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FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations

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Why OIG Did This Review

Youth tobacco use in the United States remains a high public health concern. The Food and Drug Administration's (FDA's) Tobacco Retailer Compliance Check Inspection Program is a critical part of its approach to prevent youth access to tobacco. Through that program, FDA inspects tobacco retailers to determine whether they are in violation of tobacco law or regulation. If FDA finds a violation, it may issue an advisory action, such as a warning letter, or an enforcement action, such as a civil money penalty (CMP). When FDA issues an enforcement action, it must consider mitigating factors including the nature, circumstances, extent, and gravity of the violation and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, and the degree of culpability.

How OIG Did This Review

We analyzed data from FDA on retailer inspections; violations; and advisory and enforcement actions from 2010 through 2019. We also analyzed retailer inspection and violation histories for a random sample of retailers that were subject to enforcement actions. To determine whether FDA inspection, advisory, or enforcement actions varied by neighborhood socioeconomic characteristics, we compared FDA inspection data to the Area Deprivation Index. We also interviewed FDA officials about the agency's direction and management of the Tobacco Retailer Compliance Check Inspection Program.

FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations

Key Takeaway

Over the 10 years ending in 2019, FDA inspected nearly three-quarters of tobacco retailers nationwide at least once. However, it could take stronger action against retailers with histories of noncompliance.

What OIG Found

FDA conducted more than 1 million inspections from 2010 through 2019, by inspecting, at least once, 74 percent of tobacco retailers that were in business nationwide as of 2020. FDA almost always returned to inspect retailers where it found violations within 12 months. In some States, inspection activities were correlated with neighborhoods' socioeconomic conditions, raising questions about how

FDA and its contractors select retailers to inspect. Overall, FDA's actions against retailers that violated tobacco laws and regulations were in accord with its policies.

However, retailers with histories of violations were often not subject to the strongest enforcement actions. FDA collected the full amount for only 9 percent of the CMPs it issued to retailers with histories of violations compared to 60 percent of CMPs it issued to retailers with fewer violations. Also, retailers in our sample that could have been subject to a no-tobacco-sale order (NTSO) usually did not receive one. However, we did not determine the extent to which FDA's consideration of mitigating factors or actions by Administrative Law Judges played a role in these outcomes.

What OIG Recommends

We recommend that FDA (1) give greater weight to retailers' past noncompliance when taking enforcement actions against retailers with histories of violations and (2) determine whether variation in inspection activity on the basis of neighborhoods' socioeconomic status is appropriate and the extent to which it is meeting FDA's objective for protecting vulnerable populations. FDA concurred with our second recommendation and neither concurred nor nonconcurred with our first recommendation. FDA described steps it would take toward implementing both recommendations.

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BACKGROUND

OBJECTIVES

1. To determine the extent and nature of inspections under the Tobacco Retailer Compliance Check Inspection Program.
 2. To determine the extent and nature of Food and Drug Administration's (FDA's) enforcement actions resulting from the program.
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Inspections of tobacco retailers are a critical part of FDA's efforts to prevent the sale and marketing of tobacco products to youth. The purpose of these inspections is to obtain compliance from retailers by enforcing laws and regulations intended to prevent youth access to tobacco products. Despite FDA's Tobacco Retailer Compliance Check Inspection Program having carried out more than 1 million inspections since 2010, youth tobacco use in the U.S. remains a high public health concern. In particular, e-cigarettes, a type of electronic nicotine delivery system (ENDS), have eclipsed other forms of tobacco to become the most commonly used tobacco product among youth.^{1, 2} In 2020, close to 20 percent of high schoolers, or over 3 million students, reported that they currently used e-cigarettes.³ Since then, e-cigarette use among youth may have declined, although a substantial number of youth still use these products.^{4, 5}

Preventing youth access to tobacco is one of three focus areas of FDA's Youth Tobacco Prevention Plan, which itself is a component of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation. Curbing marketing of tobacco products aimed at youth and educating youth on the dangers of tobacco use are the two other focus areas of FDA's Youth Tobacco Prevention Plan.⁶

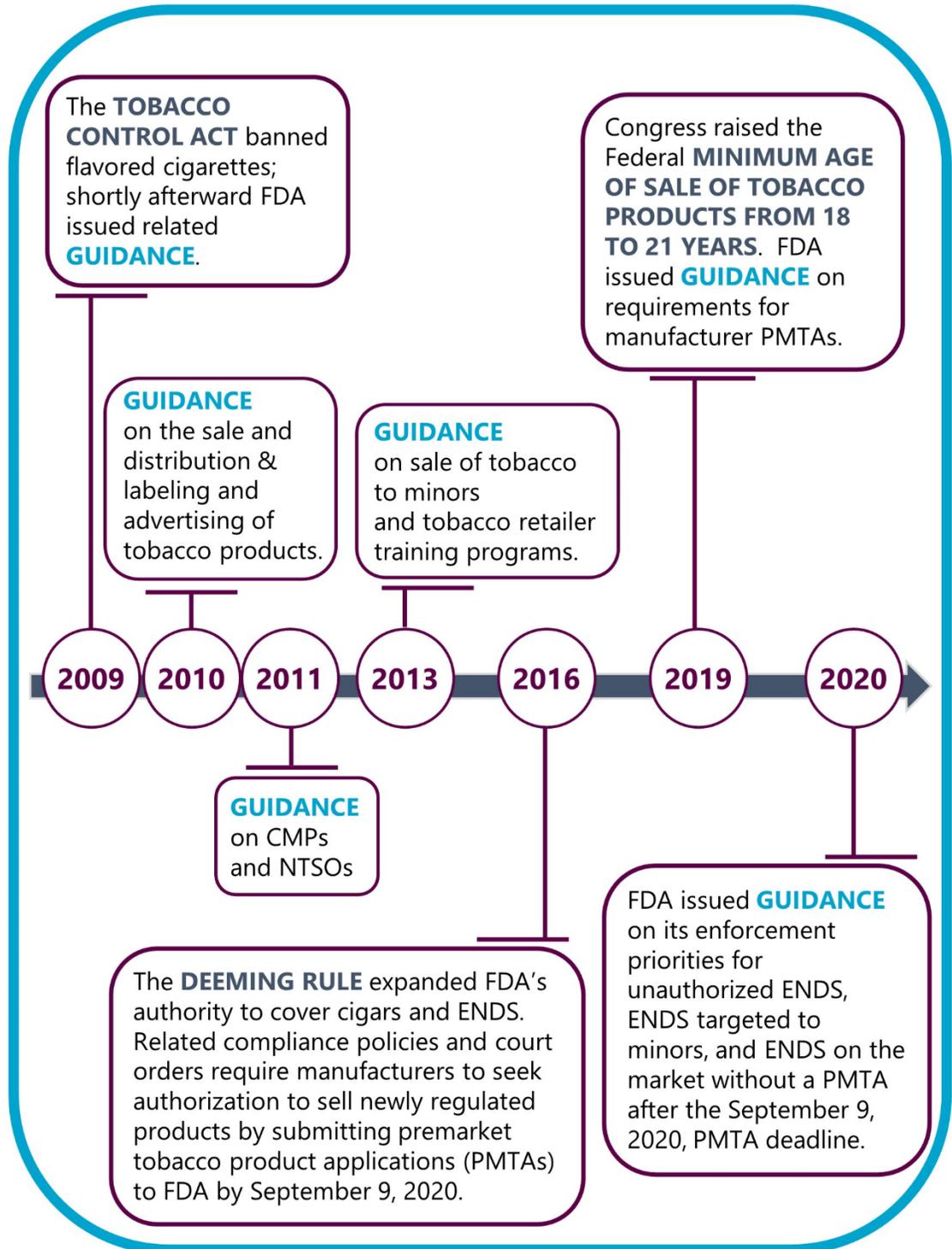
The Tobacco Control Act

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and authorized the FDA to begin regulating tobacco products in the United States.⁷ The Tobacco Control Act granted FDA comprehensive authority over certain types of domestic tobacco products, including the manufacturing, distribution, and marketing of these products.⁸ User fees from tobacco manufacturers and importers are the sole source of funding for FDA's regulation of tobacco products.⁹ The Tobacco Control Act also gave FDA authority to deem additional tobacco products subject to FDA oversight. In 2016, FDA finalized the Deeming Rule that brought other tobacco products, such as cigars and ENDS, under its authority.¹⁰

Additional Legislative and Regulatory Action to Enhance FDA's Oversight of Tobacco

Since the passage of the Tobacco Control Act, additional legislative and administrative actions have enhanced and added clarity to FDA's oversight of tobacco products. See Exhibit 1 for a timeline of these and other selected actions that have enhanced FDA's oversight over tobacco products through 2020.

Exhibit 1: Laws, regulation, and guidance have increased FDA’s oversight of tobacco products.



Source: OIG analysis, 2022

Since 2020, additional actions have further enhanced FDA's oversight over tobacco products. In March 2022, Congress amended the FD&C Act to clarify FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine.¹¹ In May 2022, FDA issued proposed rules that would prohibit characterizing flavors in cigars and menthol as a characterizing flavor in cigarettes, adding to the list of cigarette flavorings banned by the Tobacco Control Act of 2009.^{12, 13}

Through rulemaking in 2021 and in proposed rules in 2022, FDA has emphasized its interest in protecting the health of vulnerable populations through its oversight of tobacco products.^{14, 15} This aligns with Section 105 of the Tobacco Control Act, which directs FDA to ensure enforcement of restrictions against youth access to tobacco products in minority communities.¹⁶ FDA defines vulnerable populations as "groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation."¹⁷ Vulnerable populations can include, but are not limited to, youth; those with lower socioeconomic status; certain races or ethnicities; sexual or gender minorities; underserved rural populations; those pregnant or trying to become pregnant; those in the military or veterans; and those with mental health conditions or substance use disorders.¹⁸

The Tobacco Retailer Compliance Check Inspection Program



Undercover Buy Inspections

Undercover Buy (UB) inspections aim to ensure that retailers comply with restrictions on sales to underage purchasers. Inspectors do not notify retailers when a UB inspection occurs in their establishment. During a UB inspection, an undercover, underage person attempts to purchase a tobacco product at a retailer. An adult inspector accompanies the underage purchaser during the UB inspection to collect evidence and document observations that may indicate a violation occurred during the visit.

FDA's Tobacco Retailer Compliance Check Inspection Program assesses retailers' adherence to tobacco requirements established by the FD&C Act, as amended by the Tobacco Control Act. This program works in concert with FDA's other tools to prevent youth access, such as manufacturer inspections and online investigations. Businesses include, but are not limited to, independent/chain gas stations, convenience stores, and vape shops. As of 2019, FDA estimated that about 360,000 tobacco retailers were operating nationwide.¹⁹

FDA contracts with States, Tribes, and third-party contractors to inspect retailers that sell tobacco in the U.S.²⁰

Typically, FDA contracts specify a number or range of retailers that contractors must inspect annually based on the estimated total number of tobacco retail establishments in their respective States along with other factors such as contractor capacity. Since the program began in FY 2010, FDA has awarded over \$430 million in contracts.²¹

FDA conducts two types of compliance check inspections: those unrelated to restrictions on sales to underage purchasers (formerly called advertising and labeling inspections) and UB inspections.²² UB inspections aim to ensure that retailers comply with restrictions on sales to underage purchasers. After each inspection, inspectors document their findings in a database called the Tobacco Inspection Management System (TIMS). Inspectors use TIMS to document retailer information, such as name and address, as well as inspection data, such as the dates and types of inspections conducted at the retailer's location. If inspectors observe a violation during either type of inspection, inspectors may revisit the retailer to conduct a followup inspection.²³ All retailers, including those that did not have any violations observed during an inspection, may be inspected again in the future. FDA does not use a set cycle that establishes how often it should inspect retailers. See Exhibit 2 for details on FDA's process for inspecting tobacco retailers.

Exhibit 2: FDA's process for inspecting tobacco retailers



Source: OIG analysis, 2022

FDA Actions When Retailers Violate the Tobacco Control Act

FDA has the authority to take advisory and enforcement actions when it determines that a retailer has violated the Tobacco Control Act. Advisory actions include warning letters. A warning letter represents FDA's attempt to bring a retailer into compliance and establish prior notice. Enforcement actions include civil money penalties (CMPs) and no-tobacco-sale orders (NTSOs). A CMP is a fine that FDA assesses for violating the Tobacco Control Act. An NTSO is an order that prohibits a retailer from selling tobacco products indefinitely or for a specified period of time. Finally, in certain cases, FDA may pursue other enforcement actions including criminal prosecution, seizure of tobacco products, or an injunction.

The Tobacco Control Act establishes the penalties FDA may impose for violating the Act. The penalties increase with subsequent violations if the violations occur within timeframes prescribed by FDA's statutory schedule of penalties. Generally, FDA issues a warning letter the first time it finds a retailer in violation. If FDA finds the retailer in violation during subsequent investigations, it has the authority to issue CMPs that increase with each additional violation. When FDA finds that a retailer has committed repeated violations of the same FDA requirements, it has the authority to pursue an NTSO or other enforcement action.²⁴ See Exhibit 3 below for a schedule of FDA's progressive enforcement actions.

The Tobacco Control Act also requires FDA to consider mitigating factors that may affect the penalties FDA imposes for violations. Mitigating factors include "the nature, circumstances, extent, and gravity of the violation or 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."²⁵ Although the Tobacco Control Act directs FDA to consider these factors, it provides FDA with discretion in how to apply them.

Exhibit 3: FDA’s schedule of enforcement penalties for retailer violations of restrictions on the sale and distribution of tobacco products²⁶

Violation Count	Penalty
First violation	Warning letter
Second violation within 12 months	CMP of up to \$320
Third violation within 24 months	CMP of up to \$638
Fourth violation within 24 months	CMP of up to \$2,559
Fifth violation within 36 months	CMP of up to \$6,397
Sixth violation within 48 months	CMP of up to \$12,795
Five or more repeated violations within 36 months	NTSO of 30 calendar days, of 6 months, or permanent

Source: 87 Fed. Reg. 15100 (Mar. 17, 2022). FDA updates CMP amounts annually in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

Efforts by Other HHS Agencies

In addition to FDA’s compliance and enforcement efforts, FDA collaborates with other HHS agencies on significant efforts to better understand and prevent youth tobacco use. This includes working with the Centers for Disease Control and Prevention’s Office on Smoking and Health on programs such as the National Youth Tobacco Survey (NYTS) and the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Synar program. One component of the Synar program is State-run inspections of retailers to determine noncompliance rates with State laws that prohibit tobacco sales to underage buyers. States include the noncompliance rates in an annual report to SAMHSA on their efforts to prohibit youth access to tobacco products.²⁷ The Synar program does not include an enforcement component, although States may pursue State-level enforcement actions for retailer violations. Although the goals of FDA’s and SAMHSA’s compliance check inspection programs differ, the agencies coordinate their programs to prevent youth access to tobacco products.²⁸

Related OIG Work

OIG previously issued a data brief evaluating FDA’s oversight of tobacco manufacturing establishments. The data brief examined tobacco manufacturing

establishment registration and product listing as well as FDA's inspection and enforcement actions from 2010 to 2015. We found that FDA largely met its requirement to inspect manufacturing facilities biennially and that it concluded no enforcement action was needed after the inspections.²⁹

OIG also issued a report evaluating FDA's online tobacco retailer investigations program, which evaluates online retailers' compliance with tobacco laws and regulations. We found that FDA's approach to overseeing online tobacco retailers needs improvement. We recommended that FDA (1) collaborate with the Bureau of Alcohol, Tobacco, Firearms and Explosives on oversight of online tobacco retailers; (2) complete its rulemaking on non-face-to-face sales of tobacco products, as required by the Tobacco Control Act; (3) collect data to support process and outcome measures for its oversight of online tobacco retailers; and (4) publish information and performance data on its oversight of online tobacco retailers. FDA concurred with our first and fourth recommendations and neither concurred nor nonconcurred with our second and third recommendations.

Methodology

This study of FDA's Tobacco Retailer Compliance Check Inspection Program is national in scope. It includes inspections of retailers in the 50 States and the 6 U.S. territories (hereinafter referred to as States) and 4 Tribes. Our analysis covers inspections and related advisory and enforcement actions from the beginning of the program in CY 2010 through CY 2019. In certain parts of our analysis, it was appropriate to scope the analysis more narrowly.

We analyzed the following sources of information for this study: TIMS data on retailer inspections; a review of advisory and enforcement actions for a random sample of inspections; and the University of Wisconsin-Madison School of Medicine and Public Health's Area Deprivation Index (ADI). To determine if there was a relationship between the socioeconomic status of a retailer's block group and FDA's inspection, advisory, and enforcement activities, we compared the retailer's inspection and enforcement data to the ADI.³⁰ We also used information from interviews of FDA officials and followup sets of written questions and answers. Lastly, we used information from FDA's public website on relevant law, regulation, and guidance; priorities in enforcing the Tobacco Control Act; and strategies to reduce youth access to tobacco.

We note that we did not independently verify the TIMS data or information relayed to us by FDA officials. Also, although we did assess the extent to which FDA followed its schedule of penalties when determining which penalties to issue to violative retailers, we did not determine if FDA followed the appropriate administrative process to issue each penalty, including how it considered mitigating factors.

See the Detailed Methodology for details on scope, analysis, and limitations.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

From the beginning of FDA's tobacco retailer inspection program in 2010 through 2019, FDA inspected nearly three-quarters of tobacco retailers nationwide

From 2010 through 2019, FDA conducted more than 1 million inspections, covering 74 percent of tobacco retailers in business nationwide as of 2020 with at least one inspection. In 44 of 55 States, inspectors exceeded the national average by inspecting more than 74 percent of retailers. Furthermore, over this period, FDA inspected 57 percent of retailers more than once, with the average retailer inspected three times. The Tobacco Control Act does not set inspection coverage benchmarks for the Tobacco Retailer Compliance Check Inspection Program. However, FDA works with contractors to set State-level inspection coverage targets based on factors such as local conditions/geography and contractor capacity.

Undercover Buy inspections constitute the majority of inspections—63 percent. See our companion product, [Supplemental Data on Tobacco Retailer Inspections](#), for more details on State-by-State inspection data.

63%

of inspections are undercover buys to assess compliance with restrictions on youth tobacco sales.

To monitor continued compliance, FDA almost always returned to inspect retailers again within 12 months of an inspection that found violations

FDA returned to conduct a followup inspection within 1 year after 88 percent of inspections that found violations. Following up with a subsequent inspection within 12 months is important because it upholds the integrity of the progressive enforcement laid out in FDA's schedule of enforcement penalties. Failure to do so means that retailers that continue to violate restrictions on the sale of tobacco products may avoid FDA enforcement penalties intended to bring about compliance. This is because FDA's schedule of enforcement penalties considers consecutive violations in 12-month intervals.

Thus, if a retailer with a violation goes 12 months without a followup inspection, FDA is potentially missing an opportunity to identify continuing noncompliance. In some cases, this can mean that retailers that repeatedly sell tobacco products to underage people never face any penalty beyond a warning letter. In the example in Exhibit 4 below, FDA conducts a series of inspections at a retailer, including a followup inspection within 6 months of finding a violation. Yet later, FDA does not follow up

on a violation for 15 months, resulting in a second warning letter. If FDA had conducted its follow up within 12 months, it might have potentially identified a violation warranting a CMP for two violations within 12 months.

Exhibit 4: FDA may have missed an opportunity to pursue a CMP when it did not return to inspect a retailer within 12 months of the retailer’s prior violation for selling tobacco to an underage person.

Example of a missed opportunity to pursue a CMP against a retailer that sold tobacco to a minor.



*All violations observed on an inspection date where a warning letter is issued are only counted as one violation.

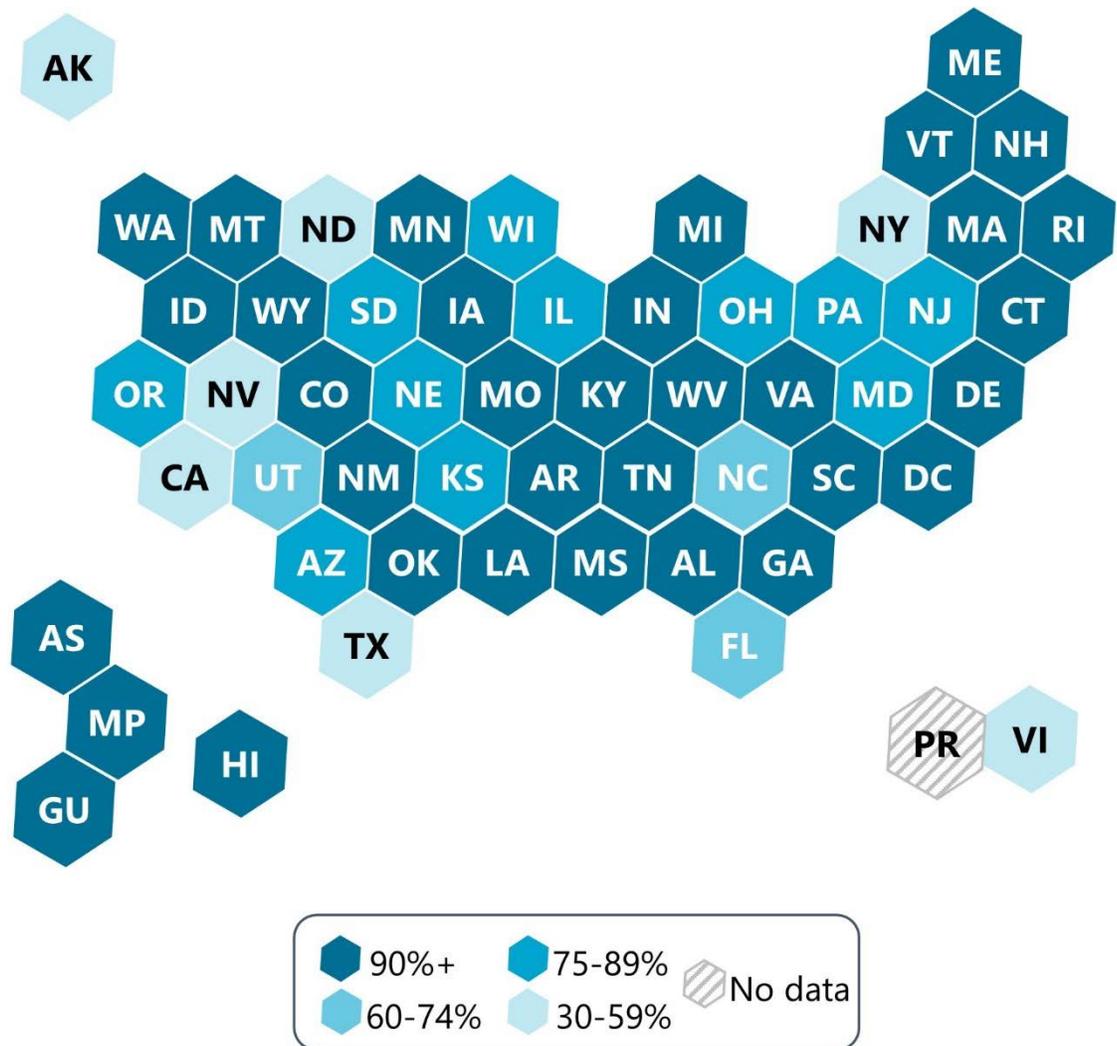
Source: OIG analysis, 2022

The median number of days between an inspection that found a violation and a followup inspection was 178 days, or about 6 months. Oregon (33 percent) and Nevada (51 percent) had the lowest rates of inspections followed up on within 12 months.

FDA’s inspection coverage varied widely among States, and FDA is addressing challenges in States where it inspected the fewest retailers

From 2010 through 2019, inspection coverage varied widely by State, from as high as 99 percent to as low as 32 percent. Over half of States inspected 90 percent or more of retailers that were in business as of 2020. Yet some States lagged significantly. For example, 32 percent of retailers in Nevada and 37 percent of retailers in the Virgin Islands had an inspection. See Exhibit 5 for a map of coverage by State.

Exhibit 5: Percentage of retailers with at least one inspection from 2010 through 2019



Source: OIG analysis, 2022

FDA told us that each State has had its unique challenges and circumstances for completing inspections, and sometimes these related to securing contractors to conduct inspections. One contracting challenge is that some States were unable or unwilling to contract with FDA to inspect tobacco retailers. In response, FDA established contracts with third-party entities where it was not feasible to contract with States. This delayed establishing the Tobacco Retailer Compliance Check Inspection Program in those States, which affected inspection coverage in the first 10 years of the program. Indeed, in five of the seven States where FDA inspected fewer than 60 percent of retailers, FDA used third-party contracts that it initiated in 2014 or later—4 years later than its earliest contracts with States.

Furthermore, in States where FDA inspected the fewest retailers, FDA reported addressing other types of contracting challenges.



Nevada: In Nevada, where FDA inspected 32 percent of retailers, FDA was unable to establish a contract with the State and initially used a cadre of FDA’s own inspectors. In 2014, FDA brought on a third-party contractor, but, according to FDA, that contractor failed due to problems meeting Nevada’s licensure requirements for inspectors. In 2018, FDA brought on a new contractor that was able to meet Nevada’s licensure requirements.



California: In California, where FDA contracts with the State and inspected 42 percent of retailers, FDA reported that California’s budget problems have hampered the State’s ability to fund inspections up-front. FDA told us it has been working with California to mitigate the challenge, including modifying its contract to prioritize inspecting retailers in areas that have not had an inspection yet.



Virgin Islands and Puerto Rico: Finally, FDA struggled to establish viable contracts in the U.S. Virgin Islands and Puerto Rico before the territories suffered widespread destruction in 2017 from Hurricanes Irma and Maria. After the storms, FDA put a hold on inspections in the Virgin Islands and has since brought on a new contractor. In Puerto Rico, according to FDA, it canceled its contract because storm damage made it difficult to carry out inspections. FDA has been working with a new contractor to rebuild its database of retailer addresses. For this reason, FDA could not provide us with data to determine the percentage of retailers it inspected in Puerto Rico.

Inspections on Tribal Lands

FDA contracts with some Tribes to conduct tobacco retailer compliance checks on Tribal lands. From 2014 through 2019, FDA had inspection contracts with four Tribes. In addition, FDA told us that it sends its own inspectors to conduct inspections on Tribal lands. The Tobacco Control Act prohibits States from conducting tobacco retailer inspections on Tribal lands without written permission from Tribes. FDA told us that it conducts outreach to Federally recognized Tribes to inform them of FDA’s tobacco authorities and explain how Tribes can work with FDA, such as through inspection contracts. Data about tobacco compliance check inspections on Tribal lands are limited. FDA could not provide TIMS data on inspections that occurred on Tribal lands before FY 2017.

FDA largely acted in accord with its policies and statutory requirements when it penalized retailers that violated tobacco restrictions

FDA's schedule of penalties for tobacco retailers establishes a progressive framework of actions that increase as retailers accrue additional violations over time. First-time violators, for example, receive warning letters, but additional violations within 12 months escalate to a CMP, or higher-level actions that FDA can take, such as an NTSO. However, according to FDA, most retailers become compliant after receiving a warning letter.

From 2010 through 2019, FDA cited violations in 10 percent of inspections. Among the 118,725 violative inspections, the majority—79 percent—resulted in warning letters, the lowest level of FDA action, and fewer than 1 percent resulted in NTSOs, the highest level. See Exhibit 6 for a breakdown of FDA's progressive enforcement actions.

Exhibit 6: From 2010-2019, FDA cited violations in 10 percent of inspections. FDA took 118,725 actions in response to these violative inspections.



Source: OIG analysis, 2022

FDA adhered to the schedule of penalties when it issued CMPs

FDA issued CMPs to retailers that aligned with the progressive levels in its schedule of penalties 97 percent of the time. Also, 95 percent of the time, FDA issued CMPs at the maximum dollar amount specified in its schedule of penalties. See Tables 1 and 2 in Appendix A for point estimates and confidence intervals.

From 2010 through 2019, FDA issued 24,708 CMPs. Most CMPs were for two to three violations within 24 months. See Exhibit 7 below for a breakdown of all FDA actions, including CMPs, by penalty level.

Exhibit 7: Percentage of CMPs issued by penalty level 2010-2019

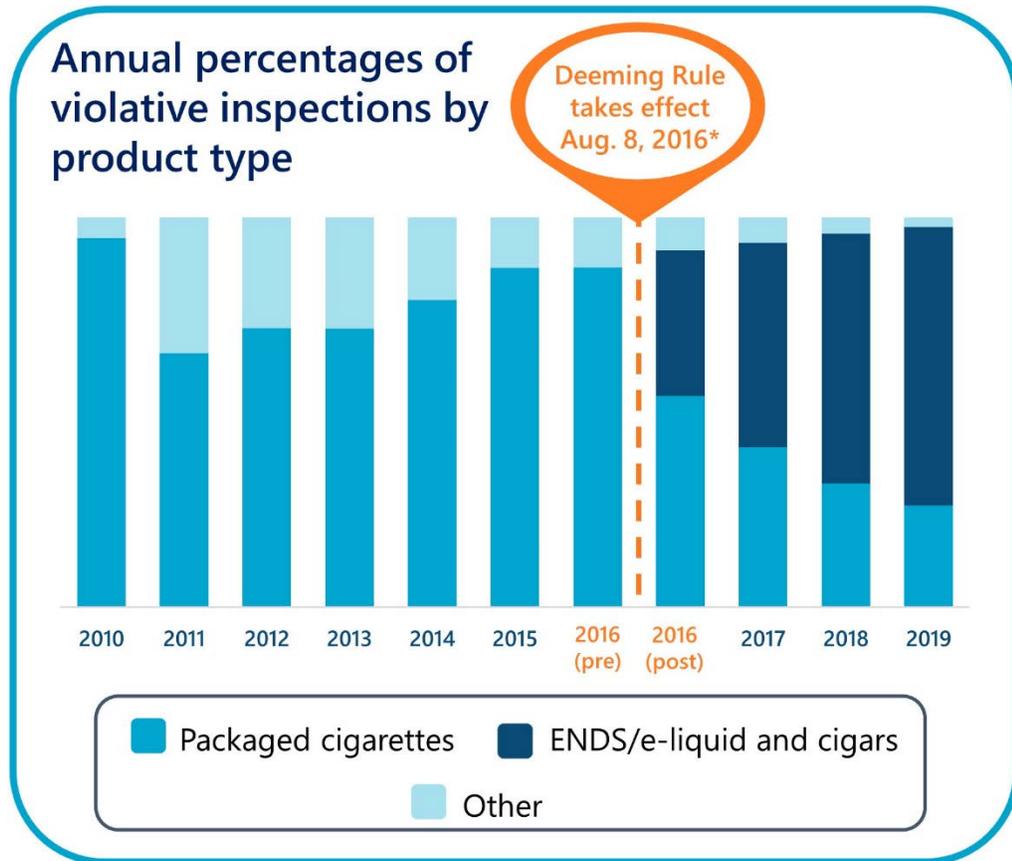
Violation Count	Possible CMP Amount	Number of CMPs Issued	Percent of All CMPs
2 violations within 12 months	\$250 to \$292	7,305	30%
3 violations within 24 month	\$500 to \$584	12,421	50%
4 violations within 24 months	\$2,000 to \$2,340	2,054	8%
5 violations within 36 months	\$5,000 to \$5,849	2,043	8%
6 violations within 48 months	\$10,000 to \$11,698	885	4%

Source: OIG analysis, 2022

FDA prioritized enforcement for newly covered tobacco products after the Deeming Rule took effect in 2016

After FDA deemed cigars and ENDS as covered tobacco products, cigars and ENDS comprised most of the products cited in inspections with violations (38 and 21 percent respectively). FDA considers a range of factors when setting enforcement priorities for tobacco retailers, including TIMS data; research on national youth tobacco use; and insights from program coordinators about local youth trends and conditions. FDA prioritized enforcement for ENDS products; e-liquids; and these products' components or parts in response to the growth of ENDS use among youth over the past decade.³¹ Prior to the Deeming Rule, packaged cigarettes were associated with the most violations. See Exhibit 8 below, for details on the products associated with violations before and after the Deeming Rule.

Exhibit 8: After the Deeming Rule took effect, the percentage of violative inspections related to selling cigars and ENDS products accounted for nearly 60 percent of all violative inspections.



*Note: 2016 is divided into pre- and post-Deeming Rule periods

Source: OIG analysis, 2022

In some States, inspection activities were correlated with neighborhoods' socioeconomic conditions

We observed a strong relationship between neighborhoods' socioeconomic status, indicated by the Area Deprivation Index (ADI), and measures of inspection activity in 26 States.^a In some States, more disadvantaged neighborhoods had more inspection activity; in other States, they had less.

^a Spearman rank correlations of at least +/- 0.8. These correlations show a strong association between neighborhoods' socioeconomic status and measures of inspection activity, but not whether variation in one caused variation in the other.

We note that Section 105 of the Tobacco Control Act directs FDA to ensure enforcement of restrictions against youth access to tobacco products in minority communities. Also, FDA directs contractors to consider socioeconomic status as one of several factors to consider when identifying retailers to inspect. Furthermore, FDA directs contractors to conduct followup and other inspections of certain retailers, while contractors choose the remaining retailers to inspect. However, the relationships we identified raise questions as to how FDA and its contractors select retailers to inspect. Identifying which factors may be driving the correlations we observed or the relative contribution of FDA-versus contractor-directed inspections to the correlations was outside the scope of this review.

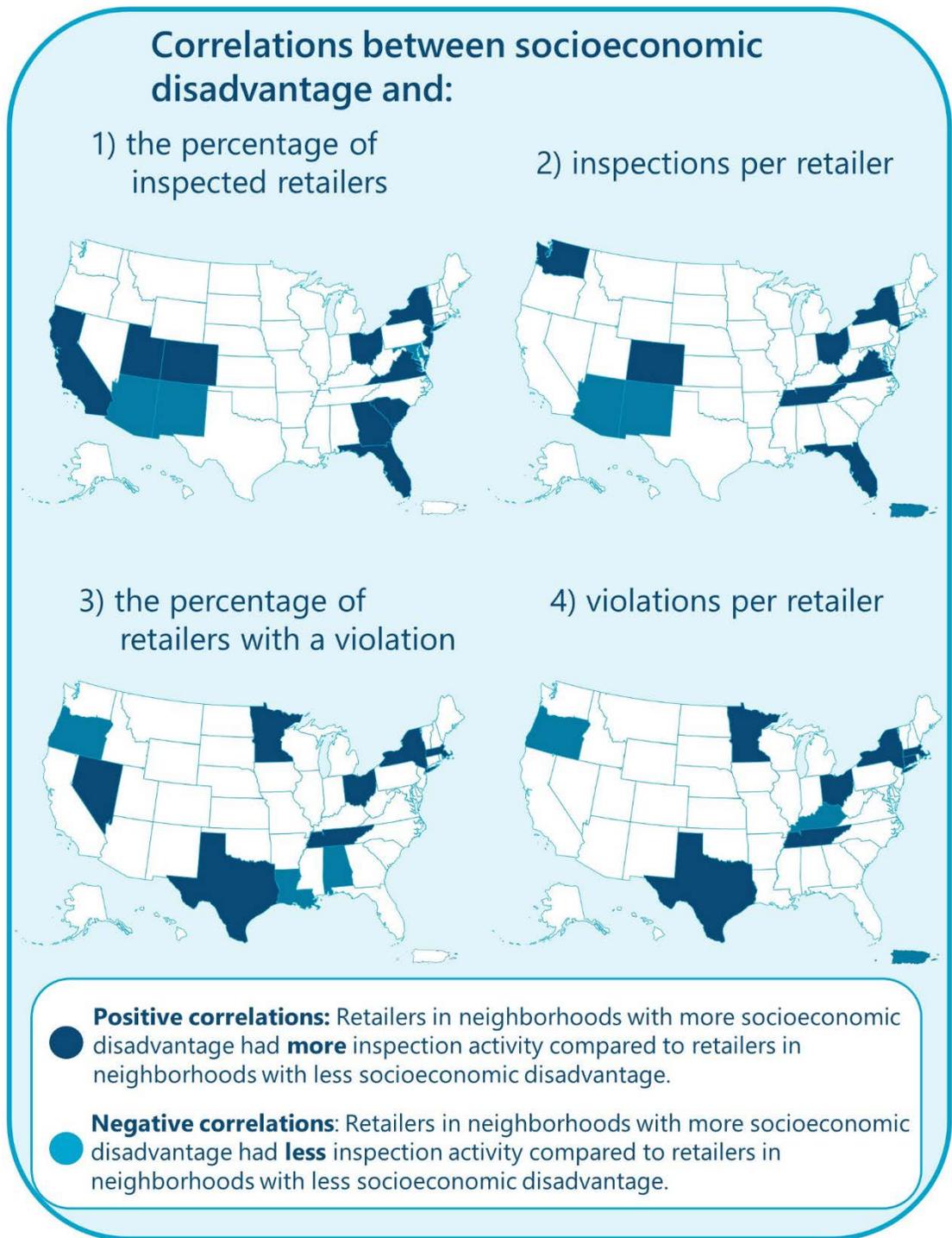
See Exhibit 9 below for details on States with strong correlations.³² For detailed State-by-State inspection data and correlations with ADI, see our companion product, [Supplemental Data on Tobacco Retailer Inspections](#).

As required by FDA's retailer inspection contracts, in identifying retailers to inspect, contractors must consider:

- (1) areas with high rates of youth tobacco use;
- (2) areas where youth report easy access to tobacco products;
- (3) areas located in close proximity to middle and high schools; and
- (4) regions with lower socioeconomic populations.

Contractors are also required to conduct inspections in a variety of different locations (urban, suburban, and rural) and of a variety of outlet types.

Exhibit 9: States with strong correlations between neighborhoods' socioeconomic status and inspection activity



Source: OIG analysis, 2022

In 18 States, more socioeconomic disadvantage in a neighborhood was correlated with more inspection activity, as indicated by strong positive correlations between ADI and one or more measures of inspection activity. More socioeconomic disadvantage

in a neighborhood was correlated with a greater percentage of inspected retailers and/or more inspections per retailer in 13 of these States. In eight States, more socioeconomic disadvantage in a neighborhood was correlated with more inspections finding violations and/or more violations per retailer than for retailers in less disadvantaged areas. In New York and Ohio, there were strong positive correlations between more disadvantage and all four measures of inspection activity.

Conversely, in eight States, more socioeconomic disadvantage in a neighborhood was correlated with less inspection activity, as indicated by strong negative correlations between ADI and one or more measures of inspection activity. More socioeconomic disadvantage was correlated with a smaller percentage of inspected retailers and/or fewer inspections per retailer in four States. In five States, retailers in areas with more socioeconomic disadvantage had fewer inspections finding violations and/or fewer violations per retailer. Puerto Rico had strong negative correlations between socioeconomic disadvantage and inspections and violations per retailer.

Given that in some States, more disadvantaged neighborhoods had more inspection activity, and in other States, they had less, we are unable to conclude if FDA's objectives for distributing inspection activity or protecting vulnerable populations are being met.

Retailers with histories of violations were often not subject to the strongest enforcement actions

In considering the enforcement actions it will take, FDA relies on its schedule of penalties as well as mitigating factors relevant to retailers' individual circumstances. Mitigating factors include, among other things, the retailer's degree of culpability and history of prior violations. Although FDA must consider mitigating factors when determining what enforcement actions to take, it has discretion in how it applies them. In some cases, it may find that mitigating factors merit settling with the retailer for a lower dollar amount than originally sought in the CMP. Indeed, it is in FDA's interest to work with retailers that take steps to comply with the Tobacco Control Act after their first violations. In some cases, other entities could affect the penalties retailers face after a violation. For example, an Administrative Law Judge could reduce the penalty after an administrative hearing. Also, the Department of Justice can pursue a retailer for failing to pay a CMP.

"In determining the amount of a civil penalty, or 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 violation or 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."

—Section 303(f)(5)(B) of the FD&C Act

Nevertheless, we found that the small number of retailers that repeatedly violate the Tobacco Control Act are often not subjected to more punitive actions. This risks undermining FDA's efforts to control youth access to tobacco and enforce other restrictions on tobacco intended to safeguard public health.

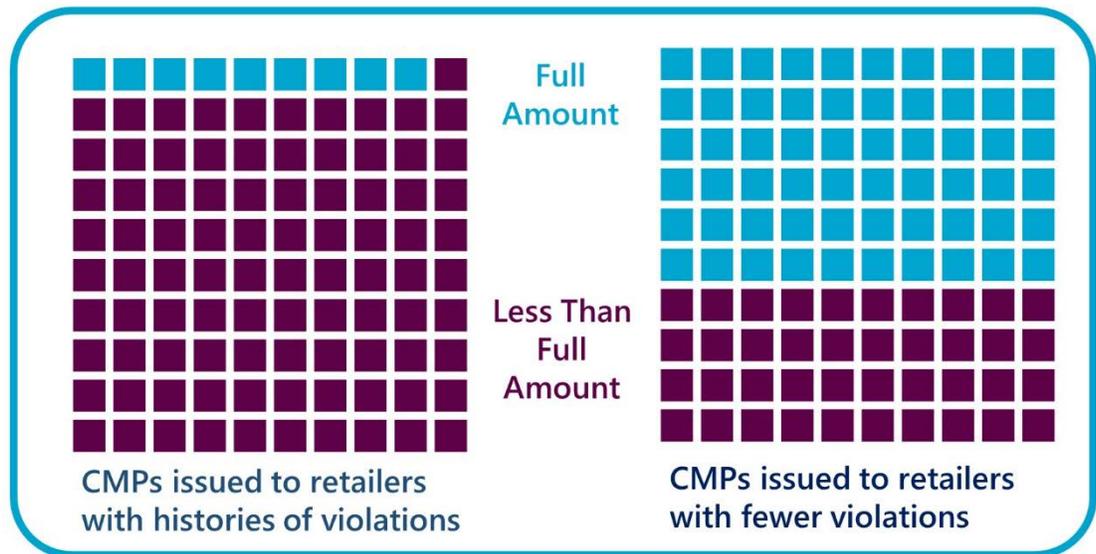
Retailers with histories of violations did not pay CMP amounts sought in full as often as retailers with fewer violations

Retailers with histories of violations paid in full for only 9 percent of CMPs they received. By comparison, retailers with fewer violations paid in full for 60 percent of the CMPs they received. When a retailer accumulates five or more violations in the last 3 years of inspections, FDA can issue a CMP of \$5,000 or more. From 2010 through 2019, FDA issued 2,927 such CMPs to retailers with such histories of violations.

However, retailers only paid the full amount of 272 of these CMPs of \$5,000 or more. This compares to CMPs that FDA issued to retailers with fewer violations, for which retailers paid 13,034 of 21,781 CMPs in full. CMPs that were not paid in full include CMPs that were lowered from the amounts originally sought by FDA during the settlement process or after a hearing with an Administrative Law Judge. See Exhibit 10 below for details on the portions of CMPs that FDA collected from retailers with histories of violations versus from those with fewer violations. See Exhibit 11 below for details on the total amounts of CMPs issued to and collected from retailers with histories of violations versus from those with fewer violations.

Retailers did not pay nearly \$18 million of the CMPs they received, the majority of which was due from retailers with histories of violations.

Exhibit 10: Collection of CMPs issued to retailers with histories of violations versus retailers with fewer violations (2010-2019)



Source: OIG analysis, 2022

Exhibit 11: Amounts of CMPs that FDA issued and collected to retailers with histories of violations versus retailers with fewer violations (2010-2019)

	Total amount issued	Total amount collected	Total amount uncollected
CMPs issued to retailers with histories of violations	\$21,058,382	\$8,009,087 38%	\$13,049,295 62%
CMPs issued to retailers with fewer violations	\$13,085,543	\$8,481,073 65%	\$4,604,470 35%

Source: OIG analysis, 2022

Retailers in our sample that could have been subject to an NTSO usually did not receive one

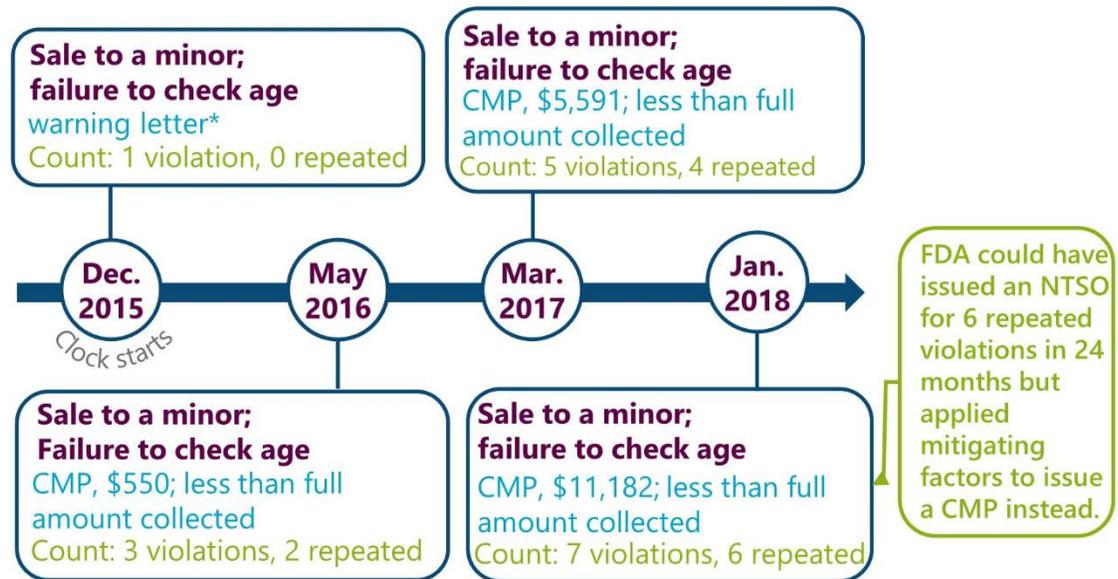
FDA issued NTSOs to only 7 of the 22 retailers in our sample that met its criteria, based on repeat violations over time, for an NTSO. Accordingly, each of the 22 retailers accrued first-time violations of one or more requirements of the Tobacco Control Act followed by at least five subsequent, repeat violations of the same

requirements. These retailers previously received a warning letter and, possibly, three CMPs from FDA for those violations.

Despite the histories of noncompliance of the remaining 15 retailers, FDA issued them additional CMPs ranging from \$2,000 to \$11,410 rather than issuing them NTSOs. FDA collected less than half of these CMPs in most cases. FDA collected the full amount of the CMP it sought in only one instance—from the retailer that received the lowest CMP of \$2,000. However, we did not determine how FDA's treatment of mitigating factors, which it is required to consider, played a role in its decision to forgo issuing NTSOs to these retailers or the amount of CMPs they paid. We also did not determine whether decisions by Administrative Law Judges affected these outcomes. See Exhibit 12 below for an example of the enforcement history for 1 of the 15 retailers in our sample with a history of violations that did not receive an NTSO from FDA.

Exhibit 12: Although a gas station’s violations from 2015 through 2018 met NTSO criteria, FDA did not impose an NTSO against the retailer.

Inspections at a Gas Station 2015-2018



*All violations observed on an inspection date where a warning letter is issued are only counted as one violation

Source: OIG analysis, 2022

FDA told us that it reserves NTSOs for “particularly egregious offenders where previous monetary penalties associated with CMPs have not brought the retailer into compliance.” However, among the retailers in our sample with a history of violations, FDA largely continued issuing CMPs and then did not collect the full amount of those CMPs. Given estimates that the average American convenience store makes about \$1,000 per day in tobacco sales, even the shortest NTSO that FDA has ever issued—10 days—represents a more significant penalty than what the 15 retailers in our sample faced.³³ Although we did not assess how mitigating factors influenced FDA’s decision to impose CMPs in lieu of NTSOs, our findings raise concern that FDA may not be giving sufficient weight to retailers’ history of violations when imposing enforcement actions.

Furthermore, in determining a history of violations, FDA counts certain violations related to products covered by the Deeming Rule separately from violations related to other tobacco products. In other words, when FDA cites a retailer for selling cigarettes or smokeless tobacco products to youth and then cites the same retailer for selling newly covered tobacco products to youth after the Deeming Rule, it cannot count the second citation as a repeat violation for selling to an underage person. FDA’s interpretation of the Tobacco Control Act, which FDA communicated in guidance, considers those as distinct, and not repeat, violations.³⁴

Repeat violations matter because they determine whether retailers could face the most stringent enforcement action in FDA's schedule of penalties, an NTSO. In our 10-year review period, FDA issued a total of 204 NTSOs. Also, in our random sample of 110 inspections out of 2,912 with three or more prior violations, we identified nine instances in which this required approach of counting repeated violations separately for tobacco products covered by the Deeming Rule prevented FDA from considering an NTSO. This suggests that there may be many instances in which FDA cannot issue an NTSO simply because the tobacco products involved fall under different regulatory provisions, even if the retailer's action is fundamentally the same (e.g., selling tobacco to an underage person, whether the product sold was a cigarette or an ENDS product).

CONCLUSION AND RECOMMENDATIONS

This report, alongside our companion product, [Supplemental Data on Tobacco Retailer Inspections](#), sheds light on FDA's 10 years of experience inspecting tobacco retailers. In that time, FDA's Tobacco Retailer Compliance Check Inspection Program has made strides and faced challenges in preventing youth access to tobacco and other violations. FDA inspected the majority of retailers at least once in that period and followed up on almost all with violations within 12 months. FDA adhered to the schedule of penalties when it issued CMPs. Also, it has worked to address a range of challenges that have arisen as it established and managed inspection contracts in each of 60 State, territorial, and Tribal jurisdictions.

Nevertheless, responding effectively to serial violators remains a challenge for FDA. A small number of retailers with histories of violations have emerged over the 10 years. These retailers have often not been subject to the strongest enforcement actions.

Given that tobacco products represent a significant threat to public health, FDA must use each of the tools within its schedule of penalties as effectively as possible. Furthermore, FDA must act in accordance with its interpretation of the Tobacco Control Act regarding repeat violations for purposes of issuing an NTSO. The Tobacco Control Act also requires FDA to consider mitigating factors in enforcement. FDA does, however, have discretion in how it weighs these mitigating factors. Our findings raise questions about how FDA applies this discretion.

To that end, we recommend that FDA:

Give greater weight to retailers' past noncompliance when taking enforcement actions against retailers with histories of violations

CMPs: FDA accepted less than the original amount as payment in full for over half of CMPs it issued for \$5,000 or more. When pursuing enforcement actions such as CMPs and NTSOs, FDA must consider the nature and circumstances surrounding the violation; the retailer's ability to pay; its ability to continue to do business; and any history of similar violations by the retailer. Considering these issues is an important safeguard to ensure that retailers are not unfairly or unduly punished for violating the Tobacco Control Act. However, by the time FDA issues a CMP of \$5,000, a retailer's history of violations should figure much more prominently among the factors FDA considers when negotiating any settlement with the retailer. Failure to follow through on these higher-dollar CMPs weakens incentives for such retailers to change behavior.

NTSOs: From 2010 through 2019 and over 1 million inspections of tobacco retailers, FDA only issued 204 NTSOs. The Tobacco Control Act requires FDA to cite a retailer with five violations that are repeated violations of the same requirements before it can issue an NTSO, not just five subsequent violations to a first violation. This means that by the time retailers have met this threshold, they have, in a 36-month period, accrued at least six and potentially many more violations of the Tobacco Control Act.

We understand that the mitigating factors that FDA must consider play a role in FDA's decision making on NTSOs. However, FDA only issued NTSOs to 7 of the 22 retailers in our sample that could have received one. This this raises questions about whether FDA is giving proper weight to retailers' past noncompliance, which is another factor that FDA must consider.

Determine whether variation in inspection activity on the basis of neighborhoods' socioeconomic status is appropriate and the extent to which it is meeting FDA's objective for protecting vulnerable populations

Section 105 of the Tobacco Control Act directs FDA to ensure enforcement of restrictions against youth access to tobacco products in minority communities. Also, socioeconomic status is one of several considerations that FDA's contractors must consider in selecting retailers to inspect. We found that, at least according to the Area Deprivation Index, more disadvantaged neighborhoods had more inspection activity in some States, and in other States they had less. FDA should use our analysis as a starting point to explore whether variations in inspection activity are appropriate and serving FDA's goals to protect vulnerable populations. If FDA detects unintended bias in how it directs its contractors or in how contractors allocate resources that is counter to these goals, it should take appropriate action.

AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with one of our recommendation and neither concurred nor nonconcurred with the other, as detailed below.

First, FDA neither concurred nor nonconcurred with our recommendation that it give greater weight to retailers' past noncompliance when taking enforcement actions against retailers with histories of violations. FDA agreed with OIG that it is appropriate to give greater weight to histories of noncompliance when determining penalties for such retailers and stated that it already does so. FDA stated that many retailers are small businesses and it must balance a retailer's history of violations with mitigating factors including the retailer's ability to pay and the effect of a penalty on its ability to continue to do business. Nonetheless, FDA stated that it will initiate internal discussions, including with its counsel, to determine whether history of violations can be given greater weight in the settlement process, increasing with each subsequent violation.

Second, FDA concurred with our recommendation that it determine whether variation in inspection activity on the basis of neighborhoods' socioeconomic status is appropriate and the extent to which it is meeting FDA's objective for protecting vulnerable populations. FDA affirmed its commitment to health equity and stated that contractors are required to consider several risk-based factors in selecting areas for inspections and ensure that they conduct inspections in a variety of locations and outlet types. However, FDA also noted that FDA-directed inspections, such as those of retailers with prior violations, do not consider risk-based factors. To address our recommendation, FDA stated that it will initiate meetings with subject matter experts within the agency to evaluate the variation we identified and make recommendations on how to better address and achieve health equity should its evaluation findings warrant doing so.

OIG appreciates the steps FDA committed to taking to address our recommendations.

For the full text of FDA's comments, see Appendix B.

DETAILED METHODOLOGY

Scope

This evaluation of FDA's Tobacco Retailer Compliance Check Inspection Program is national in scope. It includes inspections of retailers in the 50 States and 6 U.S. territories. Our analysis covers Undercover Buy and other inspections, and related advisory and enforcement actions from the beginning of the program in 2010 through 2019. Our analysis of the percentages of retailers inspected focused on retailers listed in TIMS as in business as of January 1, 2020. In certain parts of our analysis, it was appropriate to scope the analysis more narrowly. We describe those instances in the relevant sections that follow.

Data Sources

We analyzed the following sources of information for this study: data on retailer inspections from FDA's Tobacco Inspection Management System (TIMS); a review of a random sample of inspections; and the University of Wisconsin-Madison School of Medicine and Public Health's Area Deprivation Index (ADI). We also used information from interviews of FDA officials and followup sets of written questions and answers. Lastly, we used information from FDA's public website on relevant law, regulation, and guidance; priorities in enforcing the Tobacco Control Act; and strategies to reduce youth access to tobacco.

Inspection Activity

To assess the extent and nature of inspections and violations, we requested TIMS data from FDA, which included data on the population of tobacco retailers known to FDA; inspections; and advisory and enforcement actions. FDA provided the data we requested covering the beginning of the program in 2010 through 2019. From these data, we selected inspections that TIMS identified as closed and resolved by FDA as to whether the inspections found violations. We used the TIMS data provided by FDA to determine the extent of FDA advisory and enforcement actions and to identify the trends and patterns in FDA's inspections of tobacco retailers. Although we did not independently verify TIMS data, we occasionally used data from FDA's website and online dockets to correct for anomalies we discovered in the data.

Our analysis of inspection rates among retailers that were in business as of 2020 excludes retailers in the Northern Mariana Islands and Puerto Rico due to the natural disasters experienced in these jurisdictions and the impact on the data available for analysis.

Adherence to FDA’s Schedule of Enforcement Penalties

To determine the extent to which FDA followed its schedule of penalties, we conducted a review of a random sample of violative inspections. This review was necessary because the TIMS data that FDA provided to us only had details on the number and types of violations FDA cited during inspections that resulted in warning letters. Details on the violations cited during inspections that resulted in CMPs and NTSOs were not available in the data. This prevented us from analyzing TIMS data alone to identify and count retailers’ violations. Therefore, for a random sample of violative inspections, we abstracted violations data from dockets on FDA’s website. We then projected these data to the population of all violative inspections.

Population and Sample Selection

The population for our review of FDA’s adherence to its schedule of penalties comprises 118,725 retailer inspections in TIMS that found violations of the Tobacco Control Act between 2010-2019. We stratified this population into three strata based on the count of prior inspections with violations that the inspected retailers had. We did so to ensure that the inspections we sampled were associated with retailers with a range of inspection histories. This is important because retailers’ inspection histories drive the levels of progressive discipline called for in FDA’s schedule of penalties. Exhibit 13 below describes the strata and the population’s distribution among them.

We note that, for stratum A, we sampled all 81,584 violative inspections for review because we could verify the outcome of all inspections using TIMS data. For these inspections, retailers had no prior violations. FDA’s policy is to issue a warning letter for a retailer’s first violative inspection, no matter how many violations FDA cites during that inspection. Using TIMS, we could verify that retailers did indeed receive warning letters in accordance with FDA policy.

Exhibit 13: Population of violative inspections by stratum

Stratum	Violative Inspections	Sampled Violative Inspections
Stratum A: 0 prior inspections with violations	81,584	81,584
Stratum B: 1 or 2 prior inspections with violations	34,229	110
Stratum C: 3 or more inspections with prior violations	2,912	110
Total	118,725	81,804

Data Abstraction

For each sampled inspection in strata B and C, we compiled data on the sampled inspection and the inspected retailer's inspection history from docket on FDA's website.³⁵ For each sampled inspection, we looked up FDA's enforcement docket and reviewed it to identify and record the violations FDA cited during the inspection, such as selling cigarettes to an underage buyer or failing to verify a buyer's age. In addition, for the retailer associated with each sampled inspection, we reviewed the retailer's previous 4 years of inspections. For each of these inspections, if they resulted in violations, we looked up FDA's enforcement docket to identify and record the violations FDA cited. The result was a full picture of the violations FDA cited during each sampled inspection and any violations it cited the retailer for in the previous 48 months, which is the window of time that FDA's schedule of penalties considers.

Analysis

For each inspection, we reviewed the violations contained in the sampled inspection and the associated retailer's inspection history. We determined the extent to which FDA issued CMPs and NTSOs in accordance with the schedule of penalties. Additionally, we assessed the extent to which FDA issued CMPs for the dollar amount called for in the schedule of penalties effective at the time of the violation. To do so, we used a two-stage review with automated analysis of the abstracted data followed by a manual review to confirm potential disagreements between FDA-issued penalties and OIG-determined penalties.

Finally, we projected the results of our review. Our findings are generalizable to the population of 118,725 violative inspections in TIMS that took place from 2010 through 2019.

Socioeconomic Analysis

To determine if there was a relationship between a retailer's socioeconomic status and FDA's enforcement, we compared the retailer's inspection and enforcement data to the University of Wisconsin-Madison School of Medicine and Public Health's Area Deprivation Index (ADI). The ADI is a measure based on the Health Resources and Services Administration's American Community Survey and is validated to the Census Block Group.³⁶ ADI measures socioeconomic conditions within Census Block Groups. ADI considers 17 measures related to education, income, employment, housing, and household characteristics.³⁷ A higher ADI score means that an area has a higher level of advantage compared to other regions. We reported correlations between the ADI and FDA's inspection activities and its advisory/enforcement actions if the Spearman rank correlation coefficient was ≥ 0.8 or ≤ -0.8 . We referred to such correlations as strong correlations. The correlation statistics are shown in our companion product, [Supplemental Data on Tobacco Retailer Inspections](#).

To tie retailers to their U.S. Census Block Group, we created a data set that included each retailer's unique ID; address; and inspection and violation counts. We geocoded retailer location data using Esri ArcMap to match the retailers with the appropriate U.S. Census Block Group identifier.³⁸

We then joined the geocoded retailers to the ADI using ArcMap. We manually geocoded 336 retailers, mainly those located along water borders such as coastal areas, that were not assigned an ADI value. This resulted in 559,935 retailers assigned an ADI value through ArcMap or by manual geocoding.

We excluded some retailers from our ADI analysis. We excluded six retailers for which ArcMap was unable to match a location and eight retailers that were either from dummy inspections or not assigned a zip code in the original inspection data. We also excluded 2 retailers that were located in the wrong state in the original data and 633 retailers that were too close to state borders to be correctly located. In addition, we excluded seven retailers in Puerto Rico that could not be geocoded. Our analysis also excluded retailers in America Samoa, Guam, the Northern Mariana Islands, and the Virgin Islands because the ADI does not assign values in those locations.

In addition, we excluded 50,962 retailers because they were located in block groups with suppressed ADI values. The ADI suppresses certain block groups when (1) there is a low population and/or housing in that block group; (2) there is a high percentage of the population living in group quarters populations; (3) there is a combination of 1 and 2; or (4) a block group was not assigned an ADI value because there were data missing from the American Community Survey.³⁹

After excluding these retailers from our analysis, there were 559,300 retailers that were properly geocoded and assigned an ADI value.

We grouped each of the retailers into one of 148,405 unique block groups. We then ran correlation analyses to determine whether there was any relationship between the block group ADI and our variables of interest at the state level. We analyzed correlations between a block group's ADI and the following metrics for retailers at each ADI level in each state: (1) average count of inspections, (2) average number of violations, (3) average number of warning letters, (4) average number of CMPs, and (5) average number of NTSOs.

Legal and Policy Analysis

We consulted several sources to understand relevant laws, regulations, and guidance. Sources included a review of laws including the Tobacco Control Act and subsequent legislation; FDA regulations; guidance on FDA's website; interviews; correspondence with FDA officials; and consultation with OIG's Office of Counsel.

Limitations

We did not independently verify the TIMS data or information relayed to us by FDA officials. Because TIMS data do not contain the dates on which retailers closed, our analysis of repeat inspections does not account for retailers that could not be re-inspected because they had closed. Also, although we did assess the extent to which FDA followed its schedule of penalties when determining which penalties to issue to violative retailers, we did not determine if FDA followed the appropriate administrative process to issue each penalty including how it considered mitigating factors. Additionally, although we evaluated FDA's oversight of the Tobacco Retailer Compliance Check Inspection Program as a whole, we did not evaluate FDA's oversight of individual contracts.

APPENDICES

Appendix A: Statistical Tables

Table 1. Point estimate and confidence intervals for instances in which FDA could have issued a CMP but issued a warning letter instead, 2010-2019

Outcome	Point estimate	95-percent confidence interval
CMP issued (n = 201)	97.25	92.24 – 99.06
CMP not issued (n = 5)	2.75	0.94 – 7.76

N = 206

Table 2. Point estimate and confidence intervals for frequency with which FDA issued CMPs for the appropriate dollar amount according to the schedule of penalties, 2010-2019

Dollar difference amount between OIG's calculated money penalty and CTP's issued penalty	Point estimate	95-percent confidence interval
CMP amount within the range of one degree of difference on the schedule of penalties (n = 190)	94.86	89.54 – 97.55
CMP amount outside the range of one degree of difference on the schedule of penalties (n = 16)	5.14	2.45 – 10.46

N = 206

Appendix B: Agency Comments

Following this page are the official comments from FDA.



DATE: August 31, 2023

TO: Ann Maxwell
Deputy Inspector General
Office of Evaluation and Inspections

FROM: Beethika Khan
Associate Commissioner for Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Beethika
Khan -S Digitally signed by
Beethika Khan -S
Date: 2023.08.31
09:51:43 -04'00'

SUBJECT: Draft Report, OEI-01-20-00240

Attached are the Food and Drug Administration's general and technical comments to the Office of Inspector General's August 1, 2023 draft report entitled *FDA Could Take Stronger Enforcement Action Against Tobacco Retailers with Histories of Sales to Youth and Other Violations*. Thank you for the opportunity to provide feedback.

Attachments

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA's General Comments

OIG Draft Report: *FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations*, OEI-01-20-00240

Thank you for the opportunity to review and comment on OIG's draft report.

FDA's enforcement work is a key part of the Agency's efforts to protect youth from tobacco products. The Agency has a comprehensive compliance and enforcement program that oversees all entities in the supply chain – importers, manufacturers, distributors, and retailers. Since enactment of the Tobacco Control Act in 2009, FDA has secured contracts with states, territories, and third parties to conduct in-person inspections of tobacco retailers, which has resulted in more than 1.4 million inspections.

FDA staff carefully review the results of each inspection and take action, as appropriate. Many retailers comply with the law but when violations are found, FDA staff put together the evidence to develop a warning letter. FDA first issues a warning letter to achieve compliance. When retailers do not come into compliance after receiving a warning letter, FDA then typically utilizes enforcement actions such as civil money penalties (CMPs), and no-tobacco sale orders (NTSOs) for subsequent violations. To date, FDA has issued more than 128,000 warning letters, 30,000 CMPs, and 220 NTSOs based on violations found during retailer inspections.

FDA continuously monitors the marketplace and takes actions to maximize public health impact, including, for example, action against products with targeted advertising to young people or an uptick in use among youth. Informed by marketplace data, for example, FDA's retailer inspection program recently conducted a nationwide inspection blitz cracking down on the sale of unauthorized e-cigarettes commonly used by youth. This blitz resulted in the issuance of nearly 200 warning letters to brick-and-mortar retailers. As described above, if retailers do not come into compliance after receipt of a warning letter, the Agency will seek enforcement actions, including escalating CMPs and NTSOs, as necessary, until a retailer comes into compliance. The amount of enforcement action needed varies depending on the facts and individual circumstances of each case.

More information about FDA's compliance and enforcement activities can be found at: <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-selling-tobacco-products-underage-purchasers> and <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products>.

FDA's comments on OIG's recommendations are below.

Give greater weight to retailers' past noncompliance when taking enforcement actions against retailers with histories of violations

FDA agrees that giving greater weight to retailers' past noncompliance is appropriate and we currently do that when determining appropriate enforcement tools and during the settlement

process. We understand that OIG is recommending FDA gives even greater weight for histories of violations and we will further consider this recommendation.

FDA remains committed to implementing the escalating penalty schedules for repeated violations within prescribed timeframes in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is concerned about retailers that continue to violate the law and does heavily weigh that mitigating factor against the retailer when settling a case with a retailer who has received multiple CMPs, generally settling for progressively higher amounts in those subsequent CMP cases.

For violations of the statutory prohibition on the sale of tobacco products to youth and the sale and distribution regulations found under 21 Code of Federal Regulations part 1140, FDA follows the penalty schedule outlined in the Tobacco Control Act to determine the amount sought in a CMP complaint. This schedule escalates based on the number of violations observed during certain timeframes. Similarly, FDA may seek NTSOs only when a retailer commits five repeated violations of particular requirements under the law.

The law also requires the Agency to take into account the following mitigating factors in determining the amount of the civil penalty or time period of the NTSO:

- the nature, circumstances, extent, and gravity of the violation or violations;
- 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.

Many retailers are considered small businesses and factors such as their ability to pay and the effect on their ability to continue to do business must be balanced with the history of violations and other mitigating factors. While FDA makes every effort to hold retailers, including small businesses, accountable by seeking escalating penalties for historically violating the law, we must by law consider the information and evidence presented by a retailer during the settlement process.

By November 2023, FDA's Center for Tobacco Products (CTP) will initiate discussions within the agency, including counsel, to determine whether the history of violations can be given even greater weight, increasing more with each subsequent violation, when considering mitigating factors and reduction in settlement amounts.

Determine whether variation in inspection activity on the basis of neighborhoods' socioeconomic status is appropriate and the extent to which it is meeting FDA's objective for protecting vulnerable populations

FDA concurs with the recommendation. Advancing health equity is a high priority for CTP. Ensuring health equity and protecting vulnerable populations¹ is an integral part of FDA’s work to protect public health generally and prevent and reduce tobacco use by young people.

The Tobacco Control Act required FDA to develop an enforcement action plan. To develop the plan, FDA solicited and analyzed input from stakeholders including public health organizations, minority community groups and leaders, other stakeholders with demonstrated expertise and experience in serving underserved communities, groups serving youth, patient groups, advertising agencies, and the regulated industry. In 2010, FDA issued its enforcement action plan, available on its website at: <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/enforcement-action-plan-promotion-and-advertising-restrictions>. Consistent with this plan, FDA requires the contractors that conduct tobacco retail inspections in the states and territories to prioritize geographic areas with a higher risk for regulatory violations. Contractors must consider:

1. Areas with high rates of youth tobacco use;
2. Areas where youth report easy access to tobacco products;
3. Areas located in close proximity to middle and high schools; and
4. Regions with lower socioeconomic populations (which is included due to these areas having been historically targeted via marketing and is therefore attempting to remedy past biases).

Further, contractors are required to ensure inspections are conducted at a variety of different locations (urban, suburban, and rural) and include a variety of outlet types throughout the jurisdiction. We also note that other factors impact the inspection assignments such as prioritizing retailers with prior violations, which are FDA-directed inspections and do not consider whether the violative retailers are in these higher risk categories.

FDA evaluates how the contractors propose to meet these requirements for routine inspections; however, we recognize more can be done to evaluate the variation in inspection activity on the basis of neighborhoods’ socioeconomic status; whether it is appropriate; and the extent to which we are addressing health equity.

To address this recommendation, by December 2023, CTP will initiate meetings with subject matter experts within the agency to evaluate this variation and make recommendations on how we may better address and achieve health equity, if the evaluation findings warrant it. These subject matter experts may include CTP’s Senior Advisor for Health Equity, senior staff in CTP’s Office of Science, and staff in FDA’s Office of Minority Health and Health Equity.

¹ FDA uses the term “vulnerable populations” to refer to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQI+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions or substance use disorders.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Matt Blackburn served as the lead analyst for this study. Others in the Office of Evaluation and Inspections who conducted the study include Jac Carreiro, Caitlin Foster, Rachel Pavia, and Elizabeth Sandefer. Office of Evaluation and Inspections headquarters staff who provided support include Kevin Farber, Rob Gibbons, Althea Hosein, and Michael Novello.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Justin Koppa.

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Ken Price, Deputy Regional Inspector General.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General
U.S. Department of Health and Human Services
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ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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ENDNOTES

- ¹ Gentzke, A.S., Wang, T.W., Cornelius, M., et al. "Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021." *MMWR Surveill Summ* 2022;71 (No. SS-5):1–29. Accessed at https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w on March 30, 2023.
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- ⁴ FDA. "Youth E-cigarette Use Remains Serious Public Health Concern Amid COVID-19 Pandemic," September 30, 2021. Accessed at <https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic> on April 26, 2023.
- ⁵ FDA notes that the 2021 National Youth Tobacco Survey (NYTS) was fully conducted amid the global COVID-19 pandemic, during which time eligible students could participate in the survey in classrooms, at home, or at some other place. Thus, estimates from the 2021 NYTS should not be compared with previous NYTS survey waves that were primarily conducted on school campuses. (FDA. "Results from the Annual National Youth Tobacco Survey," March 10, 2022. Accessed at <https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey> on March 30, 2023.)
- ⁶ FDA. *Youth Tobacco Prevention Plan*, 2020. Accessed at <https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan> on April 26, 2023.
- ⁷ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, P.L. No. 111-31 (enacted July 22, 2009).
- ⁸ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, P.L. No. 111-31, Div. A., Sec. 3 (enacted July 22, 2009).
- ⁹ Federal Food, Drug, and Cosmetics Act § 919. FDA. FY 2021 Justification of Estimates for Appropriations Committee, 2020, p. 268. Accessed at <https://www.fda.gov/media/135078/download> on March 30, 2023.
- ¹⁰ 81 Fed. Reg. 28974 (May 10, 2016).
- ¹¹ Consolidated Appropriations Act, 2021, P.L. No. 117-103, Div. P, Sec. 111 (enacted March 15, 2022).
- ¹² 87 Fed. Reg. 26396 (May 4, 2022).
- ¹³ 87 Fed. Reg. 26454 (May 4, 2022).
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- ³⁰ Block groups are defined as follows: "A unit of U.S. census geography that is a combination of census blocks. A block group is the smallest unit for which the U.S. Census Bureau reports a full range of demographic statistics. There are about 700 residents per block group. A block group is a subdivision of a census tract." (Esri. *GIS Dictionary*. Accessed at <https://support.esri.com/en-us/gis-dictionary/block-group> on March 30, 2023.)
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- ³² An increase in the average number of enforcement actions per violative retailer was correlated with more socioeconomic disadvantage as observed in Minnesota (0.93) and Connecticut (0.87). An increase in the percentage of retailers with enforcement actions was correlated with more socioeconomic disadvantage in Connecticut (0.86).
- ³³ Convenience Store News. *Industry Report 2021 Deep Dive: Tobacco*. Accessed at <https://www.csnews.com/industry-report-deep-dive-2021-tobacco> on October 17, 2022.
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³⁶ University of Wisconsin School of Medicine and Public Health Center for Health Disparities and Research. "About the Neighborhood Atlas." Accessed at: <https://www.neighborhoodatlas.medicine.wisc.edu/> on March 30, 2023.

³⁷ Maroko, Andrew R., et al. "Integrating Social Determinants of Health With Treatment and Prevention: A New Tool to Assess Local Area Deprivation," September 15, 2016. Accessed at https://www.cdc.gov/pcd/issues/2016/16_0221.htm on March 30, 2023.

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