

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Kat Party Store, Inc.  
d/b/a Mr. Grocer Liquor Store,

Respondent.

Docket No. T-16-1684  
FDA Docket No. FDA-2015-R-3482

Decision No. TB509

Date: November 22, 2016

**INITIAL DECISION**

I impose a No Tobacco Sale Order (NTSO) against Respondent, Kat, Party Store, Inc. d/b/a/ Mr. Grocer Liquor Store 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**

This case was assigned originally to another administrative law judge and then transferred to me. Respondent conceded that it sold tobacco products in violation of federal regulations but challenged the Center for Tobacco Products' (CTP) request that I impose an NTSO against it for 30 consecutive calendar days. The parties briefed the issue of whether the request is reasonable in light of the undisputed facts.

CTP offered four proposed exhibits in support of its position. These exhibits, CTP Ex. 1 – CTP Ex. 4, consist of copies of decisions in other cases involving violations of federal tobacco regulations. It is unnecessary that I receive these exhibits into evidence inasmuch as they comprise material that is on the public record.

## **II. Issues, Findings of Fact and Conclusions of Law**

### **A. Issue**

The issue is 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), (2).

Remedies may consist of civil money penalties and NTSOs. NTSOs are authorized at 21 U.S.C. § 333(f)(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. NTSO Guidance (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 at 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 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.*

I find CTP's guidelines to be entirely reasonable when they are read in the context of the Act's language and purpose. They 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.

The undisputed facts of this case establish that Respondent is a repeated violator of law and regulations. CTP's Complaint; Respondent's Answer. Between August 2, 2012 and April 26, 2015, Respondent sold tobacco products to minor purchasers on four occasions. On three of these occasions Respondent failed to verify the photographic identification of the minor purchasers. Thus, Respondent committed a total of five repeated violations of regulations governing tobacco sales in a period of less than 36 months. CTP imposed civil money penalties against Respondent twice, but those civil money penalties did not deter Respondent from continuing to sell tobacco products to minor purchasers.

These undisputed facts render entirely reasonable CTP's request that I impose an NTSO of 30 consecutive calendar days against Respondent. 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 without merit. First, Respondent argues that it is not a repeated violator of applicable regulations. Effectively, it contends that CTP is double-counting those instances in which Respondent both sold tobacco products to minors in violation of law and failed to check those minors' photographic identifications. Respondent's assertion notwithstanding, it committed seven distinct violations of law within a 36-month period.

According to Respondent, a sale/failure to check identification should count only as one violation and not as two. Based on that logic, according to Respondent, it committed only four violations in a 36-month period, and not seven, as CTP contends. And, from that, Respondent argues that its violations were only sporadic and not repeated as defined by the Act.

I find this argument to be unpersuasive. An appellate panel of the Departmental Appeals Board recently decided the issue of whether failure to check identifications and unlawful sales to minors are separate violations, holding that they are separate. *Orton Motor Co. d/b/a Orton's Bagley*, DAB No. 2717 (2016).

The law defines selling tobacco products to minors and failing to check minors' identifications as separate violations, and with good reason. Failure to check identification must be considered to be separate from an unlawful sale because it constitutes a separable problem. Conceivably, a retailer that fails to check identifications

might not actually sell tobacco products to minors if all of the purchasers whose identifications aren't checked are actually 18 years old or older. But, nevertheless, the *potential* for selling tobacco products remains very high in such an instance because production of identification is an essential safeguard against making such sales.

Second, Respondent contends that as a matter of equity and fairness it should not be subject to an NTSO that applies for 30 consecutive calendar days. It argues that the NTSO should be applicable on non-consecutive days, which would allow Respondent to continue to function as an ongoing business. In support of this argument Respondent contends that, as a matter of its own policy, it has always sought to comply with the requirements of law. It asserts that unlawful sales and failures to check identification occurred only because certain of Respondent's employees acted in an unauthorized and improper manner.

I find this argument to unpersuasive for several reasons. Imposing an NTSO on non-consecutive days would render its purpose to be meaningless. The intent of an NTSO is to deter Respondent from continuing to engage in unlawful sales of tobacco products. Diluting that order by applying it only on non-consecutive days diminishes the deterrence effect to the extent that the order might become meaningless. Furthermore, CTP would find it very difficult to enforce such an order. An order that applies on consecutive days can be checked for effectiveness by visiting Respondent's retail establishment at random during the period that the order is in effect. However, an order that applies on non-consecutive days can only be checked on those announced days when the order is in effect, thus giving the retailer advance notice of likely inspection dates. Moreover, CTP runs a vast enforcement program that applies to many thousands of retailers, nationwide. Requiring CTP to calendar the nonconsecutive days when an NTSO is in effect would require an unreasonable expenditure of resources by CTP.

I am not swayed by Respondent's assertion that the fault for its repeated transgressions lies with its employees. Respondent's employees are its agents and Respondent bears the onus for assuring that these employees comply with legal requirements.

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/s/  
Steven T. Kessel  
Administrative Law Judge