

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Chambers Drive, Inc., d/b/a Dynasty Deli Quick Stop,

Respondent.

Docket No. C-12-310

ALJ Ruling No. 2012-3

Date: August 23, 2012

RULING AND ORDER

The Center for Tobacco Products (CTP) charges that Respondent, Chambers Drive, Inc., d/b/a Dynasty Deli Quick Stop (Dynasty Deli), violated the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 331(k)) and regulations (21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1)), because its employees sold tobacco products to a minor and failed to verify the age of a person purchasing them. Respondent denies the charges.

CTP now moves for a summary decision. Because this case presents genuine issues of material fact, I deny CTP's motion.¹

Background

The Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. 111-31, 123 Stat. 1776 (2009), amended the Food Drug and Cosmetics Act (Act). Among its

¹ With its motion and memorandum in support, CTP has filed three exhibits (CTP Exs. 1-3), which include Exs. 1-A through 1-N. Respondent, Dynasty Deli, which is not represented by counsel, has filed an answer but did not respond to the motion.

provisions, the statute prohibits “misbranding” of a tobacco product, and provides that a tobacco product is “misbranded” if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); 21 U.S.C. § 387(c)(a)(7)(B); 21 C.F.R. § 1140.1(b). Section 906(d) (21 U.S.C. § 387f(d)) authorizes the Food and Drug Administration (FDA) to regulate tobacco products, including their retail sales. *See also* 21 U.S.C. § 331 *et seq.*² Pursuant to that authority, the FDA has published regulations, which, among other provisions, prohibit the sale of cigarettes and smokeless tobacco to anyone under the age of 18. 21 C.F.R. § 1140.14(a). Retailers must verify the purchaser’s age by means of a photographic identification containing the bearer’s date of birth. 21 C.F.R. § 1140.14(b)(1).

In Mississippi (and other states), FDA-commissioned state inspectors check tobacco retailers for compliance with the tobacco regulations. *See* 21 U.S.C. § 372(a)(1)(B)(i); CTP Ex. 1 at 2 (Goldman Decl. ¶¶ 3, 4). Among other strategies, inspectors accompany minors to retail establishments, where the minors attempt to purchase tobacco products. CTP Ex. 1 at 2 (Goldman Decl. ¶ 5).

If the FDA determines that the retailer violated FDA rules, it must give the retailer “timely and effective notice” of each alleged violation before it conducts a follow-up compliance check; it must also give notice of all previous violations before it can charge the retailer. TCA § 103(q)(1)(B), (D); 21 U.S.C. § 333 (Guidance); *see also* CTP Ex. 1 at 6 (Goldman Decl. ¶ 12). Consistent with these requirements, the FDA sends the retailer a warning letter the first time it finds a violation. That letter lists the alleged violations, warns of future inspections, and explains the consequences of future violations. CTP Ex. 1 at 3-4 (Goldman Decl. ¶ 7).

The FDA may impose penalties, including civil money penalties (CMPs) for violations. The amount of the CMP is related to the number of violations committed within a 24-month period and increases significantly with every additional violation.³ Where, as

² The CTP is the division of the Food and Drug Administration (FDA) that oversees implementation of the Tobacco Control Act.

³ The statute calls for two schedules of maximum penalties: one for retailers with an approved training program and one for retailers without such a program, for whom the amounts should be higher. However, until the FDA promulgates regulations establishing standards for approved retailer training programs, it imposes the lower range of penalties for all retailers. The penalty for two violations is \$250; the penalty for three violations is \$500; the penalty for four violations is \$2,000; the penalty for five violations is \$5,000, and the penalty for six violations is \$10,000. TCA § 103(q)(2); 21 U.S.C. § 333 (Guidance); <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252810.htm>.

here, CTP alleges that the retailer violated regulations three times within a 24-month period, it imposes a \$500 CMP. Significantly, under current FDA policy, all violations listed in the warning letter count as one for purposes of calculating the penalty.

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252810.htm>.

Discussion

Here, Dynasty Deli is a state-licensed tobacco retailer, located in Booneville, Mississippi. CTP Ex. 1 at 6-7 (Goldman Decl. ¶ 14); CTP Ex. 1-A. CTP alleges that, three times in a 24-month period, Dynasty Deli employees violated federal regulations restricting the sale and distribution of cigarettes and smokeless tobacco. Specifically, according to CTP:

- On June 9, 2011, a clerk at Dynasty Deli sold smokeless tobacco (Grizzly Long Cut Wintergreen Moist Snuff) to a minor, who made the purchase under the supervision of FDA-commissioned inspector, Randy Tutor. Complaint ¶ 10; CTP Ex. 1-C.
- On June 9, 2011, the Dynasty Deli clerk did not verify the minor's age prior to selling him the tobacco product. Complaint ¶ 10; CTP Ex. 1-C.
- In a warning letter dated August 25, 2011, CTP advised Respondent of the alleged June 9 violations, instructed the retailer to stop violating the tobacco regulations, and warned that failing to correct the violations could "result in regulatory action being initiated . . . without further notice. These actions may include, but are not limited to, a [CMP], no-tobacco-sale order, seizure, and/or injunction." Complaint ¶ 10; CTP Ex. 1-E.⁴
- On October 18, 2011, a clerk at Dynasty Deli sold smokeless tobacco (Grizzly Long Cut Wintergreen Moist Snuff) to a minor, who made the purchase under the supervision of FDA-commissioned inspector, Randy Tutor. Complaint ¶ 9; CTP Ex. 1-K.
- On October 18, 2011, the Dynasty Deli clerk did not verify the minor's age prior to selling him the tobacco. Complaint ¶ 9; CTP Ex. 1-K.

Respondent categorically denies these allegations. In its March 1, 2012 answer, Respondent Store Manager Khaled Aljalal declares that all employees deny selling tobacco products to minors. He also asserts that he checked the store's security cameras

⁴ In keeping with the policy mentioned above, CTP counts as one the two June 9 violations listed in the warning letter.

“to see if anyone came to the store on those dates and gave a ticket to any of the employees,” but saw nothing.

I am authorized to grant a motion for summary decision “if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.” 21 C.F.R. § 17.17(b). Here, Respondent’s answer shows that virtually all the material facts are in dispute. Dynasty Deli employees deny selling tobacco products to minors; and they deny failing to verify a purchaser’s age.

Moreover, in examining the evidence for purposes of determining the appropriateness of a summary decision, I must draw all reasonable inferences in the light most favorable to the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962). Drawing those inferences in Respondent’s favor here, I could not find that CTP is entitled to judgment as a matter of law.

CTP rests its case on some remarkably weak evidence, which suggests that it may not be able to prove its case, even in the absence of witness declarations from Respondent, Dynasty Deli. Not one of CTP’s witnesses claims that he observed the alleged violations. The two minors say that they worked with Inspector Randy Tutor one to two days per week, visiting approximately ten retail establishments per day. CTP Ex. 2 at 1 (Poe Decl. ¶ 3); CTP Ex. 3 at 1 (Tutor Decl. ¶ 3). Witness Kolton Poe says that he was 17-years-old in June 2011, when he worked with Inspector Tutor. CTP Ex. 2 at 1 (Poe Decl. ¶¶ 1, 2). He “recall[s] visiting retail establishments that sold tobacco products in Booneville, Mississippi,” and that he was able to purchase Grizzly Long Cut Wintergreen Snuff or Newport cigarettes at every establishment. CTP Ex. 2 at 2 (Poe Decl. ¶¶ 5, 6). But he does not mention visiting Respondent, Dynasty Deli. From this, I could reasonably infer that Witness Poe never set foot in Dynasty Deli.

Witness Timothy Tutor (who is not related to Inspector Tutor) says that he was born in December 1994, and worked with Inspector Tutor from February 2011 to February 2012. CTP Ex. 3 at 1 (Tutor Decl. ¶¶ 1, 2). He also remembers visiting retail establishments in Booneville, Mississippi, and “specifically recall[s]” visiting an establishment in Booneville named Dynasty Deli Quick Stop. CTP Ex. 3 at 2 (Tutor Decl. ¶ 5). He says that he was able to purchase Grizzly Long Cut Wintergreen Snuff “at the majority of establishments” he visited, but, significantly, he does not claim that he purchased snuff or anything else at Respondent’s establishment. CTP Ex. 3 at 2 (Tutor Decl. ¶ 6). From this, I could reasonably infer that Witness Tutor made no purchases from Dynasty Deli.

CTP submits no receipts establishing that any purchase was made from Dynasty Deli on June 9, October 18, or any other day.

CTP submits no declaration from Inspector Tutor, who has been deployed to Afghanistan and is currently unavailable. Instead, it relies on the inspector's business records and practices to prove its case. While likely admissible in these proceedings, CTP should be prepared to show that it had systems in place to prevent, or at least minimize errors. Drawing all reasonable inferences in the light most favorable to Dynasty Deli, however, I infer that CTP had no such systems in place. In fact, Inspector Tutor's reports suggest a system rife with the potential for errors. According to the minor witnesses, they accompanied Inspector Tutor to ten retailers per day. CTP Ex. 2 at 1 (Poe Decl. ¶ 3); CTP Ex. 3 at 1 (Tutor Decl. ¶ 3). The inspector did not, as a matter of course, photograph the establishments he visited in order to demonstrate that he had been there. His "diaries" for June 9 and October 18 say that he was in Booneville, Corinth, Baldwyn, and Tupelo, but do not mention specific visits to Dynasty Deli. CTP Exs. 1-D, 1-L. The minors allegedly purchased identical products (with identical bar codes) at multiple establishments throughout the day, and the inspector did not photograph the purchases until after he returned to his office. CTP describes no method by which he insured that the tobacco product he eventually photographed was the same product the minor purchased at Dynasty Deli. CTP Ex. 1-C at 3-7; CTP Ex. 1-J at 3-7. Although Inspector Tutor drafted narrative reports, he did so only after he returned to his offices, increasing the risk of confusion and error. CTP Exs. 1-C, 1-J.⁵

CTP Supervisory Safety Officer Tara Goldman notes that, during the inspections, inspectors also record their inspection information into the FDA's Tobacco Inspection Management System (TIMS), a "web interface," and CTP produces copies of what appear to be TIMS reports. These reports indicate that the minors purchased smokeless tobacco at Dynasty Deli on June 9 and October 18. CTP Exs. 1-B, 1-I. While this evidence appears to link Respondent Dynasty Deli with the purchases of tobacco products, as alleged, Respondent has every right to challenge their reliability and, at a minimum, to cross-examine CTP's witnesses about them.⁶

⁵ According to the reports, Inspector Tutor drafted them after returning to his office the same day the minors made their purchases. According to CTP Supervisory Safety Officer Tara Goldman, inspectors typically take photographs and draft their narrative reports within 24-72 hours after the close of the inspection. CTP Ex. 1 at 2-3 (Goldman Decl. ¶ 5). The longer the delay between inspection and reporting, the greater the likelihood of error.

⁶ These reports constitute the sole evidence directly linking Dynasty Deli with the violations. I am not convinced that I can appropriately enter judgment against Respondent based on this evidence, inasmuch as Respondent will not have the opportunity to cross-examine the purported initiator of the reports, Inspector Tutor. The parties will have an opportunity to address this issue before I decide the case.

