Documents for the Record

Subcommittee on Health Hearing
"Evaluating FDA Human Foods and Tobacco Programs"
September 10, 2024

Majority:

- September 9, 2024 – Statement from the Council for Citizens Against Government Waste
- September 9, 2024 – Statement from the National Association of Manufacturers
- September 9, 2024 – Statement from the National Taxpayers Union
- September 10, 2024 – Statement from Rep. Graves, submitted by Rep. Bucshon
- September 10, 2024 – Statement from the Center for Science in the Public Interest
- September 10, 2024 – Statement from the American Academy of Pediatrics, submitted by Rep. Joyce
- September 10, 2024 – Statement from the North American Society for Pediatric Gastroenterology, submitted by Rep. Joyce
- September 10, 2024 – Statement from the School Nutrition Association, submitted by Rep. Joyce
- September 10, 2024 – Statement from the Premium Cigar Association
- September 10, 2024 – Statement from the National Fisheries Institute, submitted by Rep. Carter
- September 10, 2024 – Article submitted by Chair Guthrie
- September 10, 2024 – Statement from the National Association of Convenience Stores, submitted by Chair Guthrie
- September 10, 2024 - Letter from Leader Scalise, submitted by Chair Guthrie

Minority:

- September 9, 2024 – Coalition letter in support of The Food Safety Information Sharing Act
- September 9, 2024 – Letter in opposition to H.R. 1462, the DAIRY PRIDE Act
- September 10, 2024 – letter from the Center for Science in the Public Interest

September 9, 2024

The Honorable Brett Guthrie
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Eshoo,

On behalf of the more than one million members and supporters of the Council for Citizens Against Government Waste (CCAGW), I am submitting the following statement for the record for the House Energy and Commerce Subcommittee on Health September 10, 2024, hearing on "Evaluating FDA Human Foods and Tobacco Programs."

CCAGW is concerned that the Food and Drug Administration (FDA) and the Center for Tobacco Products (CTP) have failed to adopt tobacco harm reduction policies that would encourage smokers to use less dangerous alternatives and result in better outcomes for smokers looking to quit. CTP has had authority for nearly 15 years to assess and collect user fees and has collected $712 million in user fees annually paid by manufacturers of certain tobacco products since fiscal year 2019. Yet, there is lack of accountability over the agency. For example, it is unclear if CTP is using these funds to meet and comply with its statutory obligations under the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"). It is also unclear if CTP is performing as a fair, effective, and efficient product regulator when there is no review of the agency's performance.

Congress made harm reduction a critical component of the Tobacco Control Act and established a process to allow manufacturers to bring products to market in a timely manner. The directive that CTP deny or approve Premarket Tobacco Product Applications (PMTA) within 180 days after the application is submitted is not being met. Currently, the application process is cumbersome and time-consuming, vague, and frequently changing, which adversely affects manufacturers' ability to innovate and invest in harm reduction products.

To date, the FDA has only authorized 45 products out of 26 million product applications. In lieu of mitigating the problem, the FDA is more focused on talking about death due to tobacco-related illnesses, which would be mitigated by more timely approval of tobacco harm reduction (THR) products. The government red tape contributing to the backlog of PMTAs has resulted in an influx of unregulated foreign-made products to meet consumer demand. And even with the FDA's crackdown on THR products, the number of unique e-cigarette devices sold in the U.S. has tripled to more than 9,000 since 2020. This increase is, unfortunately, driven mainly by unauthorized disposable vaping products from China.

Additionally, efforts to ban menthol flavoring in cigarettes has negatively impacted state and federal budgets that rely on tobacco tax revenues, hurt small businesses, fail to reduce youth cigarette use even though youth cigarette use is currently at historic lows, and created a black market of unregulated menthol cigarettes. According to the Centers for Disease Control and Prevention (CDC), menthol cigarettes are no more dangerous than any other cigarettes. Banning the sale of menthol cigarettes will mean lost tax revenues at all levels of government, which have used this money to fund various programs for

decades. In 2019 and 2020, menthol-flavored cigarettes made up 37 percent of all cigarette sales in the U.S., according to the CDC. If banned, the lost tax revenues will reduce government budgets and require either higher taxes or cuts in spending to make up for the financial loss. A March 2, 2022, Tax Foundation analysis estimated that state governments would lose $4.7 billion, and the federal government would lose $1.9 billion annually if the FDA follows through on the proposed menthol ban.

The menthol cigarette ban will also have an adverse effect on public health and safety due to higher black-market sales and illegal smuggling. Making a product illegal will not only fail to reduce demand, but also put smokers at increased risk by criminalizing smoking and enforcing strict penalties. States with high tobacco taxes are already at risk for illicit cigarette sales, like New York, which has a thriving black market for tobacco products. Imposing high tobacco taxes, which are intended to deter behavior, does not lead to less smoking. Instead, consumers purchase unregulated products at a lower cost to avoid the high taxes. In 2015, New York lost $1.63 billion due to untaxed tobacco sales. If smokers can't buy menthol products in a regulated market, they will find a way to purchase the products in an unregulated, dangerous market.

A January 23, 2020, Reason Foundation study found that youth menthol smoking is less popular than non-menthol smoking. States with the highest rates of menthol smoking also had the lowest rates of youth smoking. Banning menthol cigarettes is a solution in search of a problem. It would be far more effective to enforce ID verification laws and hold retailers accountable for selling to minors instead of implementing an all-out ban that impacts everyone.

If the FDA proceeds to implement a menthol ban, the doors will open to an illegal, unregulated, and dangerous black market which increases the risk to public health and safety. This ban will also drain local, state, and federal governments of tax revenue streams. Small businesses that rely on tobacco sales will be subjected to lost revenues as a result of the menthol prohibition.

CTP should be evaluated on performance and the backlog of PMTAs should be addressed. Millions of Americans utilize THR products each year to quit smoking and instead of using evidence-based data the FDA is using fear tactics to limit access, slow approvals, and overall harm Americans who use THR to quit.

Thank you for your consideration of our testimony for this hearing.

Sincerely,

Tom Schatz

President, CCAGW

NATIONAL ASSOCIATION OF Manufacturers

Charles Crain

Vice President,
Domestic Policy

September 10, 2024

The Honorable Brett Guthrie
Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chair Guthrie and Ranking Member Eshoo,

The National Association of Manufacturers appreciates the Subcommittee holding today's hearing to evaluate the FDA's Human Foods and Tobacco Programs and discuss relevant legislative proposals. We are thankful for this opportunity to comment on these issues and are writing to address H.R. 2901, the Food Labeling Modernization Act of 2023, sponsored by Rep. Frank Pallone (D-NJ) and Rep. Rosa DeLauro (D-CT).

The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM is the largest U.S. manufacturing association, representing small and large manufacturers all 50 states and in every industrial sector, including many parts of the food and beverage supply chain.

The Food Labeling Modernization Act would create a novel symbol system with the express purpose of highlighting "interpretive" nutrition information. This system, in essence, would require food and beverage manufacturers to label their products based on preemptive judgements about what Americans should or should not consume, without any regard for consumers' individual dietary needs. Instead of making it easier for consumers to identify and understand nutrition information, such a one-size-fits-all rating would force consumers to decipher the government's shifting judgements on what does and does not constitute a healthy amount of any given nutrient.

Food and beverage producers already have widely adopted a front-of-pack labeling system that provides clear and factual information to help consumers make healthier dietary choices. This existing industry standard, called Facts Up Front, focuses on highlighting key nutrition facts in a simple, easy-to-read format that makes it easier for consumers to decide if the product fits their dietary needs.

Facts Up Front was developed by the industry in 2011 with feedback from the FDA to go above and beyond federal labeling requirements. The Facts Up Front system takes key information from the Nutrition Facts Panel and displays it prominently on the front of the package in a clear and consumer-friendly manner. It has evolved alongside the FDA's labeling requirements as well as guidance outlined in the Dietary Guidelines for Americans. For instance, the Facts Up Front system now displays information on added sugars to better align with the FDA's recent updates to the Nutrition Facts Panel.

Another forward-leaning initiative adopted by the industry is SmartLabel: an open, free, and easy-to-use digital tool that provides detailed product information beyond standard nutrition data. Using a

smartphone, consumers can use SmartLabel to learn how each ingredient contributes to a product's taste, form, or texture, as well as how those ingredients are sourced and processed.

It is important that American consumers have the tools to be able to make informed choices about their diets, and the Facts Up Front and SmartLabel programs demonstrate food and beverage manufacturers' commitment to that end. The Food Labeling Modernization Act would supersede these efforts with a labeling mandate focused on one-size-fits-all health recommendations rather than factual information. The NAM respectfully encourages the Subcommittee to carefully consider the ramifications of such an approach, and the impact a government mandate could have on the industry-led programs on which consumers already rely, before advancing this legislation.

Sincerely,

Charles Crain
Vice President, Domestic Policy
National Association of Manufacturers

NATIONAL TAXPAYERS UNION
122 C Street N.W., Suite 700, Washington, DC 20001

September 10, 2024

The Honorable Brett Guthrie, Chair
The Honorable Larry Bucshon, M.D., Vice Chair
The Honorable Anna Eshoo, Ranking Member
Subcommittee on Health, Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair Guthrie, Vice Chair Bucshon, Ranking Member Eshoo, and Members of the Committee:

On behalf of National Taxpayers Union (NTU), America's oldest national-level taxpayer advocacy organization, I write to offer commendations as well as comments on the Subcommittee's hearing, "Evaluating FDA Human Foods and Tobacco Programs." Aside from NTU's abiding interest in the fiscally responsible and efficient administration of government programs, recent analysis that NTU provided to an executive branch entity may be of interest to Subcommittee members today.

On June 26, the Tobacco Products Advisory Committee (TPSAC) convened a public meeting to consider a renewal request of a risk modification order from Swedish Match, along with "[a]dditional discussion about broader Modified Risk Tobacco Products (MRTP) program developments related to the conceptualization and measurement of consumer understanding." It was toward these "broader developments" that NTU directed oral and written testimony at the TPSAC meeting.

For background purposes, I have attached to this communication a full copy of our TPSAC testimony. We humbly submit this in hopes that the contents and citations may prove useful both for this hearing and for Subcommittee members and staff going forward. To summarize our remarks:

1) **Taxpayer-funded Public Health Programs Could Fiscally Benefit over the Longer Term by More Products Entering the Market More Quickly; and the Overall Net Fiscal Picture, including Non-Health Care Programs, Can Become Clearer as a Result.** Research on the *gross* fiscal impact of combustible tobacco use on programs such as Medicaid and Medicare is reasonably conclusive, but the *net* fiscal impact to taxpayers, considering health and non-health related government programs (e.g., retirement), is a more interpretative matter. Little more can be known if products are

never given the time and space in the market to demonstrate whether they can control costs to the economy and the public fisc.

2) **The Application Process, in General, Needs Greater Certainty, Transparency, and Alacrity to Encourage the Development of and Investment in New Products. From PMTA (premarket tobacco product application) to the Substantial Equivalence Pathway, to MRTP, both TPSAC and CTP can facilitate accumulation of better knowledge on the fiscal outcomes noted in 1).** However, CTP does have an advantage over many other federal agencies facing transition, in the form of a detailed management assessment report sanctioned by cabinet-level leadership. In December 2022, the Reagan-Udall Foundation for the FDA published "Operational Evaluation of Certain Components of FDA's Tobacco Program," led by an independent expert panel that gathered views and input from numerous individuals and organizations—including two taxpayer organizations with which NTU has partnered in the past.
3) **Participants in the Process Deserve Value for the Considerable Regulatory Costs and Charges They Must Bear for Engaging in that Process.** The fourth recommendation in the Reagan-Udall report goes on at length to discuss expansion and revision of the regulatory user fee regime that CTP currently operates. NTU is quite familiar with the operation of government user charges in other contexts.

Given the scope of today's hearing, we respectfully suggest that our comments to TPSAC may elicit some questions for discussion with at least one of the hearing's witnesses, the Center for Tobacco Products (CTP) Director, Dr. Brian King. In NTU's view, among these items are:

1) Will CTP recommit to the administrative reforms recommended in the Reagan-Udall report, particularly in providing transparency, clarity, and consistency in regulatory, guidance, and enforcement actions, especially in the PMTA and MRTP application submission and review stages? If so, does CTP have a strategic plan with specific milestones and timetables to do so?
2) As CTP considers how to improve transparency, clarity, and consistency in fees charged to regulatory entities, what models from inside (e.g., prescription drug user fees) and outside FDA (e.g., air traffic control services outside the U.S.) will it emulate?
3) What are the sources of the slow pace of PMTA and MRTP application hearings and approvals, and how can the pace be improved for the benefit of both government and stakeholders? Since the publication of NTU's testimony, for example, the latest National Youth Tobacco Survey from FDA reports declining use of e-cigarettes to its "lowest level in a decade" and continued low usage of nicotine pouches (less than 2 percent).[1] If concern over youth consumption of these products is one reason for CTP's reluctance to clear massive PMTA and MRTP dockets, how can a more realistic approach toward risk be adopted?
4) How can more collaborative approaches between the government and regulated entities inform CTP's and TPSAC's own processes? Examples include ombudsman/advocate entities to facilitate problem resolution between stakeholders and the government, "regulatory sandboxes," or the Internal Revenue Service "Job Aid" concept to CTP's own

[1] See the FDA's News Release at https://www fda.gov/news-events/press-announcements/youth-e-cigarette-use-drops-lowest-level-decade.

regulatory guidance. Has CTP considered these or other processes for constructive management of its relationships with stakeholders, and if not, why not?

The breadth of topics and limitations on time may require follow-up discussions between the Subcommittee and CTP well beyond this hearing. Nonetheless, NTU believes that in the best interests of taxpayers, it is vital for Subcommittee members to exercise robust oversight of CTP in the future, and to insist upon updates from CTP on its progress in resolving longstanding issues in the administration of PMTA, MRTP, and other initiatives under its purview.

I thank you for your consideration of NTU's views, and should you or your staff have any questions, we are at your service.

Appreciatively,

Pete Sepp
President

Enclosure: Written comments of NTU to the Center for Tobacco Products' (CTP) Tobacco Products Scientific Advisory Committee's (TPSAC) June 26, 2024 Public Meeting on Docket No. FDA-2024-N-0008

Statement for the Record
Congressman Garret Graves (LA-06)
House Committee on Energy and Commerce
Subcommittee on Health
H.R. 4547, the Laws Ensuring Safe Shrimp (LESS) Act
September 10, 2024

Thank you for including this important legislation at the hearing today and for allowing us to submit this statement for the record. This bill would help provide a fair chance for our shrimpers to compete in the domestic and global markets.

Background:

In South Louisiana, and across the southern coast, shrimp is an integral part of our culture and our economy. For generations, shrimpers have supported their families and communities by delivering healthy, wholesome, and fresh wild-caught shrimp to Americans across the country. Unfortunately, each year we see more and more shrimp boats tied to the dock and businesses closing their doors. In just the last 20 years, the number of licenses held by Louisiana shrimpers has decreased by more than half. The toll has been devastating to our coastal economies.

The reality is that domestic shrimp is being pushed out of the market by a much cheaper foreign product. However, this is not a simple case of being outcompeted; imported shrimp is well known to often come as the result of illegal, cost-cutting corners. Just last week, Indian shrimp was added to the U.S. Department of Labor's "List of Goods Produced by Child Labor or Forced Labor." This comes on the heels of recent media reporting that highlighted the poor labor conditions, but it also unveiled that foreign producers regularly lie about their shrimp meeting health standards. This is not news to people in South Louisiana.

A 2020 study conducted by Louisiana State University detected banned antibiotics or other substances in two-thirds of samples of imports available on the market. Despite us knowing that these products are regularly contaminated, they continually find themselves on grocery store shelves and dinner plates. This is because the Food and Drug Administration routinely tests less than one-percent of imported shrimp. For comparison, the European Union tests fifty percent. Foreign producers know this, and they flood the U.S. market, running the odds that their product will not be tested and stopped—and it almost never is.

We are allowing foreign industries to cripple one of our most historic and culturally important professions while poisoning our consumers with banned substances along the way.

H.R. 4547:

The Laws Ensuring Safe Shrimp (LESS) Act establishes a long-term, durable solution to ensure the survival of the U.S. shrimp industry in a manner consistent with free-trade principles that would preserve consumer access to healthy, safe shrimp, both foreign and domestic.

The LESS Act creates a consistent funding mechanism to ensure that domestic shrimp has a level playing field. In addition to supporting U.S. Department of Agriculture purchases, this bill would substantially increase the capacity of the FDA to prevent harmful, antibiotic-contaminated shrimp from reaching U.S. consumers by utilizing funds that would otherwise go to the Treasury.

September 10, 2024

The Honorable Brett Guthrie
Chair
House Committee on Energy and Commerce, Subcommittee on Health
U.S. House of Representatives

The Honorable Anna Eshoo
Ranking Member
House Committee on Energy and Commerce, Subcommittee on Health
U.S. House of Representatives

The Honorable Cathy McMorris Rodgers
Chair
House Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
U.S. House of Representatives

Dear Chairs Rodgers and Guthrie, and Ranking Members Pallone and Eshoo,

The Center for Science in the Public Interest (CSPI), Your Food and Health Watchdog, is an independent, science-based consumer advocacy organization that since 1971 has fought to improve the food system to support healthy eating and food safety. We submit this letter in response to the legislative hearing titled "Evaluating FDA Human Foods and Tobacco Programs."

As we detail below, this hearing will incorporate important legislation to modernize food labeling and enhance food and infant formula safety. Unfortunately, some of the bills under consideration would harm consumers by eviscerating critical consumer safety protections and undermining clear and accurate food labeling.

We urge you to support:

- **H.R. 2901**, *Food Labeling Modernization Act of 2023* (Rep. Pallone). We urge you to support the FLMA, which would overhaul U.S. food labels to increase transparency, encourage healthier product formulations, counter misleading food claims, and promote informed choices. To make nutrition information more accessible, the FLMA directs the U.S. Food and Drug Administration (FDA) to establish a simple, standard front-of-package labeling system for foods sold in the United States. Dozens of countries have implemented similar systems and seen significant public health gains.[1] The FLMA also brings food labels into the 21st century by requiring that nutrition, ingredient, and allergen information be available for grocery items sold online. Nearly one in five U.S. consumers

[1] World Cancer Research Fund International. Building momentum: lessons on implementing a robust front-of-pack food label. 2019. https://www.wcrf.org/policy/our-publications/building-momentum-series/lessons-implementing-robust-front-of-pack-food-label/. Accessed September 9, 2024.

buys groceries online at least once per month,[2] but basic product information is not always available until after the product is purchased and delivered.[3] Updates to align food labeling laws with modern consumer practices are long overdue. The bill also requires clearer labeling of fruit, vegetable, and whole grain content in foods and of ingredients like caffeine and gluten-containing grains. These changes are needed to ensure consumers have the information they need to evaluate products and make healthy choices.

- **H.R. 6512,** *Stephen Hacala Poppy Seed Safety Act* (Rep. Womack). We urge you to support this bill, which would prohibit the sale of contaminated poppy seeds to consumers and would direct the FDA to establish a maximum limit on the opiate content of poppy seeds, which can become contaminated when improperly harvested and processed. There have been at least 19 deaths and 20 overdoses from consuming highly contaminated poppy seeds.[4] Contaminated poppy seeds can also lead to false positive drug tests for new mothers who are then separated from their children after childbirth,[5,6] and for service members, who have been cautioned to avoid poppy seeds altogether.[7] This legislation is crucial to ensuring the safety of such a commonly used product.
- **H.R. 6770,** *Improving Newborns' Food and Nutrition Testing Safety (INFANTS) Act of 2023* (Reps. Sykes, Pallone, Cardenas). We urge you to support the INFANTS Act of 2023, a commonsense measure that will protect infants from toxic elements like lead and mercury and pathogens like *Salmonella* and *Cronobacter* in baby food and infant formula, by requiring manufacturers to conduct testing for such contamination, keep records of such testing, and share the results with the FDA.
- **H.R. 9443,** *Federal and State Food Safety Information Sharing Act of 2024* (Rep. Ross). We urge you to support the FSFSA, a bill that would permit the FDA to share important information with state and local regulatory agencies. This provision was listed as an urgent recommendation for Congress to consider in the Reagan-Udall Foundation's

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[2] Restrepo BJ, Zeballos E. New Survey Data Show Online Grocery Shopping Prevalence and Frequency in the United States. U.S. Department of Agriculture, Economic Research Service; February 8, 2024. https://www.ers.usda.gov/amber-waves/2024/february/new-survey-data-show-online-grocery-shopping-prevalence-and-frequency-in-the-united-states/. Accessed September 9, 2024.

[3] Pomeranz JL, Cash SB, Springer M, Del Giudice IM, Mozaffarian D. Opportunities to address the failure of online food retailers to ensure access to required food labelling information in the USA. *Public Health Nutr*. Jan 24 2022:1-9.

[4] Center for Science in the Public Interest. Petition to Establish a Maximum Limit of Opiate Alkaloid Contamination of Poppy Seeds. February 4, 2021. https://www.cspinet.org/resource/petition-establish-maximum-limit-opiate-alkaloid-contamination-poppy-seeds. Accessed September 9, 2024.

[5] Salam E. Two US Mothers Sue Hospitals Over Drug Tests After Eating Poppy Seed Bagels. The Guardian. March 20, 2023. https://www.theguardian.com/us-news/2023/mar/20/mothers-positive-drug-tests-poppy-seed-bagels. Accessed September 9, 2024.

[6] Brice-Saddler M. A Mother Briefly Lost Her Newborn After Failing a Drug Test. Her Doctor Suspects Poppy Seeds. The Washington Post. February 3, 2020. https://www.washingtonpost.com/health/2020/02/03/poppy-seed-drug-test/. Accessed September 9, 2024.

[7] Department of Defense. Warning Regarding Poppy Seed Consumption and Military Drug Testing. February 17, 2023. https://media.defense.gov/2023/Feb/21/2003164614/-1/-1/1/POPPY-SEEDS-WARNING-MEMO-SIGNED-CONTACTREDACTED.PDF. Accessed September 9, 2024.

evaluation of the foods program, and has been supported by the Safe Food Coalition.[8] The change would allow public health authorities to take action needed to prevent foodborne illnesses, which cause an estimated 48 million Americans annually.[9]

We urge you to oppose:

- **H.R. 7563,** *The Food Traceability Enhancement Act of 2024* (Rep. Franklin). We urge you to oppose the FTEA, which misleadingly purports to enhance food traceability to facilitate investigation of foodborne outbreaks. In reality, this bill does just the opposite. As stated in a letter of opposition by the Safe Food Coalition published June 2024,[10] this bill would more accurately be titled the *Food Traceability Evisceration Act* because it would effectively gut FDA's rule by allowing retailers to discard critical lot code information that has been carefully developed and maintained by suppliers subject to the rule to facilitate tracing of food in the event of an outbreak or recall. We oppose such language, as well as language directing FDA to conduct pilots of the rule without using lot code information. Lot code information is critical to solving outbreaks, and any outbreak investigation that excludes such information essentially negates the benefits of this critical consumer safety protection.
- **H.R. 1803,** *Codifying Useful Regulatory Definitions (CURD) Act* (Reps. Steil and Craig). We urge you to oppose the CURD Act because it would carve out a federal statutory protection for cheese manufacturers to use the term "natural" on cheese that includes artificial ingredients, such as synthetic food dyes. As described further in a letter by CSPI, Consumer Reports, Consumer Federation of America, and National Consumers League in February of 2020, survey data show that 81 percent of consumers believe that the term "natural" means a product does not use artificial ingredients, making this use of the term misleading.[11]
- **H.R. 1462,** *Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday (DAIRY PRIDE) Act* (Reps. Joyce, Kuster, and Craig). We urge you to oppose the DAIRY PRIDE Act, which would prohibit plant-based products from being labeled with the terms "milk," "cheese," and "yogurt." The dairy industry claims this is necessary to prevent consumer confusion, but there is no

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[8] Consumer Federation of America. Safe Food Coalition Asks Congress to Give FDA Authority to Address Infant Formula and Other Food Safety Hazards. April 12, 2023. https://consumerfed.org/testimonial/safe-food-coalition-asks-congress-to-give-fda-authority-to-address-infant-formula-and-other-food-safety-hazards/. Accessed September 9, 2024.

[9] Centers for Disease Control and Prevention. Burden of Foodborne Illness: Findings. November 5, 2018. https://www.cdc.gov/foodborneburden/2011-foodborne-estimates html. Accessed September 9, 2024.

[10] Consumer Federation of America. Safe Food Coalition Letter to Congress. June 25, 2024. https://consumerfed.org/wp-content/uploads/2024/06/SFC-Traceability-letter-to-Congress-6-25-24.pdf. Accessed September 9, 2024.

[11] Consumer Reports. Letter to U.S. House opposing S. 2322, the CURD Act. December 20, 2018. https://advocacy.consumerreports.org/research/letter-to-u-s-house-opposing-s-2322-the-curd-act/. Accessed September 9, 2024.

evidence that consumers currently mistake products like "almond milk" and "vegan cheese" to be dairy products. The bill would unfairly advantage dairy products over plant-based alternatives without providing any meaningful benefit to consumers. This is particularly concerning because plant-based dairy alternatives have environmental benefits. Greenhouse gas emissions from most plant-based milk alternatives are roughly 62-78% lower than cow's milk.[12]

In addition, we urge the committee to schedule hearings immediately on the following bills which would provide key advances for consumers in the safety and labeling of foods regulated by the FDA:

- **H.R. 4110**, The Expanded Food Safety Investigation Act (Rep. DeLauro), a bill that would enhance FDA to investigations of foodborne outbreaks by enabling public health officials to conduct basic microbial sampling on concentrated animal feeding operations as needed.
- **H.R. 6766**, The TRUTH in Labeling Act (Rep. Schakowsky), a bill that, like the FLMA, would establish a simple, standard front-of-package labeling system for foods and beverages sold in the United States.

Thank you for your consideration of these requests to improve food safety and food labeling. For any additional questions or supplemental information, please do not hesitate to contact Rhea Jayaswal at rjayaswal@cspinet.org.

Sincerely,

Philip Kahn-Pauli
Director of Legislative Affairs
Center for Science in the Public Interest

[12] Ramsing R, Santo R, Kim BF, et al. Dairy and plant-based milks: implications for nutrition and plantary health. *Current Environmental Health Reports.* 2023;10:291-302.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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January 23, 2019

The Honorable Scott Gottlieb, MD
C/O Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2018-N-3522 Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

Dear Commissioner Gottlieb:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I write to respond to FDA's Request for Comment on the Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.

The AAP is pleased by the efforts FDA has undertaken in recent years to modernize regulations for nutrition-related labeling to reflect current science, provide information in ways that are understandable and useful to consumers, and encourage industry efforts to develop and introduce healthier food products through innovation or reformulation.

Dairy products play an important role in the diet of children. Milk, yogurt, cheese, and other milk products supply calcium for building and maintaining strong bones and teeth and protecting bones from osteoporosis.[i,ii] They also provide children with the protein, vitamins, and minerals that they need to thrive including phosphorous, vitamin A, vitamin D, riboflavin, vitamin B12, potassium, zinc, choline, magnesium, and selenium.[iii] In fact, milk is the leading food source of three of the four nutrients of public health concern (calcium, vitamin D, and potassium) in the diet of American children 2-18 years.[iv]

AAP recommends that children consume two to three servings per day of milk and milk products.[v] For adolescents, three or more servings per day of milk and milk products are recommended.[vi] These recommendations are consistent with those of the Dietary Guidelines for Americans (DGA).[vii] The DGA also notes that while average dairy intake for most young children ages 1-3 meets recommended amounts, all other age groups have average intakes that are below recommendations.[viii]

Dairy-free alternatives to milk are becoming increasingly popular, even among

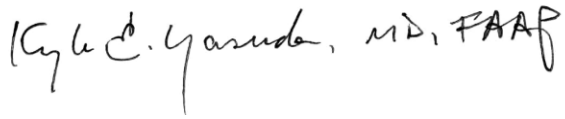
children who do not have a medical condition that prevents the consumption of dairy.[ix] While some of these products are fortified with calcium and protein, many of these products lack the essential nutrients that dairy products contain to promote the healthy development of children, notably protein, calcium, and vitamin D.[x] These essential nutrients can be difficult to replace in a healthy dietary pattern, and if plant-based alternative beverages are substituted in place of milk without the addition of other foods to supply the missing nutrients, Americans may move further away from dietary recommendations.[xi]

Pediatricians report that using the term "milk" in the labeling of dairy-free alternatives has caused parental confusion, leading to the purchase of products that they assume contain traditional dairy ingredients and, thereby, unintentionally causing harmful nutritional deficiencies in their children. Consumer studies reinforce these anecdotal reports, indicating that consumers do not understand the nutritional differences between milk and plant-based alternative beverages labeled "milk".[xii] Further, many of these plant-based alternative products are perceived as having the same or more vitamins, protein, or other key nutrients as compared to milk.[xiii]

Given the importance of dairy products in the diet of children and the confusion that parents exhibit with regards to the nutrients contained in plant-based alternative products, the AAP recommends that FDA reserve the label of "milk" solely for traditional dairy products to ensure that children receive the optimal nutrition they need to thrive.

Thank you for the opportunity to respond to this request for comments. The AAP looks forward to working with FDA to ensure that the nutritional needs of all children and families are met. If we may be of further assistance, please contact Tamar Magarik Haro in our Washington, DC office at 202-347-8600 or tharo@aap.org.

Sincerely,



Kyle E. Yasuda, MD, FAAP

KEY/mrc

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NASPGHAN
NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION

November 19, 2018

Comment to the United States Food and Drug Administration
RE: Docket No. FDA-2018-3522 for "Use of the Names of Dairy Foods in the Labeling of Plant-Based Products"
From the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and the Council for Pediatric Nutrition Professionals (CPNP)

Members of The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) are Board Certified Pediatric Gastroenterologist physicians who care for children with a broad spectrum of gastrointestinal disorders including primary nutrition and secondary nutrition disorders related to gastrointestinal, liver and other diseases. The Council for Pediatric Nutritional Professionals (CPNP) is an associated group of certified dietetic professionals serving a similar patient base. We are pleased to see the FDA request for comments regarding plant-based foods that may be labelled or used like milks. Our interest in this topic stems from increased consumption of these alternatives in recent years[1,2], our clinical experience and a large body of published literature related to adverse clinical effects when certain non-standardized plant-based beverages have been used inappropriately in lieu of standardized milk products in the feeding of infants and children[3]. Such product use places children at risk of slowed growth[4], protein-calorie malnutrition, failure to thrive and specific nutrient deficiencies, such as vitamin D[5], compromising current and future health and development. In addition, there are concerns that high intakes of some plant-based products may lead to excessive toxin intake, such as arsenic from rice-based milks[6]. Further, enterocolitis has long been known to be possible in cow milk protein intolerant infants or children fed soy formulas or milk, but may also occur with some other plant-based milk products[7-9]. Due to such concerns, the European Society for Pediatric Gastroenterology Hepatology and Nutrition recommends the use of an infant formula for the first two years of life in children who cannot consume cow milk rather than other milk substitutes[10].

The universally preferred milk for infants is human milk[11], but there are many infants fed infant formula due to maternal choice or other complex factors[12]. U.S. infant formulae are regulated under the Infant Formula Act that requires that products labelled as infant formula support healthy growth. Since introduction of the Infant Formula Act, reports of nutritional deficiencies related to US formulas have become exceedingly rare. By one year of age, most infants are weaned to some form of "milk." USDA recommendations are for intake of 2-3 servings of dairy products/day for a well-balanced,

nutritionally complete diet, which encompasses approximately 25-30% of total energy needs of 1-3 year-olds. Most infants and children tolerate cow milk-based formulae and milks with only 2-7.5% of infants and young children having true cow milk protein intolerance[13]. These infants and children suffer adverse medical consequences from consuming cow milk-based infant formulae and standardized milk products. For these children, nutritious infant formulae and alternative beverages are needed, and have become widely available. When a hypoallergenic or cow milk-free milk substitute is needed, some vegetable-based products may be attractive alternatives to consumers, but may not prove hypoallergenic and may not provide necessary nutrition. There are also aroma, taste and texture differences between alternative products and cow milk that may influence choices among hypoallergenic or plant-based cow milk alternatives[14]. Financial considerations can also play a role in substitution decisions. The cost of expensive, hypoallergenic infant formulas is not uniformly covered by health insurers, as they are nutritional products, not drugs and this may have health consequences[15]. In addition to caring for milk-intolerant infants and children who require a cow milk alternative, we increasingly see families with religious or cultural values that preclude cow milk intake, or who have strong a preference to avoid cow milk[12], which lead them to seek alternatives.

The FDA currently defines "milk" and related milk products by the product source and the inherent nutrients provided by bovine milk[16]. There is insufficient consumer recognition of why some milk alternatives meet pediatric nutritional needs and others do not. In our clinical experience, consumers and mothers understand what standardized milk products are (with varying degrees of understanding of the nutrition provided by milk), but also may see "milk" as a white beverage given to children as a source of fluid and nutrition. There are potential health risks when this second understanding leads to selection of a nutritionally inferior "milk" with resultant inadequate nutritional intake from the total diet[17,18]. The misguided substitution of a plant-based "milk" for cow milk, without adequate compensation for nutrients not supplied in those products, can place a child at risk. Breastmilk or infant formula (most commonly containing cow milk), is an infant's sole food for the first 4 to 6 months, and milk beverages continue to play an important role in providing infant and childhood nutrition because of the high nutritional value of milk with its calories, protein content, minerals and other nutrients. Substitution of a milk that does not provide similar nutrition is deleterious to a child's nutritional status[19], growth and development. Table 1 highlights nutritional differences between cow milk and plant-based nontraditional "milks." Figure 1 provides examples of plant-based "milk" and cow milk labels. Even among products based on the same plant source, there may be substantial nutrient content differences. In the absence of informative food labeling and clear standards of identity, consumers with strong dietary preferences and good intentions may be led to select a nutritionally inferior "milk," believing that one product labeled as "milk" is nutritionally equivalent to another.

Nutritional Comparison of Cow's Milk and Plant-Based "Milks"

Per 1 cup (240mls)	Cow's Milk	Vegetable Milks*								
		Almond	Cashew	Coconut	Flax-Seed	Hemp	Oat	Pea	Rice	Soy
Calories	150	30-100	25-80	45-90	55	70-170	130	115	110	90
Protein (g)	8	1-5	0-1	0-1	0	2-4	4	8	1	6
Fat (g)	8	3	2-3.5	5	2.5	5-6	2.5	5	2.5	3.5
Carbohydrates (g)	13	9-22	1-20	8-13	9	1-35	24	11	20	15
Sugars (g)	12	7-20	0-18	0-9	9	0-23	19	10	13	9
Calcium (mg)	300	300	100-450	100-450	300	400	350	450	300	400
Vitamin D (IU)	120	110	125	125	100	150	120	150	120	120

*There are variations with non-dairy milk nutrients due to different products available; averages or ranges are reported.

Figure 1. Labels of cow milk and plant-based "milks"

A. Cow milk, B. Soy milk, C. Coconut milk; D. Almond milk, E. Rice milk, F. Pea milk

Examples of adverse effects from the misuse of certain plant-based beverages have been well-documented and include failure to gain weight, decreased growth in stature, electrolyte disorders, kidney stones[20], severe nutrient deficiencies[3] including protein calorie malnutrition with edema (kwashiorkor)[21], iodine deficiency[22,23], iron deficiency anemia, rickets and scurvy, and the known risks for developmental damage related to malnutrition occurring during infancy and early childhood[24]. Tables 2, 3 and 4 reproduced from a 2017 publication by Dr. Isidro Vitoria with his permission document more than 30 such cases described in the US and international medical and nutritional literature in the past 30 years[3]. Many more such cases are seen in clinical practice, but not documented by publication.

Table II. Published clinical cases of nutritional problems associated with soy beverages consumed by infants and toddlers

Authors Year	Reasons for introduction of soy beverage	Age of introduction of soy beverage (age of diagnosis)	Characteristics of feeding	Daily intake	Laboratory findings	Diagnosis
Carvalho NF et al. (6) 2001	Taste preference Breastfeeding without vitamin D supplement	10 months (17 months)	Soy beverage, vegetables, fruits	900 ml	Ca 2.22 mmol/l P 0.55 mmol/l AP 1879 U/l VitD 19.2 nmol/l PTH 12.1 pmol/l	Rickets Failure to thrive
Fox AT et al. (16) 2004	Breastfeeding without vitamin D supplement Urticaria with infant formula at 6 months	6 months (14 months)	Breastfeeding, soy beverage, vegetables, fruits	--	Ca 1.71 mmol/l P 1.06 mmol/l AP 2054 U/l VitD 15 nmol/l PTH 44.1 pmol/l	Rickets Failure to thrive Ferropenic anemia
Imataka G et al. (17) 2004	Eczema at 3 weeks Parental decision	1 month (5 months)	Soy beverage Calcium: 28.9 mg/l No vitamin D	--	Ca 1.32 mmol/l P 1.6 mmol/l AP 2303 U/l VitD 19.9 nmol/l PTH 254 pmol/l	Hypocalcemic tetany Rickets Failure to thrive

AP: Alkaline phosphatase; Ca: Calcium; P: Phosphorus; PTH: Parathyroid hormone; VitD: 25-OH-vitamin D_3

Table III. Published clinical cases of nutritional problems associated with rice beverages consumed by infants and toddlers

Authors Year	Reasons for introduction of rice beverage	Age of introduction of rice beverage (age of diagnosis)	Characteristics of feeding	Daily intake	Laboratory findings	Diagnosis
Massa G et al. (24) 2001	Dermatitis unimproved with a soy formula (homeopathic physician)	16 weeks (33 weeks)	Rice beverage Fruits, vegetables	RB: 1.0-1.38 l	Alb 26 g/l	Kwashiorkor
Carvalho NF et al. (6) 2001	Eczema and perceived milk intolerance	13-15 months? (22 months)	Rice beverage Vegetables	RB: 1.5 l 0.3 g prot/kg/d 79 kcal/kg/d	Alb 10 g/l Zinc 32.2 µg/dl	Kwashiorkor
Liu T (25) 2001	Perceived intolerance of formula	? (4 months)	Rice beverage Vitamins	--	Alb 14 g/l TProt 29 g/l Zinc 22 µg/dl	Kwashiorkor
Novembre E et al. (26) 2003	Atopic dermatitis (naturopathic doctor)	5 months (6 months)	Rice beverage, rice cream, vegetables, fruits	RB: 660 ml 0.5 g prot/kg/d 86 kcal/kg/d	Alb 14 g/dl TProt 28 g/l	Kwashiorkor
Kuhl J et al. (27) 2004	Atopic dermatitis positive RAST to multiple foods	14 months (17 months)	Rice beverage, 1-2 tablespoons of baby food	5 g prot/d 600 kcal/d	Alb 12 g/l TProt 35 g/l Zinc 27 µg/dl	Failure to thrive Kwashiorkor
Katz K et al. (28) 2005	Breastfed 8 m Rejection of infant formula	8 months (14 months)	Rice beverage, meat, vegetables	--	Alb 14 g/l TProt 36 g/l Zinc 28 µg/dl	Kwashiorkor
Katz K et al. (28) 2005	Rejection of infant formula	2 months (7 months)	Rice beverage, baby food, iron supplementation	--	Alb 15 g/l TProt 34 g/l Zinc 31 µg/dl	Failure to thrive Kwashiorkor
Barreto-Chang OL et al. (29) 2010	Cow's milk allergy	13 months (16 months)	Rice milk (0.4 g proteins/100 ml)	--	VitD 9 nmol/l PTH 20.4 pmol/l	Failure to thrive Rickets
Tierney E et al. (30) 2010	Scalp rash	4 months (8 months)	Rice milk, bananas, sweet potatoes	--	Alb 20 g/l TProt 37 g/l Zinc 91.5 µg/dl	Kwashiorkor
Diamanti A et al. (31) 2011	Cow's milk allergy (3 cases)	3 months (4 months) 1.5 months (4 months) 3 months (5 months)	Rice beverage	--	Alb < 20 g/l TProt < 40 g/l	Kwashiorkor

(Continue in the next page)

Table III (Cont.). Published clinical cases of nutritional problems associated with rice beverages consumed by infants and toddlers

Authors Year	Reasons for introduction of rice beverage	Age of introduction of rice beverage (age of diagnosis)	Characteristics of feeding	Daily intake	Laboratory findings	Diagnosis
Keller MD et al. (32) 2012	Eczema. Allergy to cow's milk, soy, egg, peanut, etc.	13 months (19 months)	Rice beverage, rice, potatoes, carrots	--	Alb 16 g/l TProt 33 g/l	Kwashiorkor
Keller MD et al. (32) 2012	Suspected cow's milk allergy (eczema, vomiting)	12 months (16 months)	Rice beverage Lentils, chick-peas, olives	--	Alb 12 g/l Hb 7 g/dl	Kwashiorkor Anemia
Fourreau D et al. (33) 2013	Suspected cow's milk allergy (naturopathic doctor)	7 months (9 months)	Rice beverage (0.1 g prot/100 ml), fruits, vegetables	RB:800-900 ml	Alb 7 g/l Hb 10 g/dl	Kwashiorkor Anemia
Fourreau D et al. (33) 2013	Suspected cow's milk allergy (parental decision)	13 months (14.5 months)	Rice beverage	RB: 300 ml	Alb 7 g/l Hb 3.5 g/dl Vit B_{12} 143 ng/l	Failure to thrive anemia
Le Louer B et al. (5) 2014	Vomiting	2 months (4.5 months)	Rice beverage	--	Hb 5.7 g/dl Alb 1.8 g/dl Zinc 3.5 µmol/l	Failure to thrive anemia
Le Louer B et al. (5) 2014	Eczema	1 months (7 months)	Rice beverage	--	Hb 8.7 g/dl Alb 1.98 g/dl Zinc 3.9 µmol/l	Failure to thrive Kwashiorkor Anemia
Mori et al. (34) 2015	Atopic dermatitis (naturopathic doctor)	4 months (6 months)	Rice milk, fruits, rice poultry and vegetable broth.	--	Alb 13 g/l TProt 30 g/l Hb 5.7 g/dl	Kwashiorkor Anemia

Alb: Albumin; Hb: Hemoglobin; PTH: Parathyroid hormone; RB: rice beverage; TProt: total protein; VitD: 25-OH-vitamin D_3.

Table IV. Published clinical cases of nutritional problems associated with almond beverages consumed by children

Authors Year	Reasons for introduction of almond beverage	Age of introduction of almond beverage (Age of diagnosis)	Characteristics of feeding	Daily intake	Laboratory findings	Diagnosis
Kanaka C et al. (36) 1992	Eczematous reaction to cow's milk formula (maternal decision)	2.5 months (7.5 months)	Self-prepared extract of almonds Cereals Fruits	98% DRI proteins 54% DRI energy	TSH 378 µIU/ml Iodine 47 nmol/l Free carnitine 12 µmol/l	Failure to thrive Iodine and carnitine deficiency
Mesa O et al. (37) 2009	--	Birth (31 days)	Almond beverage	--	Cl- 94 mmol/l Na+ 136 mmol/l K+ 3 mmol/l CO_3H- 40.3 mmol/l	Dehydration Metabolic alkalosis
Mesa O et al. (37) 2009	--	Birth (4 months)	Almond beverage	--	Cl- 74 mmol/l Na+ 124 mmol/l K+ 2.2 mmol/l CO_3H- 49.8 mmol/l	Metabolic alkalosis
Fourreau D et al. (33) 2013	Suspected gastro-esophageal reflux	12 months (13 months)	Almond beverage (17 mg sodium/100 ml; 24 mg chloride/100 ml) Yogurt Vegetables	840 ml	Cl- 69 mmol/l Na+ 127 mmol/l K+ 1.9 mmol/l CO_3H- 48 mmol/l	Metabolic alkalosis
Doron D et al. (38) 2013	Diarrhea and vomiting attributed by the mother to cow's milk protein allergy	4 months (6 months)	Almond-based home made "formula" (Almond 10 g/water 100 ml)	1,000 ml	Ca 1.4 mmol/l P 1.2 mmol/l AP 818 U/l vitD < 12 nmol/l PTH 30.3 pmol/l Hb 7.7 g/dl	Failure to thrive Rickets Anemia
Doron D et al. (38) 2013	Rash	4-5 months (8 months)	Almond-based and honey home made "formula" (20 gr almonds / 100 ml water)	600 mL	Alb 20 g/l TProt 36 g/l	Kwashiorkor
Le Louer B et al. (5) 2014	Gastro-esophageal reflux, eczema	3.5 months (5 months)	Almond and chestnut beverage	-	Alb 19.5 g/l Ca 0.64 mmol/l Zinc 7 µmol/l	Hypocalcemic tetany Malnutrition

(Continue in the next page)

Table IV (Cont.). Published clinical cases of nutritional problems associated with almond beverages consumed by children

Authors Year	Reasons for introduction of almond beverage	Age of introduction of almond beverage (Age of diagnosis)	Characteristics of feeding	Daily intake	Laboratory findings	Diagnosis
Le Louer B et al. (5) 2014	Parental decision	8.5 months (16.5 months)	Almond and walnuts beverage	--	VitD < 12.5 nmol/l Ca 2.32 mmol/l P 1.71 mmol/l PTH 8.8 pmol/l	Rickets
Ellis D et al. (39) 2015	Tourette syndrome (1 case) Lactose intolerance (2 cases)	3 years 9 years 10 years	Almond milk and varied diet	700-1,000 ml	Urine oxalate 53.5, 81.5 and 97.9 mg/1.73 m²/d (27.6-35.4)	Hyperoxaluria Hematuria (2 cases) Kidney stones (1 case)
Vitoria I et al. (7) 2016	Medical indication (atopic dermatitis)	2.5 months (11 months)	Almond milk Almond flour Cereals	840 ml/d	Ascorbic acid < 10 µmol/l VitD 31 nmol/l	Scurvy

Alb: Albumin; Ca: Calcium; Hb: Hemoglobin; P: Phosphorus; TProt: total protein; VitD: 25-OH-vitamin D_3.

We believe such adverse nutritional outcomes are preventable through FDA mandated labeling of non-standardized plant-based beverages, consumer nutrition education and efforts directed to heighten health care practitioners' awareness of these nutritional issues. These challenges are not limited to the US. Codex Alimentarius similarly defines milk as coming from an animal lacteal source, but reported cases of children with nutritional compromise related to the inappropriate use of plant-based milks come not just from the US, but also from other high-income countries that use the Codex Alimentarius as the basis of their food regulation.

A food labeling challenge is that "good nutrition" has varying meanings to different segments of the population. To some, good nutrition means generally following Dietary Guidelines for the various age groups with foods that have long been part of the American diet. To others, it may relate more to the avoidance of specific foods or food components (e.g., animal-derived food products, cow milk or gluten) or the avoidance of toxins, food additives or genetically modified foods and ingredients. Food labeling needs to provide information to facilitate appropriate food choices based on personal preferences as to ingredients and ingredient sources, nutrient content and the role of specific foods in meeting daily dietary requirements, all in the small space of the food label.

Based on our clinical experience and the available relevant medical literature, we believe that labelling a product as "milk" that: 1) does not come from cow milk, or 2) does not contribute the nutritional value of milk to the diet[18,25], is not in consumers' interests. For plant-based products with a nutritional composition that requires extensive fortification[14] (e.g., calcium) to achieve a nutritional label value approximating that of "milk," it is difficult to know to what extent the actual nutritional value of milk is achieved, in the absence of bioavailability studies[18]. The biologic value of the protein source and its physical matrix relative to cow milk also needs to be considered in this regard[14,26,27]. Similarly, there may be physical stability issues with such products that require extensive shaking or special handling or instructions[14]. From a pediatric medical and nutritional standpoint, it is advisable that "milk" be: 1) milk products as currently defined by FDA, or 2) provide comparable nutritional value to standard "milk". Such labeling,

and education regarding this labeling, may reduce adverse nutritional effects from consuming nutritionally non-equivalent plant-based products labeled as “milk.”

Russell J. Merritt, MD, PhD, FAAP
On behalf of the Nutrition Committee of NASPGHAN and the CPNP

Karen Murray,
President, NASPGHAN

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November 27, 2018

Documents Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 20852

FDA Docket No. FDA-2018-N-3522

Dear Documents Management Staff (HFA-305):

These comments are submitted on behalf of the 58,000 members of the School Nutrition Association (SNA) and in response to *the Use of the Names of Dairy Foods in the Labeling of Plant-Based Products*, Docket Number FDA-2018-N-3522 notice in the Federal Register on September 28, 2018. Our membership includes school nutrition professionals serving K-12 schools, college level academic instructors/professors in related fields, state agency personnel administering Federal child nutrition programs and other related professionals. SNA is responding to three (3) areas related to the questions you seek comments that are related to the school population. There are complexities to the nutrition standards and regulatory environment of school meal operations that must be met for student meals. With oversight from the US Department of Agriculture (USDA), there are various memoranda and related documents defining the meal pattern's food components and application to the school meals program, including but not limited to dairy foods. SNA recommends conferring with the Food and Nutrition Service at USDA for related information to this notice.

Regarding the request for comments on *Consumer Understanding, Perception, Purchase and Consumption of Plant-Based Products, Particularly Those Manufactured to Resemble Dairy Foods such as Milk, Cultured Milk, Yogurt and Cheese*, schools are consistent with the consumer marketplace in observing confusion among products due primarily to packaging and naming similarities. Due to the trends in the packaging of these plant-based beverages and their frequent placement in the same display cases as dairy milk and other dairy products, there needs to be clear identification and labeling to identify products. Some packaging identifies the product as a 'milk beverage' while others use the term 'milk,' which based on the current standard and consumer understanding of milk, is misleading. Consumers need significant education on the differences of these products in order to be equipped to distinguish between

them. A key place for that consumer education lies in labeling these products as plant-based beverages.

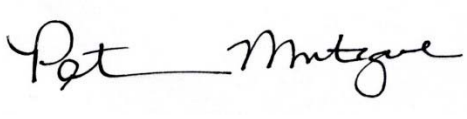
These challenges for consumers transfers to the school environment making the *Consumer Understanding Regarding the Basic Nature, Characteristics and Properties of Plant-Based Products* difficult for school nutrition professionals as they try to explain the differences when addressing menu substitutions for food allergies or offering separate a la carte items. Although not a beverage referenced within this notice, an example is that there has been considerable need for education on the difference between orange juice and orange juice like beverages. Similarly, dairy milk and many of these plant-based products may be used interchangeably yet the basic nature and characteristics are different. Many consumers (parents and students) in our environment do not see the difference. They are not aware of the chemical make up, nor whether there has been fortification. While there are instances where substitutions are necessary, as in allergies, many simply aren't aware of the nutritional differences among the beverage options. As with other foods that are part of the *Dietary Guidelines for Americans*, it is important that these plant-based beverages and foods are accurately identified to provide consumers with information that would limit confusion.

The third area looking for comments, *Consumer Understanding of the Nutritional Content of Plant-Based Products and Dairy Foods and the Effect, if any, on Consumer Purchases and Use*, the consumer in the school environment has similar issues as the general consumer except in school nutrition programs there are specific nutrition standards required with the menu offerings. When a parent or guardian contacts the school nutrition department regarding a food allergy, often the school nutrition professional is educating the parent on the nutritional content of a beverage and food substitutions. School nutrition professionals serve students with lactose intolerances, milk allergies and other dietary needs and it is critical that the student and parent/guardian understand their options. Conveying that information relative to the school setting also raises a need to be informed and educated as a general consumer.

In conclusions, nutrients in dairy milk, such as calcium and Vitamin D are valuable for the growth and development of school age children. The nutrient value of dairy milk and plant-based beverages is not equivalent. Consumers should know the difference and have a clear standard of identity. Consumer education that provides clear information is necessary. As new products get introduced into the general consumer marketplace, they eventually appear in the school nutrition environment. Being explicit in a standard of identity and having clear labeling would assist students in a multitude of food environments to make informed healthful eating choices.

Sincerely,

Gay Anderson, SNS
President



Patricia Montague, CAE
Chief Executive Officer

120 Waterfront St. | Suite 300 | National Harbor, MD 20745 | phone: 301.686.3100 • 800.877.8822 | fax: 301.686.3115 |
www.schoolnutrition.org

Re: Energy and Commerce Health Subcommittee Legislative Hearing: "Evaluating FDA Human Foods And Tobacco Programs" and H.R. 9425 *Tobacco User Fee Modernization Act of 2024*

On Dec. 19, 2022, the Reagan-Udall Foundation issued a report including 15 recommendations across various areas, including the need to enhance the science base for regulatory decision-making, strengthen stakeholder engagement, and improve the transparency of regulatory decision-making. These are not failures in funding.

Since inception, CTP has been allowed to operate as a quasi independent entity, leading to an ideological culture that operates outside of the checks and balances that govern every other agency in the federal government. At its best, the agency acts of its own accord, not at the direction of the elected government. At times, this has gone so far as to allow agency actions, even in contradiction to scientific data produced by the agency's own research. At its worst, it has provided passive justification when senior officials act out of motivation for access to the billion dollar anti-tobacco scheme that awaits those who are most committed to advancing the priorities of specific organizations.

Unlike most federal agencies, CTP continues to view industry engagement as an afterthought and not a means to effectively understand how its approaches can be better designed in the developmental phase of regulations, guidance or strategic planning. This has resulted in multiple misguided and failed regulatory attempts, struck down in Federal Court. Such wasted resources do nothing to protect public health, yet even in failure earn applause from within FDA's bloated bureaucracy.

This culture is no better illustrated than by the agency's failure to issue Congressionally mandated regulations instituting T-21 for nearly 5 years. Completing the regulation required little more than codifying what Congress had already enacted. In the interim, state regulators and industry were left to guess at implementation while CTP diverted its regulatory resources towards more ideologically expedient efforts aimed at limiting consumer choice and raising regulatory barriers for manufacturing with questionable authority.

The fact remains that tobacco consumption was in steady and decades long decline prior to the establishment of the CTP under the Tobacco Control Act. Rather than increase funding for an agency with shrinking mission, Directors of all divisions of the Food and Drug Administration, and especially CTP should be appointed by the President of the United States with the advice and consent of the US Senate. Furthermore, the agency should be subject to Congressional appropriations, as is every other Federal Agency. Such accountability is warranted considering:

(1) The Directors of all divisions of the Food and Drug Administration lead all aspects but the executive level of the Food and Drug Administration with a total budget that exceeded $6,100,000,000 for fiscal year 2021;

(2) The Food and Drug Administration has the highest budget of any regulatory agency in Health and Human Services;

(3) As of 2019, the Directors of the Food and Drug Administration oversaw industries with a total worth of over $7,666,838,100,000. This represents over 30% of the US economy;

(4) The Directors of the Food and Drug Administration oversee 18,000 federal employees;

Such changes will not only establish a system of accountability within the agency, but also charge the Directors with taking the necessary actions towards reform. Until CTP abandons its ideological focus on prohibition, an ideology that is statutorily prohibited by the Tobacco Control Act, the agency will continue to flounder.

September 9, 2024

The Honorable Brett Guthrie
Chairman
Subcommittee on Health
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

On behalf of the over 300 members of the National Fisheries Institute (NFI), we are writing in connection with your Committee's September 10 Legislative Hearing on H.R. 4547, the *Laws Ensuring Safe Shrimp Act*, introduced by Rep. Garret Graves.

For nearly 80 years, NFI has been the leading voice for the seafood industry as America's largest seafood trade association. Our members span the entire seafood value chain—from domestic harvesters, growers, processors, importers, and exporters to distributors, cold storage providers, retailers, and seafood restaurants. The industry accounts for over 1.6 million U.S jobs and provides American families with tens of millions of delicious, sustainable seafood meals every year.

NFI and its member companies are steadfast advocates for the safety of both domestic and imported seafood, actively promoting industry initiatives and regulatory measures to ensure Americans have access to safe and wholesome products. NFI played a pivotal role in fostering adoption of FDA's Seafood Hazard Analysis and Critical Control Points (Seafood HACCP) regulatory system and creation of the Seafood HACCP Alliance. Seafood HACCP is a critical component of the FDA's successful food safety approach by directing all seafood processors—both foreign and domestic—wholesalers and importers to meet specific, strict requirements.

To provide a bit of background, in 1995, FDA mandated Seafood HACCP controls in domestic and international seafood operations, an effective and widely recommended approach to identify and control food safety issues before they happen rather than relying on finished product testing. Many nations and other commodities have adopted food safety control programs using the HACCP approach as a model, including USDA's HACCP for meat and poultry products.

Since 1995, the Seafood HACCP Alliance (the "Alliance") has maintained one of the most recognized and copied seafood safety training programs in the world, developed in true collaboration between government, academia and industry food safety experts. The Association of Food and Drug Officials ("AFDO"), the over 100-year professional organization for all food safety authorities in our nation, maintains the protocols to ensure that the training continues in a consistent and robust manner. To date, over 45,000 seafood inspectors, plant workers and QA/QC managers—in the U.S. and abroad—have completed the Alliance training to be certified in Seafood HACCP. Thousands continue to be trained each year. The Seafood HACCP Alliance training materials were and continue to be developed in cooperation with FDA to ensure that the teachings represent accurate interpretations of FDA's regulatory and food safety policy expectations.

This successful Alliance has also become a model nationally and internationally of workforce training for safe food processing and is being emulated by other food sectors as they seek to implement the wide-ranging regulations mandated by the Food Safety Modernization Act. NFI played a leading role in the coalition of food groups that were instrumental in supporting the passage of the Food Safety Modernization Act, landmark legislation that modernized the U.S. food safety system. Beyond these initiatives, we have collaborated with seafood, hospitality, and restaurant groups to address crucial issues like proper labeling and other high priority food safety concerns.

As this record of engagement demonstrates, NFI and its members support a robust inspectional regime and—where particularized evidence warrants it—appropriate enforcement action against specific goods, whether farmed or harvested here or overseas. Further, we also believe there is no place for labor abuse in the seafood supply chain. Every worker—in the United States or abroad—should be treated fairly, humanely and with dignity.

H.R. 4547, however, raises some concerns. Shrimp is not only a highly nutritious protein but is also the number one seafood product consumed in the U.S. Both domestic and imported shrimp have consistently maintained a strong food safety record, with imported shrimp accounting for only a small fraction of overall reported foodborne illnesses. Given this, it is counterproductive to direct increased enforcement efforts solely toward shrimp; this ultimately diverts FDA focus away from areas which may require closer attention. A regulatory scheme with focuses on testing finished products (as would be the case with testing shrimp upon entry into the U.S.) goes against the basic preventive concepts of the Seafood HACCP program—understanding and controlling problems at the source—and FDA's comprehensive program for ensuring the safety of imported foods, including seafood. The preventive, HACCP approach to food safety was emulated by Congress in the creation of FSMA.

The cumulative effect of H.R. 4547 will not enhance food safety outcomes but instead will impose unnecessary burdens on industry. Extended, unnecessary delays at U.S. ports will lead to longer (and less predictable) delivery times, increasing costs for U.S. producers and raising food prices for American families. This will diminish access to an affordable and healthy protein source for many Americans at a time when they are struggling to absorb higher food, fuel, and other costs of living.

We hope to continue to work with the Committee to help ensure that seafood products continue to be a safe and healthy option for all. We encourage the Committee to carefully consider the broader implications of this legislation on both the seafood industry and consumers. As regulatory issues related to FDA and seafood safety are addressed, NFI and its member companies stand ready to assist the Committee, so that collectively we can maintain access to a consistent supply of a variety of safe and affordable seafood products for American families.

Thank you for your time and consideration of our views.

Sincerely,

Lisa Wallenda Picard
President and CEO

POLITICO

Youth e-cig use hits decade low, survey says

By **LAUREN GARDNER** and **DAVID LIM** | 09/06/2024 12:00 PM EDT

With Carmen Paun and Erin Schumaker

DRIVING THE DAY

NEW VAPE LOWS — The FDA and the CDC on Thursday touted the latest National Youth Tobacco Survey results as a public health win, with e-cigarette use among middle and high schoolers falling 25 percent over the past year to reach its lowest level in a decade.

But public health advocates say the burden is now on the FDA to ensure illegal vapes — and flavorful nicotine pouches sold in small tins — marketed to kids are kept out of their hands.

"The most effective strategy to avoid a lifetime of nicotine addiction is preventing young people from ever picking up a tobacco product, so I am encouraged by the progress in this declining rate of e-cigarette use by children," Sen. Dick Durbin (D-Ill.), a vocal anti-smoking advocate and critic of the agency's tobacco work, said in a statement. "But FDA is at a crossroad — and faces real tests of its ability to regulate and enforce the law against illegal vapes that target children."

Clear the shelves: To Durbin and groups like the American Heart Association, the agency and the Justice Department must do more to eliminate the backlog of premarketing applications for tobacco products and yank all unauthorized vape products from the market.

Brian King, director of the FDA's Center for Tobacco Products, indicated more operations to prevent illegal vape shipments are in the works after pointing to interagency partnerships over the last year that have resulted in product seizures and fines against manufacturers and retailers.

A looming threat? Despite the positive numbers, anti-tobacco groups remain concerned about the allure of nicotine pouches to children. Youth use of those products remains under 2 percent, but booming sales and the availability of myriad flavors worry advocates.

"Nicotine pouches have the same characteristics that made e-cigarettes so appealing to young people, including kid-friendly flavors, heavy promotion on social media and being easy to hide," said Yolonda C. Richardson, president and CEO of the Campaign for Tobacco-Free Kids.

Luis Pinto, a spokesperson for tobacco giant Reynolds, said the brand is committed to preventing underage use of tobacco and nicotine products.

"Our mission is simple: Transition adult smokers to potentially reduced-risk alternatives," he said.

NACS

Advancing Convenience & Fuel Retailing | convenience.org

September 10, 2024

The Honorable Brett Guthrie
Chairman
Subcommittee on Health of the
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health of the
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

RE: Hearing on "Evaluating FDA Human Foods and Tobacco Programs"

Dear Chairman Guthrie and Ranking Member Eshoo:

Thank you for holding a hearing on "Evaluating FDA Human Foods and Tobacco Programs." Our industry has significant concerns about FDA's tobacco programs. A number of aspects concerning regulated tobacco products are unclear and leave the regulated industry in a difficult position to try to ensure compliance with the law. The lack of clarity leads to bad outcomes for health and should be corrected.

The clearest example has resulted in a situation in which illegal e-cigarettes have flooded the U.S. market. We would like to focus on this one example today, and urge the Subcommittee to more fully explore a number of ways in which the FDA's Center for Tobacco Products could improve its regulation of tobacco products.

The current market for e-cigarettes is characterized by a large number of illicit products and a number of actors, from manufacturers to retailers, acting irresponsibly to make and sell products that should not be sold in the United States. In fact, many of these illicit products are coming in from China.

The market for e-cigarettes (also referred to as electronic nicotine delivery systems or "ENDS" products) needs to be cleaned up and needs more enforcement. We and many members of our industry have asked for exactly that. We would like to work with the Committee to achieve this goal.

An important aspect of the current situation is that there is widespread regulatory confusion in this market. Businesses have tremendous difficulty deciphering the regulatory status of ENDS products. The result is that even good actors who expend significant resources attempting to comply with the legal limits on sales of ENDS products may inadvertently sell products that should not be sold.

Many responsible retailers invest significant time and resources in training employees on policies and procedures on the sale of age-restricted programs. They try to fully comply with the law and follow, as best they can, all relevant regulations. But, getting clear information is challenging even for large companies with in-house legal departments, not to mention for the majority of the industry which consists of single-store operators. These businesses need regulators to provide complete information so that everyone knows how to comply.

<u>Background on the Convenience and Fuel Retailing Industry</u>

NACS is an international trade association representing the convenience store industry with more

than 1,500 retail and 1,600 supplier companies as members, the majority of whom are based in the United States.[1]

The convenience and retail fuels industry employed approximately 2.74 million workers and generated more than $859.8 billion in total sales in 2023, representing 3.1 percent of U.S. gross domestic product. Of those sales, approximately $532.2 billion came from fuel sales alone.

The industry, however, is truly an industry of small business. More than 60 percent of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses.

Members of the industry process more than 165 million transactions every single day. That means about half the U.S. population visits one of the industry's locations on a daily basis. In fact, 93% percent of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and center of a community.

History on ENDS Market Confusion

To understand the breadth and depth of the challenges presented by the current regulatory regime, it helps to recognize how we got here. Prior to 2016, ENDS products were not regulated by the U.S. Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP). In May 2016, the CTP deemed ENDS products subject to its regulatory authority conferred by the Family Smoking Prevention and Tobacco Control Act.

Given that decision, the CTP could have ordered ENDS products to be swiftly removed from the market because they were not on the market as of February 15, 2007, (and therefore considered "pre-existing tobacco products") and had not received the premarket authorization required under the Federal Food, Drug, and Cosmetic Act before new tobacco products can be introduced to the U.S. market. But the CTP did not order all ENDS products off of the market. Instead, it decided that manufacturers of products on the market at the time the CTP began regulating ENDS products (i.e., August 8, 2016) should submit premarket tobacco product applications (PMTAs) by a certain date and that products for which such applications were timely submitted could continue to be sold while the CTP reviewed those applications.

The CTP, however, was flooded with applications, and the review process has taken much longer than anyone anticipated. In fact, that process continues today. Following multiple extensions of the application filing deadlines, a number of groups sued the FDA in an attempt to speed up the process. The result of the lawsuit was that applications would have to be submitted by May 2020 (later extended to September 2020 due to COVID)[2] and that products for which an application was submitted by the deadline could remain on the market for up to one year following the date of submission during the CTP's review. The idea was that those applications would be reviewed, and decisions would be made as to whether each of those products could continue to be sold within one year of submission of those

[1] Data on the industry comes from the NACS, State of the Industry Annual Report of 2021 Data *available at* https://nacsannualreport.convenience.org.

[2] It is worth noting that final rules specifying the content, format, and review of PMTAs were finalized in October of 2021. See 86 Fed.Reg. 55,300 (October 5, 2021), available at Federal Register :: Premarket Tobacco Product Applications and Recordkeeping Requirements.

applications. That is not what happened.

Prior to that application deadline, the CTP published a guidance document in April 2020.[3] That guidance document made a number of difficult to follow statements. First and foremost, it laid out what the CTP considered as its "enforcement priorities" for ENDS products. The term itself was difficult to understand. The CTP had for years said that ENDS products could stay on the market based on CTP's exercise of its "enforcement discretion" with respect to ENDS products that were on the market on August 8, 2016. Were "enforcement priorities" the same thing as "enforcement discretion?" The answer appeared to be no, but that was less than fully clear – particularly to regulated businesses, many of them small businesses. If the terms were not the same, how exactly did they differ? That too was less than fully clear.

The April 2020 guidance also provided one year of "enforcement discretion" for the ENDS products for which applications had been filed by the September 2020 deadline and for which the CTP had not reached a decision. Other things were not so clear. For example, the guidance stated that priorities for enforcement would include pod-based ENDS products with flavors other than tobacco and menthol as well as any products for which premarket approval applications were not filed by the deadline. That gave a clear indication of products that should not be sold because they were "enforcement priorities" for the CTP. But it left things somewhat murky regarding the status of products that did not fall within the CTP's "enforcement priorities." Could those continue to be sold? For how long? The basic question of what could and could not be sold was not clearly answered.

The lack of clarity was recognized at the time as a problem. Senator Patty Murray took the lead on a letter from ten senators (including some from this committee) to the FDA in May 2020 seeking more information so that policymakers and the public had the information they needed regarding the status of these products.[4] Specifically, the letter sought development of a comprehensive list of the products for which applications were submitted by the September 2020 deadline so that everyone would know what products the CTP was allowing to remain on the market. Thanks to these efforts, there are now public lists of products for which applications have been filed, but those lists remain unclear in several respects.[5]

Current Guidance Remains Unclear

The lists of products for which timely applications have been filed are headed by a category that reads "Lists of products for which continued marketing until September 9, 2021 may fall outside of CTP's stated enforcement priorities."[6] The reference to a date three years ago raises confusing questions including what the status of those products is after September 9, 2021. Is CTP exercising enforcement discretion with respect to those products? Why haven't they clearly stated on the website what the status of those products is today?

This uncertainty is compounded by other information on CTP's website regarding these products. For example, CTP includes in its description of the category of "Tobacco products that cannot be legally marketed and risk enforcement by FDA" the following:

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[3] Food and Drug Administration Center for Tobacco Products, "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*" April 2020 (available at Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry (fda.gov)).

[4] Letter from Ten Senators to FDA Commissioner Stephen Hahn, May 28, 2020 (available at Letter on Public List of Tobacco Products For Which Applications Submitted_05-20_20_final.pdf (senate.gov)).

[5] See "Deemed New Tobacco Product Applications Lists" (last accessed March 28, 2024; "content current as of 08/09/2021") (available at Deemed New Tobacco Product Applications Lists | FDA).

[6] See *Id*.

- "In general, a product that is on the market and not the subject of a pending, timely-filed premarket application (excluding pre-existing and previously authorized tobacco products)."[7]

That description seems to imply that a product that is the subject of a timely-filed premarket application is not a product that "cannot be legally marketed" or risks enforcement. Anyone participating in the market would likely conclude from that description that products with timely-filed applications still under review can be sold. Nothing in the descriptions of the categories of e-cigarette products on the website clearly contradicts that common-sense conclusion.

The category also includes the following reference:

- "Products as described in the guidance on Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization."

That guidance would appear to allow products with timely-filed applications to be sold as they were not enforcement priorities.

CTP's website also includes a category of ENDS products described as "Tobacco products that cannot be legally marketed but, consistent with a court order, generally might remain on the market pending FDA premarket review while FDA continues to defer enforcement." The products in this category, however, are uncertain as the information on these from CTP's marketing denial order list generally identifies the manufacturer that submitted the application but not the actual products that are the subject of the court order. A list of applications on CTP's marketing denial order list that have exceptions allowing the products to be sold during the pendency of court or administrative reviews is attached to this testimony. It shows more than twenty different exceptions but it is unclear how many products can still be sold due to these exceptions because in most instances the specific products covered are not identified by CTP, only the manufacturers are listed without any clarity as to the number of products effected.

CTP also provides the following disclaimer on its website: "It is important to keep in mind that the lists are only one source of information. For example, retailers should discuss with their suppliers about the current status of any particular tobacco product's application or any product's marketing authorization." For retailers, however, that disclaimer is not adequate. How are retailers to know which suppliers will provide fully accurate information and which will not do so? Obviously, some suppliers are manufacturers or financially tied to manufacturers who have a vested interest in moving one particular brand or product. It is the responsibility of CTP, as the regulatory agency, to provide this information to retailers. Are retailers supposed to rely on any information they receive from suppliers given the lack of clarity from CTP?

Given the problems getting accurate information from suppliers, retailers need complete and clear information from CTP. We do not have that today.

<u>The ENDS Market Today</u>

In the shadow of this lack of regulatory clarity, bad actors have taken advantage of the situation and flooded the market with new ENDS products. Many of these are single-use products that were not

[7] *Id.*

described as enforcement priorities in the April 2020 guidance.[8] And many of these clearly illegal products are being made and shipped to the U.S. from China. It is estimated that these clearly illegal products may make up as much as half of the U.S. market for ENDS products today.[9]

While regulated businesses are informed when the CTP announces enforcement actions regarding a particular product and there is a list of the 30+ marketing granted orders that the CTP has issued for ENDS products, there are thousands of products with timely-filed applications for which clarity remains lacking.

One thing that the CTP has written, in spite of some statements suggesting the contrary, is that *there are ENDS products that have not received marketing granted orders that can be sold*. We have pressed for, but have not been provided, a listing of the specific products that can be sold. In a letter responding to our requests last year, for example, the CTP wrote:

> There are a few products that have received a marketing denial order (MDO) that are under further agency review and for which FDA has stated the Agency does not intend to pursue enforcement action during the pendency of the re-review. In addition, in a very limited number of instances, some courts have granted stays of MDOs pending judicial review in order to maintain the status quo, or FDA has administratively stayed MDOs. In those particular instances, FDA does not intend to take enforcement action.

The CTP did not provide any additional information regarding the products that fell into these categories. The marketing denial order list on the CTP's website, for example, does not list the products that are the subject of denial orders. It lists only the companies that submitted the applications that were denied. At least some of the denials cannot cover all of a company's products because many companies are listed more than once on the list. There are notations on the list for at least 18 companies indicating that some or all of the products that are the subject of the denial order might still be able to be sold because part or all of the denial order was rescinded or because it is the subject of further agency review or court challenges. The result is that the status of the ENDS products from those 18 companies cannot be known with any certainty.

The CTP also has not provided clarity regarding the status of ENDS products that were on the market in 2016 and are covered by timely filed PMTAs that remain under review. The one-year timeframe for enforcement discretion following the filing of those applications has ended, but it is not entirely clear what the CTP wants to happen with those products today as they are not part of its "enforcement priorities."[10] Importantly, following the close of the one-year period, CTP leadership never expressly or impliedly communicated an expectation that applicants remove their ENDS products from the market during the pendency of the CTP's evaluation of them.

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[8] "Once a niche market, cheaper disposables made up 40% of the roughly $7 billion retail market for e-cigarettes last year, according to data from analytics firm IRI obtained by the AP." Matthew Perrone, "Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors," APNEWS.COM (June 26, 2023) (available at https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f); "The market share of disposable e-cigarettes increased from 24.7 % to 51.8% during the study period, with disposable brands Elf Bar and Breeze Smoke among the top-selling e-cigarette brands alongside Vuse, JUUL, and NJOY." Truth Initiative, "E-cigarette market surges amid urgent need for comprehensive regulation and enforcement," TRUTHINITIATIVE.ORG (July 12, 2023) (available at https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarette-market-surges-amid-urgent-need).

[9] See *Id*.

[10] Does the CTP, for example, think it makes sense for products that it has denied authorization but which are undergoing additional review to be sold on the market, while products for which CTP has never issued a denial order because it still has not completed its review many years after filing should be removed from the market?

The situation with JUUL provides one case study of the regulatory confusion. Last year, CTP announced that it was denying applications for all JUUL ENDS products and that those products would need to be removed from the market. While this was momentous, it was at least clear that it applied to all JUUL products. Announcements relating to some other manufacturers were not clear regarding the specific products covered.

Following FDA's denial order, JUUL sued the FDA. Rather than defend its decision in court, however, FDA quickly asked for a stay of the litigation while it reconsidered its decision.[11] That meant the denial order was stayed and JUUL products could continue to be sold. That remained the situation for JUUL products until this summer – when FDA announced it was rescinding its denial order for JUUL products entirely. Now, the applications for JUUL products are in the category of the many such applications that were timely filed and remain under review.

Some have advocated that products with pending applications under review should not be able to be sold. But it is very difficult to see that result as coherent. That would mean that JUUL and many other categories of products could be sold while they had denial orders from the CTP which were being reviewed but that if CTP decided it was in error in denying those products and rescinded those orders, then the products actually could not be sold. That does not seem to be a reasonable or coherent result.

Clarity and Enforcement

Without regulatory clarity and increased enforcement, we are likely to see bad actors continue to exploit the current state of confusion to grow sales of illicit products. The best way to get that clarity is for CTP to finish reviewing the applications it has and issue decisions. As with JUUL, it may face challenges for products it denies, but it is better to start that process sooner rather than later so that we can all know what can and cannot be sold. The more time that elapses with products in the indeterminate state of being considered by CTP – particularly with the lack of clarity about what can or cannot be done with those products in the meantime – the worse the current situation with large numbers of illegal products on the market will become.

We also need additional enforcement efforts to stop imports of illegal products coming in from China. Of course, that job is more difficult for Customs and Border Protection officials if they do not have a clear picture of which products are and are not legal. The FDA has sent some warning letters and brought some enforcement actions against some of the worst offenders in this market. That is a helpful start, but more of that enforcement activity is needed.

[11] See Matthew Perrone, "FDA weighs oversight changes after formula, JUUL troubles," APNEWS.COM (July 19, 2022) (available at https://apnews.com/article/science-health-tobacco-industry-regulation-robert-califf-bbf49dd28719a34872771d82cd60cf02).

CTP, as the agency with regulatory authority over these products, has the responsibility to provide the clarity that stakeholders and enforcement officials need regarding which products can and cannot be on the market. If the CTP would provide an up-to-date and accurate list of the status of ENDS products (not just manufacturers or applications covering multiple products), the many different aspects of enforcement become much easier to achieve – and voluntary compliance with the law becomes possible. With widespread voluntary compliance, CTP will be able to focus its enforcement efforts on bad actors and can become much more effective clearing the market of illegal products.

Sincerely,

Doug Kantor
NACS General Counsel

MDO List Exceptions

The list of marketing denial orders (MDOs) issued by the Center for Tobacco Products (CTP) can be found here: Tobacco Products Marketing Orders | FDA. The list generally includes manufacturer names but not product names. As a result, regulated entities cannot know which specific products have been reviewed and cannot be sold. It cannot be assumed that all of a manufacturer's products have received an MDO because many manufacturers are listed more than once.

In addition, the MDO list includes many notations seemingly indicating that those manufacturers' products may be sold either because of ongoing court proceedings or further agency proceedings. Each of those notations are copied below and in total there are such notations for more than 20 manufacturers. It is not clear how many products those manufacturers have that are subject to the noted exceptions. Only a couple of those entities note the specific products involved.

- SWT Global Supply: "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Diamond Vapor: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Johnny Copper: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Bidi Vapor: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- My Vape Order Inc.: "On October 18, 2021, the Agency issued a stay for this MDO pending its review. On January 19, 2022, FDA partially rescinded this denial with respect to certain products."
- Vaporized Inc.: "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Fumizer LLC: "On October 22, 2021, FDA partially rescinded this denial with respect to certain products."
- Paradigm Distribution: "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- ECS Global: "On October 26, 2021, FDA partially rescinded this denial with respect to certain products."
- SV Packaging LLC: "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- TPB International LLC: "This order was rescinded on October 7, 2021."
- Wages & White Lion Investments dba Triton Distribution: "On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA."
- Humble Juice Co., LLC: "This order was rescinded on November 2, 2021."

- Union Street Brand: “On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Paradigm Distribution: “On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Vapetasia LLC: “On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA.”
- Pop Vapor Co, LLC: “On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Vapornine LLC dba New Leaf Vapor Company: “On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Cloud House: “On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Vapor Unlimited: “On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Al Khalifa Group LLC: “This order was rescinded on March 1, 2022.”
- Fontem US LLC: “On Aug. 29, 2023, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in Fontem US, LLC v. FDA, which affirmed in part and vacated and remanded in part MDOs issued on April 8, 2022, for certain myblu products. Specifically, the court’s opinion affirmed the MDOs for new products, including myblu Intense Tobacco Chill 2.5% and myblu Intense Tobacco Chill 4.0%. The court’s order granted Fontem's petition for review with respect to the myblu Device Kit, myblu Intense Tobacco 2.4%, myblu Intense Tobacco 3.6%, myblu Gold Leaf 1.2%, and myblu Gold Leaf 2.4%, setting aside the MDOs for those products, and remanding those matters to FDA.”
- JUUL Labs, Inc.: “On Jun. 6, 2024, FDA rescinded these denials.”
- R.J. Reynolds Vapor Company: “On March 23, 2023, the United States Court of Appeals for the Fifth Circuit granted a stay of the MDO issued to R.J. Reynolds Vapor Company’s Vuse Vibe menthol e-cigarette products pending review.”
- R.J. Reynolds Vapor Company: “On March 29, 2023, the United States Court of Appeals for the Fifth Circuit granted stay of the MDOs issued to R.J. Reynolds Vapor Company’s Vuse Solo menthol e-cigarette products pending review.”
- SWT Global: “On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- R.J. Reynolds Vapor Company: “On February 2, 2024, the United States Court of Appeals for the Fifth Circuit granted a stay of the MDOs issued to R.J. Reynolds Vapor Company’s Vuse Alto menthol e-cigarette products pending review.”
- Fontem US, LLC: “On Oct. 13, 2023, FDA rescinded this denial.”

STEVE SCALISE
1ST DISTRICT, LOUISIANA

MAJORITY LEADER

2049 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–1801
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Congress of the United States
House of Representatives
Washington, DC 20515–1801

September 9, 2024

The Honorable Robert M. Califf M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. James "Jim" Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf and Mr. Jones,

I write to ensure the U.S. Food and Drug Administration (FDA) fulfills its duty to comply with the health and safety standards of imported seafood to the United States.

Shrimp imports from countries like China and India have increased drastically in recent years. These imports often fail to meet U.S. health and safety standards as some foreign producers use illegal veterinary drugs and antibiotics while Louisiana shrimpers work hard every day to provide safe and sustainable products to U.S. consumers. I have long fought to defend the integrity of U.S. shrimp proudly produced in Louisiana and across the entire Gulf Coast of the United States.

Many state and local officials in Louisiana have expressed concerns with the lack of transparency by the FDA regarding imported seafood inspections.[1] Because imported seafood is not held to the same health and safety standards as domestic seafood, foreign competitors are able to flood the U.S. market with this potentially hazardous seafood. To protect American seafood producers and consumers, my colleagues and I directed the FDA to develop and, if necessary, implement strategies to inspect the import of foreign shrimp to the U.S. through multiple laws, including previous appropriations statutes.

I respectfully request answers to the following questions no later than October 7, 2024, on the FDA's plan to fulfill its duties regarding the inspection and testing of imported seafood products, including shrimp.

- How has the FDA complied with the directive language outlined in the various appropriations laws from previous fiscal years?
- What steps has the FDA taken to increase oversight of the safety of shrimp products imported into the United States?

[1] https://legis.la.gov/legis/ViewDocument.aspx?d=1372470

111 VETERANS MEMORIAL BLVD, SUITE 803
METAIRIE, LA 70005
(504) 837–1259

21454 KOOP DRIVE, SUITE 2C
MANDEVILLE, LA 70471
(985) 893–9064

8026 MAIN STREET, SUITE 700
HOUMA, LA 70360
(985) 879–2300

110 WEST HICKORY STREET
PONCHATOULA, LA 70454
(985) 340–2185

- What percentage of the total amount of imported seafood does the FDA inspect for food and safety compliance? How does that compare to the inspection percentage of imported shrimp?

- Does the FDA believe that increased inspections are necessary to ensure the health and safety of imported seafood for U.S. consumers?

- A 2021 Government Accountability Office (GAO) report found that the FDA failed to enforce its own policies and procedures regarding violations of food safety laws and regulations by foreign suppliers.[2] How has the FDA improved enforcement to ensure that imported seafood is safe for consumers?

Thank you for your attention to this matter, and I look forward to your response.

Sincerely,

Steve Scalise
House Majority Leader

[2] https://www.gao.gov/products/gao-21-231

September 9, 2024

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce

The Honorable Brett Guthrie
Chair
Subcommittee on Health

The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Guthrie, and Ranking Member Eshoo,

We, the undersigned organizations, urge you to work in a bipartisan manner to address pressing food safety issues related to FDA's partnership with state, local, territorial, and tribal (SLTT) food safety agencies by supporting the Federal and State Food Safety Information Sharing Act of 2024.

As evidenced by recent food safety crises related to infant formula and applesauce and the actions being taken to reorganize the FDA's Human Foods Program, a strong food safety system is vital to the health and well-being of Americans across the country. The Federal and State Food Safety Information Sharing Act would give SLTT food safety agencies, including laboratories, the tools needed to protect food safety while ensuring that limited federal and state food inspection dollars are well-spent.

SLTT food safety agencies, including laboratories, continually collaborate with FDA while conducting food processing, produce, and retail inspections. They also perform key roles in identifying potential illness outbreaks, investigating illnesses, and effectuating product removals through recalls. Further, FDA often requests the use of state authority to expedite product recalls, such as those recently announced for applesauce pouches contaminated with heavy metals.

Information sharing is critical to the success of this work. Historically, SLTT agencies have enjoyed a good working relationship with FDA and frequently collaborated in the best interest of public health. However, in recent years, FDA's Office of the Chief Counsel has altered its interpretation of the Federal Food, Drug & Cosmetic Act (FFDCA). As a result, state authorities have been asked by FDA to conduct important food safety investigations, only to have critical details necessary to conduct the investigation redacted. State officials have also been asked to take immediate regulatory action at facilities based on the FDA inspections but were not provided sufficient information to pursue needed actions under state law.

Prior to FDA's recent determination that the *FFDCA* restricted information sharing, FDA and the states collaborated in ways that made the best use of limited resources while reducing the burden on regulated industry. For example, states would share inspection information on concurrent jurisdiction facilities with FDA, and FDA would do the same. This prevented a state from inspecting a facility that had just been inspected by the FDA and vice versa. Now, states must file Freedom of Information Act requests to gain access to these routine inspection reports.

A modification to the FFDCA that would permit the FDA to share important information with state and local regulatory agencies was listed as an urgent recommendation for Congress to consider in the Reagan-

Udall Foundation's evaluation of the foods program. This change would allow public health authorities to take action needed to prevent foodborne illnesses, which cause an estimated 46 million Americans to be sickened, resulting in lost productivity and medical costs estimated to be as high as $90 billion annually.

This bill would also lengthen the terms of cooperative agreements. SLTT food safety organizations use cooperative agreements to carry out essential prevention-focused food safety functions, including inspections, training, and education initiatives. The length of these agreements, currently limited to three years, detracts from their effectiveness and creates unnecessary burdens for both state and local agencies and FDA, which must review and approve the applications. FDA has submitted proposals to HHS for inclusion in the budget for multiple years, but this issue has not risen to the level of importance for inclusion in the budget policy recommendations. Five years is the typical duration allowed under most of FDA's authority for cooperative agreements and grants.

Agencies have increasingly found that by the time a cooperative agreement has been executed, it is time to begin the lengthy process of reapplying. In addition, it's hard to attract and retain talented staff to implement these cooperative agreements when there is so much uncertainty. Further, maintaining staff funded by cooperative agreements is only exacerbated by the shortened three-year duration.

Lengthening the term of cooperative agreements from three to five years would allow more continuity and provide the agency with more data as they seek to evaluate the effectiveness of each individual cooperative agreement while improving the cooperative agreements as a whole.

Thank you for your consideration of this important legislation and for your leadership.

Sincerely,

Austin Therrell, Executive Director, Association of American Feed Control Officials (AAFCO)

Steven Mandernach, Executive Director, Association of Food and Drug Officials (AFDO)

Peter Kyriacopoulos, Chief Policy Officer, Association of Public Health Laboratories (APHL)

Joseph M. Kanter, MD, MPH, CEO, Association of State and Territorial Health Officials (ASTHO)

Sarah Sorscher, Director of Regulatory Affairs, Center for Science in the Public Interest (CSPI)

David McSwane, Executive Director, Conference for Food Protection (CFP)

Sarah Gallo, Vice President of Product Policy, Consumer Brands Association (CBA)

Thomas Gremillion, Director of Food Policy, Consumer Federation of America (CFA)

Brian Ronholm, Director of Food Policy, Consumer Reports

Hilary Thesmar, PhD, RD, CFS, Chief Science Officer, FMI - The Food Industry Association

Catherine Burns, CEO, International Fresh Produce Association (IFPA)

Roberta Wagner, Senior Vice President of Regulatory and Scientific Affairs, International Dairy Foods Association (IDFA)

Keith Skiles, Executive Director, Interstate Shellfish Sanitation Conference (ISSC)

Chelsea Gridley-Smith, PhD, Director of Environmental Health, National Association of County and City Health Officials (NACCHO)

Ted McKinney, CEO, National Association of State Departments of Agriculture (NASDA)

David Dyjack, DrPH, CIH, Executive Director, National Environmental Health Association (NEHA)

Dana Brooks, President and CEO, Pet Food Institute

Mitzi D. Baum, CEO, Stop Foodborne Illness

De Ann Davis, PhD, Senior Vice President, Science, Western Growers

September 9, 2024

The Honorable Cathy McMorris Rodgers, Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair McMorris Rodgers and Ranking Member Pallone,

As companies and employers in the United States' plant-based and innovative protein sectors, we are writing to express our opposition to H.R. 1462, the DAIRY PRIDE Act.

In 2023, U.S. retail plant-based food sales reached $8.1 billion, reflecting strong consumer demand and the growing importance of sustainable alternatives. This restrictive legislation would stifle innovation, mislead consumers, and unfairly disadvantage this thriving industry.

We believe the proposed bill undermines consumer choice and limits market competition.

Thank you for considering our views.

Sincerely,

Upfield US Inc.
Califia Farms
The Not Comapny (NotCo)
Daiya Foods Inc.
Eat Just Inc.
Pulmuone Foods
Plant Ahead
Jindilli Beverages / milkadamia
Nature's Fynd
Upton's Naturals
NUMU Food Group
PURIS
Next Gen Foods Inc.
UPSIDE Foods
Forager Project
Armored Fresh

BlueNalu
Clever Carnivore
AQUA Cultured Foods
Hungry Planet
The Better Meat Co.
2foods
The Pink Bakery, Inc.
Greenhaus Kitchen
Lifestock
Change Foods
Plantible
Planetarians
Sonomono Inc.
Shiru
NUKE FOODS
New Culture
Rebellyous Foods
Sugiyo USA, Inc.
Nobell Foods
NUMU Food Group
Pleese Foods, Inc.
MIssion Barns
Atlantic Fish Co.
Fullgren Inc.
All Y'alls Foods
MISTA
Joyful Ventures
Century Pacific North America Enterprise Inc.
Good Startup
Bombadil Ventures
Unovis Asset Management LLC
Alwyn Capital
Stray Dog Capital
Sugiyo USA, Inc
Nobell Foods
Mission Barns
Sugiyo USA, Inc.
Fullgreen Inc.
SOSV
Aleph Farms
Plant Based Foods Association
Food Solutions Action
Good Food Institute