TAXPAYERS PROTECTION ALLIANCE

April 9, 2024

The Honorable James Comer
Chair
Committee on Oversight and Accountability
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

Re: April 11, 2024, Hearing Entitled: "Oversight of the U.S. Food and Drug Administration"

Dear Chair Comer, Ranking Member Raskin, and Members of the House Oversight Committee,

The Taxpayers Protection Alliance (TPA) is a nonprofit, nonpartisan taxpayer and consumer advocacy organization representing millions of Americans. Ahead of this week's upcoming hearing concerning oversight of the U.S. Food and Drug Administration (FDA), TPA calls attention to the agency's struggles and lack of responsivity to the needs of Americans. For example, the FDA completely bungled its response to the infant formula safety crisis after Cronobacter contamination killed two infants.[1] FDA investigations and testing proved inconclusive, and parents are still left wondering whether their newborns are safe from harm.[2-3]

Meanwhile, drug shortages have resulted in millions of patients going without the care they need. According to a *Medscape* report, "Over about 6 months in 2023, cancer centers across the United States struggled to obtain more than a dozen oncology and supportive care drugs, including two mainstays of treatment: Cisplatin and carboplatin."[4] Onerous FDA regulations up and down the supply chain have exacerbated these dire shortages and compromised patient care.

Finally, the FDA continues to deny smokers access to lifesaving, reduced-risk products such as flavored vapes that are at least 95 percent safer than cigarettes.[5-6] Pulling harm-reduction products from the market has become standard operating procedure despite overwhelming evidence confirming vapes' relative safety and efficacy as quit-smoking aids.[7]

As your committee prepares to examine these crises and receive testimony from Commissioner Robert Califf, we urge you to consider the following questions.

1. **Why Not Approve Phage-Based Products to Bolster Infant Formula Safety?**

It is unacceptable that parents must take a leap of faith when buying formula for their babies. In response to the deadly contamination of formula products, some lawmakers have proposed ramping up inspections of these pivotal products.[8] But, inspections are often limited by faulty compliance communications and the agency doing

[1] https://www.foodsafetynews.com/2023/11/fda-issues-new-compliance-measures-for-infant-formula-testing-and-reporting/
[2] https://www.nbcnews.com/health/kids-health/feds-find-no-match-bacteria-samples-sick-infants-samples-baby-formula-rcna24361
[3] https://www.cbsnews.com/news/nutramigen-baby-formula-recalled-possible-bacterial-contamination-reckitt-mead-johnson/
[4] https://www.medscape.com/viewarticle/nothing-rivaled-this-navigating-oncology-drug-shortage-2024a10006fe
[5] https://thehill.com/policy/healthcare/4253168-vuse-banned-fda-e-cigarettes/
[6] https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update
[7] https://kclpure.kcl.ac.uk/ws/portalfiles/portal/200086434/Warner_NatMed_accepted_version.pdf
[8] https://www.congress.gov/bill/117th-congress/house-bill/7933

an overall lousy job of looking after consumers.[9-10] One far better alternative to increased inspections is allowing manufacturers to ensure the safety of their own products.

The FDA mandates that infant formula producers have safeguards in place to "ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment."[11] This doesn't seem like a big deal, until one considers living organisms called "bacteriophages" that can be cheaply injected into foods and destroy deadly contaminants. These phages were originally used in World War II to treat soldiers' many infections, but research in the 1990s concluded that phage cocktails could work wonders when applied to the food supply. But, thanks to broad FDA requirements about composition and adulteration, phages are a no-go in infant formula. FDA leadership should be held to account for this longstanding food safety oversight.

2. Are Onerous Drug Approval Standards Contributing to Shortages?

According to the FDA, "drug shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations... the FDA is aware of the supply situation and is working with the manufactures on efforts to mitigate the supply disruption."[12] However, the agency fails to understand the link between shortages and its shortchanged and onerous approvals process.

For example, the FDA recently rejected a drug called zolbetuximab designed to treat gastric/gastroesophageal cancer.[13] The issue was neither safety nor efficacy. Clinical trials demonstrated that the medication improved median progression-free and overall survival by 2-3 months compared to chemotherapy alone.[14] Apparently, the issue boiled down to "unresolved deficiencies following its pre-license inspection of a third-party manufacturing facility."[15] These issues apparently aren't insurmountable for Japanese regulators, who approved the medication.[16] But, in the U.S., patients are left to scramble for months due to a likely-minor issue that could probably be resolved post-approval.

Commissioner Califf, and the whole leadership at the FDA, can mitigate shortages by streamlining approvals and not letting small facility/licensing issues get in the way of patient health.

3. Why Continue Targeting Life-Saving Harm Reduction Products?

Tobacco harm reduction products such as e-cigarettes, heat-not-burn, and oral nicotine products make quitting smoking easier by offering adults who smoke a similar sensation to smoking with far fewer health risks. However, regulations from the FDA have hampered availability of these life-saving products. Even worse, FDA is walking back from its 2017 sentiment when the agency announced they "envision[ed] a world … where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for adults who need or want them."[17]

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[9] https://compliancearchitects.com/why-do-fda-inspections-often-turn-out-bad/
[10] https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/
[11] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106/subpart-B/section-106.55
[12] https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages
[13] https://reference.medscape.com/drug/zolbetuximab-4000397
[14] https://www.medscape.com/viewarticle/fda-rejects-gi-cancer-drug-over-manufacturing-issues-2024a10000p1?form=fpf
[15] https://www.prnewswire.com/news-releases/astellas-provides-update-on-zolbetuximab-biologics-license-application-in-us-302028855.html
[16] https://pink.citeline.com/PS150040/Japan-Grants-GlobalFirst-Approval-To-Zolbetuximab-15-Other-New-Drugs
[17] https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017

Despite recognizing a continuum of risk among tobacco products nearly a decade ago, there are less than 50 tobacco products that have been authorized for sale using the premarket tobacco product application (PMTA). The PMTA is designed for products that were not on the market prior to 2007 and are required for the majority (if not all) of tobacco products which provide users with satisfying levels of nicotine without the harms associated with combustible tobacco. Tobacco harm reduction products include e-cigarettes, heated tobacco products, nicotine pouches and/or snus. Meanwhile, thousands of combustible products have received authorization during the same period – despite the recognized harms associated with them.

Since 2017, FDA has received tobacco product applications for more than 26 million deemed tobacco products, largely e-cigarette and vapor devices.[18] The agency has claimed to have made determinations on more than 99 percent of those 26 million applications.[19] These have mainly been denials as the agency has only authorized the sale of 23 e-cigarette products – all of which are only available in tobacco flavor. The FDA thinks that it can constrain a market it deeply dislikes by denying adults harmed by cigarettes all but a few reduced-risk options. However, the agency's prohibition crusade hasn't stopped thousands of unauthorized products from flooding the U.S. marketplace.[20]

In 2023, the FDA was tasked by the Reagan Udall Foundation to address its failures in both regulating the vast tobacco harm reduction marketplace, as well as its messaging to the public on the risks related to tobacco products. Yet, study after study continue to indicate that adults – and even worse, health care professionals – are misinformed about the role of nicotine, with many (falsely) believing nicotine causes cancer.[21-22]

The FDA's regulatory process has only succeeded in making tobacco harm reduction products less regulated and convincing the adults who still smoke to think twice before switching to vaping. What steps is the agency taking to both inform the tens of millions of American adults who smoke of safer products, as well as providing them access to useful tobacco harm reduction products?

To Conclude...

Thank you for your diligent work in overseeing federal regulators, such as the FDA. The agency has continually shown willingness to pass the buck while millions of patients and smokers suffer. This harmful trend must be reversed through congressional action and oversight.

Sincerely,

David Williams
President

[18] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted
[19] https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-suorin-and-blu-plus-e-cigarette-products#:~:text=Since%202020%2C%20the%20agency%20has,%2Dflavored%20e%2Dcigarette%20products.
[20] https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f
[21] https://www.mdpi.com/1660-4601/18/14/7713
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