Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

J. Peaceful, L.C. d/b/a Town Market
Docket No. A-16-105
Decision No. 2742
October 21, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

J. Peaceful, L.C. d/b/a Town Market (Respondent) appeals the May 24, 2016 Initial Decision of an Administrative Law Judge sustaining a $250 civil money penalty (CMP) against Respondent for two instances of selling tobacco products to a person under 18 years of age within a 12-month period. *J. Peaceful, L.C. d/b/a Town Market*, DAB CR4614 (2016) (ALJ Decision). The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) imposed the CMP based on undercover inspections in September 2014 and January 2015 during which, the ALJ found, Respondent sold cigarettes to a person under the age of 18 years.

Respondent timely requested review of the ALJ Decision. For the reasons explained below, we find the ALJ Decision to be free of legal error and supported by substantial evidence. We therefore affirm the decision and sustain the CMP.

Applicable Law

The Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq*., prohibits the "misbranding" of a tobacco product held for sale after shipment in interstate commerce and authorizes CMPs against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333(f)(9). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under the Act. 21 U.S.C. § 387c(a)(7)(B). The Act directed the Secretary to establish the CTP within the FDA and authorized the Secretary to issue regulations restricting the sale and distribution of tobacco products. 21 U.S.C. §§ 387a(e), 387f(d).

The regulations, at 21 C.F.R. Part 1140, prohibit the sale of cigarettes or smokeless tobacco "to any person younger than 18 years of age" (i.e., a minor) and require retailers to "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[.]" 21 C.F.R. § 1140.14(a), (b)(1), (2) (2013), now at 21 C.F.R. § 1140.14(a)(1), (a)(2) (81 *Fed. Reg.* 28,974 29,103 (May 10, 2016)). The failure to comply with the applicable provisions of Part 1140 in the sale, distribution, and use of cigarettes and smokeless tobacco "renders the product misbranded" under the Act. 21 C.F.R. § 1140.1(b).

The Act and the regulations governing FDA CMP hearings, at 21 C.F.R. Part 17, specify in dollar amounts the CMPs that FDA imposes for violations based on the number of violations and the period of time in which they are committed. The law and 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 has stated in CMP guidance documents that it will use the lower schedule for all retailers until it has developed regulations establishing standards for training programs. *Guidance for Industry and FDA Staff – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* at 13 (May 2015)[1] (FDA Guidance); *see also Guidance for FDA and Tobacco Retailers – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* at 8-9 (June 2014).[2] For the time period relevant here, CTP assessed a CMP of up to $250 for the second violation (following a first violation with a warning) within a 12-month period. 21 U.S.C. § 333 note; 21 C.F.R. § 17.2 (table).[3]

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a "presiding officer" who is "an administrative law judge qualified under 5 U.S.C. 3105." 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiated this case before the ALJ by serving its Complaint on Respondent and filing it with the Civil Remedies Division of the Departmental Appeals Board (DAB). The regulations require a respondent to answer the complaint within 30 days or request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9.

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[1] http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf accessed October 6, 2016.

[2] http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf accessed October 6, 2016.

[3] 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, 61,565 (Sept. 6, 2016). The penalty for a second violation within 12 months for a retailer with an approved training program was increased in the new, consolidated table from $250 to $275, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 2015, Public Law. No. 114–74 (Nov. 2, 2015). 81 *Fed. Reg.* at 61,538, 61,565-67.

Before the ALJ, the parties may request from each other production of documents "that are relevant to the issues before" the ALJ; a party must provide documents within 30 days of receipt of a request for production, and may file a motion for a protective order within 10 days of receipt of a request for production. 21 C.F.R. § 17.23(a), (d)(1). The ALJ may grant a motion for a protective order, in whole or in part, if he or she finds that the request for production is unduly costly or burdensome, will unduly delay the proceeding, or seeks privileged information. 21 C.F.R. § 17.23(d)(2).

A respondent may appeal the ALJ's decision (which the regulations refer to as the "initial decision") to the Departmental Appeals Board (Board). 21 C.F.R. §§ 17.45, 17.47. The Board may "decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion)," or "reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined" by the ALJ. 21 C.F.R. § 17.47(j).

Case Background[4]

CTP by complaint dated June 9, 2015 sought a $250 CMP against Respondent for selling tobacco products (cigarettes) to a minor on September 24, 2014 and January 29, 2015, in violation of 21 C.F.R. § 1140.14(a). CTP alleged that on September 24, 2014, at approximately 6:07 p.m., James Naso, a CTP inspector and FDA commissioned officer working for a CTP contractor, accompanied a "confidential state-contracted" minor into Respondent's establishment, Town Market, in Naples, Florida, and witnessed her purchase a package of cigarettes in violation of the regulations. CTP Complaint at 1-2; CTP Ex. 1, at 1-3 (Naso decl.). CTP provided Respondent a "Notice of Compliance Check" on September 26, 2014 and a warning letter on October 16, 2014 reporting the violation and warning that further violations could result in CMPs or other actions.[5] CTP Complaint at 3. Respondent admits having made this sale to a minor, and attributes it to an "honest mistake" made "under stress" by a cashier. Respondent's Notice of Appeal of ALJ Decision (NA) at 4-5.

[4] The factual information presented in this section is undisputed and is taken from the ALJ Decision and the administrative case record before the ALJ. It is not intended to serve as new findings or substitute for any findings in the ALJ Decision.

[5] CTP alleged a second violation during the first sale on September 24, 2014 – failure to verify the age of a person purchasing tobacco products by means of photographic ID containing the bearer's date of birth – but stated that it has "adopted a policy of counting the regulation violations cited in the first Warning Letter as a single violation." CTP Resp. to NA at 2 n.2.

CTP alleged that on January 29, 2015, at approximately 4:43 p.m., the same minor again purchased a package of cigarettes at Respondent's establishment in violation of the regulations while the inspector Mr. Naso waited outside. CTP Complaint at 1-2; CTP Ex. 1, at 2-3. CTP with the complaint enclosed Mr. Naso's narrative report stating that he confirmed that the minor did not have any tobacco products prior to entering the establishment and exited the establishment with a pack of cigarettes, and that she had an ID showing her actual date of birth, which she reported having provided to a Town Market employee. CTP Ex. 4. CTP provided Respondent a "Notice of Compliance Check" on February 2, 2015 reporting the violation. Complaint at 1-2. Respondent denies having made this sale to a minor.

Respondent timely answered CTP's complaint and requested an ALJ hearing. Each party requested discovery of documents and moved for a protective order. The ALJ determined that Respondent's requests were overbroad and were irrelevant to the issue before him (whether Respondent violated applicable regulations and whether the CMP amount is reasonable) and could result in substantial prejudice to CTP's ability to conduct confidential investigations. Therefore, the ALJ granted CTP a protective order for documents related to other CTP inspections in Florida, information about pay and expenses of FDA commissioned officers and minors conducting inspections in Florida, the minors' resumes and pictures, and correspondence between CTP and the contractor administering CTP's inspections in Florida. Protective Order at 4-5 (Sept. 11, 2015). The ALJ also ordered CTP to provide a privileged document log for each document it claimed contained privileged information. *Id*. at 5.

The ALJ denied Respondent a protective order from CTP's requests for financial information for fiscal year 2014, including audited financial statements and federal tax returns, on the ground that CTP needed the documents to meet its burden of proving the appropriateness of the $250 CMP, including Respondent's ability to pay the penalty, as required by 21 C.F.R. § 17.33(b) (CTP "must prove respondent's liability . . . by a preponderance of the evidence"). Protective Order (Aug. 26, 2015). The ALJ, however, also ruled that Respondent need not provide the requested financial documents if it verified in writing that it was able to pay the $250 penalty if found liable and that the penalty will not materially affect Respondent's ability to continue to do business. *Id*. at 3. Respondent then provided the written verification.

The ALJ in the same order also denied Respondent a protective order from CTP's requests for documents relating to Respondent's inventory of tobacco products during September 2014 and January 2015, and Respondent's sales of tobacco products on the dates of the two sales. *Id*. at 4-5. The ALJ rejected Respondent's arguments and found the request to be narrowly tailored and not overly burdensome to produce, and reasonable for CTP to meet its burden under 21 C.F.R. § 17.33(b). *Id*. The ALJ, however, granted Respondent a partial protective order from CTP's request for documents related to the

identity of persons working at Respondent's store on the dates of the two sales, finding it unduly burdensome with respect to those not involved with the sale of tobacco products. The ALJ also limited the request to employees who as part of their job sold or supervised the sale of tobacco products. *Id*.

Respondent then moved that the ALJ recuse himself on the ground that "it is clear from the Protective Order issued on September 11, 2015, that . . . the Administrative Law Judge is under the 'clout' of the Complainant, therefore this Case cannot be heard impartially due to a conflict of interest." R. Motion for ALJ Recusal (Sept. 15, 2015). The ALJ denied the motion for recusal. Order Denying Motion to Recuse (Sept. 18, 2015).

Respondent then filed with the Board a notice of intent to appeal the ALJ's protective orders and the order denying recusal, under regulations permitting interlocutory appeals of ALJ rulings before the ALJ issues the decision in the appeal. 21 C.F.R. § 17.18, "Interlocutory appeal from ruling of presiding officer." That regulation permits interlocutory appeals of ALJ rulings "if the presiding officer [i.e., the ALJ] certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest." 21 C.F.R. § 17.18(b). The Board ruled that it had no authority to review the orders because the notice of intent to appeal did not include the required ALJ certification and contained no indication that Respondent planned to seek ALJ certification before filing the appeal. Rejection of Appeal, Appellate Div. Docket No. A-15-112 (Sept. 25, 2015). Respondent then requested the required certification from the ALJ, which the ALJ denied on the basis that Respondent had offered "an insufficient basis" to certify an interlocutory appeal. R. Motion Requesting ALJ to Issue Certification Allowing Respondent to File Interlocutory Appeal (Sept. 26, 2015); Order Denying Motion to Certify (Sept. 29, 2015).

The ALJ convened a hearing by telephone on February 18, 2016. Prior to the hearing, CTP filed its Informal Brief and 16 proposed exhibits, including the declarations of two witnesses. Respondent filed an answer to the CTP complaint, a response to CTP's informal brief, and a post-hearing brief. Respondent did not file any proposed exhibits, or identify any proposed witnesses, in response to the ALJ's order establishing procedures. Acknowledgment and Pre-Hearing Order (July 10, 2015). At the hearing, the ALJ formally received CTP's 16 exhibits and Respondent cross-examined Mr. Naso, the CTP inspector.

The ALJ Decision

The ALJ recounted that Mr. Naso, accompanied by the minor working under his supervision, inspected Respondent's establishment on September 24, 2014 and January 29, 2015 and on each occasion "verified that the minor did not have cigarettes in her possession prior to entering Respondent's establishment." ALJ Decision at 2, citing CTP

Ex. 1, at 2-4 (Naso Decl.). On September 24, 2014 the inspector "entered the establishment and personally observed the minor purchase a package of cigarettes from an employee" and "observed also that the employee did not check the minor's identification." *Id*. As noted, Respondent agrees that the minor purchased cigarettes at its establishment on September 24, 2014. NA at 4-5.

On January 29, 2015, the ALJ stated, "Mr. Naso waited outside while the minor entered the store [and] subsequently exited the store and advised him that she had purchased a package of cigarettes from an employee" and "provided Mr. Naso with a package of Marlboro Gold Pack cigarettes," which he labeled and photographed. ALJ Decision at 2, citing CTP Ex. 1, at 4; and CTP Ex. 13 (photograph of cigarette pack in evidence bag). The ALJ found "the fact that the minor exited the store on January 29, 2015 with a package of Marlboro Gold Pack Cigarettes to be persuasive evidence that she purchased them in the store, given that Mr. Naso verified that the minor did not have tobacco products in her possession prior to entering the store." *Id*. at 3.

The ALJ found "this evidence to be more than sufficient to prove that Respondent sold tobacco products (cigarettes) unlawfully to a minor on two occasions, September 24, 2014 and January 29, 2015, and that on one occasion (September 24) Respondent unlawfully failed to check a minor's identification before selling tobacco products to that individual." *Id*. The ALJ rejected the Respondent's arguments that CTP relied on hearsay testimony to what the minor told the inspector because "CTP's case does not depend on anything that the minor said, but rather, on Mr. Naso's observations, which are not hearsay, and on the physical evidence obtained on January 29, 2015." *Id*. The ALJ also rejected Respondent's argument that CTP's case was undercut by the minor's failure to obtain receipts for her purchases, finding that "Mr. Naso's observations and the physical evidence that was obtained on January 29, 2015 are, in and of themselves, adequate to prove CTP's case" and "[t]he absence of receipts doesn't derogate from that evidence." *Id*. Finally, the ALJ found that Respondent did not assert that it could not pay the $250 CMP, which was "nominal" and "authorized by regulations." *Id*., citing 21 C.F.R. § 17.2.

The ALJ thus sustained CTP's determination to impose a $250 CMP against Respondent. *Id*. at 1.

Standard of Review

"The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous." 21 C.F.R. § 17.47(k).

Analysis

I. The ALJ's finding that Respondent sold cigarettes to a minor on two occasions is supported by substantial evidence on the whole record.

The ALJ found that Respondent sold cigarettes to a minor on September 24, 2014 based on the inspector's testimony that while he was in Respondent' store on that date he witnessed the minor purchase cigarettes without her ID being checked. ALJ Decision at 2-3, citing CTP Ex. 1 (Naso decl.). The inspector's testimony is consistent with his narrative report prepared September 24, 2014, stating that he confirmed that the minor did not have any tobacco product prior to entering Respondent's establishment, that he accompanied the minor into the establishment and saw an employee sell cigarettes directly to the minor, who did not provide an ID, and also that he confirmed that the minor had an ID showing her actual date of birth. CTP Ex. 3. The inspector's testimony is also consistent with the "inspection results" shown in a printout of the FDA "Tobacco Inspection Management System" (TIMS) that the inspector testified he recorded shortly after the inspection. CTP Exs. 7; 1, at 3. Respondent as noted does not dispute that the minor purchased cigarettes at its establishment on September 24, 2014 and concedes liability for selling cigarettes to the minor on that date. NA at 4-5. Substantial evidence on the whole record supports the ALJ's finding that Respondent sold tobacco products to a minor on September 24, 2014.

The ALJ found that Respondent sold cigarettes to the minor on January 29, 2015 based on the inspector's testimony that on that date he witnessed the minor enter the store without cigarettes and exit with cigarettes, and on the physical evidence in the form of the cigarettes the minor purchased. ALJ Decision at 2-3. The inspector's testimony is consistent with his narrative report, prepared January 29, 2015, stating that he confirmed that the minor did not have any tobacco product prior to entering Respondent's establishment, that he did not accompany the minor into the establishment (because he felt his presence would compromise the undercover nature of the inspection), and that the minor after exiting the establishment immediately gave him a pack of cigarettes, which he labeled and placed in an evidence bag, and also that he confirmed that the minor had an ID showing her actual date of birth. CTP Ex. 4. The inspector's testimony is also consistent with the inspection results shown in a TIMS printout that the inspector testified he recorded shortly after the inspection. CTP Exs. 12; 1, at 4. This evidence supports the ALJ's finding that Respondent sold cigarettes to a minor on January 29, 2015.

Respondent questions that finding because "[t]he cashier insisted all along that he followed the Respondent's procedures" forbidding the sale of tobacco to minors "and he doesn't remember any suspicious transaction from anyone during his shift." NA at 7. This assertion, like Respondent's other assertions of fact, is unsupported because Respondent submitted no evidentiary exhibits or witness statements, and no offers of witness testimony, in response to the ALJ's order setting the procedures for the case.

The ALJ's "Acknowledgment and Pre-Hearing Order" (Order) told the parties "what they must do to present evidence and arguments in this case." Order at 1. The Order instructed each party to submit "A list of all proposed exhibits," including "the written direct testimony of any proposed witness . . . A copy of each proposed exhibit" and "A list of all proposed witnesses, if any, and a brief summary of the proposed testimony." *Id*. at 3. Respondent submitted no lists of proposed exhibits or witnesses, no proposed exhibits and no written direct testimony in response to the Order. During the hearing, Respondent voiced no disagreement when the ALJ stated that he was "unaware of any Exhibits that were filed" by Respondent (and Respondent did not object to the ALJ receiving CTP's 16 exhibits into evidence), and the hearing was limited to Respondent's cross-examination of Mr. Naso. Tr. at 5-6.

Respondent attached documents to its initial answer to the CTP Complaint but did not file any of those documents, or any other documents, as exhibits for the ALJ's consideration in accordance with the ALJ's instructions in the Order.[6] In any event, none of those documents support an assertion that the cashier did not sell or recall selling tobacco products to the minor on January 29, 2015. Respondent's failure to offer any exhibits or testimony is significant given that Respondent's specific factual assertions suggest that its employees recalled details about the two sales and that it had video showing the transactions. *See, e.g.*, R. Answer to CTP Complaint at 2 (in the January 29, 2015 sale "the Cashier confused this individual [the minor] with another customer"); R. Reply to CTP Resp. to NA (R. Reply) at 2 (alleging that the January 29, 2015 sale was "watched on the video surveillance"). Yet, Respondent offered no testimony of any of its staff, or of any other witnesses, and no video evidence. As we discuss further below, Respondent's failure to offer any documentary evidence or testimony seriously undercuts its arguments and assertions on appeal.

Respondent also questions the reliability of the inspector's testimony that the minor was not given a receipt for the cigarettes purchased in either sale, because "the system print[s] automatically a receipt for every transaction . . . to avoid transactions not entered by the cashier" and "failing to give a receipt, make[s] the cashier liable to pay the customer $5

[6] Attachment 1 to Respondent's answer to the CTP Complaint is Respondent's October 31, 2014 letter responding to CTP's October 16, 2014 warning letter reporting the first violation. Attachment 2 is a set of three receipts from September 24, 2014 showing that customer IDs were verified with the date of birth. Attachment 3 is a set of excerpts from Respondent's training manual. Attachment 4 includes, among other things, a set of employee schedules for the week ending January 31, 2015 and wage/earning statements for one employee, presumably the cashier during the sale on January 29, 2015. Attachment 5 is a one-page excerpt from the Florida tobacco product laws. Attachments 6 and 7 are a total of six pages of search results for "Compliance Check Inspections of Tobacco Product Retailers Through 5/31/15." Attachment 8 is a list of "FDA Tobacco Retail Inspection Contracts" for U.S. states and territories from the FDA website. Attachment 9 is a photograph of the interior of Respondent's store with a partially visible sign allegedly displaying Respondent's policy of offering $5 to customers not offered a sales receipt. Respondent's answer to the CTP Complaint refers to a tenth attachment, but no Attachment 10 was uploaded by Respondent to the DAB electronic filing system.

for failing to do so." NA at 7; CTP Ex. 1, at 3, 4 (Naso decl.). Respondent notes that its answer to the CTP Complaint included a photograph of "[t]he sign over the cashier counter in direct view" reading "We owe you a Sale[s] Receipt, if we fail to do so ask for the manager and we will give you $5 in cash," and argues it is thus "second nature for the Cashier to ask or hand a Receipt to the customer to avoid being penalized." R. Reply at 4-5.

Respondent's assertions about its receipt policy do not establish that the minor was given or offered receipts contrary to Mr. Naso's testimony or that Respondent did not sell cigarettes to the minor on January 29, 2015. As the ALJ pointed out, Mr. Naso testified that minors working in CTP investigations were instructed not to request a receipt if none is offered to avoid possible confrontational situations. ALJ Decision at 3; Tr. at 14-15, 17. Absent any actual evidence that the inspector testified falsely regarding the lack of receipts, the ALJ could reasonably credit his testimony and the physical evidence as showing that Respondent sold cigarettes to the minor on both occasions. *See* ALJ Decision at 3 (the "absence of receipts doesn't derogate from that evidence").

Accordingly, the ALJ reasonably found that Respondent sold cigarettes to the minor on January 29, 2015 where the evidence establishes that the minor entered Respondent's establishment without cigarettes and exited shortly thereafter with cigarettes. Substantial evidence on the whole record thus supports the ALJ's findings that Respondent sold tobacco products unlawfully to a minor on January 29, 2015.

II. Respondent's other arguments show no error in the ALJ Decision.

Respondent argues that the ALJ presumed Respondent liable for the second sale based on the first sale, relied on hearsay testimony and was biased against Respondent, and that the investigation used deceptive tactics in violation of CTP requirements. Respondent also argues that the FDA regulations imposing progressively higher CMPs for successive violations conflict with a 2015 Supreme Court decision. As we explain below, Respondent's arguments provide no valid basis to reverse the ALJ Decision.

A. The ALJ did not rely on hearsay evidence or presume Respondent liable for the second violation based on the first violation.

Respondent argues that the ALJ "mixed two events" and "concluded that if the First Event [on September 24, 2014] witnessed by the Inspector himself was true, therefore the second 'Event' [on January 29, 2015] not witnessed by the Inspector but reported by a minor" was "true as well, as if the Inspector witnessed it himself, since we failed the first inspection in which the Inspector was present!" NA at 4. Respondent argues that the

ALJ relied on "minor Hearsay" and disputes the ALJ's finding that CTP's case for the second sale "'does not depend on anything that the minor said [to Mr. Naso], but rather, on Mr. Naso's observations, which are not hearsay, and on the physical evidence obtained on January 29, 2015.'" NA at 8, 4, quoting ALJ Decision at 3.

Respondent's arguments do not accurately describe the ALJ's analysis, which neither conflates the evidence of the two sales nor relies on hearsay testimony. The ALJ recognized that the CTP investigator did not enter the store with the minor during the second sale as he had during the first sale. The ALJ stated that during the second sale, "[o]n January 29, 2015, Mr. Naso *waited outside while the minor entered the store* [and] subsequently exited the store and advised him [Mr. Naso] that she had purchased a package of cigarettes from an employee [and] provided Mr. Naso with a package of Marlboro Gold Pack cigarettes, which Mr. Naso labeled and photographed." ALJ Decision at 2 (italics added), citing CTP Exs. 1, at 4 (Naso decl.); 13.

While the ALJ did note the inspector's testimony to what the minor told him after the second sale, the ALJ also made clear that he was not relying on that testimony in "find[ing] this evidence to be more than sufficient to prove that Respondent sold tobacco products (cigarettes) unlawfully to a minor" on January 29, 2015. *Id*. at 3. Specifically, the ALJ found "the fact that the minor exited the store on January 29, 2015 with a package of Marlboro Gold Pack Cigarettes" to be "persuasive evidence that she purchased them in the store, given that Mr. Naso verified that the minor did not have tobacco products in her possession prior to entering the store." *Id*. The ALJ furthermore rejected Respondent's hearsay argument on the ground that "CTP produced independent proof of Respondent's violations in the form of Mr. Naso's observations of the September 24 transaction and the package of Marlboro Gold Pack Cigarettes that the minor obtained on January 29." *Id*.

The ALJ Decision thus distinguishes between the two sales, recognizes that the inspector did not enter the store during the second sale, and does not depend on the inspector's hearsay testimony about the second sale.[7]

[7] The inspector's hearsay testimony in any event would not have been automatically inadmissible because the rules governing this proceeding provide that the ALJ is not bound by the Federal Rules of Evidence and, as the Board has long observed, hearsay is admissible in administrative proceedings generally and can be probative on the issue of the truth of the matter asserted, where sufficient indicia of reliability are present. 21 C.F.R. § 17.39(b); *Britthaven, Inc., d/b/a/ Britthaven of Smithfield*, DAB No. 2018, at 3 (2006), citing *Pacific Regency Arvin*, DAB No. 1823, at 14 n.6 (2002); and *Richardson v. Perales*, 402 U.S. 389, 402 (1971). The question facing an ALJ presented with hearsay evidence is not whether it is admissible, but what weight it should be accorded. *Gateway Nursing Ctr.*, DAB No. 2283, at 6 (2009).

B. Respondent has not shown that the CTP investigation used deceptive tactics or entrapped Respondent.

Respondent calls CTP's evidence of the second violation "spoiled, since it was obtained by deceitful actions" that Respondent describes as the minor wearing "[a]ttire not suitable for a teen ager" and providing an ID that may have been false. NA at 6 (accusing minor of "inducing the Cashier in error about her age by having in her hand an ID (showing or not an age under l8 years)"); *see also* CTP Ex. 1, at 4 (Naso testimony that minor reported to him "that her photographic identification was provided to the employee prior to the purchase" of cigarettes on January 29, 2015). Respondent asserts these alleged actions constitute entrapment and violated what the CTP inspector testified were instructions to minors participating in CTP investigations "to always dress in age-appropriate attire when working" and "tell the truth if they are asked about their age or whether they have an ID." R. Reply at 6; CTP Ex. 1, at 2 (Naso decl.).

Respondent asserts that the minor did not wear "age-appropriate" attire during the January 29, 2015 investigation but wore "[b]usiness appropriate" attire consisting of "fancy clothes, nice pants, and high heels" and "dress [g]rey pants [and] an assorted grey scarf" and makeup and that she looked "far over 20" years old. R. Reply at 2; NA at 5-6. Mr. Naso during cross examination could not describe the minor's specific attire on January 29, 2015, but testified that the minor would have been a 16-17 year old high school student who simultaneously attended college and who had (as of the hearing in February 2016) graduated high school early and "that outfit she wore to college that day, that would be her age-appropriate attire." Tr. at 11, 19-20, 27. Respondent, however, has not supported its factual assertions about the minor's attire with any documentary evidence or witness testimony.

Respondent argues that the CTP inspector indicated that the minor was not attired appropriately for her age because he "justified [the minor's alleged] attire as 'College appropriate' since the minor was in High school but attending the college as well" and that age-appropriate attire for a minor is "not appropriate attire to College." NA at 5-6. Based on Mr. Naso's testimony that the minor wore clothing appropriate for her age and activities, including college classes, there is no basis to conclude that her attire was somehow deceptive or worn to make her appear old enough to purchase cigarettes legally. Respondent also has furnished no basis for its premise that high school and college students necessarily wear such drastically different clothing that a minor's wearing attire appropriate for attending college classes during an investigation would constitute deceit sufficient to excuse illegal tobacco sales to a minor.

Respondent also argues that the ID the minor provided the cashier on January 29, 2015 logically had to have been false because Respondent employs a system that scans the IDs of tobacco purchasers. Respondent acknowledges that this system can be overridden by

the cashier, but argues that the cashier would logically not have done so unless convinced that the minor was of age because she lied about her age and displayed a false ID. Respondent states:

> [O]ur Point of Sale requires [the cashier] to scan an ID to complete any Tobacco sale, overriding the system is not logical when a customer has the ID available and as the minor stated: handed the ID card to the cashier, the logical conclusion is to the fact that the ID was in fact scanned, so how such illogical act occurred, unless the Minor was not telling the truth, or if her ID was a Faked ID, which, unfortunately many teen agers easily obtains to obvious reasons.

NA at 7. Again, Respondent did not support its speculation about the minor's ID with any documentary evidence or witness testimony. In the absence of such evidence, the ALJ reasonably could credit instead the inspector's sworn testimony that the minor had a valid ID showing her correct age.

When a respondent in another case argued that the CTP program using minors to attempt to buy cigarettes from its business was "'a scheme' that amounts to 'illegal entrapment,'" the Board found that a defense of "entrapment would not appear to be available in a federal enforcement action for sale of tobacco products to minors." *TOH, Inc. d/b/a Ridgeville Serv. Ctr.*, DAB No. 2668, at 14-15 (2015). The Board cited a federal district court decision reviewing the history and purpose of the entrapment defense and stating that "[a]ccording to the federal jurisprudence, the defense of entrapment is apparently non-available in the federal civil litigations and is limited only to criminal actions." *Id*. at 15, quoting *Rodriguez v. United States*, 534 F. Supp. 370, at 373-74 (D.P.R. 1982). The Board ultimately found that it "need not, however, resolve the question of whether an entrapment defense might ever lie in a tobacco enforcement proceeding," because Respondent had "not described, much less proven, that either minor engaged in any trickery or dishonesty to induce the illegal sales" and had thus "not proven the elements of such a defense." *Id*. The same conclusion is warranted here, where Respondent has offered no evidence to support its claims that the evidence of the sale on January 29, 2015 "was obtained by deceitful actions[.]"[8] NA at 6.

[8] CTP argues that Respondent "never properly raised the entrapment defense by setting out the elements of such defense," nor "offer[ed] any evidence for the ALJ . . . related to this claim [and that therefore] the entrapment issue is not properly before the Board on appeal." CTP Resp. to NA at 8. Respondent did, however, allege entrapment in its initial answer to the CTP Complaint, and argued in its post-hearing brief that the January 29, 2015 investigation was "deceitful" based on its allegations about the minor not wearing "age appropriate" attire and displaying an ID. R. Post-Hearing Br. at 2-4. As we agree that Respondent offered no evidence supporting its allegations of a deceitful investigation, we need not consider whether Respondent properly raised the elements of an entrapment defense to the ALJ.

Additionally, our determination above that the ALJ found Respondent liable for the violation on January 29, 2015 based solely on evidence relating to that transaction and did not presume liability based on the uncontested earlier sale does not constrain us from observing that the first sale nonetheless shows that Respondent's alleged safeguards are not infallible and their mere existence does not demonstrate that the later sale could not have occurred.

Accordingly, Respondent has not supported its allegations that the CTP investigation employed deceptive techniques and has failed to meet its burden to "prove any affirmative defenses and any mitigating factors by a preponderance of the evidence." 21 C.F.R. § 17.33(c).

C. Respondent has not shown that the ALJ was biased.

Respondent asserts that the ALJ's "[b]ias was extremely clear" from his denial of Respondent's request for discovery of general information about CTP inspections in Florida and his grant of CTP's discovery request relating to Respondent's stock of tobacco products during September 2014 and January 2015, which Respondent considers abusive. NA at 2. Respondent also argues that the ALJ showed bias by ignoring evidence that the second violation did not occur and presuming liability based on the earlier, uncontested violation. NA at 8 (ALJ's actions "were bias and favoring" CTP for "stat[ing] that a prior Event justify the next Event" without "taking in consideration the fact that all our Cashiers did in many instances IDed individual[s] in line with the Federal and State Laws and Statutes. We did provide [] Evidence, so why we were not given the same benefit of the doubt?").

As discussed above, we reject Respondent's arguments that the ALJ showed bias against the Respondent. We also reject Respondent's arguments that the ALJ premised liability for the second violation on Respondent's uncontested liability for the first violation, and find that Respondent provided no evidence to support its allegations about its business practices, and we concluded that even accepting those allegations would not undermine the ALJ's finding that the second violation occurred. Those unfounded arguments thus do not show that the ALJ was biased against Respondent.

Further, the Board has observed that the standard for disqualifying a judge for bias requires that the alleged bias "must stem from an extrajudicial source and result in an opinion on the merits on some other basis than what the judge learned from his participation in the case." *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 15-16 (2009), quoting, among others, *St. Anthony Hosp.*, DAB No. 1728, at 83-84 (2000), *aff'd*, 309 F.3d 680 (10th Cir. 2002), and *Edward J. Petrus, Jr., M.D., & The Eye Center of Austin*, DAB No. 1264, at 23 (1991), *aff'd sub nom., Petrus v. I.G.*, 966 F.2d 675 (5th Cir. 1992); both quoting *U.S. v. Grinnell Corp.*, 384 U.S. 563, 583 (1966). The Board has also noted

that, in civil proceedings, a judge's rulings do not by themselves establish bias constituting a sufficient basis for disqualification. *Britthaven of Goldsboro*, DAB No. 1960, at 15 (2005); *see also In re Rouse*, 582 F. App'x 132, 133 (3rd Cir. 2014) ("[a]dverse rulings alone generally do not constitute a sufficient basis for holding that a judge's impartiality is in doubt"). Accordingly, the discovery rulings Respondent views as unfavorable here do not by themselves establish ALJ bias.

Moreover, Respondent's argument that the ALJ's discovery rulings show bias overlooks the ALJ's rulings favorable to Respondent. The ALJ granted Respondent a partial protective order from CTP's discovery request for all documents related to the identity of persons working at Respondent's store on the dates of the two sales, finding it unduly burdensome with respect to those employees not involved with the sale of tobacco products. Protective Order (Aug. 26, 2015). The ALJ also afforded Respondent the opportunity, which Respondent took, to forgo providing the financial documents CTP requested if Respondent verified in writing that it was able to pay the $250 penalty if found liable and that the penalty will not materially affect Respondent's ability to continue to do business. *Id*. At the very least, information about Respondent's tobacco inventory during the months of the sales to the minor, which the ALJ required Respondent to produce, is relevant for establishing that Respondent sold the particular cigarettes that the minor purchased and which the inspector photographed.

Respondent's allegations of bias thus provide no basis to reverse the ALJ Decision.

D. The penalty system in the FDA regulations does not conflict with a 2015 Supreme Court decision.

Respondent argues that the penalty system subjecting it to progressively higher penalties for future violations ($11,000 for "the 6th 'Violation' within 48 months," R. Reply at 3) conflicts with a 2015 Supreme Court decision that Respondent says struck down Environmental Protection Agency rules for imposing "unjustifiable cost" on regulated industries. R. Reply at 3, citing R. Answer to CTP Complaint at 6 (unnumbered), citing *Mich. v. E.P.A.*, 135 S. Ct. 2699 (2015). The Supreme Court decision in *Michigan* does not apply here. The "costs" in *Michigan* were the estimated costs an EPA rule regulating emissions of hazardous air pollutants would impose on power plants, and the Court "held [that] EPA may not decline to consider cost as part of a required threshold inquiry under [the Clean Air Act] into whether it is 'appropriate and necessary' to regulate power plants." *Nat'l Ass'n for Surface Finishing v. E.P.A.*, 795 F.3d 1, 9 (D.C. Cir. 2015), citing *Michigan*, 135 S. Ct. at 2704. Unlike in *Michigan*, however, where the federal agency had not followed Congress's requirements to consider the potential costs of its

rulemaking, in this case it was Congress that set the "costs" – the penalty amounts – that are imposed for different violations. 21 U.S.C. § 333 note. Neither the ALJs nor this Board are empowered to ignore or overturn applicable statutes or regulations. *See*, *e.g.*, 21 C.F.R. § 17.19(c) ("presiding officer does not have the authority to find Federal statutes or regulations invalid").

Conclusion

We conclude that the ALJ Decision is legally sound and its factual basis is supported by substantial evidence. We affirm the ALJ Decision and sustain the $250 CMP imposed by CTP.

/s/
Leslie A. Sussan

/s/
Susan S. Yim

/s/
Christopher S. Randolph
Presiding Board Member