

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Vasudevay LLC, d/b/a Town News and Tobacco
Docket No. A-16-97
Decision No. 2746
November 1, 2016

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Vasudevay LLC, d/b/a Town News and Tobacco (Vasudevay, Respondent) appeals the April 26, 2016 Initial Decision by an Administrative Law Judge imposing a \$5,000 civil money penalty (CMP) against Respondent for violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and implementing regulations, 21 C.F.R. Part 1140. *Vasudevay LLC, d/b/a Town News and Tobacco*, DAB CR4593 (2016) (ALJ Decision). Vasudevay admitted that it repeatedly sold tobacco products to minors and had a self-service display of tobacco products accessible to minors in violation of the Act and regulations, but argued that the amount of the CMP would have a substantial adverse financial impact on Respondent. The ALJ concluded that the CMP amount was appropriate because, he determined, Respondent egregiously violated the law and put the health and safety of minors at risk even after the U.S. Food and Drug Administration (FDA) warned it not to do so. The ALJ also determined that Respondent had sufficient resources to pay the penalty and its argument did not provide a sufficient basis for reducing the CMP.

Respondent asks the Board to reduce the amount of the CMP on the grounds that its owner is unable to pay his bills and is in debt. For the reasons explained below, we sustain the \$5,000 penalty amount. We determine that Respondent has not established that it is unable to pay the penalty amount or that the fine will have an adverse impact on its ability to continue to do business.

I. Legal background

The Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), authorizes the FDA 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). The Act authorized the Secretary of the Department of Health and Human Services to issue regulations restricting the sale and distribution of tobacco products and to establish the Center for Tobacco Products (CTP) within the FDA. 21 U.S.C. §§ 387a(e), 387f(d).

The regulations require each retailer to ensure that all cigarette and smokeless tobacco sales comply with specific requirements. 21 C.F.R. §§ 1140.14, 1140.16.¹ Among those requirements:

- “No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;”
- Retailers must “verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the product is younger than 18 years of age” except that “[n]o such verification is required for any person over the age of 26;”
- In general, “a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);” and
- Vending machines and self-service displays of cigarettes or smokeless tobacco products are not permitted unless located in exempted facilities where no person younger than 18 years old is present, or permitted to enter, at any time.

21 C.F.R. § 1140.14(a), (b)(1), (2), (c); 1140.16(c)(2)(ii). The Act and regulations specify the maximum CMP amounts that may be imposed based on the number of violations a retailer has committed and the period of time in which the violations occurred.² 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The maximum penalty for five violations within a 36-month period was \$5,000. *Id.* The Act also authorizes the FDA to impose a no-tobacco-sale order against a person found to have committed repeated violations of particular restrictions within a 36-month period at a particular retail outlet. 21 U.S.C. § 333(f)(8).

II. Case background

The events from which this case arose are not in dispute. On October 9, 2013, an FDA-commissioned inspector observed unlocked display cases containing a variety of cigarette tobacco and smokeless tobacco and a self-service display containing cigarette tobacco on Respondent’s sales floor, which was open to the general public, including minors. Administrative Record, CRD Docket No. C-15-3873 (AR) 15c (First Complaint). On

¹ This decision cites to the regulations in effect when the violations occurred unless noted otherwise.

² The number of violations committed by Respondent is not at issue here. During the relevant period, section 103(q)(2)(A) of the TCA and section 17.2 of the regulations set out two parallel CMP schedules, with lower CMPs assessed against a retailer who has an “approved training program.” 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The FDA stated in CMP guidance documents, however, that it would use the lower schedule for all retailers until it developed regulations establishing standards for training programs. Guidance for Industry and FDA Staff – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions at 13 (May 2015) (FDA Guidance), <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf>.

December 12, 2013, CTP issued a Warning Letter to Respondent stating that Respondent was in violation of tobacco retailer requirements at 21 C.F.R. § 1140.16(c) and that “[f]ailure to correct these violations may lead to federal enforcement actions, including monetary penalties.” AR 15d (emphasis in Warning Letter).

On March 10, 2014, a Vasudevay employee sold a package of cigarette tobacco to a minor and failed to verify the purchaser’s age by means of photographic identification containing the bearer’s date of birth in violation of 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1). AR 15c, at 1-2. In addition, on March 10, 2014, a person younger than 18 years of age was able to enter Respondent’s establishment and access a tobacco product from a self-service display in violation of 21 C.F.R. § 1140.16(c). *Id.* On March 11, 2014, an FDA inspector observed an unlocked display case containing cigarette tobacco on Respondent’s main sales floor, where minors were permitted, in violation of 21 C.F.R. § 1140.16(c). *Id.*

On September 15, 2014, CTP filed an administrative complaint against Respondent, seeking a CMP in the amount of \$2,000 for four violations of 21 C.F.R. Part 1140 within a 24-month period. *Id.* at 6. On September 29, 2014, Respondent’s owner signed an Acknowledgment Form in which he: 1) acknowledged that the violations described in the First Complaint occurred; 2) agreed to make payment to settle the matter; 3) waived the establishment’s ability to contest the violations in the future; and 4) acknowledged that the violations identified in the First Complaint may be counted in determining the total number of violations for purposes of future enforcement actions. AR 15b.

On May 6, 2015, a Vasudevay employee sold a package of cigarettes to a minor in violation of 21 C.F.R. § 1140.14(a). AR 1, at 1-2. On September 8, 2015, CTP issued a Second Complaint against Respondent requesting that a CMP of \$5,000 be assessed against Respondent for five violations of 21 C.F.R. Part 1140 within a 36-month period. *Id.* In answer to the complaint, Respondent admitted to the alleged violations but contested the appropriateness of the penalty. AR 3. As noted, the ALJ concluded that the CMP amount was reasonable.

III. 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.*

IV. The ALJ's decision to impose a \$5,000 penalty is supported by substantial evidence and free of legal error

The sole issue raised on appeal is whether the amount of the CMP imposed on Vasudevay, \$5,000, is appropriate. The Act provides that in determining the amount of a CMP, the Secretary must take into account: “the nature, circumstances, extent, and gravity of the violation or 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.” 21 U.S.C. § 333(f)(5)(B).³ The implementing regulation provides, “When determining an appropriate amount of [CMPs] and assessments,” the ALJ and Board “shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.” 21 C.F.R. § 17.34(a). In addition, the ALJ and Board “shall refer to the factors identified in the statute under which the penalty is assessed” and may consider “any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.” 21 C.F.R. § 17.34(b), (c).

We conclude that the ALJ Decision to impose a \$5,000 penalty is supported by substantial evidence and free of legal error. The record shows that the nature, circumstances, extent and gravity of Vasudevay's violations were significant. As Respondent admitted, it sold tobacco products to a minor twice, failed to verify identification once, and had a self-service tobacco product display in a facility open to minors twice in violation of 21 C.F.R. § 1140.14(a), (b)(1),(c). We agree with CTP that each violation was serious because it contravened federal laws enacted to protect minors from the adverse health effects associated with tobacco use. Furthermore, the number of infractions and the extensive period in which they occurred -- five violations spanning more than 18 months (from October 9, 2013 through May 6, 2015) -- indicate that Respondent did not appreciate the seriousness of its ongoing failure to comply with the tobacco sales requirements. Moreover, that Respondent committed different types of violations, some of which involved face-to-face transactions and others self-service sales, further demonstrates a pervasive disregard of the federal restrictions designed to protect the health of minors from a dangerous and highly-addictive substance.

We also concur in the ALJ's conclusion that Respondent's failure to bring its premises into compliance with the tobacco retail sales requirements after December 2013 was particularly egregious in light of the FDA's Warning Letter to Respondent. The Warning Letter explained that Vasudevay's self-service tobacco product displays violated federal requirements, advised Vasudevay that a failure to correct its violations could result in

³ In addition, section 103(q)(2)(C) of the TCA states that for purposes of mitigating a CMP, the Secretary must consider the amount of any penalties paid by the retailer to a state for the same violation. There is no indication in this case that Respondent paid any state penalty for the same violations.

monetary penalties, and directed Vasudevay to the FDA website for further information about how to assure compliance with the tobacco sales requirements. Similarly, Respondent's May 6, 2015 violation is quite serious under the circumstances; it was the second time that Respondent sold tobacco products to a minor in a two-year period. In addition, the May 6, 2015 violation occurred after Respondent's September 2014 admission that it committed the violations described in the First Complaint and that it understood that any future violation could result in additional monetary penalties. Vasudevay's history of violations and unwillingness to comply with federal tobacco laws demonstrates that it was highly culpable.

Based on the factors identified above, we conclude that a \$5,000 CMP is appropriate. We also conclude that Respondent has not established that there are mitigating factors for reducing the penalty amount. Vasudevay's owner argues that the CMP should be reduced because he is unable to pay the fine and it would harm his ability to do business. He argues that the \$5,000 amount is very high for a small business, the business is not making enough money to pay the fine, and he is already in debt. Vasudevay's owner states that he "openly invit[es] the Board to come to [his] store personally" to view his financial statements. May 17, 2016 Notice of Appeal. Vasudevay's owner presented the same argument to the ALJ, stating that he was unable to pay the penalty and the CMP would "have a very strong negative impact on [his] ability to continue to do business." AR 3, at 2; AR 5, at 6. To support the contention that he does not have sufficient funds to pay the CMP, the owner submitted evidence to show that on October 22, 2015, burglars stole \$770 in cash from Respondent and damaged property requiring \$294 in repair costs. AR 5, at 9-10. Respondent's owner also submitted a December 30, 2015 mortgage statement showing a monthly principal, interest and escrow payment amount totaling \$1,702 for his private residence. AR 12, at 12.

Despite these contentions, we conclude that Respondent has not shown that it is unable to pay the fine. Respondent has submitted documentation showing that it had net profits in excess of \$30,000 in both 2013 and 2014. AR 12, at 4, 8. We agree with the ALJ that this evidence indicates that Respondent had "substantial income in 2013 and 2014," and therefore the means to pay the \$5,000 CMP, notwithstanding the cost of Respondent's owner's mortgage payments and the losses associated with the October 22, 2015 burglary. ALJ Decision at 3. Furthermore, while Respondent invited the Board to travel to its establishment in New Jersey to personally inspect its owner's bank account and credit card statements, we do not agree, as a threshold matter, that Respondent's owner has demonstrated the relevance of his personal finances to the issue of Respondent's ability to pay the CMP. However, even if his personal finances are relevant, Respondent has not provided copies of those documents or any other evidence to contradict the ALJ's finding that Respondent would be able to pay the fine.

The record evidence also does not show that payment of the fine will have an adverse impact on Respondent's ability to continue to do business. While Respondent stated that the fine would have a strong negative impact on its ability to continue to do business, Respondent has not articulated how payment of the penalty would impede its business operations. We note, moreover, that unlike a no-tobacco-sale order, payment of a CMP does not preclude Respondent from continuing to sell tobacco products. Accordingly, we conclude that Respondent has not established grounds for mitigating the penalty amount.

V. Conclusion

For the reasons explained above, we sustain the ALJ Decision to impose a \$5,000 CMP on Respondent for five violations of the Act within a 36-month period.

_____/s/
Sheila A. Hegy

_____/s/
Leslie A. Sussan

_____/s/
Christopher S. Randolph
Presiding Board Member