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Underutilisation of no-tobacco-sale orders against retailers that repeatedly sell to minors, 2015–2019, USA

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ABSTRACT

Importance Research demonstrates that policies aimed at retailers who sell to minors must be strongly enforced to have an impact on youth usage rates.

Objectives In the USA, the Food and Drug Administration (FDA) conducts compliance checks, issues fines, and can order retailers to stop selling tobacco products (ie, no-tobacco-sale orders (NTSOs)) to enforce the Family Smoking Prevention and Tobacco Control Act. We sought to assess FDA's utilisation of NTSOs.

Methods We conducted a quantitative content analysis of FDA's enforcement actions for inspections decided between 1 October 2015 and 29 March 2019. From the 536 134 inspection records we identified 148 NTSOs and 249 720 unique retailer locations, of which 2095 had three or more violations. We randomly sampled NTSOs (n=76) and retail locations (n=152) with frequent violations. We calculated the proportion of NTSOs that could have been issued earlier by FDA. We then calculated the proportion of retailers that could have been issued an NTSO, and the proportion actually issued an NTSO using FDA's approach and a more stringent approach.

Results Among NTSOs, 94.7% (95% CI: 89.8% to 97.4%) of NTSOs could have been issued earlier under a more stringent approach. On average, when an NTSO could have been issued earlier, it could have been issued 453 days earlier (95% CI: 418 to 489; range: 89–1159). Among frequently violating retail locations, 73.6% (95% CI: 66.0% to 80.0%) were eligible for an NTSO. Of those, 1.9% (95% CI: 0.5% to 7.0%) had received an NTSO.

Conclusions The FDA's failure to fully leverage its powers to address retailers' underage sales of tobacco products has weakened efforts to curb the youth e-cigarette epidemic.

INTRODUCTION

In 2018, youth use of any commercial tobacco product reached the highest rate since 2011 in the USA—27.1% of high school students had used any tobacco product in the last 30 days.[1] This concerning increase was primarily driven by youth e-cigarette use, which was characterised as an epidemic and prompted policymakers at all levels of government to consider effective approaches to addressing youth use of any commercial tobacco product. While Congress recently raised the federal minimum legal sales age from 18 to 21 years, that policy must be coupled with other policies to have the maximum public health benefit—such as stringent enforcement in retail compliance checks. Enforcing bans on illegal sales of tobacco products in the retail environment has been an evidence-based public health strategy that many local communities and states have used for decades.[2] When the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law in 2009, Congress adopted a similar approach at a federal level: a system of fines and suspensions against retailers who sell to underage persons. The Food and Drug Administration (FDA) works with private contractors and state agencies throughout the USA to conduct controlled buys.[3] These buys follow a confidential inspections protocol, which includes hiring youth and young adults under the minimum legal sales age to enter stores and attempt to purchase tobacco products.[4]

Youth access to tobacco products at retailers continues to contribute to underage tobacco product use. In the 2018 Monitoring the Future Survey, 66.6% of 10th graders reported that it would be easy or very easy to get vaping devices (and 60.4% report the same for e-liquids).[5] Youth e-cigarette users report that while many obtain their e-cigarettes from social sources (approximate 72.6% of middle and high school e-cigarette users in 2018), 16.5% obtain them from vape shops, and 9.8% obtain them from convenience stores.[6] A survey focused on teenage users of Juul, the most popular brand of e-cigarette among youth, revealed similar statistics. Among past 30-day Juul users 13–17 years old, 79.6% reported obtaining Juul from social sources and 20% reported obtaining Juul by purchasing the products. Of those that purchased Juul, 53.1% bought them in a gas station or convenience store, 28.2% bought at a grocery store, 21.8% bought at a vape shop and 15.3% reported buying from the internet.[7] Even though social sources remain a primary source of e-cigarettes for youth users, it is worth noting that historical youth surveys focused on where youth obtained cigarettes have shown those who sell as the 'social source' are often underage buyers themselves.[8–10]

Youth access interventions require enforcement to be effective,[2] and retailer practices can be considered a corporate determinant of health.[11] The FDA has the power to issue both civil monetary penalties (CMPs) and no-tobacco-sale orders (NTSOs) to compel compliance with youth access and other retail restrictions. Table 1 shows current escalating penalties for CMPs related to violations of the Tobacco Control Act.

NTSOs prevent retailers from selling tobacco products for a specified amount of time. The time period for first NTSOs generally ranges from 9 to

Table 1 Current escalating fines, that is, civil monetary penalties (CMPs), from the FDA, March 2020

Violation	CMP
1 (warning letter only)	–
2nd in 12 months	$297
3rd in 24 months	$594
4th in 24 months	$2381
5th in 36 months	$5952
6th or subsequent in 48 months	$11 904 (case-by-case basis)

These amounts are updated regularly per the statute.[22]
FDA, Food and Drug Administration.

31 days of no tobacco sales, with an average of 24 days from the NTSO going into effect. This period is determined on a case-by-case basis by an administrative law judge who looks at a series of factors to determine whether the violating retailer has done due diligence in educating and training employees on the law.

Retailers are subject to NTSOs when they have committed 'repeated violations'. The statute defines 'repeated violations' as 'at least five violations of particular requirements over a 36-month period at a particular retail outlet'.[12] In the most stringent sense, 'repeated violations' would mean any five violations within a 36-month period. However, the FDA's interpretation appears to be more lenient and permissive. The FDA's guidance documents for industry and the FDA's enforcement actions indicate that the FDA interprets the statute to mean:

- There are at least five violations of requirements issued under section 906(d) of the (Tobacco Control Act) at a particular outlet.
- Each of five violations represents the second or subsequent violation of a particular requirement.
- Each of the five violations occurs within 36 months.

This means that for each category of violation type (eg, a sale to a minor or a failure to check an ID), the retailer gets a 'free pass' on the first violation. In order to have 'repeated violations', there must be a sum of five violations that are at least the second violation in each category. Thus, three inspections that result in three sales to minors and two failures to check an ID would result in only three violations in FDA's approach to counting violations for NTSOs. Of the three sales to minors, only two are the 'second or subsequent' and of the two failure to check an ID there is only one 'second or subsequent' violation (please see the Discussion section and figure 1 for more explanation on counting).

While the FDA has made headlines highlighting efforts to restrict youth access to tobacco products through compliance checks,[13 14] it is important to know whether the FDA has used its enforcement authority to address the epidemic of youth tobacco product use. This includes measures such as more quickly escalating penalties for retailers who continually violate the law despite prior warnings. To quantify the extent of the FDA's enforcement efforts, we sought to (1) determine if the FDA was diligently calculating penalties using its own counting methods, (2) identify the proportion of NTSOs that would have been issued earlier if the FDA counted violations as stringently as the Tobacco Control Act allows, and (3) identify the proportion of 'frequently violating retailers' (which we defined as those retailers who have received three or more violations in the study period, following the rationale of prior 'three strikes' approaches) that could have received an NTSO but did not. To answer these research questions, we used the FDA Center for Tobacco Products' publicly available retail inspections database,[15] which has been used to assess FDA enforcement, evaluate policies and identify corporate non-compliance.[16–19]

METHODS

Study design and data source

In summer 2019, we conducted a quantitative content analysis[20] of FDA enforcement actions from 1 October 2015 to 29 March 2019. Starting with 536 134 inspection records,[15] we used SPSS v25 software to identify duplicate locations based on street addresses and ZIP codes (FDA does not provide a unique identifier in its data for retail locations). This resulted in 249 720 unique retailer locations. Following best practice in content analysis coding, we iteratively developed a coding protocol, piloted it, revised it and assessed inter-rater reliability using Krippendorff's alpha.[21] Our coding protocol is publicly available (East Carolina University Dataverse, available from: https://doi.org/10.15139/S3/SWNWJG).

	Violative Inspection Dates					
Charged Violation[2]	02/12/2017	06/15/2017	10/07/2017	01/11/2018	10/18/2018	**Number of Repeated Violations**
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a)(1)	NA/I **OV**	1/II **X**	2/IV **X**	4/VI **X**	6/VIII **X**	**4**
Failing to verify ID for cigarettes / smokeless tobacco sale, 21 C.F.R. § 1140.14(a)(2)(i)		NA/III **OV**	3/V **X**	5/VII **X**	7/IX **X**	**3**
FDA Action	Warning Letter Sent 02/23/2017	First CMP Initiated 08/14/2017 FDA-2017-H-4865, CRD T-17-5830	Second CMP Initiated 10/25/2017 FDA-2017-H-6251, CRD T-18-213	Third CMP Initiated 06/21/2018 FDA-2018-H-2383, CRD T-18-2633	Current Complaint	**Total: 7 Repeated Violations**

Figure 1 Excerpt from FDA complaint showing original violation (OV) and count of violations by FDA in Arabic numerals and count of total violations allowed by statute in Roman numerals. CMP, civil monetary penalty; FDA, Food and Drug Administration; NA, not applicable.

For the first and second research questions regarding the FDA's application of its own counting method and the proportion of NTSOs that could have been issued earlier, we identified all NTSOs issued during the study period (N=148). We conducted a power analysis to obtain 80% confidence and a ±5-point margin of error in the proportion. Using SPSS v25 Complex Samples, we used simple random sampling to select NTSOs (n=76) for analysis. We then obtained the actual NTSO complaint from FDA's website.[22] Using each NTSO complaint, we coded the date of the inspection that prompted FDA to issue the NTSO (reliability of coding Krippendorff's alpha=1.00), the date of the fifth *repeated* violation (ie, the way FDA's guidance prescribes counting violations, alpha=1.00), the date of the fifth *total* violation (ie, when FDA could have issued the NTSO per the statute; alpha=1.00), and if the first five violations (counting both ways) were within 36 months of each other (alpha=1.00). This allowed us to calculate if the FDA is following its own more lenient guidance in issuing NTSOs. It also allowed us to assess if an NTSO could have been issued after an earlier inspection result and, if so, how many days earlier. When an NTSO was the second NTSO issued for the same location (n=3), we excluded it from these analyses. A second NTSO is rare but can be issued after one additional violation by a retailer that has already received an NTSO so long as the most recent violation is also the fifth violation within 36 months.

For the third research question regarding the proportion of frequently violating retailers eligible for and receiving NTSOs, we included in our sampling frame all retail locations that had failed FDA inspections three or more times. This resulted in a sampling frame of 2095 locations. After conducting a power analysis with the same parameters, we created a simple random sample of these retail locations for analysis (n=152). We then identified all inspections for these retail locations (n=758). FDA's public data did not directly include the number of violations identified in each inspection, nor did they include the date of the inspection. However, FDA warning letters, CMPs and NTSOs do provide these details. Thus, we constructed a data file of all inspection results from the sampled locations and manually cross-referenced each linked FDA warning letter, CMP, and NTSO to assess the total number of violations and their timing. We coded for receipt of an NTSO (alpha=1.00), total number of inspections (alpha=1.00), total number of violations (alpha=0.98), and when there were five or more violations if they were within 36 months of each other (alpha=0.75). This allowed us to calculate the estimated proportion of frequently violating retail locations that had received an NTSO and that could have received an NTSO under the most stringent interpretation of the statute.

All analyses used SPSS V.25 and took into account the sampling strategy including use of a finite population correction and appropriate corrections for subpopulation analyses.

RESULTS

Our three research questions and their results are shown in table 2. Based on our sample from the 148 NTSOs issued by the FDA between 1 October 2015 and 29 March 2019, we found that 2.6% of NTSOs could have been issued earlier according to the FDA's guidance (95% CI: 1.0% to 6.9%). Few NTSOs were repeated NTSOs at the same location (3.9%, 95% CI: 1.8% to 8.6%). However, for our second research question, following the most stringent reading of the statute, we found that 94.7% (95% CI: 89.8% to 97.4%) of NTSOs could have been issued earlier. On average, when an NTSO could have been issued earlier, it could have been issued 453 days earlier (or approximately 1 year and 3 months; 95% CI: 418 to 489; range in our sample: 89–1159) based on the date of the fifth violation.

Our third research question addressed the proportion of frequently violating retail locations that could have received an NTSO but did not. Among these retail locations, 73.6% (95% CI: 66.0% to 80.0%) were eligible for an NTSO according to the stringent reading of the statute but, of those eligible, 1.9% (95% CI: 0.5% to 7.0%) had actually received an NTSO. The average number of violations at frequently violating retail locations was 5.7 (95% CI: 5.4 to 5.9).

DISCUSSION

Principal findings

Our findings indicate that the FDA is largely following its own more lenient interpretation of the statute. Had the FDA interpreted and applied the statute more stringently, the FDA would have already issued NTSOs to nearly three-quarters of retailers

Table 2 No-tobacco-sale orders (NTSOs), n=76, and eligibility for NTSOs among retailers that failed three or more inspections, n=144, 1 October 2015–29 March 2019

	Estimated proportion (95% CI)	Count in sample	Estimated count in population
Research question 1: Is FDA implementing NTSOs according to its own interpretation of the statute?			
NTSO not issued at 5th violation under FDA's interpretation	2.6% (1.0% to 6.9%)	2	4
NTSO issued at 5th violation under FDA's interpretation	93.4% (88.1% to 96.4%)	71	138
NTSO was a second or later NTSO for a location	3.9% (1.8% to 8.6%)	3	6
Research question 2: Is FDA implementing NTSOs according to our interpretation of the statute?			
NTSO not issued at 5th violation under our interpretation of the statute	94.7% (89.8% to 97.4%)	72	140
NTSO issued at 5th violation under our interpretation of the statute	1.3% (0.3% to 5.2%)	1	2
NTSO was a second or later NTSO for a location	3.9% (1.8% to 8.6%)	3	6
Research question 3: What proportion of retailers who failed three or more inspections are eligible for an NTSO according to our interpretation of the statute?			
Retail location eligible for NTSO under our interpretation of the statute	73.6% (66.0% to 80.0%)	106	1461
Retail location ineligible for NTSO under our interpretation of the statute	26.4% (20.0% to 34.0%)	38	524

The population of NTSOs in our study period was N=148. The sample contained n=76 NTSOs. The population of inspections from retailers who frequently failed inspections (ie, failed three or more) in our study period was N=2095. The sample contained n=152 inspections of which n=8 had details unavailable at the time of our study for an analytical sample of n=144. The one NTSO in which the FDA issued the NTSO at the fifth violation by our count had an earlier violation outside of the 36-month date range that FDA counted as the 'original violation'. The CI for the estimated count of retailers who frequently fail inspection and would be subject to an NTSO is 1312 to 1610. CI is calculated with a finite population correction. Estimated count is rounded to the nearest whole retailer. Percentages and weighted counts do not sum due to rounding.
FDA, Food and Drug Administration.

who repeatedly violated the Tobacco Control Act. Yet, when we examined frequently violating retailers, the FDA had actually issued NTSOs to fewer than 2% of retailers who could have been issued an NTSO under the more stringent interpretation. These findings are likely due to a difference in how the FDA is counting violations between the statute (after the fifth violation within 36 months) and FDA's practice (after the fifth violation within 36 months when each violation is the second violation of its specific type[23]). Figure 1 documents the difference between the counting that the more stringent interpretation of the statute provides (Roman numerals) and that the FDA is using in practice (Arabic numerals) in an example complaint.[24] In this example, per the most stringent reading of statute, the FDA could have issued an NTSO on 7 October 2017, but did not issue it until 18 October 2018, after two additional inspections that resulted in four additional violations.

RESULTS IN CONTEXT

It has been over 3 years since the US Surgeon General and the FDA first described youth use of e-cigarettes as a national epidemic.[25] This concerning epidemic has reversed the decade-long downward trend in youth commercial tobacco use overall.[26] In that time, the FDA has made headlines regarding its enforcement actions to address the epidemic, however, the youth e-cigarette usage rates have continued to climb. The present research demonstrates one reason why making headlines is not enough: consistent and strong enforcement of a policy against retailers selling tobacco products is the only youth access intervention that actually impacts youth usage rates.[2] Research examining the effectiveness of minimum legal sales age laws over time demonstrates that having comprehensive and strong laws 'on the books' and retailer education are not enough; the only way to have long-term, downstream results is effective and consistent enforcement of these laws.[2 27] In the present case, it is clear that the FDA is neither assessing penalties in a timely fashion nor escalating penalties to the fullest extent of the law.

In the law, deterrence doctrine argues that to be effective, penalties must be certain, swift and severe enough to outweigh the benefit of non-compliance.[28] The lack of appropriate escalation and timeliness of CMPs and NTSOs undercuts these basic principles. There are no known studies that separate the impact of an NTSO or licence suspension (an equivalent in jurisdictions that enforce through licensing) versus escalating fines. However, each NTSO represents a monetary value to the retailer in the amount of sales that are missed. In many places, this amount could be much higher than the CMP schedule established by statute. Because NTSOs are the most significant penalty that the FDA can issue, delayed or missed NTSOs also indicate that the lower level penalties, in this case CMPs, are also not being maximised.

Finally, failure to appropriately and timely assess NTSOs represents other missed opportunities for impact. At least one study demonstrates that a higher density rate of non-compliant retailers correlates with higher youth access and usage rates.[8] Per 1000 youths, each additional non-compliant retailer increases the odds of initiation by 49%. Removing a retailer from an area through an NTSO, even temporarily, impacts non-compliant retailer density and likely impacts initiation by youth.[8] This could be because, to the extent that youth frequent known bad actor retailers for their own use or to share or sell to friends, an NTSO on these specific retailers has the potential to be more successful at reducing supply.

While our research strongly indicates that the FDA should fully use its authority with stringent enforcement, it should be noted that federal penalties are limited to retailers—not imposed on youth purchasers. This distinction is important given potential unintended consequences of criminalising youth or young adult behaviour,[29 30] and this paper should not be interpreted to support imposing, increasing, or more stringently enforcing penalties against youth or young adult purchasers that may exist at other levels of government.

Strengths and limitations

First, this research is unable to answer the question of why the FDA chose to implement a more lenient method of counting violations than is required by the Tobacco Control Act. It is also beyond this research project to answer the question of whether the FDA's more lenient interpretation of the statute is legal, while acknowledging that a more lenient interpretation is harmful to public health. Additionally, this analysis was limited to the data that the FDA collects and reports; we could not do analysis into other interesting aspects of compliance such as different compliance rates for different types of retailers. Another important limitation of our approach is that FDA inspections likely substantially undercount the actual prevalence of violations.[31 32] While the FDA's inspection protocol is not public, commonly used protocols frequently fail to replicate real-world youth and young adult behaviours and thus underestimate youth and young adult sales.[33 34] Additionally, the lack of a unique ID number in the FDA's public data means that records with changes to their address would be calculated as unique locations. We note that each of these limitations could influence our results by *underestimating* the repeated violations. The total number of unique locations in our data is reasonable given estimates of ~375 000 total retailers in the country,[12] gaps in state implementation of FDA's inspections programme[18 35] and the fact that the FDA sets the minimum percentage of stores to be inspected per year at 20%.[4]

CONCLUSIONS

The youth vaping epidemic combined with the substantial burden of morbidity and mortality from the use of commercial tobacco products requires robust interventions. Existing powers assigned by Congress to the FDA are not being fully leveraged to address the persistent problem of retail sales of tobacco products to those under the minimum legal sales age. This is not due to the lack of resources: the FDA is well funded through user fees (fees paid by the industry) to accomplish all of its statutory duties, including effective enforcement.[36] Public health advocates, as well as FDA officials, should strongly consider ways to increase the enforcement against retailers of existing laws to sales of tobacco products to youth and young adults. Additionally, concerned members of Congress should consider investigating the FDA's enforcement actions.

What this paper adds

- While the Food and Drug Administration's (FDA) data on enforcement actions are public, very few original research projects have endeavoured to systematically analyse the data to identify areas of improvement. This paper adds to the literature by revealing that the FDA has more work to do to ensure that they are stringently enforcing retailer compliance check system.

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Contributors DJ conceived the study, provided legal analysis, coded the data and drafted sections of the manuscript. NH provided legal analysis, coded the data and drafted sections of the manuscript. BB helped design the data collection, developed coding protocols, coded the data and provided critical feedback on the manuscript. JGLL developed the sampling strategy, conducted the analysis, coded the data and drafted section of the manuscript. All authors revised the manuscript, approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests JGLL reported receiving licensing royalties from a store audit and compliance and mapping system owned by The University of North Carolina at Chapel Hill. The tools and audit mapping system were not used in this study. JGLL also holds a contract from the NC Department of Health and Human Services to update lists of tobacco retailers for FDA inspections in that state. No other disclosures were reported.

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