

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Daniel Koshy
d/b/a 7-Eleven 11321,

Respondent.

Docket No. T-17-519
FDA Docket No. FDA-2017-H-3562

Decision No. TB1762

Date: August 14, 2017

DECISION

I sustain the determination of the Center for Tobacco Products (CTP) to impose a civil money penalty of \$5501 against Respondent, Daniel Koshy d/b/a 7-Eleven 11321 (Respondent).

I. Background

Respondent requested a hearing in order to challenge CTP's civil money penalty determination. The parties filed pre-hearing exchanges. Petitioner then waived his right to an in-person hearing. The parties filed final written arguments.

CTP filed 19 proposed exhibits with its pre-hearing exchange that it identified as CTP Ex. 1-CTP Ex. 19. Petitioner filed an assortment of documents, none of which he identified as exhibits. Petitioner attached some of these documents to his written arguments and filed others independently.

I have assigned exhibit numbers to each of these documents, designating them as Respondent (R.) Ex. 1-R. Ex. 11. At the close of this decision, I attach an appendix describing the various exhibits and identifying them by exhibit number and filing date. I receive the parties' exhibits into the record.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether:

1. Respondent sold tobacco products (cigarettes) to a minor in violation of federal law; and
2. A civil money penalty of \$5501 is reasonable.

B. Findings of Fact and Conclusions of Law

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.). The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). The Food and Drug Administration and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18 and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a), (b)(1).¹

There is no dispute that Respondent sells tobacco products to members of the public or that these products are manufactured and distributed in interstate commerce.

Respondent has a history of violations of the Act and implementing regulations. These prior violations are administratively final. On March 20, 2016, Respondent acknowledged having made unlawful sales of tobacco products on April 2, 2014, and September 9, 2015. On both occasions, Respondent sold cigarettes to a minor and on both occasions Respondent also failed to verify the minor's age by photographic identification. CTP Ex. 2; *see also*, CTP Ex. 1, at 3.

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information, *see* <https://federalregister.gov/a/2016-10685>. For the purpose of this decision, all citations to the regulations refer to the regulations in effect prior the change.

The most recent allegations of violation involve an alleged unlawful sale of tobacco products to a minor and failure to check identification on April 19, 2016. CTP asserts that on that date, Theresa McClain, an inspector, accompanied a minor to Respondent's business. CTP Ex. 4. Ms. McClain averred that she verified, prior to the minor entering the store, that she carried state-issued identification showing her actual age and that the minor was not carrying any tobacco products on her person. *Id.* at 2-3. Ms. McClain stated additionally that she entered Respondent's business and that she personally observed an employee sell a package of Newport cigarettes to the minor. *Id.* at 3; CTP Ex. 8-CTP Ex. 15. Ms. McClain averred further that she did not see the employee request to view the minor's identification before making the sale. CTP Ex. 4, at 3.

I find this evidence to be persuasive. Most relevant is the fact that Ms. McClain personally observed the transaction. Images of the cigarettes that the minor purchased are preserved as corroborating evidence.

Respondent argues that the evidence offered by CTP is insufficient to prove the noncompliance allegations. He contends that a photograph of a package of cigarettes does not prove that the product was sold from his store and he contends additionally that, as a condition for proving noncompliance, CTP should be required to produce either a receipt for the cigarettes sold on April 19, 2016, or a photograph of the actual sale. *See* Respondent's FDA Case Letter of Response.

Respondent's argument notwithstanding, the evidence of noncompliance is more than adequate to prove that Respondent made an unlawful sale to a minor, and also failed to check a minor purchaser's identification. I find Ms. McClain's personal observation to be compelling proof.

Respondent did not produce any affirmative evidence to counter CTP's proof. He did not produce the testimony of any witness nor did he produce photographic evidence showing that the sale was not made on April 19, 2016, as CTP alleges. The preponderance of the evidence thus clearly supports CTP's contentions.

CTP determined to impose a \$5501 civil money penalty against Respondent based on the fact that Respondent's violations on April 19, 2016, are its fourth and fifth violations of regulations governing the sale of tobacco products to minors within a 36-month period (the previous violations having been admitted by Respondent). A penalty of \$5501 is the maximum allowed under the regulations based on five violations of the regulations governing sale of tobacco products within a 36-month period. 21 C.F.R. § 17.2. CTP asserts that the maximum penalty is justified here based on Respondent's history of noncompliance and its multiple violations of law. I agree.

Respondent not only is liable for multiple violations of the regulations governing sale of tobacco products, but it is liable for *repeated and systematic* violations of those regulations. Again and again inspectors have observed Respondent's employees selling tobacco products to minors and failing to check their identification. Respondent's multiple violations establish a disturbing pattern of disregard for the law. A maximum civil money penalty is justified based on Respondent's obvious disregard of the law's requirements.

Respondent makes several arguments to oppose CTP's penalty demand. First and foremost among these arguments is his assertion that a penalty of \$5501 would cause him to suffer unreasonable financial hardship. I find this argument to be unpersuasive.

Respondent offered evidence to show that he has numerous liabilities. However, he did not offer a complete picture of his financial condition and I do not infer that Respondent is unable to pay the proposed civil money penalty from evidence that shows only his liabilities. For example, Respondent did not offer an audited financial statement, or other similarly trustworthy documents that provided a clear picture of his financial assets. In the absence of such proof, I do not find Respondent's plea of inability to pay the penalty amount to be credible.

Respondent makes various additional assertions. For example, Respondent claims that the sale of tobacco products is not a profitable aspect of his business. He further asserts that Pennsylvania state law, which he contends bars criminal prosecution of sales personnel who sell tobacco products to minors, is incentive for his employees to be careless in making sales. *See* Respondent's FDA Case Letter of Response. He argues that he rigorously and carefully trains his employees not to make unlawful sales of tobacco products. He asserts that his employees are verbally harassed at times when they refuse to make sales. Furthermore, he contends that the purchase of tobacco products by minors is something that falls within their parents' authority to control and should not be his responsibility. He contends that these assertions mitigate his culpability and should be grounds for him to be excused from paying the civil money penalty. *Id.*; *see also*, Respondent's Part 2 Final Proposal.

I find these, and Petitioner's other, similar arguments not to be persuasive. Nothing that he says obviates the reality that his business repeatedly has violated the law by selling tobacco products to minors and by failing to check minor purchasers' identification. Nothing asserted by Petitioner shields him from the fact that he, as proprietor of a business, is responsible for the actions of that business and by its employees.

Appendix
Respondent's Exhibits Organized by Filing Date

Respondent Ex. 1: Respondent's Informal Brief, March 1, 2017

Respondent Ex. 2: "Answer 2 with proof of debts," April 28, 2017

Respondent Ex. 3: "Documents", May 31, 2017

Respondent Ex. 4: "Few Pictures," May 31, 2017

Respondent Ex. 5: "FDA Case Letter of Response," July 6, 2017

Respondent Ex. 6: "Customer Count File 1," July 6, 2017

Respondent Ex. 7: "Proof of Debts File 2," July 6, 2017

Respondent Ex. 8: "Pictures of Certificates and Job List File 3," July 6, 2017

Respondent Ex. 9: "FDA Case Letter of Response," July 6, 2017

Respondent Ex. 10: "UPS Delivery Tracking Info," July 6, 2017

Respondent Ex. 11: "Part 2 Final Response" July 9, 2017

Respondent Ex. 12: "Proof of Inventory Dead Items," July 9, 2017