Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Jeremy G Worley d/b/a J's Tavern and Sparkys,

Respondent.

Docket No. T-17-6240 FDA Docket No. FDA-2017-H-5349

Decision No. TB2715

Date: May 15, 2018

INITIAL DECISION

I sustain the determination of the Center for Tobacco Products ("CTP") of the United States Food and Drug Administration ("FDA") to impose a civil money penalty of \$559 against Respondent, Jeremy G Worley d/b/a J's Tavern and Sparky's.

I. Background

Respondent requested a hearing in order to challenge CTP's determination to impose a civil money penalty. CTP filed a pre-hearing exchange that included a brief and 26 proposed exhibits that it identified as CTP Exhibit (Ex.) 1-CTP Ex. 26. CTP's evidence includes the written direct testimony of three witnesses. Respondent did not file exhibits. He filed a one-page statement in which he denied CTP's allegations. I afforded Respondent the opportunity to advise me whether he wished to cross-examine any of CTP's witnesses. Respondent did not file a request to cross-examine, nor did he object to

my receiving any of CTP's proposed exhibits, including witnesses' statements, into evidence. I receive into evidence CTP Ex. 1-CTP Ex. 26.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether:

1. Respondent sold tobacco products to minor purchasers and failed to verify the purchasers age by means of photographic identification in violation of federal regulations governing the sale of tobacco products;

and

2. A civil money penalty of \$559 is a reasonable remedy.

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 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)(1) and 1140.14(a)(2)(1).

CTP premises its case on the results of inspections of Respondent's facility, conducted on October 7, 2016 and on July 13, 2017. On October 7, 2016, a then-FDA-commissioned inspector, David Gandesbery, went to Petitioner's establishment accompanied by a minor ("Minor A") to conduct an undercover buy ("UB") compliance check inspection. Minor A was employed for the purpose of attempting to purchase tobacco products from business establishments under inspection. CTP Ex. 9 at 1-2. Mr. Gandesbery testified that he verified that the minor carried photographic identification that stated his or her age and that he or she was not carrying tobacco products. He testified that he entered Respondent's establishment and then observed the minor enter moments later. He averred that he had a clear and unobstructed view of the minor while he or she was in the establishment. He testified that he watched the minor purchase a package of cigarettes without presenting identification to the establishment's employee. *Id.* at 2-3. He asserted that after the inspection he photographed the cigarettes purchased by the minor. *Id.* at 3; *see also* CTP Exs. 13-14.

On July 13, 2017, another FDA-commissioned inspector, Debra Gruver, also went to Respondent's establishment accompanied by a minor ("Minor B") to conduct a second UB compliance check inspection. CTP Ex. 18. Ms. Gruver testified that she verified that the minor carried photographic identification that verified his or her age and that he or she was not carrying tobacco products. Ms. Gruver asserted that she entered Respondent's establishment prior to the minor entering, observed the minor in the establishment, and observed the minor purchase a package of cigarettes without presenting his or her identification. *Id.* She testified that she photographed the package of cigarettes that the minor purchased. CTP Exs. 22-23.

Respondent denies that his establishment's employees made unlawful tobacco sales. However, Respondent neither impeached the credibility of Mr. Gandesbery's or Ms. Gruver's testimony nor did he offer any affirmative evidence to support his denials. I find to be credible the evidence offered by CTP to establish Respondent's unlawful sales of tobacco products and failures to check identification. That evidence does not consist solely of the inspectors' testimony but also includes photographs of the cigarettes that the minors purchased, that were taken immediately after Respondent's employee sold those cigarettes to the minors. I find that the photographs are solid corroborating evidence that buttresses the credibility of Mr. Gandesbery's and Ms. Gruver's testimony.

CTP has proven that Respondent violated regulations governing the sale of tobacco products to minors, committing three violations¹ during a period of less than one year. That is egregious conduct. Regulations authorize a penalty of up to \$559 for the violations committed by Respondent. 45 C.F.R. § 102.3; 21 U.S.C. § 333(f)(9).

The egregiousness of Respondent's conduct must amply justify the penalty amount. On two occasions within about nine months, Respondent sold tobacco products to minor purchasers in violation of the law. It did so despite being warned by CTP after the October 7, 2016 violations that penalties would be imposed against Respondent for future unlawful sales.

¹ As a matter of administrative discretion, CTP opted to count the sale of cigarettes to a minor purchaser on October 7, 2016 and the failure to verify the purchaser's age by means of photographic identification on the same date as a single violation of the regulations governing tobacco sales.

I take notice that tobacco products are highly addictive and dangerous to the health of those who consume them. They may have lethal long-term effects on consumers. Younger purchasers are highly susceptible to becoming addicted. A penalty of \$559 is plainly reasonable given the dangers of tobacco products and Respondent's repeated unlawful sales of these products to minor purchasers.

/s/ Steven T. Kessel Administrative Law Judge