Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Baydoun Brothers, Inc.
d/b/a Shell Food Mart,

Respondent.

Docket No. T-17-4958
FDA Docket No. FDA-2017-R-3855

Decision No. TB2939

Date: July 30, 2018

DECISION

I impose a No Tobacco Sale Order (NTSO) against Respondent, Baydoun Brothers, Inc. d/b/a Shell Food Mart, for a period of 30 consecutive calendar days based on Respondent's repeated violations of federal tobacco regulations over a period of 36 months.

I. Background

Respondent requested a hearing in order to challenge the Center for Tobacco Products' (CTP's) proposal to impose an NTSO against it. The parties filed pre-hearing briefs, and I held a hearing on April 11, 2018. At the hearing, I received into evidence exhibits from CTP that are identified as CTP Exhibit (Ex.) 1-CTP Ex. 13. I also received an exhibit from Respondent consisting of the affidavit of Ghazzey Baydoun. I identified that affidavit as R. Ex. 1. Transcript (Tr.) at 7; Feb. 26, 2018, Order Scheduling Hearing.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are: whether Petitioner committed five violations of applicable regulations governing sales of tobacco products to minors within a period of 36 months; and whether an NTSO of 30 consecutive days' duration is a reasonable remedy.

B. Findings of Fact and Conclusions of Law

CTP asserts that I should impose an NTSO 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 (FDA) and its agency, CTP, may seek the imposition of remedies against 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)(1), (a)(2)(i).

Remedies may consist of civil money penalties and NTSOs. NTSOs are authorized at 21 U.S.C. § 387f(8). The section allows for the imposition of an NTSO against a person who has committed "repeated violations" of restrictions on the sale of tobacco products. The term "repeated violations" is defined to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet . . . ." 21 U.S.C. § 333.

The Act establishes factors that must be considered in deciding on the length of an NTSO, but it does not specify specific time NTSO periods:

> In determining the . . . period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the . . . violations, and with respect to the violator, . . ., 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).

CTP developed policy guidelines that establish maximum NTSO durations. For a first NTSO, CTP recommends that the maximum duration be 30 calendar days. Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with Order at 3-4, available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM446547.pdf (last updated Aug. 2015) (Guidance) at 4.

CTP's policy is to, in general, seek the maximum duration for an NTSO established by the guidelines. It explains its rationale for establishing these recommended maximum NTSO durations as follows:

> First, if there are grounds for imposing an NTSO, the retailer has already engaged in repeated violations of the law and regulations restricting the sale and distribution of tobacco products, and therefore has a prior history of violations. Second, the restrictions codified in part 1140 [of the regulations] are intended to protect the public health, especially children and adolescents, and FDA therefore considers repeated violations of these restrictions to be very serious. Nearly 9 out of 10 adult daily smokers smoked their first cigarette by age 18 (87 percent). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking. Third, FDA believes that imposing NTSOs where the periods of time gradually increase, starting with a maximum of 30 days and then a maximum of 6 months before issuing an order permanently prohibiting the sale of tobacco products, strikes an appropriate balance between considerations related to the number, extent, and gravity of the violations on one hand, and the retailer's ability to do business on the other hand. The increasing periods of time for which FDA intends to impose NTSOs are also consistent with the scheme of increasing [civil money penalties] . . . .

Id. (footnotes omitted).

I find CTP's guidelines to be entirely reasonable when read in the context of the Act's language and purpose. The guidelines are not written as regulations and are not, therefore, binding as a matter of law. But, they are persuasive, and I accord CTP deference in view of its expertise in administering the Act and implementing regulations. I find especially persuasive the guidelines' reliance on statistics showing the terrible consequences of smoking on our population and the strong linkage between tobacco addiction and commencement of smoking at an early age.

I am mindful also that an NTSO may have a profound effect on a retailer's business and even on that retailer's ability to stay in business. However, this remedy is reserved only for the most egregious offenders – individuals and entities that have repeatedly violated the law despite the imposition against them of escalating civil money penalties – and is necessary if for no other reason than to protect the public against these offenders' inability to comply with law and regulations governing tobacco sales. Generally speaking, the need to protect the public 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.

Respondent is a repeated violator of law and regulations. This case constitutes the third time that CTP pursued sanctions against Respondent. On November 24, 2015, CTP charged Respondent with unlawful sales of tobacco products to minor purchasers on July 16 and March 26, 2015, in violation of 21 C.F.R. § 1140(a)(1); and on March 26, 2015, failing to verify the age of a purchaser by checking that individual's photographic identification in violation of 21 C.F.R. § 1140.14(a)(2)(i). CTP Ex. 1. Respondent admitted these allegations and that case became administratively final. CTP Ex. 3. On September 23, 2016, CTP filed a second complaint against Respondent, charging Respondent with again unlawfully selling tobacco products to a minor purchaser and failing to verify the age of a purchaser by checking that individual's photographic identification, in violation of 21 C.F.R. § 1140(a)(1) and (a)(2)(i). That unlawful sale and failure to check identification occurred on March 5, 2016. On November 22, 2016, Respondent admitted these allegations, and as with the first complaint, this second complaint became administratively final. CTP Ex. 4.

In the instant case, CTP alleges that on February 1, 2017, Respondent again unlawfully sold tobacco products to a minor and failed to verify that purchaser's age by checking her photographic identification. CTP offered convincing and unrebutted proof to establish its allegations. Justin Bishop, an FDA-commissioned inspector, testified that, on February 1, 2017, he went to Respondent's establishment accompanied by a minor. CTP Ex. 13 ¶ 10. He verified that the minor had no tobacco products in her possession prior to entering the establishment but that she had photographic identification verifying her age. *Id.* ¶ 9. He entered Respondent's establishment immediately after the minor entered, and took up a position from which he had an unobstructed view of Respondent's sales counter. He watched the minor purchase a package of cigarettes (Newport Box 100s) and observed the clerk fail to check the minor's identification. *Id.* ¶¶ 13-14.

I find Inspector Bishop's testimony to be credible. Inspector Bishop's testimony is supported by his contemporaneous photographs (CTP Exs. 7-8), narrative report (CTP Ex. 10), and inspection form (CTP Ex. 9).

The evidence of additional noncompliance coupled with Respondent's past history of violations establishes that Respondent repeated violations of the regulations governing sales of tobacco products to minors five times in a 36-month period.[1] In light of that, an NTSO is an authorized remedy.

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[1] Respondent's original violation of 21 C.F.R. § 1140.(a)(1) was on March 26, 2015, and Respondent repeated that violation on July 16, 2015, March 5, 2016, and February 1, 2017. Respondent's original violation of 21 C.F.R. § 1140.(a)(2)(i) was on March 26, 2015, and Respondent repeated that violation on March 5, 2016, and February 1, 2017.

I find that imposition of an NTSO for 30 consecutive days is reasonable. It is evident that multiple civil money penalties have not deterred Respondent from continuing to sell tobacco products in violation of law. I impose the remedy because something other than a civil money penalty plainly is needed here. Moreover, I do so because, if for no other reason, the public needs to be insulated from Respondent's business practices for a reasonable period of time.

I have considered Respondent's arguments in opposing the imposition of an NTSO of 30 consecutive calendar days and I find them to be insufficient to mitigate or eliminate the remedy. Respondent contends that an NTSO would cause it to suffer severe financial hardship. It estimates that it would lose sales in the range of $40,000 to $50,000 if it were barred from selling tobacco products for 30 consecutive days and that such a loss might jeopardize its ability to continue in business. R. Ex. 1. However, Respondent has offered nothing by way of corroboration for this contention – no financial records whatsoever. I do not find this assertion to be credible in the absence of corroboration.

Moreover, I do not find Respondent's assertion as to anticipated sales losses to be persuasive even if it accurately states the likely impact of an NTSO on its business operations. Respondent's premise is that the heart of its business is tobacco sales. It asserts that few customers would patronize its establishment if it were barred from making such sales. Maybe so, but if, in fact, tobacco sales are the heart of Respondent's business, then Respondent should exercise diligence in assuring that it does not sell tobacco products to minors. The record establishes that Respondent has been anything but diligent. And, given that, removing Respondent from the stream of sales of tobacco products for a 30-day period is eminently reasonable.

_________/s/_____________
Steven T. Kessel
Administrative Law Judge