Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Atty's Parti Expo, Inc., d/b/a Parti Expo
Docket No. A-18-111
Decision No. 2925
February 1, 2019

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Atty's Parti Expo, Inc., d/b/a Parti Expo (Parti Expo or Respondent) appeals the July 6, 2018 initial Decision of an Administrative Law Judge (ALJ) imposing a 30-calendar-day No-Tobacco-Sale Order (NTSO) against Parti Expo, *Atty's Parti Expo, Inc., d/b/a/ Parti Expo,* DAB TB2906 (2018) (ALJ Decision).

For the reasons explained below, we affirm the ALJ Decision.

Introduction

The ALJ imposed an NTSO after finding that Parti Expo, within 36 months, had committed five repeated violations of regulations at 21 C.F.R. Part 1140 issued by the Secretary of Health and Human Services (Secretary) to implement 21 U.S.C. § 387f(d), a provision of section 906 of the Food, Drug, and Cosmetic Act (Act), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31. ALJ Decision. The repeated violations, found during inspections of Respondent's business by Food and Drug Administration (FDA) – commissioned inspectors, included two violations on November 13, 2015 – a violation of 21 C.F.R. § 1140.14(a)(1) (selling a tobacco product to a minor) and a violation of § 1140.14(a)(2)(i) (failing to verify that the purchaser of a tobacco product was 18 years of age or older) – and three prior violations of one or both of those regulations that Respondent concedes.

The ALJ issued the ALJ Decision after conducting further proceedings as instructed in the Board's remand of her earlier decision, *Atty's Parti Expo, Inc., d/b/a Parti Expo*, DAB TB2263 (2017) (Initial Decision or DAB TB2263). *See Atty's Parti Expo., Inc., d/b/a Parti Expo*, DAB No. 2871 (2018) (Board Remand). The Board Remand did not reach the merits of the Initial Decision because the Board concluded the ALJ had committed a harmful error in her consideration of the evidence. Specifically, although the ALJ initially treated a statement by Johnny Atty (admitted to the record as

Respondent exhibit C) as "written testimony under oath," the ALJ noted in her decision that the statement was not actually "a written declaration that is signed by the witness under oath" and stated that for that reason "I cannot accord it such weight." DAB No 2871, at 8, 9; DAB TB 2263, at 3, n.3. The Board instructed the ALJ on remand "to provide Parti Expo with an opportunity to refile a statement of Johnny Atty (with the same text as the statement currently in the record . . .) that complies with 21 C.F.R. §§ 17.25(a), 17.37(b) and the ALJ's [Acknowledgment and Pre-hearing Order (APHO)]." DAB No. 2871, at 9. The Board further instructed the ALJ to determine whether the newly-filed statement (assuming Respondent filed one) complied with those regulations and the ALJ's APHO and, if so, to "conduct such further proceedings as necessary to reach a decision that treats the statement as written direct testimony, weighs it against the other evidence of record and is otherwise consistent with 'substantial justice.'" *Id*.

As discussed in more detail below, the ALJ fully complied with the Board's instructions on remand.

Applicable Law

The Act prohibits "the doing of any . . . act" with respect to a tobacco product "held for sale . . . after shipment in interstate commerce" that results in the product being "misbranded" and authorizes the FDA to impose certain remedies against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333. A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 387f(d) of the Act. *Id.* § 387c(a)(7)(B). Congress authorized the Secretary of Health & Human Services (Secretary) to adopt regulations that impose "restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product" as appropriate to protect public health. *Id.* § 387f(d). Congress also directed the Secretary to establish the Center for Tobacco Products (CTP) within the FDA to implement the tobacco products provisions of the Act. *Id.* § 387a(e). The regulations adopted by the Secretary provide that "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age." They also require retailers "to verify by means of photographic identification containing the bearer's date of birth that no purchaser of the [tobacco] products is younger than 18 years of age," except that "[n]o such verification is needed for any person over the age of 26[.]" 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i).[1]

[1] At the time of the FDA inspections at issue here, these regulations were codified at 21 C.F.R. § 1140.14(a) and (b). Effective August 8, 2016, the regulations were recodified to the sections to which we cite without any substantive change. 81 FR 28,973, 28,974, 29,103; *see* https://federalregister.gov/a/2016-10685.

CTP may seek to impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products . . . ." 21 U.S.C. § 333(f)(9). CTP also may seek to impose an NTSO (alone or in addition to a CMP) when it finds "that a person has committed repeated violations of restrictions promulgated under section 387f(d) . . . at a particular retail outlet . . . ." *Id.* § 333(f)(8). "Repeated violations" are defined as "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet . . . ." Act § 103(q)(1)(a); *see also* FDA Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers: Guidance for Industry at 3, 5-6 (December 2016), *available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf.

A person is entitled to a hearing before an NTSO is imposed. 21 U.S.C. § 333(f)(8). The Act does not specify the duration of an NTSO but does specify the factors that must be considered in determining the length of an NTSO: "the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , ability to pay, effect on ability to continue to do business, any history of prior such violations the degree of culpability, and such other matters as justice may require." *Id.* § 333(f)(5)(B). CTP policy guidelines establish 30 calendar days as the maximum NTSO duration for a first NTSO. *See* Determination Guidance for Tobacco Retailers (August 2015) at 4, available at http://www.fda.gov/downloads/Tobacco Products/Labeling/RulesRegulationsGuidance/UCM460155.pdf

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a "presiding officer" who is "an [ALJ] qualified under 5 U.S.C. 3105." 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before the ALJ by serving a Complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The retailer (the respondent in the administrative appeal proceedings) requests a hearing by filing an answer to the complaint within 30 days but may request one 30-day extension. *Id.* § 17.9(a),(c). If the respondent does not file an answer within the prescribed time, the ALJ "shall assume the facts alleged in the Complaint to be true" and enter a default judgment "if such facts establish liability under the relevant statute . . . ." *Id.* § 17.11(a). Assuming a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

A respondent dissatisfied with an ALJ decision may appeal that decision (to which the regulations refer as the "initial decision") to the DAB. *Id.* §§ 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. *Id.* § 17.47(j).

Background

The factual findings we discuss in this decision are taken from the ALJ Decision (DAB TB2906), and from the Initial Decision (DAB TB2263); the ALJ expressly incorporated her findings from the Initial Decision into the ALJ Decision. *See* ALJ Decision at 5 ("The Board did not make a finding regarding my treatment of CTPs evidence or my determinations regarding the credibility or weight to be 'accorded either party's evidence.' [Board Remand] at 9. Accordingly, the factual findings in the Initial Decision are incorporated herein, and I will restate or refer to the Initial Decision as appropriate.") We find no error in the ALJ's incorporation of her findings of fact from the Initial Decision, and we make no new findings of fact here.[2] For background on the facts related to the violations and penalty being appealed,[3] as well as to the ALJ proceedings in the Initial Decision, DAB TB2263, we refer the reader to the case background section in DAB No. 2871.

Standard of review

The standard of review for the Board 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.*

Discussion

A. The ALJ did not err in concluding that Respondent committed the violations alleged, after weighing Respondent's evidence, including the Atty Declaration, against CTP's.

1. The ALJ's conclusion that Respondent is liable for imposition of a 30-day NTSO – a conclusion reached after fully complying with the Board's remand instructions – is supported by substantial evidence on the record and free of error.

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[2] The facts stated here are undisputed unless we indicate otherwise.

[3] We note the ALJ's finding that this is the third Complaint CTP has filed against Respondent and that Respondent conceded the violations alleged in the first two complaints, thus making them final and binding and providing a basis, taken together with the proven allegations in the third Complaint, for a penalty addressing five repeated violations of the Act and its implementing regulations over a 36-month period. ALJ Decision at 5; *see also* DAB TB2263 at 2, 5, 10-11. Respondent does not dispute this ALJ finding, and the ALJ's conclusion that the prior enforcement actions are final and binding is legally correct. 21 C.F.R. § 17.45(d). Accordingly, we affirm that finding without further discussion.

a) The ALJ fully complied with the Board's remand instructions.

On remand, the ALJ fully complied with the Board's instructions. The ALJ issued an order permitting Parti Expo to refile the Johnny Atty statement that appears in the record as Respondent Exhibit (Ex.) C. ALJ Decision at 3. On June 8, 2018, Parti Expo filed a Declaration by Mr. Atty (Atty Declaration). *Id.* at 4. The ALJ found that "the Atty Declaration appears to contain the same text as the statement currently in the record as Respondent [Ex.] C," *id* at 5, thus following the Board's instruction that any Declaration submitted must contain "the same text as the statement currently in the record as Respondent exhibit C . . . ," DAB No. 2871, at 9. The ALJ concluded that "[b]ecause Respondent attached the statement to a declaration signed by Mr. Johnny Atty under penalty [of] perjury for false testimony, I hereby admit the Atty Declaration as written direct testimony in lieu of in-person testimony." ALJ Decision at 5. Accordingly, the ALJ complied with the Board's instruction to determine whether the Atty Declaration, as refiled, complied with 21 C.F.R. §§ 17.25(a), 17.37(b) and the ALJ's APHO. DAB No. 2871, at 9.

Finally, the ALJ complied with the Board's instruction to treat a compliant Atty Declaration as written direct testimony and to weigh it against the other evidence of record. *Id*. The ALJ stated, "Even after admitting the Atty Declaration into evidence and giving it the appropriate weight, I find that Respondent failed to rebut the sworn testimony of Inspector Shafto and CTP's corroborating evidence." ALJ Decision at 7; *see also id*. at 5 ("After according the Atty Declaration the same weight as written direct testimony and weighing it against the other evidence of the record, I find that Respondent failed to provide sufficient evidence to refute CTP's evidence.") After discussing how she weighed the evidence, the ALJ concluded,

> Accordingly, I find that CTP has established that on November 13, 2015, Respondent Atty's Part[i] Expo, Inc. d/b/a Parti Expo, sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age, and Respondent is therefore liable under the Act. For these and the reasons previously set forth in the November 30, 2017 Initial Decision, I find that an NTSO is an appropriate penalty.

Id. at 7.

Respondent does not dispute that an NTSO is an authorized penalty for five repeated violations of the regulations within a 36-month period. Nor, as stated earlier, does Respondent dispute that it committed within that period three previous violations or that the alleged repeated violations found during the November 13, 2015, inspection occurred within that period. Respondent, however, disagrees with the ALJ's conclusion regarding

his liability for the NTSO, that is, that the alleged November 13, 2015, violations occurred as alleged, thus establishing the five repeated violations within a 36 month period required to impose the NTSO. As discussed below, we conclude that the ALJ's determination of Respondent's liability for the NTSO is supported by substantial evidence and free of legal error.

Respondent does not dispute that on remand the ALJ considered the Atty Declaration and weighed it against the other evidence of record, and the ALJ Decision clearly shows that the ALJ did this. The ALJ began by noting, "Respondent has submitted the Atty Declaration for consideration 'as rebuttal and counter evidence.'" ALJ Decision at 6. The ALJ then discussed the statements in the declaration but "f[ou]nd that [the declaration] states the same arguments and defenses that Respondent already raised in its Answer, pre-hearing brief, Parti Expo Letter to FDA . . . , and post-hearing brief . . . ," which she had "thoroughly addressed . . . in the Initial Decision." *Id*. (citing Initial Decision at 5-10); *see also id*. at 7 ("I stand by the analysis, findings of fact and NTSO penalty determination that I made in the Initial Decision."). The ALJ correctly stated that the Board's Remand Decision "did not make a finding regarding my treatment of CTP's evidence or my determinations regarding the credibility or weight to be 'accorded either party's evidence.'" *Id*. at 5 (citing Remand Decision at 9). Therefore, it was permissible for the ALJ to incorporate the factual findings from her initial decision into the ALJ Decision and to restate or refer to those findings as appropriate. Having reviewed the ALJ's analysis in both the Initial Decision and the ALJ Decision, we agree that the ALJ has acknowledged and discussed Respondent's contentions, as well as CTP's, in some detail, including the contentions in the Atty Declaration.

b) We defer to the ALJ's findings regarding credibility and weight.

While not disputing that the ALJ weighed the Atty Declaration against the other evidence of record, Respondent argues that the ALJ "improperly minimizes the value and weight of Johnny Atty's sworn statement, while affording full weight and credibility to that of the inspector, despite the Complainant's refusal to cross-examine [Johnny Atty] after requiring him to appear at the hearing." Notice of Appeal (NA) at 2-3, 8-10.[4] Respondent further asserts,

> What Judge Ravinski's opinion does not do is mention why Inspector Shafto's testimony was so credible and, more importantly, what made it more credible than Johnny Atty's statement. Furthermore, it does not point to any weaknesses or inconsistencies in Johnny Atty's statement. Complainant did not even bother to cross examine this witness, despite

[4] Respondent submitted a Notice of Appeal and a brief entitled "Respondent's Appeal and Post-Hearing Brief in Support" (Appeal Brief) that had no pagination. To avoid confusion, we have paginated the Appeal Brief and cite to "NA at __".

> demanding his presence at the hearing. The opinion does not state what claims Johnny Atty's statement failed to address or rebut. Meanwhile, Respondent has found many holes in the testimony of Inspector Shafto, which was hazy at best in terms of recollection and consistency.

NA at 10.[5]

In addressing these contentions, we begin by reiterating the well-settled law that the Board defers to ALJ findings on credibility and the weight of testimony absent a compelling reason for not doing so. *E.g. TOH, Inc. d/b/a/ Ridgeville Serv. Ctr.*, DAB No. 2668, at 18 (2015); *Putnam Ctr.*, DAB No. 2850, at 13 (2018). Thus, the issue here is whether we find that Respondent's contentions of alleged flaws in the ALJ's findings on credibility and weight provide a compelling reason to disturb those findings. We do not.

Contrary to Respondent's suggestion (NA at 9-10), the ALJ considered the FDA inspector's answers to the questions Respondent's counsel asked on cross-examination and specifically found as follows:

> Inspector Shafto testified credibly during the hearing. While Respondent's counsel attempted to discredit Inspector Shafto's testimony, I am convinced that Inspector Shafto testified truthfully about his November 13, 2015 documented observations.

ALJ Decision at 7 (citing Initial Decision at 7-9). It is clear from the ALJ's citation to the Initial Decision that her statement about counsel's attempt to discredit Inspector Shafto's testimony refers to all of counsel's cross-examination, including the questions now listed by Respondent on page 9 of its Notice of Appeal.[6] The ALJ had the opportunity to observe the inspector's demeanor as he answered questions on cross-

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[5] Contrary to Respondent's suggestion, CTP was not required to cross-examine Mr. Atty. *See* Hearing Transcript (Tr.) at 9 (ALJ swears in Mr. Atty but with the understanding that CTP might choose not to cross-examine him, which, the ALJ stated, was "[CTP's] decision to make" and "no problem at all."). Nor was the ALJ required to accord significance to CTP's decision not to cross-examine Mr. Atty when weighing the evidence. The ALJ ultimately admitted the Atty Declaration as written direct testimony and could determine the credibility of that testimony and how much weight to accord it, as she did, regardless of whether CTP cross-examined Mr. Atty.

[6] In any event, Respondent's assertion that the inspector "answered "No" to every single one of [the questions listed on page 7 of the NA][]" is not correct and distorts the inspector's answers and, in some cases, the questions. For example, asked whether he had observed the sale of cigarettes to the minor, the inspector answered, "Yes, I did." Tr. at 16. Respondent's counsel did not ask the inspector if he "knew whether Minor 433 had a fake ID." NA at 7. Counsel stated "So you don't know if the decoy [not this minor in particular] ever presents a fake ID." The inspector answered, "I ask to see the decoy's ID before the inspection. So I know . . . ." Counsel then cut him off and said "But you didn't have her empty her pockets to verify if there was a fake ID." The inspector answered, "I did not have the decoy empty pockets. I - - that's not part of the protocol. Tr. at 17.

examination; we have not had that opportunity. The ALJ also stated in both her Initial Decision and the ALJ Decision her observation that many of the questions asked by Respondent's counsel were outside the scope of the inspector's declaration, which constituted his written direct testimony. ALJ Decision at 7; Initial Decision at 7, n.8. Respondent does not specifically dispute this statement and the statement is consistent with the record.

Moreover, we have reviewed Respondent's briefs and the transcript, as Respondent requested (NA at 9) and disagree with his allegation that there are "many holes" in the inspector's testimony. We find no basis to question the ALJ's finding in the Initial Decision (incorporated into the ALJ Decision) that "Inspector Shafto testified credibly **and comprehensively** about his observations during the November 13, 2015 inspection at which he observed Respondent selling tobacco products to Minor 433." DAB TB 2263, at 7 (emphasis added). Respondent's focus on the inspector's in-person testimony also ignores the fact that in concluding that Respondent had committed the violations as CTP alleged, the ALJ did not rely exclusively on the inspector's testimony but also on corroborating evidence submitted by CTP. The ALJ Decision states, "Even after admitting the Atty Declaration into evidence and giving it the appropriate weight, I find that Respondent failed to rebut the sworn testimony of Inspector Shafto and CTP's corroborating evidence." ALJ Decision at 7; *see also* Initial Decision at 6-8 (citing the inspector's sworn declaration; the Narrative Report the inspector completed at the time of the inspection; CTP's Notice of Compliance Check Inspection (NCCI); the Tobacco Inspection Management System (TIMS) record; and a copy of the minor's identification, with personal identifiers redacted), CTP Exs. 24, 17, 18, 19.

By contrast, none of the evidence submitted by Respondent corroborates assertions the Atty Declaration makes to try to rebut the violations. Aside from the Atty Declaration, Respondent submitted only a copy of a letter from Respondent's counsel to the FDA (dated 12/2/2015); the FDA's email response to the letter (dated December 3, 2015) and three copies of Respondent's undated tobacco and liquor policy.[7] *See* DAB TB2263, Respondent Exhibits (Resp. Ex.) B, D, E, F and G. The letter from Atty's counsel, like the Atty Declaration, denied that the sale to a minor had occurred or that any employee matched the description of the seller, but arguments by counsel are not evidence. The FDA email merely confirmed that CTP had sent an NCCI for the November 13, 2015, inspection to Respondent and advised that FDA was reviewing the evidence, and the December 2, 2015, letter from Respondent's counsel to which the email was responding acknowledged receiving the NCCI. As for the policies Respondent submitted, they are

[7] Respondent marked each copy of the policy as a separate exhibit, and each was written in a different language, but all three bore no date. Petitioner also submitted an Exhibit A, a copy of its Answer to the Complaint and Request for Hearing, but that document is a pleading, not an evidentiary exhibit. *See* DAB TB2263, CRD Docket (Dkt.) Entry 18.

undated and, therefore, do not serve as proof of Respondent's policies at the time of the inspection. For that reason, the policies are not capable of corroborating the following statements in the Atty Declaration: "[W]e require everyone who works for us to shave their face clean at all times"; and, "Nobody worked there at the time, or now, that has a beard." Resp. Ex. C at 1. When weighing the evidence, the ALJ appropriately considered whether the parties had submitted corroborating evidence. We find nothing in Respondent's exhibits that causes us to question (much less compels us) to disturb the ALJ's finding according more weight to CTP's evidence on the liability issue due, in part, to the documentary evidence corroborating the inspector's testimony.

The record also does not support Respondent's assertion that the ALJ Decision "does not point to any weaknesses or inconsistencies in Johnny Atty's statement." NA at 10. As noted above, the ALJ discounted the Atty Declaration, in part, because it merely reiterated arguments and defenses she "thoroughly addressed . . . in the Initial Decision." ALJ Decision at 6 (citing Initial Decision at 5-10). By incorporating her prior findings and discussion, the ALJ was implicitly concluding that those findings and discussion equally addressed the reasons she did not credit the Atty Declaration. A key finding involved the ALJ's treatment of Respondent's assertion that no employee matched the description of the employee that is given in the inspector's Narrative Report, the TIMS record and the NCCI (*see also* Tr. at 30 – inspector's testimony that the description in the NCCI is consistent with the description in Narrative Report). The ALJ specifically found --

> Respondent failed to support is argument that no employee matches [the inspector's description of the employee]. Without some corroborating evidence for example, a written policy that all employees must be clean shaven in effect during the time period at issue, or footage of the employee in question on that day, this assertion does not hold water. Moreover, Respondent should have maintained the video footage of the date and time specified in the November 18 2015 [NCCI].

DAB TB2263, at 9 (emphasis removed). Respondent, as we discussed above, presented no such corroborating evidence.

1. The ALJ did not impose an unfair burden of proof on Respondent.

In an ALJ hearing on a CTP Complaint, CTP is required to prove a respondent's liability and the appropriateness of the penalty sought for that liability by a preponderance of the evidence, and the respondent is required to prove any affirmative defenses by the same standard. 21 C.F.R. § 17.33(b),(c). The ALJ found CTP's evidence of the violations alleged here "overwhelming," which more than meets that regulatory standard. *See* ALJ Decision at 9.

Respondent argues that the ALJ's requirement of corroborating evidence, and, in particular her statement about maintaining the video footage, imposed an unfair burden of proof on Respondent to rebut the unlawful sale. NA at 5-7. Respondent argues that this "improperly places the burden of proof solely on the Respondent, where the only way to obtain a dismissal is to provide video footage of that day and time proving the contrary." *Id.* at 5. There is no basis in fact or law for this assertion. The ALJ's statements quoted immediately above were preceded by the ALJ's finding that "Inspector Shafto testified credibly regarding the description of the employee [who sold the cigarettes to the minor]." DAB TB2263, at 9. The ALJ also cited the inspector's Narrative Report, which she found (and we agree) is consistent with his testimony. *See id.* at 7, 8. Thus, the ALJ rested her conclusion that the alleged violations had occurred on the affirmative case made by CTP, not just on her finding that Respondent had failed to support its rebuttal argument.

Respondent nonetheless argues that "[i]t is unreasonable to expect the establishment to maintain video footage for a year without hearing from the agency, especially when they were informed the worst case scenario would be a warning or a fine if a violation was found to have taken place."[8] NA at 6 (emphasis removed). This assertion assumes a finding that the ALJ did not make. She did not find that Respondent must maintain a video in order to be able to corroborate its claim that it had no employee matching the inspector's description; she only found, correctly, that Respondent had not presented such corroborating evidence. This assertion also rests on an unsupported theory that CTP was somehow responsible for Respondent's not keeping the tape. Respondent suggests that CTP was required to have pictures or its own video footage of the unlawful sale. *Id.* However, Respondent cites no authority supporting that assertion, and we find none.[9] Respondent also suggests that the FDA was required to come to Respondent's establishment to review the video footage when Respondent's counsel invited it to do so.

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[8] Respondent also claims that the ALJ should have discounted CTP's evidence because the minor to whom Respondent sold the cigarettes "was not allowed to testify and there was not even a written statement submitted on his/her behalf." NA at 6. The Board rejected similar arguments in another case and does so here. *See TOH, Inc. d/b/a/ Ridgeville Serv. Ctr.*, DAB No. 2668 at 9, 11 (holding that the respondent had not shown it "had a real need to receive the unredacted license of the minor to address any concerns about authenticity" or to "prepare a defense" and that "CTP raised substantial and legitimate concerns about the potential impact of disclosure of the photographs, names and addresses of the minors . . . .").

[9] The ALJ case Respondent cites, *Daniel D. Moore, d/b/a ABC*, DAB TB4705 (2016), actually undercuts its assertion because the ALJ there found that the sale had taken place as alleged even though, unlike here, the inspector did not accompany the minor into the store and testified to observing the minor's entry into and exit from the store, not the sale itself. DAB TB4705, at 3. Moreover, ALJ decisions do not bind the Board, or even other ALJs. *E.g. Mohammad Nawaz, M.D. and Mohammad Zaim, M.D., PA*, DAB No. 2687, at 7 (2016), *aff'd*, *Mohammad Nawaz, M.D. & Mohammad Zaim, M.D., P.A. v. Price*; *Zille Shah, M.D. & Zille Huma Zaim, M.D., P.A. v. Price*, Nos. 4:16cv386 and 4:16cv387, 2017 WL 2798230 (E.D. Tex. June 28, 2017).

See id. at 10 ("Respondent, in December 2015, offered corroborating evidence in the form of video footage . . . but this was ignored by the FDA, and was not requested until about a year later, *after* a Complaint was filed . . . .") (emphasis in original).[10] Respondent cites no legal authority, and we find none, that requires the FDA (or CTP) to respond to a retailer's invitation to view video footage at the establishment or that CTP seek such footage, although it may seek it during discovery after a complaint is filed, as CTP did here.

Nor is there any support for Respondent's suggestion that it did not receive timely and effective notice of the enforcement action and potential penalties that would have prompted it to preserve the tape.[11] *See* Atty Declaration at 1 (Resp. Ex. C); NA at 4, 5, 6. As we discuss more fully in the next section of our decision, there is no authority requiring CTP to send an NCCI within a specific amount of time after the inspection. Nonetheless, the record here shows that Respondent received the NCCI, which included the inspector's description of the employee, on November 20, 2015, seven days after the inspection. CTP Exs. 19, 20. Respondent thus had notice, although none was required, as of November 20, 2015, that the tape might be important enough to its rebuttal case to warrant preserving it. Indeed, Mr. Atty states in his declaration that after receiving the notice, "[t]he first thing I did, before even contacting an attorney, was review the video." Resp. Ex. C at 1. He then states that "[n]obody worked there at the time, or now, that has a beard." *Id*. This statement indicates that Respondent was aware that the description of the employee might be an issue in the enforcement action yet failed to keep the tape. Thus, not keeping potential rebuttal evidence was clearly Respondent's choice, and the FDA and CTP cannot be blamed for that choice.

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[10] This apparently is a reference to the following statements in Respondent's counsel's December 2, 2015, letter to FDA:

> My client maintains surveillance footage for the establishment. After reviewing the . . . footage based on the date and time in the notice, no such transaction took place. You are welcome to send an agent or authorized representative to review this footage with my client.

Resp. Ex. B.

[11] Respondent requested oral argument based on an alleged "issue of effective notice and due process" that it contends "remains outstanding". NA at 11; *see also* Reply at 8 (requesting oral argument because the Board Remand did not address "all the other issues presented in the Appeal"). We reject that request. Oral argument is not necessary to address the notice and procedural fairness issues raised by Respondent since we have addressed those issues here and find no outstanding issue. We have decided all of the issues we did not reach in the Board Remand, without the need for oral argument. Finally, we note, as did CTP, that the federal court cases cited by Respondent as addressing the issue of whether particular laws were too vague to provide proper notice (*see* NA at 11-14) have no application here. *See* CTPs' Memorandum In Opposition to Respondent's Notice of Appeal (CTP Br.) at 19-20. Respondent has not argued that the regulations it violated are vague, and those regulations clearly notify retailers that selling tobacco products to minors and not verifying that a purchaser is 18 or older by means of photographic identification are violations of law providing a basis for administrative penalties including NTSOs. Administrative penalties protect the public and do not involve the policy issues in punitive damages cases such as those cited by Respondent.

In summary, we find no basis for concluding that the ALJ misallocated the burden of proof, and conclude that substantial evidence supports her conclusion that the violations occurred and provided a basis to impose the NTSO.

B. The ALJ lawfully determined that a 30-day NTSO was an appropriate penalty for Respondent's Violations.

1. CTP was not required to state in the NCCI or the email communication with Respondent's counsel that an NTSO was a possible penalty.

Respondent argues that NCCI and the FDA's email response to the December 2, 2015, letter from Respondent's counsel somehow made it unlawful for the ALJ to impose the 30-day NTSO. There is no basis for this argument. The statutes plainly authorize imposition of an NTSO as a penalty for repeated violations of the regulations such as those that occurred here. 21 U.S.C. § 333(f)(8). As CTP points out, the statutes do not specify the duration of NTSOs but do specify factors to be considered when determining the length of an NTSO and contemplate that an NTSO may be permanent. CTP Br. at 11 (citing 21 U.S.C. § 333(f)(5)(B)). In addition, CTP has issued public guidance stating that for a first time NTSO, CTP will seek a maximum of 30 days, as it did here. Guidance for Tobacco Retailers (August 2015 at 4) (available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf).

Respondent had notice through these statutes and the guidance (which, as its title indicates, is specifically addressed to retailers selling tobacco products) that an NTSO, and specifically a 30-day NTSO, was a possible penalty for its repeated violations. Moreover, the ALJ correctly found that "there is no requirement that CTP provide explicit notice that an NTSO could occur" and "that Respondent had many interactions with CTP's enforcement program and was provided sufficient notice that repeated violations result in increasingly severe penalties." DAB TB2263, at 10. The applicable statutes require only "timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a follow-up compliance check," and "notice to the retailer of all previous violations at that outlet" prior to charging a person with a violation. 21 U.S.C. § 333 Note (Tobacco Control Act (TCA) § 103(q)(1)(B), (D)). Neither requirement applies to the NCCI (or to email correspondence), and it is undisputed that CTP complied with both requirements in the present case. With respect to the first requirement, the Board has held that it "may reasonably be read as requiring only that, having found the retailer to be committing acts in violation of law, CTP must so inform the retailer before returning to

the establishment to conduct another inspection . . . ." *Orton Motor Co., d/b/a Orton's Bagley*, DAB No. 2717, at 19 (2016), *aff'd, Orton Motor, Inc., d/b/a/ Orton's Bagley, v. U.S. Dep't of Health & Human Servs.*, 884 F.3d 1205, 2018 WL 1386141 (D.C. Cir. 2018). Here (as in *Orton*), CTP complied with this regulation by sending Respondent a Warning Letter notifying it of the illegal sale of tobacco to a minor and failure to check the purchaser's identification found during the initial inspection on March 1, 2014. CTP Ex. 22. Moreover, that warning letter expressly stated that an NTSO was a potential penalty if Respondent failed to correct the violations when it stated, "Failure to correct the violations may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, [CMPs], [NTSOs], seizure, and/or injunction." *Id*. at 2; *see also* Tr. at 18-20.

2. *Contrary to Respondent's suggestion, the ALJ Decision shows that the ALJ properly weighed the evidence of record in concluding that the 30-day NTSO is appropriate and correctly applied the law.*

Respondent argues, "Imposition of any NTSO, especially one with a length of thirty (30) days, would deal a devastating blow to Respondent's ability to conduct business." NA at 8. The ALJ rejected that argument in the Initial Decision, stating, "I am not persuaded that the NTSO would severely hinder Respondent Parti Expo's ability to continue other lawful retail operations during the NTSO period." DAB TB2263, at 11. Respondent argues that in reaching that conclusion in the Initial Decision, the ALJ "incorrectly state[d] that there was no evidence presented regarding the effect of the 30-day NTSO on Respondent's ability to conduct business."[12] NA at 8 (citing DAB TB2263). Respondent points to the Atty Declaration as "attesting to the fact that the NTSO would seriously hinder its ability to conduct business."[13] *Id*. Respondent also points to "evidence" in its post-hearing brief about alleged "saturation of the market in the area where Respondent conducts business." *Id*. This "evidence," Respondent asserts, "shows that there are at least twenty-four (24) businesses within a 1-2 mile radius that sell alcohol and tobacco, and that is not counting those that just sell tobacco . . . ."[14] *Id*. After reviewing the ALJ Decision and these allegations by Respondent, we find no reason to disturb the ALJ's finding that she was not persuaded the NTSO would "severely hinder" Respondent's ability to conduct its business.

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[12] The ALJ did not make this statement in the ALJ Decision now before us where, as we discuss below, she considered the Atty Declaration as testimony on this issue but found the statements in it unpersuasive.

[13] Mr. Atty's actual statement was, "If we can't sell tobacco, we won't be able to effectively run our business." Resp. Ex. C at 2.

[14] We note that the Atty Declaration states that there are "at least 20 businesses (not 24) in a 1-2 mile radius that sell alcohol and tobacco." Resp. Ex. C at 2

The ALJ did state in her Initial Decision that "Respondent has not presented any evidence about the effect of a 30-day NTSO on its ability to conduct its business." DAB TB2263, at 11. However, that was not an incorrect statement at that time. The ALJ had made clear earlier in the decision that she did not accord the Atty Statement evidentiary weight because it was not sworn. *Id*. at 9. Moreover, the purported "evidence" in Respondent's post-hearing brief relating to alleged "saturation of the market" was not, in fact, "evidence" but, rather, a link to a website. Neither Respondent's exhibit list nor its exhibits at that time contained any evidence about the possible effects of the NTSO on its business. *See* Respondent's List of Proposed Witnesses and Exhibits and Resp. Exs. A-G. The ALJ's not being persuaded that the NTSO would cause severe harm to Respondent's ability to do business is not surprising given these circumstances.[15] However, the ALJ also made clear that, even if she credited Respondent's assertions, she would conclude that the need to protect minors would outweigh any hindrance to Respondent's ability to do business.

> Moreover, "the need to protect the [minors] outweighs the adverse effects that an NTSO may have on an individual retailer's business, especially in light of the fact that imposition of this remedy is reserved only for those retailers who demonstrate indifference to the requirements of law."

DAB TB2263, at 11 (citing *Kat Party Store, Inc./b/a/ Mr. Grocer Liquor Store*, DAB T509, at 3-4 (2016)).

On remand, the ALJ admitted the Atty Declaration into the evidentiary record. However, she found she had "thoroughly addressed . . . in the Initial Decision" the same points reiterated in the Declaration. DAB TB2906, at 6 (citing Initial Decision at 5-10). The ALJ then concluded that she stood "by the analysis, findings of fact, and NTSO penalty determination" she had made before. *Id*. at 7 (citing Initial Decision at 7-12). One of these findings, as discussed above, was the ALJ's statement that she was "not persuaded that the NTSO would severely hinder Respondent Parti Expo's ability to continue other lawful retail operations during the NTSO period." DAB TB2906, at 6; *see also* DAB TB2263, at 11. Thus, the ALJ Decision makes clear that even after according the Atty Declaration full evidentiary status, her decision had not changed with regard to both liability and the appropriateness of the NTSO. As the ALJ Decision states,

[15] Even assuming the link constituted evidence of "saturation," we would not find that fact alone a basis to disturb the ALJ's finding that she was not persuaded Respondent's ability to do business would be severely hindered by the NTSO.

> Accordingly, I find that CTP has established that on November 13, 2015, Respondent . . . sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age, and Respondent is therefore liable under the Act. For these and the reasons previously set forth in the November 30, 2017 Initial Decision, I find that an NTSO is an appropriate penalty.

DAB TB2906, at 7. We conclude that the ALJ appropriately weighed the evidence of record in concluding that a 30-day NTSO is appropriate, and, having already affirmed her conclusion that Respondent was liable for that penalty, we affirm her imposition of the NTSO.

Conclusion

For the reasons stated above, we affirm the ALJ Decision that Respondent committed five repeated violations of 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) within a 36-month period and affirm her imposition of a 30-day NTSO for that noncompliance.

/s/
Christopher S. Randolph

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member