Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

TOH, Inc. d/b/a Ridgeville Service Center
Docket No. A-15-103
Decision No. 2668
December 10, 2015

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

The Administrative Law Judge (ALJ) issued an initial decision on August 3, 2015 sustaining the imposition of a civil money penalty (CMP) of $250 by the Center for Tobacco Products (CTP) of the United States Food and Drug Administration (FDA) on TOH, Inc. d/b/a Ridgeville Service Center (Respondent) for violation of the Federal Food Drug and Cosmetics Act (Act), 21 U.S.C. § 387c(a)(7)(B), and implementing regulations at 21 C.F.R. § 1140.14(a). *TOH, Inc. d/b/a Ridgeville Service Center*, DAB CR4096 (2015). The ALJ found that the FDA established that Respondent unlawfully sold cigarettes to a minor twice within a twelve-month period and sustained the $250 CMP. *Id.* at 1.

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 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" 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). The regulations also state that 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 to be imposed 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, however, 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 Industry and FDA Staff – Civil Money Penalties for Tobacco Retailers* at 12 (June 2014).[2] As applicable here, the FDA will assess a CMP of up to $500 in the case of a third violation within a 24-month period. 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. CTP initiates the imposition of a CMP by serving a complaint on the retailer (the respondent) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). 21 C.F.R. §§ 17.3, 17.5, 17.7, 17.33. The respondent may request a hearing before an ALJ by filing an answer to the complaint within 30 days or may request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9. 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 protective order within 10 days of receipt of a request for production. 21 C.F.R. § 17.23(a), (d)(1).

A respondent may appeal the ALJ's decision (which the regulations refer to as the "initial decision") to the "DAB" (Departmental Appeals Board or "Board" which consists of Board Members supported by the Appellate Division). 21 C.F.R. §§ 17.45, 17.47. The Board may "decline to review the case, affirm the initial decision or decision granting

[1] http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf accessed Nov. 25, 2015.

[2] http://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm339438.pdf accessed Nov. 25, 2015.

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[3]

Respondent operates a service center in Maryland which, among other items, sells tobacco products, including Newport cigarettes. An adult inspector, Jeremy Ricewick, working on behalf of FDA/CTP conducted undercover operations at Respondent's business on two separate occasions, accompanied each time by a minor employed by contract with a state agency to participate in FDA/CTP undercover buys. On June 6, 2012, Inspector Ricewick brought with him a minor identified as Minor 013; on April 11, 2013, he returned with a different minor identified as Minor 012. For each date, Inspector Ricewick reported that he observed the minor show identification on request and then purchase a package of Newport cigarettes. ALJ Decision at 2; CTP Exs. 9, 11.

CTP submitted as evidence narrative reports for each date from Inspector Ricewick in which, among other assertions, he asserted that he personally observed the sales while supervising the minors and that he immediately obtained the packages of cigarettes from the minors and photographed, labelled and sealed them in evidence bags. CTP Exs. 9, 11. CTP also submitted a declaration from Inspector Ricewick reiterating that the narrative reports were recorded contemporaneously with the visits and were true and correct when recorded. CTP Ex. 2. The declaration also stated that each minor carried and offered to the clerk authentic identification showing a date of birth establishing an age under 18 at the time of the sale. *Id.*

CTP filed an administrative complaint before the ALJ seeking to impose a $250 CMP on Respondent based on the April 11, 2013 transaction constituting a second sale to a minor within a one-year period. Respondent requested a hearing which was held on May 15, 2015. The governing regulations require that CTP must prove Respondent's "liability and the appropriateness of the penalty" by the preponderance of the evidence and that Respondent must prove "any affirmative defenses and any mitigating factors by a preponderance of the evidence." 21 C.F.R. § 17.33(b) and (c).

[3] The factual summary in this section is not intended to constitute new findings or substitute for any findings in the ALJ Decision. The ALJ either found these facts to be undisputed or to be established by the preponderance of the evidence before him. ALJ Decision at 2-3, and record citations therein. To the extent any factual issues are disputed on appeal, we discuss them later in the decision.

Prior to the hearing, both parties sought discovery from each other and both filed protective orders seeking to limit production and associated briefing. Protective Order and Order for Further Briefing at 1-2 (July 22, 2014) (ALJ Protective Order Ruling). The ALJ relied on regulations at 21 C.F.R. Part 17 to determine the scope of and limits on discovery. *Id.* at 2-3. Section 17.23 provides in relevant part as follows:

> a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.
> (b) For the purpose of this part, the term *documents* includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party. . . .
> (d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.
> (2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:
> (i) Is unduly costly or burdensome,
> (ii) Will unduly delay the proceeding, or
> (iii) Seeks privileged information.
> (3) The burden of showing that a protective order is necessary shall be on the party seeking the order.
> (4) The burden of showing that documents should be produced is on the party seeking their production.

Further, the ALJ is authorized under 21 C.F.R. § 17.28(b) to make –

> any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20.

The ALJ granted Respondent a limited protective order (not at issue before us), ordered CTP to produce requested documents relevant to the issues in the complaint with a log of any documents withheld on a claim of privilege, and ordered the Respondent to explain further why the partially-redacted photo identification of the minors would not be sufficient to meet Respondent's needs. ALJ Protective Order Ruling, at 6-7. The ALJ

noted that CTP argued that the redacted information identifying the individual minors would be exempt from disclosure under 21 C.F.R. 20.64(a)(1) and (3) because it could reasonably be expected to interfere with law enforcement proceedings and constituted an unwarranted invasion of privacy, and requested CTP to brief how these regulations apply in the context of discovery requests. ALJ Protective Order Ruling at 7. The ALJ issued a second Protective Order on December 1, 2014 resolving disputes about documents which CTP designated as privileged in its log.

After receiving further briefing (and after the case was transferred to another ALJ), the new ALJ issued a final discovery order on January 26, 2015 addressing all remaining issues not previously ordered produced or protected. The ALJ noted that CTP asserted that it would not offer the minors as witnesses. The ALJ concluded that CTP would "have to establish its case in chief based on evidence other than that which these witnesses might offer as testimony." Final Discovery Order at 1. The ALJ therefore determined that information concerning the minors would "not be relevant to the merits of this case nor [would] it lead to relevant evidence." *Id.* He further concluded that "substantial prejudice" could occur to CTP's "investigative process if [he] compelled it to turn over identifying information relating to these witnesses," and such disclosure would create "a risk of intimidating future potential minor witnesses from participating" in CTP investigations. *Id.* at 1-2.

The ALJ proceeded to hearing and issued his decision which concluded that the evidence established that Respondent's employees sold cigarettes to minors despite being shown identification establishing that they were ineligible to purchase tobacco products and that these actions amounted to knowing violations of the law justifying the minimal penalty imposed. ALJ Decision at 3. The ALJ rejected Respondent's argument that it was "in no position to defend itself . . . because it has been denied access to information that would enable it to challenge the probative value of CTP's evidence." *Id.* He reiterated that disclosure of the minors' identities was not justified where CTP did not rely on their testimony and the potential prejudice from disclosure outweighed any benefit Respondent might derive. *Id.* Moreover, the ALJ stated that the testimony of the "minor purchasers is unnecessary here because the sale was witnessed and because there is no evidence showing that their identification was inauthentic." *Id.* He pointed out that CTP provided Respondent before the hearing the redacted state-issued identification cards showing the bearers to be minors and the inspector's eyewitness accounts of the bearers' giving these identification cards to Respondent's employees prior to the tobacco sales. *Id.* Furthermore, the ALJ found Respondent's "assertion that it is in no position to defend itself" to be "disingenuous" because Respondent "had in its possession evidence that would either have corroborated or rebutted CTP's evidence of an unlawful sale but it chose to destroy that evidence." *Id.* at 4. Specifically, Respondent received notice of the April 11, 2013 inspection five days after it occurred and yet, "by its own admission, subsequently chose to destroy a surveillance tape that would have shown the transaction in question." *Id.* (record citation and footnote omitted). The ALJ found no merit in

Respondent's other legal arguments and therefore sustained the CTP determination to impose the CMP of $250. *Id.* at 1, 4-6.

This appeal ensued.

Standard of review

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

Arguments of the parties

Respondent contends on appeal that the ALJ made the following five errors:

(1) The ALJ should have ordered production of unredacted copies of the minors' identification because Respondent needed them to adequately defend itself;
(2) The ALJ failed to rule on its argument that the FDA/CTP lacked legal authority to conduct undercover operations;
(3) The ALJ should have excluded all evidence resulting from the undercover inspections as illegally obtained through entrapment;
(4) The ALJ erred in holding Respondent responsible for illegal or improper actions of its employees because the clerks were not corporate officers and made any sales to minors against express company policies; and
(5) The ALJ's conclusions that Respondent violated the law in the alleged transactions on June 6, 2012 and April 11, 2013 were not supported by substantial evidence because Inspector Ricewick could not recall specific details of each incident, because the chain of custody of the cigarettes collected as evidence was questionable, and because the trustworthiness of the minors involved was not sufficiently established.

Notice of Appeal and Brief (NA) at 2-14. CTP responded to each contention as follows:

(1) The ALJ did not err in withholding the unredacted identification because CTP did not rely on the minors to testify, the potential damage to the minors' privacy and to the enforcement program justified the redaction, and Respondent did not show prejudice.
(2) The ALJ correctly declined to rule on whether the FDA's regulations and enforcement program exceed statutory authority.
(3) CTP's evidence was not obtained illegally through entrapment.

(4) Respondent is responsible under the law and regulations for its failure to ensure that its employees not sell tobacco to minors and its clerks acted within the scope of their employment in making the sales, even if they broke company policy by doing so.
(5) The ALJ's conclusions were supported by substantial evidence because Inspector Ricewick gave reliable testimony relying on truthful contemporaneous reports, any chain of custody concerns are unfounded and immaterial, and nothing in the record suggests that either minor was untrustworthy.

Memorandum in Opposition to Appellant's Appeal (CTP Br.) at 5-22.

Analysis

We first discuss why we conclude that the ALJ's protective order limiting disclosure of the minors' identification licenses to redact personally identifying information was a reasonable exercise of his discretion. In the following three sections, we explain why we find no error in the ALJ's legal conclusions that the FDA/CTP had authority to conduct undercover investigations, that Respondent was not entrapped, and that Respondent was accountable for the violations committed by its clerks. Finally, we discuss our conclusion that the ALJ's factual findings were supported by substantial evidence.

1. Respondent has not shown a need for unredacted identification licenses that outweighs the potential harm of disclosure under these circumstances.

    a. Respondent has not adequately demonstrated its need for access to the personally-identifying information concerning the minor purchasers.

Respondent acknowledges that CTP "did not directly rely upon the minor's testimony in supporting its case," but argues that without the actions of the minors and their licenses "no case could have been made in the first place." NA at 3. Respondent also acknowledges that CTP relied on Inspector Ricewick's testimony about both sales to minors but argues that the failure to disclose the "full data underlying" that testimony, "including the Minors' respective licenses, relegates such testimony to little more than hearsay with little to no probative value." *Id.*

These arguments lack merit. It is true that no violation would have occurred without a sale to a minor, and that in this case, the violations were based on sales to these minors despite their providing state-issued identification to the clerks prior to the transactions. It does not follow, however, that the names or identities of the individual minor purchasers are essential to proving that these transactions occurred as alleged. We do not agree, furthermore, that redacting the names of the minors on the licenses somehow converts into unreliable hearsay the eyewitness testimony of the inspector that he worked with each minor, personally observed each clerk obtain the minor's identification and

complete the sale, and that he then collected the cigarette boxes and sealed them with his initials and those of the minor. Tr. at 30-38; CTP Ex. 2, at 2-3 (Ricewick Decl.); CTP Ex. 9, at 2; CTP Ex. 11, at 1. The inspector also testified that he recorded his observations in narrative reports entered into an FDA database immediately after each sale and these narrative reports were produced as evidence. CTP Ex. 2, at 2-3; Tr. at 3; CTP Exs. 9, 11. Respondent does not even identify any testimony by the inspector that would constitute hearsay, i.e., testimony about an out-of-court statement by a declarant not available for cross-examination, since the inspector did not assert that he heard or reported the content of either minor's conversations with the clerks. His testimony and reports consisted of observations he made himself. Also, contrary to Respondent's characterization, CTP did not rely "solely" on the inspector's testimony. NA at 3. CTP provided additional corroborating evidence including photographs of the business on the transactions dates, the cigarette boxes preserved from the sales, and the redacted licenses. CTP Exs. 5, 6, 10, 13-15.

Respondent also argues access to the unredacted licenses would have allowed it to "confirm or deny, through its employees and by visual representation of the minor, that the minor was in Respondent's place of business at the time of the alleged violation" and to investigate the minors and the legitimacy of their licenses. NA at 3. We find no merit to this argument. Respondent has not adequately explained why it thinks the unredacted licenses are necessary to confirm or deny the events given the other information available to Respondent. The redacted licenses provided the age, gender, height and weight of the minors along with the birthdate and explicit notice that each minor was "under 18 until" a specific future date. CTP Exs. 14, 15. CTP also produced, as exhibits with its brief in support of the protective order, the violation notice for April 11, 2013 which identified the clerk as a female adult with light brown hair, and printouts from the FDA system confirming the minors' participation in the program in Maryland and showing dates of birth, gender and ages consistent with their state-issued identifications. CTP Brief re: Protective Order, Exs. A-D, F. Respondent stipulated that ten named clerks were on duty during the two dates in question. CTP Ex. 7 (Stipulation by Respondent's counsel). Respondent does not explain why this information, along with the exact date and time of the transaction, was insufficient to allow it to question the sales clerks on duty or indeed whether it made any effort to do so.

As far as the licenses' legitimacy, CTP argued that the redacted licenses provide sufficient information to confirm that they are what they purport to be – legitimate state-issued identification. CTP Brief re: Protective Order at 12. Further, CTP offered to disclose the redacted portions of the licenses to Respondent's counsel in camera if the ALJ determined that they appeared altered or otherwise inauthentic. *Id.* CTP provided written direct testimony concerning the operation of the undercover buy program from a branch chief supervising the program who explained that the minors are "instructed to show truthful identification that reflects their actual age if identification is requested." CTP Ex. 1, at 3; *see also* Tr. at 26. Testimony was also presented from the Maryland

official who recruits and trains minors for the program. CTP Ex. 3. Among other safeguards, she reports that a condition of their employment is that the minors present a valid state-issued identification card which she examines and copies. *Id.* at 2. On cross-examination, she remembered evaluating and training both minors involved here in accordance with her practice. Tr. at 21-26. The ALJ expressly found that there was no evidence showing the minors' identification to be inauthentic. ALJ Decision at 3. On appeal, Respondent has not demonstrated that it proffered any evidence to call the authenticity of the licenses into question. We thus do not find any showing that Respondent had a real need to receive the unredacted licenses to address any concerns about authenticity.

Most significantly, Respondent offered no response to the ALJ's finding that surveillance video of at least the second sale was available after Respondent was notified of the violation and was thereafter destroyed. Indeed, CTP produced a memorandum recording a telephone contact with Respondent's manager in which she stated that "the employee did request identification based on her review of the video." CTP Brief re: Protective Order, Ex. H. CTP also produced email correspondence with Respondent's counsel from August 2014 in which she asserts that her client does not have the video because they use a video system which "continuously records" but storage "is limited to approximately 29 days then the data is written over." *Id.*, Ex. E. Respondent has not disputed either the authenticity of these communications or the accuracy of their contents. Respondent thus does not deny having had in its possession direct evidence that would confirm or deny the presence of the minor and the fact of the sale at a time when Respondent was aware of the legal significance of that evidence. For these reasons, we reject Respondent's assertion that it could not prepare a defense to the complaint without access to unredacted licenses.

Respondent also suggests that it would be "logical" to provide the unredacted licenses during this proceeding, considering that each was "initially proffered" to Respondent in unredacted form "through its employee at time of each alleged sale." NA at 3. Of course, the same "logic" would suggest that Respondent has no need to have CTP produce the unredacted licenses when Respondent admits it has already had access to them through its clerks. The difference between displaying a state-issued license to a store clerk when attempting to purchase tobacco products and providing complete identification of a minor to the employer/respondent in a later law enforcement proceeding is the latter scenario's much greater potential for harm to the minor and to the enforcement system.

b. The protective order crafted by the ALJ reasonably responds to serious concerns about privacy, security and law enforcement processes identified by CTP.

While professing to understand and respect CTP's "desire to protect the privacy of the minors," Respondent insists that the prejudice to its defense "outweighs any privacy concerns." NA at 3. We disagree.

CTP explained at some length in its briefing in support of a protective order and again in its opposition to the appeal the multiple types of harm about which it was concerned. The minors who participate in this undercover enforcement program assume that their identities will be protected so that they will not be "subject to threats or harassment by those against whom they facilitate enforcement action." CTP Brief re: Protective Order at 7; CTP Br. at 13. The unredacted licenses contain names, photographs and home addresses of the minor purchasers which would make it easy to locate and contact them. CTP Brief re: Protective Order at 8 (citations omitted). CTP asserts a reasonable concern that minors' physical safety might be compromised especially "in small communities where minors who may be directly involved in a case that results in one or multiple CMPs may easily be recognized . . . ." CTP Brief re: Protective Order at 9 (citation omitted).

In addition to concerns about the privacy and safety of the minors involved in the present case, CTP identified several areas of potential prejudice to the tobacco enforcement program itself. Without some assurance of privacy, CTP asserts that recruitment might suffer due to fewer minors being willing to participate in undercover buys. *Id.* at 7; CTP Br. at 13. Retailers who obtain the identities of minors doing undercover work might interfere with inspections by having employees refuse to serve those individuals even if they otherwise sell tobacco products to minors and may even share those minors' identities with other retailers in the area, further damaging the enforcement program. CTP Brief re: Protective Order at 6-7; CTP Br. at 13.

The regulations cited earlier empower the ALJ to balance the need for parties to obtain documents that are relevant to the issues before him with crafting a protective order where a party's request is too costly or burdensome, will cause too much delay, or seeks privileged information. 21 C.F.R. § 17.23(a) and (d)(2). The broad discretion conferred on the ALJ is evident from the language authorizing "any order which justice requires to protect a party or person" from oppression, undue burden or expense, clearly unwarranted invasion of personal privacy, or "other information that would be withheld from public disclosure under 21 CFR part 20." 21 C.F.R. § 17.28(b).

Both ALJs who considered both parties' requests for discovery and for protective orders clearly gave careful attention to applying these authorities. ALJ Protective Order Ruling (July 22, 2014); Protective Order (Dec. 1, 2014); Final Discovery Order (Jan. 26, 2015). On the particular questions of whether to release the minors' identification licenses and, if so, whether to permit redactions, the parties were permitted extensive opportunities to fully brief their concerns. The ALJ specifically asked CTP to brief whether the restrictions in part 20 (which governs public disclosure) apply to discovery requests in enforcement proceedings. CTP did so, pointing out that section 17.28(b) expressly provides that protective orders may be granted for information that would be withheld under part 20. CTP Brief re: Protective Order at 3-4. CTP also argued that the disclosure exemption for law enforcement records in part 20 properly applies here and also tracks common-law discovery privileges available to protect law enforcement integrity and witness safety and privacy. *Id.* at 4 (case citations omitted). Respondent does not contend on appeal that the ALJ could not properly consider the provisions of part 20 in shaping the protective order providing for production of redacted licenses, so we include those provisions in reviewing the ALJ's exercise of discretion.

Section 20.64 provides in relevant part that "information compiled for law enforcement purposes may be withheld from public disclosure" to the extent it –

> (1) Could reasonably be expected to interfere with enforcement proceedings; . . .
> (3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy; . . .
> (5) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or
> (6) Could reasonably be expected to endanger the life or physical safety of any individual.

21 C.F.R. § 20.64(a). Furthermore, the information to which this exemption applies includes "all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation." 21 C.F.R. § 20.64(b). We find that CTP raised substantial and legitimate concerns about the potential impact of disclosure of the photographs, names and addresses of the minors under these provisions. While it is difficult to ascertain the likelihood of specific outcomes, CTP has explained reasonable bases to expect interference with the integrity of the enforcement program and incursions on the privacy and possibly even safety of some minor participants.

In sum, we find no reason to disturb the ALJ's balancing of the multiple competing factors in ordering disclosure of the licenses in redacted form under the circumstances of the present case.

2. The ALJ correctly declined to rule on whether the FDA's regulatory enforcement regime exceeds its statutory authority.

Respondent argues that nothing in the Act authorizes the FDA or CTP to "police the statutes via undercover operations." NA at 5. According to Respondent, the Secretary of the Department of Health and Human Services, through the FDA and CTP, therefore exceeded statutory authority by issuing regulations permitting such operations as an enforcement technique. *Id*. at 4. Respondent's argument on appeal simply repeats its brief below almost verbatim but nowhere explains how the ALJ, or this Board, has authority to strike down duly-promulgated regulations of this Department. It is not entirely clear if Respondent intended to challenge the entire regulatory program as somehow lacking in the "reasoned decision making" it notes is required of federal agencies when promulgating regulations (*id*. at 5) or only to attack the use of undercover buys as part of the inspections.

The ALJ apparently understood Respondent to be arguing broadly that the Act does not expressly authorize CTP or the FDA to issue regulations prohibiting, or imposing CMPs, for unlawful tobacco sales to minors. ALJ Decision at 4. So framed, the ALJ concluded that he had not been delegated any authority to declare regulations ultra vires the Act. *Id*. It appears, however, that Respondent agrees that at least the regulation prohibiting the sale of tobacco to minors is "appropriate to the public health" and hence permissible under the Act. NA at 5, citing 21 C.F.R. § 1140.14. Respondent also admits that the Act was amended to "authorize examinations and inspections of tobacco retailers." NA at 5, n.2, citing 21 U.S.C. § 372. Indeed, the Act expressly empowers the FDA to "conduct examinations and investigations . . . through officers and employees of the Department or through any health, food, or drug officer or employee of any State." 21 U.S.C. § 372(a)(1)(A). In the case of tobacco products, the Act encourages the FDA, "to the extent feasible," to "contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this chapter." 21 U.S.C. § 372(a)(1)(B)(i).[4]

[4] The minors and inspectors are employees of a state with which the FDA contracts to carry out inspections of retailers in connection with tobacco enforcement.

We agree with the ALJ that neither his authority nor ours extends to overturning any applicable regulations as ultra vires.[5] We read Respondent's argument, however, as more narrowly focusing on the claim that the Act does not expressly mandate or authorize undercover investigations. Thus, Respondent appears to contend that the Act had to spell out the methods for inspection and enforcement to empower undercover buys. NA at 5-6. We find no basis for the position that an agency empowered to conduct law enforcement investigations and compliance inspections may not use unidentified personnel in such activities absent some explicit statutory mandate to employ that technique. In concluding the Environmental Protection Agency could use aerial photography in site inspections even though the applicable statute never mentioned such use, the Supreme Court opined that "when Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission." *Dow Chem. Co. v. United States*, 476 U.S. 227, 233 (1986); *see also* CTP Br. at 15-16, and cases cited therein. CTP relies on similar general authority in carrying out the details of its compliance check program. CTP Br. at 14, citing FDA's Investigations Operations Manual, Ch. 4, §4.1.4.6, available at http://www.fda.gov/iceci/inspections/iom/ucm122523.htm accessed Dec. 2, 2015 (on undercover buys to acquire "official samples" where illegal activity is being investigated).

Much of Respondent's remaining argument on this issue amounts to an expression of its opinion that, as a policy matter, other regulatory requirements, such as signage and training of retail employees, are "somewhat effective," whereas undercover compliance checks are "useless and thus illogical." NA at 6. The only evidence that Respondent points to in support of this assertion is its own compliance in using various signs at the door and register and requiring its employees to request photographic identification and to sign compliance notices with their paychecks. *Id*. As this very case illustrates, however, such signs and policies do not necessarily ensure that retailers are not selling tobacco products to minors. While it may well be that, as Respondent asserts, not all "human error" can be eradicated (*id*.), that does not mean that unannounced buy inspections and escalating penalties for repeated violations are an irrational approach to providing disincentives to improper sales. In any case, the ALJ and the Board have no authority to make policy for the FDA.

[5] The Board's foundational regulations specify that we are bound by all applicable laws and regulations. 45 C.F.R. § 16.14. Respondent has not offered any basis to conclude that our review authority under the FDA regulations is broader.

3. The ALJ did not err in rejecting Respondent's entrapment defense.

Respondent describes the CTP program using minors to attempt to buy cigarettes from its business as "a scheme" that amounts to "illegal entrapment" so any resulting evidence "should not have been admissible pursuant to the Exclusionary Rule." NA at 8.[6] Respondent admits that the government may use undercover agents "to enforce the law in criminal matters" and that this "crime prevention technique has been successful." *Id*. Nevertheless, Respondent contends, the use of undercover buys may not be justified in a quasi-criminal context such as the tobacco program involving monetary penalties because the public risks are "limited" and do not outweigh "someone's basic constitutional rights." *Id*. If, as we have already found, CTP had sufficient authority to use undercover buys, Respondent argues that criminal law defenses such as entrapment should apply. *Id.* at 8-9. Respondent further asserts that the elements of entrapment are present here because the government "induced" the violation and neither Respondent nor its employees "were predisposed to sell cigarettes to minors." *Id*. at 9.

CTP denies that entrapment is available as a defense to a civil penalty resulting from an inspector observing and documenting a violation, but argues that, in any case, Respondent cannot make out the defense on these facts. CTP Br. at 21. According to the CTP, the evidence does not show that the minor or the inspector induced the violation but rather the minor's request for cigarettes (and display of a valid identification accurately showing the minor to be under 18) merely presented an opportunity to choose to comply with or violate the law. *Id*. at 21-22, *citing Mathews v. United States*, 485 U.S. 58, 62-63 (1988) (evidence that government merely afforded an opportunity for the crime is "insufficient to warrant" an entrapment instruction). If anything, the record demonstrates a predisposition to violate tobacco regulations, CTP argues, given that the ALJ found sales to minors on two separate occasions. *Id*. at 22.

Respondent cites no authority in either regulations or case law for the proposition that entrapment is available as a defense in administrative enforcement proceedings, even though the ALJ made clear that he rejected its applicability absent some legal authority. ALJ Decision at 5. We find at least some authority undercutting Respondent's proposition. *See, e.g., Rodriguez v. United States*, 534 F.Supp. 370 (D.P.R. 1982) (entrapment defense not available in administrative proceeding to exclude retailer from food stamp program for improper sales). The federal court in that case provided a cogent historical explanation of the role and purpose of entrapment defenses in federal law as follows:

[6] Respondent also contends that "FDA and CTP literally had to violate their own regulations" in performing undercover buys because "minors are prohibited from smoking tobacco products and retailers are prohibited from selling the same to minors." NA at 9. Neither the FDA nor the CTP violated either provision – the minors were not permitted to smoke and indeed were required to turn over the cigarettes immediately upon leaving the store and Respondent, not CTP, sold the cigarettes to the minors.

> The doctrine of entrapment as developed in the courts of the United States is generally circumscribed to criminal actions. *Sorrells v. United States*, 287 U.S. 435, 53 S.Ct. 210, 77 L.Ed. 413 (1932). Thus, entrapment, as defined in the *Sorrells* case, supra, at page 442, 53 S.Ct. at 212, occurs when the criminal doing originates with the officials of the government and their implanting in the mind of an innocent person the disposition to commit the alleged offense and inducing its commission in order that they may prosecute. The purpose of the doctrine of entrapment is to avoid criminal punishment for defendant who has committed all elements of a criminal offense, but was induced to commit them by the government. However, the entrapment defense has a limited application, the basic thought being that the officer of the law shall not incite crime merely to punish the offender. *Sorrells v. United States, supra*. The rationale behind this defense is that extreme forms of inducement are socially offensive and should defeat any prosecution based thereon. *Sherman v. United States*, 356 U.S. 369, 78 S.Ct. 819, 2 L.Ed.2d 848 (1958).
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> According to the federal jurisprudence, **the defense of entrapment is apparently non-available in the federal civil litigations and is limited only to criminal actions.** However, in some state litigations the defense of entrapment has been limitedly used in administrative proceedings. The instances where the entrapment defense has been permitted are quasi-criminal proceedings involving such things like the revocation of medical or dental licenses or license suspension for the operation of a liquor store. These are quasi-criminal proceedings in their nature because they are intended to be punitive and a warning for others who may incur in this particular misconduct.

534 F.Supp. at 373-4 (emphasis added). Based on this authority, entrapment would not appear to be available in a federal enforcement action for sale of tobacco products to minors.

We need not, however, resolve the question of whether an entrapment defense might ever lie in a tobacco enforcement proceeding, because we agree with the ALJ that Respondent has not proven the elements of such a defense. ALJ Decision at 6. Respondent has not described, much less proven, that either minor engaged in any trickery or dishonesty to induce the illegal sales. On the contrary, the record as found by the ALJ indicates that each individual was indeed a minor and gave the clerk on request their valid identification licenses with accurate personal information and clear notations showing age. The inspector did not identify himself in the store and neither the inspector nor the minor warned the clerk that they were there to observe whether an illegal sale would be made, but that hardly shows that the clerks were lured or tricked into violating the law.

Instead, the inspections seem to fall directly in the category of providing an opportunity to elect whether to comply or not. In support of its claim that neither it nor its clerks were predisposed to sell to minors, Respondent asserts that the clerks risked losing their jobs and got no commissions for sales and that the store made most of its money from gasoline sales and tobacco sales "are not a significant source" of income for Respondent. NA at 10. Respondent presented no evidence to establish that any of these assertions are factually accurate. The evidence does establish that Respondent's clerks willingly sold cigarettes to individuals whose identification showed they were minors on two occasions. We conclude that neither element of an entrapment defense is supported on this record. Since entrapment is either unavailable as a defense as a matter of law or unproven on this record, we need not discuss Respondent's further argument that all evidence generated by the inspection visits should be excluded as "fruit of the poisonous tree." *Id*.

4. The ALJ did not err in holding Respondent accountable for its employees' actions that violated the Act.

The ALJ addressed in some detail why he found Respondent's attempt to avoid responsibility for the actions of its employees to be unpersuasive. ALJ Decision at 4-5. The ALJ explained that the existence of a corporate policy against sales of tobacco products to minors does not in itself immunize a corporation from the actions taken on its behalf by its employees in the course of their employment even though they violate its policy. *Id*., *citing United States v. Dotterweich*, 320 U.S. 277, 284-85 (1943) and *United States v. Park*, 421 U.S. 658, 672 (1975).[7]

Respondent acknowledges that a "corporate employer may be held responsible for the actions/inactions of its employee," but states that the employee must have been "acting within the scope of his or her employment" and the conduct must have "benefited the corporation." NA at 7. Respondent further acknowledges that an employee acts within the scope of employment "if he or she acts with either actual or apparent authority." *Id.*, *citing United States v. Basic Const. Co*., 711 F.2d 570 (4th Cir. 1983). Despite these admissions, Respondent takes the position that any unlawful sales by its clerks were outside the scope of their employment because the company had express written policies against tobacco sales to minors. *Id*.

[7] Respondent argues that *Dotterweich* and *Park* are not relevant because they dealt with the liability of corporate officers for the misconduct of the corporation rather than corporate liability for the misconduct of employees. NA at 7. However, as the ALJ explained, corporations can act only through their personnel and must be held responsible for those agents' actions on its behalf, or all corporations would be immune from responsibility altogether. ALJ Decision at 4-5. Similarly, the Supreme Court in *Dotterweich* addressed corporate responsibility under the Act and concluded that a corporation was a "person" that could be held liable for violating the Act "[b]ut the only way in which a corporation can act is through the individuals who act on its behalf." 320 U.S. at 281.

Respondent's position is unsupportable. The case which it cites holds precisely the contrary. Basic Construction appealed a jury instruction that a corporation may be criminally liable for an agent's acts done with apparent authority even though the corporation provided contrary instructions to the agent. Basic Construction argued that it was contrary to the Supreme Court decision in *United States v. U.S. Gypsum Co.*, 438 U.S. 422 (1978) which held that corporate intent is an element that must be proven in an antitrust case rather than presumed from the effects of employee's practices.[8] The Fourth Circuit held that *Gypsum* did not mean that a corporation could not be held liable for its employees' actions:

> The instructions given by the district court in the instant case are amply supported by case law. *See United States v. Koppers Co.*, 652 F.2d 290, 298 (2d Cir.), *cert. denied*, 454 U.S. 1083, 102 S.Ct. 639, 70 L.Ed.2d 617 (1981); *United States v. Hilton Hotels Corp.*, 467 F.2d 1000, 1004–07 (9th Cir.1972), *cert. denied*, 409 U.S. 1125, 93 S.Ct. 938, 35 L.Ed.2d 256 (1973); *United States v. American Radiator & Standard Sanitary Corp.*, 433 F.2d 174, 204–05 (3d Cir.1970), *cert. denied*, 401 U.S. 948, 91 S.Ct. 928, 28 L.Ed.2d 231 (1971). These cases hold that a corporation may be held criminally responsible for antitrust violations committed by its employees if they were acting within the scope of their authority, or apparent authority, and for the benefit of the corporation, even if, as in *Hilton Hotels* and *American Radiator*, such acts were against corporate policy or express instructions. In *United States v. Koppers Co.*, the Second Circuit rejected the argument, as do we, that *Gypsum* changes the law on corporate criminal antitrust liability for the acts of its employees. 652 F.2d at 298.

711 F.2d at 573.

As the ALJ found, the employees here were plainly acting in the course of their employment in making these sales. ALJ Decision at 5. They were held out to the public as "cashiers" present to makes sales transactions on Respondent's behalf of products that, Respondent admits, included Newport cigarettes. CTP Ex. 7 (Stipulation by Respondent's counsel). The transactions occurred in Respondent's place of business and Respondent points to no evidence that these sales or proceeds were handled in any manner different than the usual business transactions there. The mere fact that Respondent instructed its clerks not to sell

[8] Violating the prohibition on tobacco sales to minor does not require proof of a specific level of intent; and, in any case, the ALJ here expressly found these sales to constitute a "knowing violation of the law." ALJ Decision at 3.

to minors is, as the ALJ concluded, an inadequate defense because the corporation was obliged to ensure that its policies are enforced and effective. ALJ Decision at 5.[9]

This conclusion is directly supported by the applicable regulations which provide that "each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with" the requirements, including that "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age." 21 C.F.R. § 1140.14. The regulations clearly contemplate that the retailer as an entity must effectively prevent illegal sales and ensure compliance or face the consequences of allowing such sales to occur at its business.

5. Substantial evidence supports the ALJ's conclusions that Respondent violated the law in the alleged transactions on June 6, 2012 and April 11, 2013.

Finally, Respondent argues that CTP failed to carry its burden to prove violations of the Act because it relied so heavily on the testimony of Inspector Ricewick who could not remember specifics of the incidents, because the chain of custody of the cigarette packs could have been compromised, and because the "trustworthiness or character" of the minors involved was not adequately established. NA at 11-14.

The ALJ found that the inspector's "eyewitness testimony that Respondent's employees examined the identification prior to making sales of tobacco products to minors," together with the redacted copies of the identification, was "sufficient proof that Respondent made unlawful sales of tobacco products to minors." ALJ Decision at 3. In his factual findings about the events of June 6, 2012 and April 11, 2013, the ALJ accepted the inspector's account in his declaration and his narrative reports. *Id.* at 2. It is evident that the ALJ found the inspector credible and credited the assertions in his declaration that his narrative reports were created soon after each inspection in the normal course of business and were "true and correct." CTP Ex. 2, at 2-3.

The Board generally defers to an ALJ's findings on weight and credibility of witness testimony (oral or written) unless there are "compelling" reasons not to do so. *See, e.g., River City Care Ctr.*, DAB No. 2627, at 13 (2015), and cases cited therein. Respondent suggests that Inspector Ricewick was only able to testify "in generic terms," and, on cross-examination could not provide specifics beyond those in his reports on details such

[9] The situation is analogous to cases where nursing facility staff have failed to comply with regulatory and/or corporate policies and the Board has consistently held the facility itself responsible for the violations "because 'a facility acts through its staff and cannot disown the consequences of the actions of its employee.'" *Honey Grove Nursing Ctr.*, DAB No. 2570, at 4 (2014), *quoting Gateway Nursing Ctr.*, DAB No. 2283, at 8 (2009).

as what the clerk looked like, where he parked, or exactly how far he was from the minor at the time of the sale. NA at 11-12, citing Tr. 28 et seq. Respondent also asserts that Inspector Ricewick "could not provide basic details of the transaction," that he could "only proffer that according to his notes he was present" at the business, and that no evidence exists of "any conversation between the clerk and the minor" or that the identification shown by the minor was "validly issued or indicated that the purchaser was a minor." NA at 12.

Respondent's assertions misrepresent the testimony and evidence. The inspector was able to recall the layout and physical appearance of the business location while not where he parked or stood each day. Tr. at 28-29, 33. He testified that he conducted these inspections in accordance with his customary practices which included entering the establishment shortly after the minor, standing close enough to observe the transaction (although not to read the identification during the transaction), remaining in a position where he would have heard any conversation between the minor and the clerk (which consisted only of the clerk asking for and getting the identification and then completing the sale), and that he left the store with the minor immediately after each sale and recovered the change and cigarettes from the minor. Tr. at 30-34. He testified that his practice is to enter accounts of the sales in a database system within ten minutes of leaving the establishment, that he never entered information into that system about anything that he did not see, and that he reviewed those entries carefully before signing them.[10] Tr. at 44-45.

The ALJ could reasonably conclude from the inspector's demeanor while testifying, the details he did recall confirming his presence in this establishment, his candid statements about what he no longer could recall himself without reference to his reports, and his descriptions of his practices in making inspections and preparing reports that the inspector's account was credible and reliable. We find no reason, much less a compelling one, to disturb that conclusion.

Moreover, the inspector's notes plainly show much more than his presence in the store on the relevant dates. CTP Exs. 9, 11. They document, for example, the identity of the minor employed each date (through numbers) and the fact of the sale of tobacco to the minor by the clerk after having seen the identification, and attach photographs taken at the time. *Id*. The report for the second visit contains the additional details that the inspector confirmed that the minor did not have any tobacco product and had an "ID showing . . . actual date of birth" before entering the store and that the clerk who made

[10] Reliance on these reports would thus be entirely consistent with the treatment of past recollection recorded as a hearsay exception under the Federal Rules of Evidence where a report "(A) is on a matter the witness once knew about but now cannot recall well enough to testify fully and accurately; (B) was made or adopted by the witness when the matter was fresh in the witness's memory; and (C) accurately reflects the witness's knowledge." F.R.E. 803(5).

that sale was an adult female with light brown hair. CTP Ex. 11, at 1. While the inspector testified that he could not read the identification during the sales, it is not accurate to say there is no evidence about the contents of the identification licenses. As discussed earlier, the redacted licenses were admitted into evidence and appeared on their face to be valid state-issued identification and clearly showed that the individuals were under 18 at the time of the sales. We therefore do not find that Respondent's arguments undercut the ALJ's decision to give substantial weight to the inspector's testimony and reports.

Respondent challenges the chain of custody of the cigarette packs on the grounds that there were "multiple opportunities" for someone to tamper with or alter the evidence. NA at 13. Inspector Ricewick stated in his declaration that after each sale he processed the pack of cigarettes he received from the minor in accordance with his common procedures. CTP Ex. 2, at 2-3. He testified to the following procedures:

> Q: And how do you process the evidence?
> A: The evidence is processed with -- you put in an assignment number of the establishment on the tobacco. You know, there is attestation form for the state that you sign stating that everything was -- to account for the money, where the tobacco was purchased. [The FDA database system] has the series of questions and you answer your series of questions. You know, date and time of the buy and whether ID was requested, etc. Then your evidence is placed in an evidence bag and you complete a FDA evidence deal. The tobacco is placed in the evidence bag and then you seal your evidence bag and put your seal on it. You photograph all your evidence. . . . You photograph all the evidence before it's placed in the seal and then the evidence placed in the seal -- placed in the evidence bag and then sealed and you photograph everything. You photograph your evidence bag with the seal and stuff on it. Then, you know --
> Q: Where does the bag with the tobacco product, where does it go after it leaves your possession and how does it get there?
> A: I maintain custody of it in a locked safe. I maintain custody of it in a locked safe in my residence. Then eventually I transport it to Catonsville to my head office. And then you log the evidence in an evidence log and my supervisor has to sign the evidence log and then the evidence is locked up in another facility of boxes of tobacco.

Tr. at 34-35. While Respondent speculates on points in this process at which someone might have accessed the inspector's car while he was inspecting another establishment or opened his home safe, Respondent offers nothing to establish that any such event occurred, or that there was even a serious threat of it occurring. Notably, Respondent did even question the inspector as to whether his car was broken into or who had access to

his home safe. In any event, even had the actual cigarette packs somehow been lost or destroyed, that would not necessarily undercut the inspector's testimony that he saw the minor obtain the Newport packs from the sales clerks and that the minor then delivered the packs to him immediately after obtaining them and exiting the store.

Respondent's suggestion that the minors were not shown to be trustworthy is equally irrelevant. NA at 13-14. Since they were not witnesses in the case, their actions were all observed by the inspector, and their identification licenses were valid on their face to show their minority, it is not clear why the characters of the minors would make any difference to the outcome. Moreover, CTP provided testimony on how these minors were selected including receiving referrals from other minor employees, reviewing their report cards, meeting their parents, and interviewing them. CTP Ex. 3; Tr. at 21-24. Respondent's claims that CTP should have performed independent investigations of the minors, including letters of recommendation and review of social media contacts and/or third party references, are simply gratuitous and have no bearing on the evidence in this case. NA at 14.

We conclude that the ALJ's findings of fact are supported by substantial evidence on the record as a whole.

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/
Sheila Ann Hegy

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member