Written Questions for Arun G. Rao
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Senator Dick Durbin, Chair

1. *The Food and Drug Administration (FDA) does not have independent litigation authority. Rather, the Department of Justice (DOJ) institutes injunction proceedings on behalf of FDA.*

    a. *What guidance has DOJ provided to FDA regarding the types of cases involving unauthorized e-cigarettes that are appropriate for referral to DOJ?*

    b. *Please describe each step in DOJ's internal review process upon receiving a referral from FDA regarding an unauthorized e-cigarette?*

The Department is committed to robust enforcement of the Tobacco Control Act (TCA); Federal Food, Drug, and Cosmetic Act (FDCA); and Prevent All Cigarette Trafficking (PACT) Act against any person or company who violates the law. The Department is actively working with the FDA to develop referrals for further enforcement action. As a general matter, the Department stands ready to consider any referral made by FDA where the facts and law support an enforcement action.

Referrals from FDA regarding unauthorized e-cigarettes are generally directed to the Civil Division's Consumer Protection Branch (CPB). As with any agency referral, attorneys with the Branch consider the evidentiary basis for the proposed enforcement action. Consistent with standard Civil Division procedure for moving forward with enforcement actions, if the evidence supports an action Branch attorneys may open an investigation or file suit after receiving appropriate approvals from their Department supervisors.

2. *DOJ has pursued eight injunctions on behalf of FDA.*

    a. *How many cases in total has FDA referred to DOJ for an injunction since July 1, 2022?*

b. *For the eight injunctions pursued to date, what is the average time between FDA's referral and DOJ's initiation of the injunction proceeding?*

c. *How many DOJ attorneys work on FDA cases in general? How many work on e-cigarette-related enforcement cases in particular?*

The FDA has referred a number of injunctive actions, and the Department sought injunctive relief in almost all of them. The Agency decided to pursue other forms of relief in a small number of these referrals.

Department attorneys begin to work with FDA immediately upon referral to obtain underlying evidence and other information regarding a proposed action. Consistent with Department procedures and practice, once approval to file an injunctive action is obtained, attorneys engage with the proposed defendants regarding a potential consent order. All but one of the eight injunctions obtained in ENDS matters to date was obtained via a consent decree. In such cases, the action is initiated in court after the consent decree is signed, and the time prior to filing includes that period of negotiation. In one ENDS injunction matter that did not resolve by consent decree, the United States filed suit and prevailed at the summary judgment stage.

The Civil Division's Consumer Protection Branch is the primary component assigned to handle criminal and civil FDCA matters. Given that attorneys in the Branch and across the Department work on cases involving multiple federal agencies at different times, the number of attorneys pursuing FDA-related or ENDS matters at any one time can vary significantly depending on enforcement needs across the many areas that these components cover. At present, approximately 80 CPB attorneys are handling FDA-related cases, sometimes working with additional attorneys from the Civil Division's Federal Programs Branch and the Civil Division's Appellate staff. Additionally, U.S. Attorney's Offices, in consultation with CPB, also handle a range of FDA cases in their districts.

Senator Thom Tillis

Eastern Band and Marijuana

As you may know, on March 1, 2024, I led a letter to multiple agencies and departments, including the U.S. Department of Justice and regarding the Eastern Band of Cherokee Indians (Eastern Band) and Qualla Enterprise LLC's marijuana business.

In April, the Associate Judge for the Eastern Band Tribal Court, the Superintendent at Cherokee Central Schools, and tribal health leaders raised their concerns about this venture's impact on the behavioral health of youth. Including the negative impact of marijuana vapes.

If you visit Eastern Band's website, Great Smoky Cannabis Company, you can now purchase one of over two dozen marijuana vapes. On these packages, there are no warning labels for children, no description on how the product was tested, and no indication on where the vape pens were manufactured.

1. *What is the U.S. Department of Justice (DOJ) and U.S. Drug Enforcement Administration (DEA) doing to enforce federal law when it comes to production, cultivation, and sale of marijuana in and around the reservation? Are federally recognized tribes immune from the Controlled Substance Act?*

Although the Department of Justice's (Department's) policies pertaining to the prosecution of marijuana crimes have evolved as states have passed measures to legalize marijuana use, marijuana currently remains a schedule I controlled substance. The Department is committed to enforcing the law—which includes the Controlled Substances Act (CSA) –in a manner that efficiently applies our resources to address the most significant threats to public safety.

The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. The CSA also provides for criminal liability for those who distribute controlled substances that result in death or serious bodily injury. As the Attorney General has made clear in prior testimony, personal marijuana use on its own is not currently a top federal law enforcement priority. However, there may be circumstances involving marijuana that merit federal law enforcement action. Several such cases were set forth in 2014 by the Department of the Treasury's Financial Crimes Enforcement Bureau (FinCEN), and include: preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; preventing the diversion of marijuana from states where it is

legal under state law in some form to other states; and preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.

Existing Department guidance directs prosecutors to follow well-established principles when addressing crime in their districts. And as a general matter, Main Justice works closely with U.S. Attorney's Offices to determine appropriate law enforcement actions based on the individual circumstances of the drug crisis affecting those communities. This is also true in the context of marijuana-related investigations and prosecutions. Such decisions include considerations regarding the interaction between federal and state or local law, where Congress has explicitly restricted the Department's ability to enforce federal laws in states that have state medical marijuana laws. The Department continues to prosecute drug trafficking organizations that distribute marijuana and other illegal narcotics in the United States.[1] The Department also prosecutes individuals who operate illegal marijuana delivery services or dispensaries.[2]

While the CSA applies on tribal land and to individual members of federally recognized Tribes, Tribal governments are not subject to federal criminal prosecution.

2. *What action can DOJ take if an individual(s) is harmed using the marijuana vape pens from a tribal reservation? Would Qualla Enterprise LLC as the seller be held liable?*

Marijuana is currently a schedule I controlled substance. The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. Where a controlled substance – regardless of whether it is in schedule I or III – is handled without proper authorization, individuals who are legally responsible for those actions can be held liable. DEA personnel in North Carolina routinely conduct investigations and enforcement operations in and around the Qualla Boundary in conjunction with the Bureau of Indian Affairs Office of Justice Servies, the Eastern Cherokee Tribal Police Department, and other law

[1] Office of Public Affairs | Malas Manas Transnational Criminal Organization Leadership Indicted on Charges of Human Smuggling and Drug Trafficking | United States Department of Justice
[2] Office of Public Affairs | Massachusetts Woman Pleads Guilty to Tax and Drug Charges Arising from Multimillion-Dollar Marijuana Enterprise | United States Department of Justice

enforcement partners. The CSA applies on tribal land and to individual members of federally recognized Tribes.

3. *At what point is the transportation of marijuana considered trafficking? Are federally recognized tribes immune from state and federal enforcement?*

The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. Individuals who transport controlled substances without authorization and with the intent to distribute are frequently prosecuted under the CSA for possession of controlled substances with intent to distribute or other similar offenses. While the CSA applies on tribal land and to individual members of federally recognized Tribes, Tribal governments are not subject to federal criminal prosecution.

4. *What steps does DOJ take to ensure that money from a controlled substance business is not co-mingled with legitimate funds or banking accounts?*

As described above, marijuana remains illegal under federal criminal law. However, certain U.S. states and territories have adopted laws permitting certain types of marijuana sales and other marijuana-related activities. Accordingly, on Feb. 14, 2014, FinCEN issued guidance titled, "BSA Expectations Regarding Marijuana-Related Businesses" (2014 FinCEN Guidance) to clarify Bank Secrecy Act (BSA) expectations for financial institutions seeking to provide services to marijuana-related businesses. Among other things, the BSA and its implementing regulations require financial institutions to maintain records and report certain transactions. Federal financial regulators such as FinCEN supervise financial institutions such as banks. The Department does not supervise or regulate financial institutions but, where appropriate, the Department may pursue enforcement actions against financial institutions that fail to meet BSA requirements.

The 2014 FinCEN Guidance remains in effect and identifies transactions that may trigger federal enforcement priorities, such as: preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; preventing the diversion of marijuana from states where it is legal under state law in some form to other states; and preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.

Existing Department guidance directs prosecutors to follow well-established principles when addressing crime in their districts. And as a general matter, Main Justice works closely with U.S. Attorney's Offices to determine appropriate law enforcement actions based on the individual circumstances of the drug crisis affecting those communities. This is also true in the context of marijuana-related investigations and prosecutions; the Department investigates and pursues federal criminal charges as appropriate.[3]

FDA/DOJ Multi-Agency Taskforce

1. ***Memorandum of understanding ("MOU") for multi-agency task force.*** *Have FDA, DOJ, and the other agencies that joined the task force executed an MOU that (1) defines lines of authority and responsibility, (2) clarifies processes for coordination, cooperation, and resource allocation, and (3) prevents duplication of effort? If so, please provide us with a copy of the MOU.*

    a. *If not, why is there no MOU in circumstances where FDA has a policy of executing MOUs for agency collaborations and a long history of executing MOUs with agency partners?*

    b. *Given the complexity of the e-vapor crisis – involving multiple federal agencies and multiple federal statutes – will FDA and DOJ commit to finalizing an MOU, and providing a fully executed copy to this Committee, within the next thirty (30) days?*

DOJ, FDA, and other task force members work closely together on a range of criminal and civil matters. Though this work predates the task force, the task force has helped centralized that coordination, enhancing information sharing and exploration of new enforcement strategies and targets. We do not believe an MOU is required for this work to continue.

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[3] *See, e.g.,* Office of Public Affairs | Manager of Mexico-Based Drug Trafficking Organization Sentenced to More Than 20 Years in Prison for International Methamphetamine Trafficking and Money Laundering | United States Department of Justice (announcing sentencing of a manager of a Mexico-based drug trafficking organization that served as a source of methamphetamine and marijuana supply for a Nebraska-based distribution network).

2. ***Objectives of the multi-agency task force****. FDA and DOJ's announcement on June 10, 2024 clarified that the task force aims not only to bring more civil and criminal enforcement actions, but also to protect the public health by preventing the widespread availability of illegal e-vapor products.*

   a. *Has the task force established key performance indicators, performance metrics, or enforcement action goals to measure its success in preventing the sale and distribution of illicit e-vapor products? If so, please share those metrics with this Committee.*

   b. *Does the task force agree that, more so than the number of enforcement actions it initiates, the most meaningful measure of its success will be a reduction in the actual sale and distribution of illicit e-vapor products in the marketplace? If so, please describe how the task force intends to measure its impact.*

   c. *Does the task force accept that, to meaningfully impact an illicit e-vapor market of this scale and scope, it must bring enforcement actions involving the strongest tools against the largest actors? If so, please explain how the task force will focus its efforts and resources on issuing enhanced civil money penalties, import seizures, injunctions, forfeiture applications, and criminal prosecutions against the leading manufacturers and distributors of illicit products.*
   d. *Is the task force committed to reversing the approach adopted to date by FDA – in which its injunction applications and civil money penalties have been issued only to retailers – and instead pursue the largest manufacturers and distributors of illicit imported disposable products by market share? If so, please explain how the task force will identify the largest manufacturers and distributors of illicit imported disposable e-vapor products by market share.*
   e. *As many of the largest manufacturers of illicit e-vapor products are domiciled in China, and it is difficult to impose judicial orders and administrative penalties against Chinese companies, what strategies is the task force developing to hold such Chinese companies accountable? Please describe the disclosable parts of those strategies and explain how the task force will impose penalties against Chinese companies that bear the greatest responsibility for the relentless growth of the illicit e-vapor market.*
   f. *Will the Task Force prioritize preventing the importation of illicit products or shutting the distribution down within the United States? Why is one approach better than the other?*

The purpose of the task force is to coordinate and streamline efforts to bring all available criminal and civil tools to bear against the illegal distribution and sale of e-cigarettes responsible for nicotine addiction among American youth. Its member agencies are working diligently to achieve that goal through enforcement actions using on their existing statutory authorities. The Department is actively working on cases referred by other agencies and working with its Task Force partners to develop further enforcement actions.

Unauthorized e-cigarettes and vaping products continue to jeopardize the health of Americans — particularly children and adolescents — across the country, and, given the current widespread availability of these products, the Department agrees that all available enforcement tools should be brought to bear on the problem. For its part, the Department is committed to robust enforcement of the Tobacco Control Act, the FDCA, and the PACT Act against any person or company who violates those laws. In addition, the Department stands ready to consider any referral made by task force partners, including actions against manufacturers and distributors.

The Department works closely with FDA, U.S. Customs and Border Protection (CBP), Homeland Security Investigations (HSI), and other Task Force members on the interdiction of unauthorized ENDS products from China. Task Force members have been engaged in the seizure of foreign e-cigarettes even before the Task Force was established. Since the establishment of the Task Force, this work has continued, resulting, most recently, in the seizure by CBP of more than $76 million worth of unauthorized ENDS products as part of "Operation Vapor Caper II" operation. U.S.-based distributors of unauthorized ENDS products imported from China or elsewhere are subject to administrative and judicial penalties under U.S. law.

While the Department is not able to reveal its communications with Task Force partners regarding enforcement strategy or other similarly privileged communications, the Department and the Task Force recognize that effective enforcement against unauthorized products entering the country from abroad requires interdiction at the border, as well as enforcement actions within the United States. CPB and HSI are critical members of the Task Force for this reason.

3. ***Composition of the multi-agency task force****. There is some confusion about whether Customs and Border Protection ("CBP") has joined the task force.*

FDA and DOJ's announcement about the task force did not list CBP among the agencies that have joined the task force. However, Deputy Assistant A-G Arun Rao testified as follows to this Committee: "The task force combines the expertise of multiple law enforcement partners, including ATF, the US Postal Inspection Service, the US Marshals Service, US Customs and Border Protection as well as the Federal Trade Commission."

a. Has CBP joined the task force? If CBP has not joined the task force:

i. The Committee has received reports that CBP field staff may be frustrated by a lack of timely information from FDA's Center for Tobacco Products ("CTP") regarding the admissibility or inadmissibility of shipments of e-vapor products. Has this frustration contributed in any way to CBP's decision not to join the task force, or at least its decision not to join the task force by June 10, 2024? If this was a contributing factor, please explain how the task force intends to remediate the apparently suboptimal working relationship between CBP and CTP field staff.

ii. Do you agree with FDA Commissioner Dr. Robert Califf that import prevention and enforcement is likely the most effective way to prevent the flow of illicit products into the U.S. from China, and it is therefore critically important that CBP join the multi-agency task force and take a leading role in preventing the importation of illicit products?

iii. Will FDA and DOJ commit to ensuring that CBP joins the task force within the next 30 days and provide written confirmation to this Committee once it has?

b. Has the Department of State or any other agencies responsible for national security joined the task force? If not:

i. Do FDA and DOJ understand, based on the report "The Global Illicit Trade in Tobacco: A Threat to National Security," that illicit tobaco markets are a national security threat?

ii. Do FDA and DOJ understand that illicit tobacco markets operate globally and are major funding sources for international terrorist organizations, including Hamas?

iii. *Do FDA and DOJ understand that illicit e-vapor products make billions of dollars for the Chinese Tobacco Monopoly and are a key funding source for the Chinese government?*

iv. *Will FDA and DOJ commit to ensuring that the Department of State joins the task force within the next 30 days and provide written confirmation to this Committee once it has?*

c. *In addition to federal agencies, state and local agencies are responsible for enforcement of state and local laws that implicate illicit e-vapor products. Does the task force intend to admit state or local law enforcement agencies to its membership or, otherwise, will the task force coordinate with state and local law enforcement, or the National Association of Attorneys General? Please describe how the task force will coordinate its investigations, enforcement decisions, and attorney engagements with state and local agencies.*

d. *In testimony before this Committee, Dr. Brian King said that the task force is "multi agency, and that takes time to make sure we get the right folks to the table, and we set the foundation for more programs." When does the task force expect to finalize its composition? Please explain the process by which agencies join the task force, when that process will be completed, and whether and to what extent the White House is involved in the process.*

The Department agrees that effective enforcement against unauthorized products entering the country from abroad requires interdiction at the border, as well as enforcement actions within the United States. CBP and HSI are a critical partners in the federal government's effort to combat the widespread availability of illegal e-cigarettes. Both agencies are members of, and active participants in, the Task Force. Indeed, CBP and FDA recently announced the seizure of approximately $76 million worth of illegal ENDS products as part of Operation Vapor Caper II.

The Department agrees that its state and local counterparts are key partners in the fight against unauthorized ENDS products. That is why the Task Force convened a meeting at DOJ in October with the National Association of Attorneys General (NAAG), which included representatives from 15 different states to discuss how the federal government can enhance coordination and collaboration in the fight against the illegal sale and distribution of unauthorized ENDS. During that

meeting, the Task Force, NAAG, and its members committed to work together to curb unauthorized ENDS.

As the work of the Task Force continues, we will consider additional ways to partner with our state and local counterparts and whether additional agencies should join the Task Force. The Task Force's current membership consists of the Department, FDA, ATF, CBP, HSI, the U.S. Postal Inspection Service (USPIS), the U.S. Marshals Service (USMS), and the Federal Trade Commission (FTC).

4. ***Operation of the multi-agency task force****. Please answer the following questions about the task force:*

   a. *What is the effective date and expiration date for the task force?*
   b. *When did the task force first meet and how often does it meet?*
   c. *Does the task force have a steering committee, and if so, who are its members?*
   d. *Does the task force have liaison officers from each agency, and if so, who are the officers?*
   e. *How are personnel, resources, and funds allocated to and within the task force?*
   f. *How many staff from each agency, and in total, have been assigned to the task force?*
   g. *How will agency staff not assigned to the task force share information with the task force?*
   h. *What procedures are in place for the sharing of non-public information within the task force?*
   i. *What processes has the task force adopted to ensure efficiency and avoid bureaucracy?*
   j. *How are decisions to bring enforcement actions made and how are disagreements resolved?*
   k. *Will the task force issue detailed public reports on its progress? If so, how frequently? If not, will FDA and DOJ commit to providing written updates to this Committee at least quarterly?*
   l. *How will the task force work with and learn from outside experts? What is the process for interested parties to share information?*

The Task Force was established on June 10, 2024, and will continue to coordinate enforcement actions to curb the illegal sale and distribution of unauthorized ENDS products. The formal Task Force generally meets every other week, but

discussions and cooperation among member agencies on specific matters continues on a daily basis.

The Task Force draws from existing resources and staff from participant agencies to support its efforts. It is intended to coordinate the variety of e-cigarette enforcement actions in which the participants engage, serve as a hub for information-sharing, and encourage sustained action to combat the widespread availability of unauthorized e-cigarettes. In this work, member agencies often share non-public information relevant to the work of the task force. For the Department, no special procedures are necessary for that work to continue.

The Task Force welcomes engagement with outside experts to learn about ongoing trends in the ENDS market.

Senator Amy Klobuchar

In your written testimony you stated the Department of Justice recently worked with its FDA partners "on the first judicial seizure of more than 45,000 unauthorized [e-cigarettes] from a warehouse in California."

1. *What barriers do you face to making more judicial seizures of illicit e-cigarettes?*

2. *Are there other administrative authorities the Justice Department or its partner agencies can rely on to seize illicit e-cigarettes?*

3. *What other measures has the Justice Department pursued to prevent the distribution of illicit e-cigarettes?*

The Department works closely with CBP, HSI, FDA, ATF, USPIS, and other partners to develop enforcement actions to halt the illegal distribution and sale of unapproved ENDS products. With its investigatory partners, the Department can pursue criminal prosecutions where appropriate. Upon referral from FDA, the Department can advance injunctive actions. Where possible, the Department can support agency administrative actions – for example, by assisting in the collection of judgments. The Department is committed to robust enforcement of all of its existing authorities including under the Tobacco Control Act and the PACT Act.

Senator Charles Grassley

1. *What is the Department of Justice's strategy for removing illegal THC vapor products from the market, and why are these products so readily available, including on the internet?*

2. *During the hearing, you testified that the Justice Department "will use very tool available to bolster our efforts to halt the illegal sale of unauthorized e-cigarettes" and "aggressive enforcement in this space is a priority across the executive branch."*

   As you know, I'm a strong supporter of the False Claims Act and the qui tam provision of that law which utilizes whistleblowers to root out fraud against the government. In FY 2023, False Claims Act qui tam whistleblowers were responsible for the recovery of $2.3 billion out of the total $2.68 billion recovered through False Claims Act settlements and judgments, as reported by the Justice Department. Further, for a second year in a row, qui tam whistleblowers were responsible for recovering more taxpayer money lost to fraudsters in cases where the government declined to intervene than cases initiated by the government without the help of whistleblowers. Without question, qui tam whistleblowers are a valuable resource to bring strong False Claims Act cases to the Justice Department, yet in some cases the Justice Department has declined to litigate these cases and in others its intervened to dismiss the matter.

   Chinese companies are responsible for the majority of illicit disposable vaping products in the United States, yet these products are readily accessible. These companies often avoid seizure and duties at U.S. ports of entry by intentionally mislabeling illicit vaping products as other goods. The False Claims Act has been used to successfully counter customs and duty fraud, including fraud involving the misclassification and mislabeling of goods.

   Please explain the current trend over the past two years of the Justice Department declining to intervene in strong False Claims Act cases brought by qui tam whistleblowers even though these cases have recovered more taxpayer money lost to fraud than False Claims Act cases the Justice Department initiated without whistleblowers.

Whistleblowers play an important role in identifying fraud, and the Department's efforts to protect taxpayer dollars benefit greatly from their diligence and courage. When whistleblowers file and pursue qui tam cases under the False Claims Act, their efforts can complement the United States' use of the Act to combat fraud affecting all manner of government programs. Last year, the Department recovered more than $1.8 billion in qui tam cases pursued by the Department, and whistleblowers recovered an additional approximately $440 million in declined qui tam matters. Since 1986, when Congress substantially strengthened the Act, total recoveries under the False Claims Act have exceeded $75 billion. Of that amount, more than $47 billion have been recovered in qui tam cases pursued by the Department, while whistleblowers have recovered approximately an additional $5 billion in declined qui tam cases. During that same period, the Department has also recovered an additional $22 billion in non-qui tam cases. Accordingly, it is clear that the public-private partnership created by the False Claims Act between qui tam whistleblowers and the Department remains invaluable to the success of the Act in rooting out fraud and abuse in federal programs.

3. *Given its success, has the Justice Department considered using the False Claims Act to identify and combat the illegal importation of mislabeled vape products from China and other foreign countries? If not, why not?*

The Department has effectively deployed the False Claims Act to pursue trade related fraud involving the improper evasion, decrease, or concealment of customs duties or other revenue owed to the United States. These civil cases have involved a wide variety of imported products, including wood flooring, graphite electrodes, ultrafine magnesium powder, aluminum extrusions, carbon steel pipe fittings, apparel, jewelry, and furniture. The Department will continue to utilize the False Claims Act, where applicable, to pursue trade related violations, including any potential matters involving vaping products. The Department will also utilize its other civil tools, where appropriate, to pursue trade related violations.