

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-3691)

Complainant

v.

Lafayette Hill BP, Inc.
d/b/a BP,

Respondent.

Docket No. T-17-4803

Decision No. TB2878

Date: July 11, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) of \$559 against Respondent, Lafayette Hill BP, Inc. d/b/a BP, located at 444 Germantown Pike, Lafayette Hill, Pennsylvania 19444, for three violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a period of 24-months. Specifically, CTP alleges that BP violated the Act by impermissibly selling cigarettes to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. For the reasons discussed below, I find in favor of CTP and impose a \$559 CMP against Respondent.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$559 civil money penalty on Respondent BP, Inc. d/b/a BP, at 444 Germantown Pike, Lafayette

Hill, Pennsylvania 19444, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On July 13, 2017, Respondent, represented by its owner Rasul Mavlyanov, timely filed an Answer to CTP's complaint. On July 26, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for discovery and the parties pre-hearing exchanges.

On October 16, 2017, CTP filed its pre-hearing exchange consisting of its Informal Brief, a list of proposed witnesses and exhibits, and 21 numbered exhibits (CTP Exs. 1-21). CTP's exhibits included the written direct testimony of two FDA-commissioned inspectors who conducted the inspections at issue, Melanie Swanson and Theresa McClain. Respondent did not file a pre-hearing exchange.

On December 8, 2017, I held a pre-hearing conference call. During the pre-hearing conference, we discussed the procedural history of the case and the documents submitted by both parties. Respondent advised of its intent to cross-examine CTP Inspectors Swanson and McClain.

On March 14, 2018, I conducted a hearing in this case.¹ The purpose of the hearing was to allow Respondent to cross-examine Inspectors Swanson and McClain. During the hearing, I admitted CTP's Exs. 1-21 into the record without objection. Transcript (Tr.) at 8.

On April 5, 2018, I informed the parties that the Court had received the transcript of the hearing. I also set the deadlines for the parties' simultaneous post-hearing brief submissions as May 7, 2018. Neither party filed a post-hearing brief.

¹ On January 16, 2018, I convened the initial telephone hearing. However, Respondent did not appear at the hearing, or provide any response to the Order that scheduled the hearing. On January 17, 2018, I issued an order requiring Respondent to show cause for its failure to appear at the January 16, 2018 telephone hearing. On February 15, 2018, I issued an order acknowledging that Respondent may not have been properly served with the order scheduling the hearing for January 16, 2018. Thus, in order to provide Respondent with adequate due process, I rescheduled the telephone hearing for March 14, 2018.

Analysis

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. The U.S. Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993).

I. Violations

A. Alleged Violations, Parties' Contention, and Findings of Fact

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. 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). FDA 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 cigarettes or smokeless tobacco to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(1). In addition, a retailer's failure to verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age is also a violation of the regulations.

1. Alleged Violations

CTP alleges that Respondent committed three violations of the Act and its implementing regulations over a 24-month period.² Complaint at ¶ 1.

In its Complaint, CTP asserts the following:

- At approximately 2:08 p.m. on July 13, 2015, at Respondent's business establishment, 444 Germantown Pike, Lafayette Hill, Pennsylvania 19444, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification

² Two violations were documented on July 13, 2015, and two were documented on April 26, 2017. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

containing a date of birth, that the purchaser was 18 years of age or older;

- In a warning letter dated August 6, 2015, CTP informed Respondent of the inspector's July 13, 2015 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 11:05 a.m. on April 26, 2017, at Respondent's business establishment, 444 Germantown Pike, Lafayette Hill, Pennsylvania 19444, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

In its Answer, Respondent denies all of the violations alleged in the Complaint. Answer at 1. Specifically, Respondent argued that its employees are well-trained, and that CTP offered no evidence to prove there were tobacco sales to minors. *Id.*

2. Parties' Contentions and Evidence

a. CTP's Position

CTP's case against Respondent rests on the testimony of FDA-commissioned inspectors Melanie Swanson and Theresa McClain plus corroborating evidence. CTP Exs. 4, 5, 7-10, 14-18. At the time of the respective inspections, both inspectors were FDA-commissioned officers with the state of Pennsylvania. Their duties included determining whether retailers were compliant with the age and photo identification requirements relating to the sale of tobacco products. CTP Exs. 4, at 1-2; 5 at 1-2. The officers' inspections entailed accompanying contract undercover buy minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* at 2.

i. July 13, 2015 Violation

Inspector Swanson's declaration states that she conducted a compliance check inspection at BP, located at 444 Germantown Pike, Lafayette Hill, Pennsylvania 19444 on July 13, 2015, at approximately 2:08 p.m. CTP Ex. 4, at 2. Inspector Swanson testified that during the inspection she "observed Minor A purchase a package of cigarettes from an employee at the establishment. Prior to the purchase [she] observed that Minor A did not present any identification to the employee. The employee did not provide Minor A with a receipt after the purchase." *Id.* at 3. During cross-examination, Respondent questioned whether Inspector Swanson was able to hear the conversation between the minor and sales person at the time of the alleged sale. Tr. at 16-17. Inspector Swanson testified:

. . . I may or may not have heard the conversation, but we train our minors to – to behave in a certain way when they go into stores and they conduct these inspections. And I can say, without a doubt that the minor did not do anything to influence the sale either way

Tr. at 20.

Inspector Swanson further testified that she “was able to observe the transaction.” Tr. at 24. Specifically, Inspector Swanson stated: “. . . I was able to observe the transaction . . . I actually observed [the undercover buyer minor] approach the counter and leave with the cigarettes.” *Id.*

ii. April 26, 2017 Violation

Inspector McClain’s declaration states that she conducted a compliance check inspection at BP, located at 444 Germantown Pike, Lafayette Hill, Pennsylvania 19444, on April 26, 2017, at approximately 11:05 a.m. CTP Ex. 5, at 2. Inspector McClain further stated that during the inspection she “observed Minor B purchase a package of cigarettes from an employee at the establishment. Prior to the purchase, [she] observed that Minor B did not present any identification to the employee. The employee did not provide Minor B a receipt after the purchase.” *Id.* at 3.

During cross-examination of Inspector McClain, Respondent questioned whether Inspector McClain was able to hear the conversation and witness the transaction between the sales person and the minor during the sales transaction. Tr. at 32-35. Inspector McClain testified:

I heard him ask for a pack of Newport cigarettes and the clerk did not ask for ID. They got the cigarettes. [The clerk] told [the minor] how much it was. Asked for the money and the – the purchase was made and we walked out of the store

Id. at 32. Inspector McClain further testified:

I could see exactly what happened. I could see that the minor went up to the cashier and asked for a pack of cigarettes. And that the cashier got the cigarettes and gave them to the minor, and the minor gave him the money and we left the store after

Id. at 35.

b. Respondent's Position

Respondent filed an Answer, denying that cigarettes were sold to minors, or that Respondent failed to verify the minor's age during the inspections at issue. Answer at 1. Respondent asserted:

. . . .we have long time experience with the tobacco selling and our cashier/employee well trained. Also from beginning to end person who as saying did the inspection could not provide with . . . any evidence for this complaint, therefore the statement made by inspector about tobacco sales to minor is proofless

Id.

Respondent argues that without identifying themselves as inspectors, without a sales receipt, and without video or additional photographic evidence, among other things, CTP has not met its burden of proof. Answer at 6-7. I have considered Respondent's arguments, but find them unpersuasive.

3. *Findings of Fact*

I find Respondent's arguments to be without merit. Respondent offered no evidence to rebut the testimony of either Inspector Swanson or Inspector McClain regarding the sale of the cigarettes, or the failure to verify the ages of the purchasers. However, based on Respondent's line of questioning at the hearing, Respondent sought to attack the methodology by which the inspections were conducted. For example, during the hearing, Respondent inquired whether Inspector McClain reported to the cashier that he sold cigarettes to the minor. Inspector McClain responded, "It's an undercover buy. I'm not supposed to do that, no." Tr. at 35. When further questioned:

Q . . . Is it standard protocol for you not to identify yourself or the minor after an undercover buy?

A Yes, it is.

Q Do you know why?

A Because it's - - it's considered to be an undercover buy

Tr. at 37. How CTP conducts its inspections is irrelevant to the issue of Respondent's compliance. CTP's inspection methodology does not alter my finding that Respondent committed the violations that are at issue here.

Respondent's assertion that the inspectors could not see the actual transactions take place or that CTP failed to prove the sales by a sales receipt is not sufficient to rebut the allegations. There is no provision in the applicable regulations requiring proof of purchase in the form of a cash register receipt.

The evidence of record establishes to my satisfaction that the violations charged in this case in fact took place on the dates in question. The testimonies of Inspectors Swanson and McClain, plus the corroborating evidence is sufficient to establish that it is more likely than not that Respondent unlawfully sold cigarettes to minors and failed to verify that the purchasers were of sufficient age, in violation of 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i).

Therefore, I find that the facts as outlined above establish Respondent Lafayette Hill BP, Inc. d/b/a BP's liability under the Act for three violations within a 24-month period.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent BP is liable for a CMP not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the penalty amount, \$559, against Respondent for three violations of the Act and its implementing regulations within a 24-month period. Complaint at ¶ 1.

In its Answer, Respondent denied any obligation to pay a civil money penalty because there is insufficient proof it violated the regulations.

I have found that Respondent committed three violations of the Act and its implementing regulations within a 24-month period. When determining the amount of a civil money penalty, I am required to take into account "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." 21 U.S.C. § 333(f)(5)(B).

A. Nature, Circumstances, Extent and Gravity of the Violations

I have found that Respondent committed three violations of selling cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The repeated inability of Respondent to

comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

B. Respondent's Ability to Pay and Effect on Ability to do Business

Respondent has not presented any evidence that it does not have the ability to pay the \$559 Civil Money Penalty sought by CTP.

C. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. As noted above, Respondent has, at least three times, violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, 21 C.F.R. § 1140.14(a)(2)(i).

D. Degree of Culpability

Based on my finding that Respondent committed the violations as alleged in the current complaint, I hold it fully culpable for all three violations of the Act and its implementing regulations.

E. Additional Mitigating Factors

Mitigation is an affirmative defense for which Respondent bears the burden of proof. Respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence. 21 C.F.R. § 17.33(c). Respondent argued that it is a small business and that its employees are well-trained. Respondent also stated that it recently filed a police report after an employee was attacked for requiring identification from a customer purchasing tobacco. While I empathize with Respondent, the regulations were created as an initiative to avert minors from purchasing tobacco products.

The purpose of The Family Smoking Prevention and Tobacco Control Act is to prevent unlawful sales of tobacco products to minors. Tobacco is a highly addictive and dangerous product. The reason that sales of tobacco products to minors is unlawful is that consumption of these products at an early age can lead to a lifetime of addiction, to illness, and ultimately to premature death. Sales of tobacco products to minors are unlawful because younger individuals often lack the maturity and judgment to make informed decisions about whether to consume such inherently dangerous and addictive products. Selling tobacco products to these individuals puts them at risk for all of the adverse consequences that addiction can cause.

