco product distributed or offered for sale in any State … it is sold or distributed in violation of regulations" issued under the Act. *Id.* § 387c(a)(7)(B). The FDA may impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products …." *Id*. § 333(f)(9).

The FDA has promulgated regulations at 21 C.F.R. Part 1140 that set out "restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products and to reduce the life-threatening consequences associated with tobacco use." 21 C.F.R. § 1140.2.[1] The general responsibilities of tobacco manufacturers, distributors, and retailers are set forth in section 1140.10, which provides that "[e]ach manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part."

Among the requirements, no "retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age," 21 C.F.R. § 1140.14(a), and retailers 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" except that "[n]o such verification is required for any person over the age of 26," *id.* § 1140.14(b).

The regulation cited by CTP as the basis for the alleged violation at issue here, section 1140.16(c), is titled "Vending machines, self-service displays, mail-order sales, and other 'impersonal' modes of sale" and provides:

> (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

[1] This decision cites to the regulations in effect at the time of the alleged violations.

> (2) Exceptions. The following methods of sale are permitted:
>
> (ii) Vending machines … and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.[2]

The FDA uses the term "exempt facility" to mean a facility where no person younger than 18 years of age is permitted at any time.

The Act and the regulations governing FDA CMP hearings specify the dollar amounts for CMPs that FDA imposes based on the number of violations and the period of time in which they are committed.[3] During the period when Respondent's alleged violations took place, the maximum CMP amount for five violations within a 36-month period was $5,000; the maximum amount for six violations within a 48-month period was $11,000. 21 U.S.C. § 333 note; 21 C.F.R. § 17.2.

"The Center with principal jurisdiction over the matter," in this case, CTP, begins the CMP action by serving a complaint on the respondent. *Id.* § 17.5(a). A respondent must answer the complaint within 30 days of service of the complaint or request, within that period, an extension of time to file the answer. *Id.* § 17.9(a), (c); *see also id.* § 17.30(c) (providing that when a document has been served by mail, "an additional 5 days will be added to the time permitted for any response").

If service of the complaint is properly effected and the respondent does not file a timely answer, the ALJ "shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute" the ALJ "shall issue an initial decision … imposing: (1) The maximum amount of penalties provided for by law for the violations alleged; or (2) The amount asked for in the complaint, whichever amount is smaller." *Id.* § 17.11.

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[2] The other exception, set forth at subsection 1140.16(c)(2)(i), relates to mail order sales and is not at issue here.

[3] Section 103(q)(2)(A) of the TCA and section 17.2 of the regulations set out two parallel CMP schedules, with lower CMPs assessed against a retailer who has an "approved training program." 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The FDA stated in CMP guidance that it would use the lower schedule for all retailers until it had developed regulations establishing standards for training programs. *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions* at 13 (May 2015) (FDA Guidance), http://www.fda.gov/downloads/TobaccoProducts/Labeling /RulesRegulationsGuidance/UCM447310.pdf.

Effective September 9, 2016, the FDA removed the table of maximum CMPs from 21 C.F.R. § 17.2 and cross-referenced a new consolidated table of maximum CMPs "associated with statutory provisions authorizing such penalties for all HHS Agencies" at 45 C.F.R. § 102.3, which HHS issued on September 6, 2016. 81 *Fed. Reg.* 62,358 (Sept. 9, 2016); 81 *Fed. Reg.* 61,538, 61,567 (Sept. 6, 2016).

The regulations permit CTP or any respondent to appeal an ALJ decision to the Board. 21 C.F.R. § 17.47(a). The standard of review by the Board on a disputed issue of fact is whether the ALJ decision is supported by substantial evidence on the whole record. *Id.* § 17.47(k). The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Id.*

Case Background[4]

Respondent owns a retail establishment in Denver, Colorado. Administrative Record (AR) 14 ¶ 6. On February 23, 2013, an FDA-commissioned inspector observed a self-service display of Stoker's brand smokeless tobacco for sale on the counter in an area of Respondent's establishment that was open to the general public. Administrative Complaint, FDA-2013-H-1498, CRD Dkt. No. C-14-295, ¶¶ 9, 10.[5] On March 14, 2013, CTP issued a Warning Letter to Respondent stating that an inspector observed the self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c). *Id.* ¶ 10. The Warning Letter stated that failure to correct the violation may result in a CMP or other regulatory action by the FDA. *Id.* On March 27, 2013, Respondent's representative responded to the Warning Letter in an email stating that the self-service display of smokeless tobacco had been removed. *Id.* ¶ 11.

On June 19, 2013, Respondent sold a package of Newport Box cigarettes to a minor. *Id.* ¶ 1. In a Complaint dated November 25, 2013, CTP sought to impose a $250 CMP on Respondent for two violations within a 12-month period. *Id.* ¶¶ 1, 13, 23. To settle the case, Respondent's representative signed an Acknowledgment Form admitting that the February 23, 2013 and June 19, 2013 violations occurred, waiving Respondent's ability to contest the violations in the future, and stating that Respondent understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions. Administrative Complaint, FDA-2014-H-1885, CRD Dkt. No. C-15-352, ¶¶ 10, 11, (citing Acknowledgment Form, FDA Docket Number FDA-2013-H-1498, CRD Dkt. No. C-14-295).

On May 23, 2014, Respondent sold a package of Camel Crush Menthol cigarettes to a minor and failed to verify the age of the purchaser by photographic identification. *Id.* ¶ 1. In a Complaint dated November 10, 2014, CTP sought to impose a CMP of $2,000 against Respondent, alleging the two May 23, 2014 violations and re-alleging the two

[4] The case background is based on undisputed facts described in the ALJ Decision and documents in the administrative record, which was provided to the Board by FDA's Division of Dockets Management.

[5] Copies of the complaints filed in the prior cases involving the Respondent are attached to the ALJ Decision.

violations cited in the first Complaint. *Id.* ¶¶ 1, 9, 10. The parties settled the action after Respondent's representative admitted that all of the violations occurred; agreed to make sufficient payment to settle the matter; and waived the ability to contest the violations in the future. AR 14 ¶¶ 10, 11.

On June 10, 2015, Respondent sold a package of Newport Box cigarettes to a minor and failed to verify the age of the purchaser by means of photographic identification. *Id.* ¶ 8. In a Complaint dated October 5, 2015, CTP sought to impose a CMP of $11,000 on respondent based on six violations in a 48-month period: the two June 10, 2015 violations and the four previously-cited violations, including "Use of a self-service display in a non-exempt facility (21 C.F.R. § 1140.16(c)) on February 23, 2013." AR 1 ¶¶ 1, 10, 14. Respondent did not answer the October 5, 2015 Complaint.

By Order dated March 22, 2016, the ALJ dismissed the Complaint with prejudice because CTP did not provide adequate proof of service of the Complaint on Respondent and failed to submit a motion for issuance of a default judgment, after the ALJ told it to do both. AR 8. CTP appealed the dismissal. AR 9. On review, the Board determined that the ALJ abused his discretion in dismissing the Complaint with prejudice because the sanction was not reasonably related to the conduct for which it was imposed. *Kathy & Johnny, Inc., d/b/a Conoco at Brighton Boulevard/Shell*, DAB No. 2693 (2016). The Board remanded the matter to the ALJ for further proceedings. On remand, CTP filed an amended Complaint against Respondent. AR 14. The ALJ issued a default judgment after giving respondent an opportunity to make a substantive answer, to request an extension, or to demand a hearing. AR 16.

The ALJ Decision

As noted above, the ALJ held that the self-service tobacco product display in Respondent's facility observed on February 23, 2013 did not violate the tobacco regulations because, the ALJ concluded: 1) a sale or distribution of a tobacco product to a person is necessary to establish liability under the Act and regulations; and 2) CTP did "not allege that any Stoker's smokeless tobacco passed into the hands of a minor on February 23, 2013." ALJ Decision at 3-7. The ALJ noted that in a prior case that had settled, he asked CTP to brief the question whether a violation of section 1140.16(c) occurs if there is no evidence of a sale of a tobacco product to a consumer; the ALJ appended the relevant portion of CTP's brief in that matter to his Decision in this case. *Id.* at 4; FDA Docket No. FDA-2015-H-468, Complainant's Response to Order Re: Notice of Settlement Agreement. In the earlier appeal, CTP asserted that 21 C.F.R. § 1140.16(c) "is intended to restrict access to self-service displays." FDA Docket No. FDA-2015-H-468, Complainant's Response at 1. Therefore, "a retailer violates" the regulation "simply by having a self-service display" in a non-exempt facility; "there is no requirement that the retailer must sell a tobacco product to a minor (or any other individual) before a violation of this regulation may be charged." *Id.*

Citing section 1140.14(c), the ALJ stated that the "[r]egulations require that 'sales' of tobacco products occur through a direct, face-to-face exchange, without the assistance of any mechanical device, . . . lest the product become misbranded." ALJ Decision at 4. Section 1140.14(c) provides:

> (c) Except as otherwise provided in § 1140.16(c)(2)(ii), 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);

The ALJ did not, however, discuss the wording of the cross-referenced provision at section 1140.16(c), the regulation cited by CTP as the basis for the violation at issue. Rather, the ALJ continued, the "Secretary's mandate to create" section 1140.14(c) "appears in section [906(d)(4)(A)(i)][6] of the [TCA]," which required the Secretary to "promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products …." *Id.* The ALJ determined, "To violate these statutory and regulatory provisions as written, then, there must be an actual 'sale' or 'distribution' of product, a conclusion reinforced by use of the phrase 'for the purchase of such products.'" *Id.*

The ALJ observed that the Act and regulations do not expressly define the terms "sale" or "distribution." *Id.* Consequently, he looked to the common meaning of the terms, discussing definitions of "sale" and "sell" in the Uniform Commercial Code and Colorado statutes. According to the ALJ, "'Sell' can perhaps have [an] expansive meaning, to include 'offering for sale,'" but, he found, "both the statute and the regulation use the word 'sale.'" *Id.* at 5. The ALJ also explained that "the statutes of Colorado, where the Respondent is alleged to have committed the infractions," define "sale" for taxation purposes to "involve[] either the legal or equitable transfer of property." *Id.* (citing Colorado Revised Statutes § 39-26-102(10)). He then relied on this definition because, he determined, the Congress and the Secretary had not "preempted states' definitions by any regulation." *Id.*

The ALJ acknowledged that published FDA guidance indicated that the "mere presence of a vending machine in an establishment that permits people under the age of 18 to enter would be a violation of 21 C.F.R. § 1140.16(c)." *Id.* at 6. But he rejected the guidance because, he concluded, it did not "square[] with the actual language of the regulation, which requires an actual sale …." *Id.* The ALJ also determined that CTP's reading of the regulations was not entitled to deference because the FDA had "never taken this

[6] The ALJ cited "section 906(4)," but it appears he meant to cite section 906(d)(4)(A)(i), codified at 21 U.S.C. § 387f(d)(4)(A)(i).

position in any public notice or rule-making;" rather, "this is the litigation posture of the Agency before one of the Agency's [ALJs]." *Id.* The ALJ asserted that CTP had not "proven" the self-service display violation because CTP had not demonstrated "that any Stoker's smokeless tobacco passed into the hands of a minor on February 23, 2013." *Id.* at 3, 7. He therefore concluded that Respondent committed only five violations and reduced the CMP to $5,000.

Analysis

"As an administrative adjudicative body," the Board must follow "all applicable laws and regulations." *Orton Motor Co., d/b/a Orton's Bagley*, DAB No. 2717, at 6 (2016). Where the wording of a law is clear, the Board will apply it by its terms. When the law is silent or ambiguous, the Board will defer to a "program agency's interpretation of a statute that it is responsible for implementing and of the regulations that the agency has issued … as long as the interpretation is reasonable and the nonfederal party had timely and adequate notice of that interpretation or did not rely to its detriment on another reasonable interpretation." *Id.* (citing *Blackfeet Tribe*, DAB No. 2675, at 11 (2016); *Missouri Dep't of Soc. Servs.*, DAB No. 2184, at 2 (2008)).

For the reasons discussed below, we conclude that the ALJ's holding that a particular sale or distribution of a tobacco product to a consumer must occur in order to establish a violation of 21 C.F.R. § 1140.16(c) is inconsistent with the unambiguous language of the Act and regulations. Furthermore, we explain that even if we were to find ambiguity in the wording of the statute and regulations, we would defer to CTP's interpretation because it is reasonable, consistent with the purposes of the law, and longstanding. Moreover, CTP has provided retailers with ample notice of the meaning of the regulation in published guidance, and Respondent twice previously acknowledged that the self-service tobacco display on its premises in February 2013 violated section 1140.16(c).

1. CTP's interpretation is consistent with the language of the Act.

The Board has long recognized the basic rule of statutory construction on which the ALJ relied, that when a word is not defined by a statute, it should be construed in accordance with its ordinary or common meaning. *See, e.g., Lee G. Balos*, DAB No. 1541 (1995); *Health Sys. Agency of Cent. Georgia, Inc.*, DAB No. 341 (1982). Equally imperative, however, is the "cardinal rule that a statute is to be read as a whole … since the meaning of statutory language, plain or not, depends on context." *King v. St. Vincent's Hosp.*, 502 U.S. 215, 220 (1991) (citations omitted). The meaning of a word in isolation is not necessarily controlling in statutory construction. Rather, "Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis." *Dolan v. U.S. Postal Serv.* 546 U.S. 481, 486 (2006). The meaning of a statute

"is determined by reference to the language itself, the specific context in which that language is used, by purposes inferred from those directives or from the statute as a whole, and by the statute's overall structure." *Breton Lee Morgan, M.D.*, DAB No. 2264, at 5 (2009)(citations omitted), *aff'd*, *Morgan v. Sebelius*, 694 F.3d 535 (4th Cr. 2012). Moreover, federal courts have long determined that the Act "is to be interpreted broadly in order to protect public health." *United States v. Kaplan*, 836 F.3d 1199, 1208 (9th Cir. 2016) (citing *United States v. Article of Drug (Bacto–Unidisk)*, 394 U.S. 784, 798 (1969)), *petition for cert. filed* (U.S. Feb. 28, 2017) (No. 16-1036).

Consideration of these factors leads us to conclude that the ALJ erred by reading the terms "sale" and "distribution" in the Act and regulations in isolation, failing to give effect to the language of the statute and regulations as a whole, and contrary to the law's purposes. As set forth above, the wording of the statute prohibits "the doing of any . . . act with respect to" a tobacco product "**held for sale** . . . after shipment in interstate commerce" that results in the product being "misbranded." 21 U.S.C. § 331(k) (emphasis added).[7] A tobacco product is "deemed to be misbranded … if, in the case of any tobacco product distributed or **offered for sale** in any State … it is sold or distributed in violation of regulations prescribed under section 387f(d)" of title 21. 21 U.S.C. § 387c(a)(7)(B) (emphasis added). The Act authorizes the FDA to impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products." *Id.* § 333(f)(9).

The language of the Act quoted and emphasized above explicitly provides that a tobacco product may be "misbranded" while held or offered for sale, that is, while the product remains in the possession of a retailer and regardless whether it subsequently passes into the hands of a consumer. Furthermore, the meaning of the phrase "sold or distributed in violation of regulations prescribed under section 387f(d)" is illuminated by the language of the cross-referenced provision. Section 387f(d)(1) authorizes the Secretary to issue regulations limiting "the sale and distribution of a tobacco product, **including restrictions on the access to** ... the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health." (Emphasis added.) This wording plainly gives the Secretary the authority to promulgate regulations that solely pertain to consumer access to tobacco products.

[7] As the Board previously explained, while "the term 'misbranded' may seem an odd fit" for activities relating to tobacco products, "Congress chose in the TCA to graft FDA's role in tobacco regulation onto the existing mechanisms and terminology used for food and drug regulation." *Orton Motor* at 2.

2. CTP's interpretation is consistent with the plain language of the governing regulations.

Section 102 of the TCA expressly instructed the Secretary to reissue a regulation "identical in its provisions to part 897 of the regulations promulgated . . . in the August 28, 1996, issue of the Federal Register," with specific exceptions. In 2000, the Supreme Court struck down the earlier regulations as beyond the FDA's authority under the Act prior to the enactment of the TCA. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). Following the enactment of the TCA in 2009, the Secretary implemented section 102 by promulgating the final rule at 21 C.F.R. Part 1140. 75 Fed. Reg. 13,225 (March 19, 2010). "The fact that the statute thus effectively dictated the content of the regulations means that the regulations are particularly authoritative in their implementation of the statute's language and intent." *Orton Motor* at 8.

The wording of the regulations at Part 1140 unambiguously establishes that the presence of a self-service tobacco product display or vending machine in a retail facility accessible to minors constitutes a violation. Mirroring the terminology of the statute, 21 C.F.R. § 1140.1(b) states that a "failure to comply with any applicable provision in [Part 1140] in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded …." Under section 1140.10, "Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, **sells or** otherwise **holds for sale** comply with all applicable requirements under this part." (Emphasis added). We note that contrary to the ALJ's conclusion and as highlighted above, the regulations do use the term "sell," which according to the ALJ "can perhaps have a more expansive meaning, to include 'offering for sale ('he sells insurance'; 'that store sells cigarettes')…." ALJ Decision at 5. Thus, the language of sections 1140.1 and 1140.10, which the ALJ did not address, plainly contemplates that in certain circumstances, a retailer may "misbrand" a tobacco product while offering or holding it for sale, regardless whether the tobacco product ultimately passes into the hands of a minor or another consumer.

Furthermore, section 1140.14(e) provides that "[e]ach retailer shall **ensure that all self-service displays**, advertising, labeling, and other items, **that are located in the retailer's establishment and that do not comply** with the requirements of this part**, are removed or are brought into compliance** with the requirements under this part." (Emphasis added). Section 1140.16(c), in turn, reads:

> (c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale*. (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. **Examples of methods of sale that are not permitted include vending machines and self-service displays.**
>
> (2) *Exceptions*. The following methods of sale are permitted:

* * *

> (ii) Vending machines … and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(Emphasis added.) The highlighted language of the companion regulations at 21 C.F.R. § 1140.14(e) and 1140.16(c) makes clear that a retailer is required to remove any self-service display or vending machine on its premises unless minors are not permitted in the facility at any time. Pursuant to section 1140.1, a retailer's failure to comply with this requirement in itself constitutes a "misbranding." We therefore agree with CTP that "[u]nder the plain language of the tobacco regulations, having a self-service display or vending machine in a facility that permits entry to minors is a violation of the law, and CTP properly seeks civil money penalties from retailers who have such self-service displays and vending machines, without evidence of a sale to a consumer." CTP Br. at 20.

3. CTP's interpretation is consistent with the intent of the TCA.

We further conclude that even if we were to find the language of the statute or regulations ambiguous, we would defer to CTP's interpretation of the applicable provisions because it is reasonable and consistent with the congressional findings underlying the TCA and the express purposes of the legislation.

The TCA set out 49 congressional findings and 10 express purposes. TCA §§ 2, 3. Among the findings, Congress determined that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," and "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products. . . ." TCA § 2(1), (4). In addition, Congress found, "Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, **comprehensive restrictions on the sale, promotion, and distribution of such products are needed**." TCA § 2(6) (emphasis added). With respect to the types of comprehensive restrictions needed, Congress elaborated: The FDA's tobacco regulations "and the restriction on the sale and distribution of, including **access to** and the advertising and promotion of, **tobacco products** contained in such regulations are substantially related to accomplishing the public health goals" of the legislation. TCA § 2(30) (emphasis added).

Based on these and other findings, Congress articulated the purposes of the TCA to include: "to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco"; and "to continue to permit the sale of tobacco products to adults in conjunction with measures **to ensure that they are not sold or accessible to underage purchasers** …." TCA § 3(2), (7) (emphasis added).

The congressional findings and express purposes of the legislation make clear that Congress determined that restrictions on access to tobacco products are a necessary component to comprehensive regulations designed to prevent "new generations of tobacco-dependent children and adults." The ALJ's interpretation of the statutory language would undermine this public health goal by effectively permitting minors to have access to impersonal modes of sale from which they could obtain tobacco products. Indeed, as discussed below, it was precisely with this concern in mind that the FDA crafted the regulations establishing the restrictions on vending machines and other impersonal modes of sale, and the narrowly-drawn exceptions to those restrictions.

4. The ALJ's interpretation is inconsistent with the intent of the regulations and longstanding FDA policy.

Previously, the Board has explained that "[d]eference to an agency interpretation is especially appropriate where the interpretation has been a consistent one predating the litigation in which the agency is seeking to apply it." *Orton Motor* at 6. The history of the tobacco regulations and the FDA's published guidance supports CTP's contention that the FDA has consistently and for many years interpreted the wording of 21 C.F.R. § 1140.16(c) "as a prohibition on self-service displays and vending machines in facilities that permit entry to minors." CTP Br. at 7. As noted above, section 102 of the TCA directed the Secretary to reissue regulations promulgated in 1996 at 21 C.F.R. Part 897. Although the TCA did not expressly adopt the preamble to the earlier regulations (much of which addressed the authority of the earlier rule and is no longer relevant), discussions in the preambles to the 1995 proposed rule and 1996 final rule further clarify the intent of the regulation that was reissued at section 1140.16(c).

In 1995, the FDA first proposed the regulation at issue here to ban self-service tobacco product displays and vending machines without exception:

> *Vending machines, self-service displays, mail-order sales, and other 'impersonal' modes of sale*. Cigarettes and smokeless tobacco products may be sold only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include, but are not limited, vending machines, self-service displays, mail-order samples, and mail-order redemption of coupons.

60 Fed. Reg. 41,314, 41,374 (Aug. 11, 1995). The FDA stated in the preamble to the proposed rule that the objective of the regulation was to "prohibit specifically cigarette vending machines [and] self-service displays," among other "impersonal modes of sale." *Id.* at 41,324. "The proposed rule," the FDA explained, "would, if finalized, . . .

eliminate cigarette vending machines and self-service displays . . . ." *Id*. at 41,357 (emphasis added). The preamble also included a discussion of the studies supporting a ban on impersonal modes of sale, and explained the reasoning for the prohibition as follows:

> Vending machines and self-service displays offer young people easy access to cigarettes and smokeless tobacco products even though State laws prohibit cigarette sales to minors and some States or localities require locking devices on or specific placement of vending machines. Thus, the requirement that retailers physically provide the product to the consumer substantially advances the purpose of protecting the public health by eliminating easy, unmonitored access to such products by underage persons. This requirement is not disproportionate to the risk presented by vending machines and self-service displays because many studies demonstrate how easily minors can purchase cigarettes from vending machines, and other documents indicate that shoplifting is another method young people use to acquire these products.

Id. at 41,359. The preamble further explained that the prohibition of self-service tobacco product displays was "intended to prevent young people from helping themselves to tobacco products and to increase the direct interaction between the sales clerk and the underage customer." *Id.* at 41,325.

When the FDA issued the final tobacco regulations in 1996, the preamble explained that the proposed prohibition on vending machines at 21 C.F.R. § 897.16(c) generated more comments than any other provision aimed to reduce access to tobacco products by young people. After discussing the comments in support of or against the ban, and the studies and other evidence supporting the ban, the FDA amended the regulation to provide a limited exception for vending machines and other impersonal modes of sale. Specifically, the FDA stated that the revised regulation (identical to the regulation subsequently promulgated at section 1140.16(c)) would "allow vending machines and self-service displays in facilities that are totally inaccessible to people under 18 and employ no persons below age 18."[8] 61 Fed. Reg. 44,396, 44,435 (Aug. 28, 1996). The FDA explained that it provided the exemption "[i]n response to comments criticizing the restrictions as inconveniencing adults," but made clear that the exemption was "narrowly drawn" and "accommodate[d] adults only in locations where young people, in fact, have no access at any time." *Id.* 44,427, 44, 450. The FDA also stated that the final rule added a new section 897.14(e) (subsequently promulgated at section 1140.14(e)) "to clarify that each retailer is responsible for removing all violative self-service displays, advertising, labeling, and other items located in the retailer's establishment or for bringing those items into compliance with the requirements in this rule." *Id.* at 44,427.

[8] The final regulations also included the exception for certain mail-order sales now codified at section 1140.16(c)(2)(i). *Id.* at 44,617.

The discussions in the preambles to the proposed and final rules thus unquestionably establish that the FDA intended the mere presence of a self-service tobacco display or vending machine in a non-exempt retail facility to constitute a violation subject to penalty.

Furthermore, in June 2010, three months after the FDA promulgated the regulations at 21 C.F.R. Part 1140 pursuant to the TCA, CTP published draft guidance for the tobacco industry, titled *Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*. Included in the guidance was the following explanation of the regulation at issue:

> *§1140.16(c)--Vending machines, self-service displays, mail order sales and other "impersonal" modes of sale*
>
> If you are a retailer, the regulations require you to sell cigarettes or smokeless tobacco to your customers in a direct, face-to-face exchange, with limited exceptions. This section reinforces this requirement by prohibiting retailers from engaging in "impersonal" modes of sale. There are, however, two important exceptions. These exceptions are:
>
> ***
>
> > Vending machines and self-service displays are permitted in facilities where no one younger than 18 years of age is present or permitted to enter at any time.
> >
> > Under this exception, a retailer may have a vending machine or self-service display only if:
> > - NO ONE younger than 18 years of age is present at the facility at <u>any time</u>, and
> > - NO ONE younger than 18 years of age is permitted in the facility at <u>any time.</u>
> >
> > The purpose of this exception is to allow retailers to use vending machines and self-service displays if their retail facility, whether it's a bar, a private club, or a factory, is off limits to anyone younger than 18 years of age at all times.[9]

[9] Available at https://www.regulations.gov/document?D=FDA-2010-D-0277-0002.

(Emphasis in original.) The FDA revised the draft guidance in March 2011, but made no change to the above-quoted language.[10] When the FDA finalized the guidance in August 2013, it explained the meaning of section 1140.16(c) for retailers as follows:

> If you are a retailer, the regulations require you to sell cigarettes or smokeless tobacco to your customers only in a direct, face-to-face exchange, subject only to limited exceptions, as described below. This section reinforces this requirement by prohibiting retailers from engaging in "impersonal" modes of sale.
>
> The two limited exceptions are:
>
> ***
>
> Vending machines and self-service displays are permitted in facilities where no one younger than 18 years of age is present, or permitted to enter, at any time. The purpose of this exception is to allow retailers to use vending machines and self-service displays as long as they ensure that no person younger than 18 years of age is present in their facility or permitted to enter at any time.[11]

The above-quoted provisions in CTP's guidance establish that since March 2010, CTP has consistently read the regulation at 21 C.F.R. § 1140.16(c) to prohibit self-service displays and vending machines except in facilities that are completely inaccessible to people under eighteen. We therefore reject the ALJ's conclusion that CTP's position in this case is merely a "litigation posture."

Moreover, there is no evidence that CTP has ever acted inconsistently with the guidance or that Respondent had no notice of the interpretation in the guidance. To the contrary, as summarized in the background section of this decision, the Respondent in this case previously signed written acknowledgements to settle two earlier actions admitting that its self-service tobacco product display, observed on February 23, 2013, was accessible to minors and its use of this display therefore constituted a violation of the tobacco regulations, subject to penalty. Administrative Complaint, FDA-2014-H-1885, CRD Dkt. No. C-15-352, ¶¶ 10, 11 (citing Acknowledgment Form, FDA-2013-H-1498); AR 14 ¶ 11 (citing Acknowledgment Form, FDA-2014-H-1885).

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[10] Compare *id.* to *Revision to Draft Guidance for Industry, Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents*, at 19-20 (March 2011), available at https://www.regulations.gov/document?D=FDA-2010-D-0277-0006.

[11] *See Guidance for Industry, Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, at 20-21 (August 2013), available at http://www.fda.gov/downloads/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm248241.pdf.

Conclusion

For the reasons explained above, we reverse the ALJ's determination that Respondent did not commit a violation of 21 C.F.R. § 1140.16(c) on February 23, 2013. We affirm the ALJ's determination that Respondent committed five additional violations on June 19, 2013, May 23, 2014, and June 10, 2015. We therefore conclude that Petitioner committed six violations of the tobacco regulations within a 48-month period and impose a CMP of $11,000 for the violations.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Christopher S. Randolph
Presiding Board Member