Department of Justice

STATEMENT OF

ARUN G. RAO
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

AT A HEARING ENTITLED

"COMBATTING THE YOUTH VAPING EPIDEMIC BY ENHANCING ENFORCEMENT AGAINST ILLEGAL E-CIGARETTES"

PRESENTED
JUNE 12, 2024

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Good morning, Chair Durbin, Ranking Member Graham, and distinguished members of the Committee. My name is Arun Rao, and I am the Deputy Assistant Attorney General for the Consumer Protection Branch, a component of the Civil Division at the U.S. Department of Justice (Department). Thank you for the opportunity to testify today about the important work of the Consumer Protection Branch in combatting the illegal sale of unauthorized electronic nicotine delivery systems (ENDS) products. The sale of illegal ENDS products poses addiction and health risks to Americans, especially youth. The threat is particularly grave for teenagers, at whom these dangerous products are too often targeted. Protecting youth from both physical harm and threats to their online safety and privacy, is a critical part of the mission of the Consumer Protection Branch.

The Department and the Food and Drug Administration (FDA) are committed to enforcing the prohibition on the manufacture and sale of unauthorized ENDS products through all available legal means, including the Family Smoking Prevention and Tobacco Control Act (TCA), the Prevent All Cigarette Trafficking Act of 2009 (PACT Act), and the Federal Food, Drug, and Cosmetic Act (FDCA). In furtherance of that commitment, the Department and FDA recently created a multi-agency ENDS Enforcement Task Force with the sole purpose of addressing the threat posed by the illegal sale of unauthorized ENDS products.

OVERVIEW OF ENDS ENFORCEMENT

The factual and legal issues surrounding ENDS enforcement are complex. In the years since the 2016 FDA rulemaking to bring e-cigarettes under TCA regulation, FDA faced an avalanche of applications for approval to market these products. The market has also since been flooded with e-cigarette products. As FDA has worked to render final decisions on premarket tobacco product applications (PMTAs), manufacturers filed numerous challenges to FDA's actions in federal court. Additionally, many manufacturers have responded to FDA denial orders with new applications for slightly altered "new" products, which lengthen the regulatory process.

Congress has required that FDA make determinations on new applications within 180 days, but that has proven challenging in many cases given the large volume of applications filed with the FDA. Some overseas manufacturers have also evaded import alerts by mis-declaring shipments at ports of entry. Meanwhile, vape shops across the country have been purchasing ingredients to manufacture their own products in individual stores further complicating the landscape. The scale of the problem means illegal ENDS products remain all too accessible to young people, with illegal ENDS products available in neighborhoods across the country, as well as online.

The Department performs an important role in supporting the FDA's efforts to ensure that illegal ENDS products stay off the market: (1) defending FDA against litigation with manufacturers about marketing applications; (2) filing enforcement actions under the FDCA on FDA's behalf; and (3) coordinating enforcement actions outside the FDCA and TCA.

First, when manufacturers challenge FDA orders denying their marketing authorizations, the Department's Civil Division is responsible for defending FDA's decisions in court. We are deeply committed to defending FDA's denial of marketing authorizations to help ensure that the regulatory process can function as Congress intended. The Department has defended every petition for review that manufacturers have filed in courts of appeals challenging FDA denials of their applications to market ENDS products, which amounts to more than 80 cases and counting. While many of those matters have yet to be decided by the courts, we have prevailed in more than a dozen cases, including in unanimous decisions on the merits in seven courts of appeals. In the one circuit where we have faced a significant loss—the Fifth Circuit—the government is seeking review from the Supreme Court.[1]

An effective enforcement tool against companies that sell unapproved ENDS products is an administrative action by FDA to impose civil monetary penalties on manufacturers and retailers. As of May 1, 2024, FDA has issued more than 670 warning letters to manufacturers, importers, and distributors for illegally selling or distributing unauthorized new tobacco products, including e-cigarettes, and more than 550 warning letters to retailers. FDA has brought civil monetary penalty actions against more than 55 manufacturers and 100 retailers. The Department supports FDA's increased enforcement efforts under the FDCA, including by standing ready to assist in collection actions to ensure the civil monetary penalty judgments are not ignored and to seize unauthorized ENDS products. For example, the Department recently partnered with FDA on the first judicial seizure of unauthorized ENDS products under the FDCA, which resulted in the seizure of more than 45,000 unauthorized ENDS products from a warehouse in California.

The Department also has the authority to bring civil injunctive actions referred by FDA. This is an important tool in many contexts, but it can be challenging to deploy where there are a very large number of companies selling unauthorized products. In some circumstances, these injunctive actions can be valuable, and the Department and FDA work closely to pursue these actions where appropriate. The Department has brought a number of civil injunctive actions referred by FDA and stands ready to bring additional actions in coordination with FDA to advance enforcement efforts. Since 2022, we have obtained civil injunctions against six entities to stop them from selling unapproved ENDS products and are litigating against a seventh

[1] Wages & White Lion Invs., LLC v. FDA, 41 F.4th 427 (5th Cir. 2022).

defendant. Judicial stays entered by courts in several defensive cases constrain our present ability to bring actions involving certain products, and other products remain under review by FDA or are part of pending administrative appeals. Despite those complicating factors, we stand ready to continue working with FDA to develop cases for enforcement actions of all kinds and to pursue further civil injunction actions.

Lastly, the Department is working with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and the U.S. Postal Inspection Service (USPIS) on several enforcement activities outside of the TCA and FDCA. In particular, the Department is working closely with ATF and USPIS to identify targets and bring enforcement actions under the PACT Act. The PACT Act prohibits shipment of ENDS products via U.S. mail, requires online sellers of ENDS products to verify the age of purchasers both at the point of sale and the point of delivery, as well as to comply with tax collection provisions and state and local laws, or potentially face felony charges. With our partners at ATF and USPIS, the Department is developing actions for civil penalties and, where appropriate, criminal sanctions under the PACT Act, to help stop sellers who ignore the stringent and clear age verification requirements written into the law.

ENDS ENFORCEMENT TASK FORCE

Consistent with the longstanding mission of the Consumer Protection Branch to protect children from harm online and in the physical world—and in recognition of the urgency of the problem presented by the widespread availability of illegal ENDS products—we are continuing to build on our enforcement approach with our partners in the Executive Branch. To better coordinate these efforts and more effectively combat the public health threat created by the illegal sale of ENDS products, the Department and FDA created a multi-agency ENDS Enforcement Task Force.[2] The Task Force will bring together market knowledge, enforcement experience, and operational abilities from across the government and consider new avenues for enhanced ENDS enforcement efforts. In particular, the Task Force will meet regularly to address the illegal importation, manufacture, distribution, and sale of ENDS products, the actions being taken by each agency, and ideas for further action and coordination. Members of the Task Force will work together to identify and investigate entities engaged in the manufacture, distribution, or sale of illegal ENDS products, determine appropriate enforcement authorities, and initiate actions under those authorities, when appropriate.

The Task Force will consider and, as appropriate, engage in, a variety of enforcement strategies, including:

- Facilitating the seizure of unlawful products within the United States by FDA and USMS, including by pursuing civil seizure actions in federal court;

[2] The Task Force includes FDA, primarily the Center for Tobacco Products and the Office of Chief Counsel; the Justice Department's Civil Division, primarily the Consumer Protection Branch, with support from the Appellate Staff and the Federal Programs Branch; ATF; U.S. Marshals Service (USMS), primarily the Asset Forfeiture Division; USPIS; and the Federal Trade Commission (FTC).

- Pursuing administrative actions by FDA against U.S. distributors and retailers leading to civil monetary penalties, as well as taking actions to collect penalties from defendants who refuse to pay penalties they owe;

- Developing administrative and court actions with ATF, USPIS, and the Department to deter the trafficking of ENDS products online and through the mail;

- Developing criminal prosecutions, where appropriate, under available authorities;

- Advancing injunctive actions, the Department can take to halt the illegal distribution and sale of ENDS products; and

- Suggesting legislative measures that would provide Task Force partners with the tools needed to combat the problem, and helping to develop resource requests to better ensure these goals can be achieved.

The Department works closely with investigative and agency partners to develop cases and refer those matters to us. Communication and coordination through the Task Force will allow for more seamless identification of potential targets and collection of relevant evidence. I can assure the members of the Committee that the Department will assign a high priority to enforcement opportunities that build on the work of ENDS Task Force partners. In the near term, we expect the Task Force to consider new strategies to address the illegal importation of unauthorized ENDS products at the border, and even to bring criminal charges against those who flout the law, where the evidence allows.

Coordination between Task Force participants will support actions under the TCA, the PACT Act, and the FDCA, and will provide opportunities to share intelligence about the ENDS marketplace and significant importers and distributors of illegal ENDS products. We expect the Task Force will also gather information from advocates and legitimate industry participants who want to play by the rules but find themselves undercut by less scrupulous actors. We are confident that the Task Force will advance innovative strategies to address the unique and continually evolving problem of illegal ENDS products.

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The Department is committed to using all available tools to protect Americans, especially youth, and to address the threat posed by unauthorized ENDS products. All of us at the Department recognize the trust placed in us to do this work. We are honored to do it, and we are eager to continue our efforts to protect American consumers of all ages.

Thank you for the opportunity to testify. I look forward to your questions.