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MEMORANDUM

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BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Matz PC

RE: Senate Health, Education, Labor, and Pensions (HELP) Committee Confirmation Hearing on the Nomination of Dr. Martin Makary to serve as Commissioner of the U.S. Food and Drug Administration (FDA)

Today, the Senate Health, Education, Labor, and Pensions (HELP) Committee held the confirmation hearing on the Nomination of Dr. Martin Makary to serve as Commissioner of the U.S. Food and Drug Administration (FDA) (Hearing). The Hearing was convened seven weeks after President Trump assumed office and approximately four weeks after Mr. Robert F. Kennedy, Jr., was confirmed as Secretary of Health and Human Services (HHS). Dr. Makary's confirmation Hearing comes amid numerous concerns about FDA, including significant layoffs, the impact of the Department of Government Efficiency (DOGE), and fears about support for research, safety, and other critical areas within the agency.

If Dr. Makary advances, which we suspect he will, and is then confirmed by the Senate, he will manage FDA under the direction of Secretary Kennedy and be responsible for a wide range of programs within FDA that ensure public health and safety. These include overseeing human and veterinary drugs, human biologics, medical devices, human and animal food safety, dietary supplements, cosmetics, products that emit radiation, and tobacco products.

During his two-hour confirmation, Dr. Makary lauded the Trump Administration's commitment to reducing chronic disease, particularly in children, science-based decision-making, and radical transparency. However, he offered few specifics on what policies he would implement or how he would in practice address the root causes of chronic disease.

We note that, while this memorandum emphasizes areas where Senators questioned Dr. Makary on food-related issues, the Make America Healthy (MAHA) movement, and DOGE impacts, the Hearing largely focused on drugs, most frequently mifepristone, and vaccines. Food-related topics were not discussed at all until an hour into the Hearing. ***What was discussed during the Hearing, however, is very significant, and we urge those following the MAHA movement's impact on additives and ingredients to closely review the information below.***

Background

Dr. Makary is currently a surgeon and professor at Johns Hopkins University. He has authored several books[1] criticizing the U.S. healthcare system. During the COVID-19 pandemic, Dr. Makary frequently appeared on media outlets, where he opposed vaccine mandates and questioned the effectiveness of certain public health measures. He has also criticized FDA and other Federal agencies for their handling of the pandemic.

While Dr. Makary is a well-recognized surgeon and, for that reason, not an entirely controversial choice to lead FDA, his reputation as a "disruptor" and his close alignment with the Trump Administration, Secretary Kennedy, and the MAHA movement has made him more contentious. He has expressed concerns about the impact of food additives, pesticides, and other environmental factors on public health and has posited that chronic health issues, infertility, and attention deficit disorder may be linked to these factors. He has also criticized the U.S. food supply, calling it "poison," and has been vocal about the need for greater transparency and reform in the healthcare system.

Additionally, Dr. Makary historically has had significant financial ties to the pharmaceutical industry and insurance companies. However, it has been reported, as of March 4, 2025, that Dr. Makary, if confirmed, promises to step down as an adviser to various health technology medical device and telehealth startups to avoid conflict. He also vowed to sell off stock holdings in the companies and has already resigned from some advisory roles, according to a February 24, 2024, letter to an ethics official at HHS.

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The Hearing focused on numerous issues, which are summarized in more detail below:

- **MAHA and Food-Related Issues**
    - Generally Recognized as Safe (GRAS)

[1] For example, "*Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care*" and the "*Price We Pay: What Broke American Health Care—and How to Fix It.*"

- Seed Oils
- Red Dye #3
- Food Safety Inspection & State/Local Funding

- **Drugs, Vaccines, and Evidence-Based Approach**
- **Staffing, FDA Organization, and DOGE Concerns**
- **Commitment to Transparency**
- **Dr. Makary's Personal Ties, Knowledge, and Fitness**
- **Other Topics**
  - E-Cigarettes and Vapes
  - Electronic Labeling
  - Biosimilar Competition and Generic Drug Approvals
  - Regulatory Flexibility for Rare Diseases, Clinical Trial Diversity, and Drug Shortages
  - Healthcare Costs
  - Technology and Artificial Intelligence (AI)

I. MAHA and Food-Related Policy

Unlike Secretary Kennedy's nomination hearings a few weeks ago, which saw vocal bipartisan support for the MAHA food agenda, in this Hearing Democrats largely focused their questions on topics other than food. Like Secretary Kennedy, Dr. Makary emphasized that half of the nation's children are sick, yet past efforts have failed to tackle the fundamental issues, such as body inflammation and insulin resistance. Dr. Makary aligned with President Trump and Secretary Kennedy's emphasis on the role of food in public health, stating that food plays a significant role in these conditions. Food-related policy topics arose, particularly in exchanges with Senators Tommy Tuberville (R-AL) and Lisa Murkowski (R-AK).

A. Generally Recognized as Safe (GRAS)

On the topic of food additives and chemicals, Senator Tuberville raised concerns about the GRAS classification, questioning the presence of certain chemicals in food and whether they were safe. Makary acknowledged that while the food industry insists these additives are safe, research suggests some are problematic and may contribute to chronic inflammation in children. He specifically stated:

> These are chemicals that the industry insists are safe, a subset of which are concerning. There is a body of research now that suggests concern with some of these ingredients, we have to look at those ingredients, and you have my commitment to do so, if confirmed as FDA commissioner, these chemicals are creating an inflammatory response in the gastrointestinal tract, and with an altered microbiome lining that GI tract, kids feel sick. It's not an acute inflammatory reaction, it is a chronic low-grade reaction, and they don't feel well. And what are we doing? We are drugging our nation's children … at scale. We have to reassess what we're doing, because we're not on a good path right now."

He stressed that FDA needs to take a closer look at these ingredients and committed to reassessing their impact if confirmed as Commissioner.

B. Seed Oils

Regarding seed oils, Senator Tuberville commented that he has heard "a lot about seed oils" and some say they are "good" and others say they are "bad." He asked Dr. Makary for his thoughts. Dr. Makary largely avoided the question. While he noted that there is ongoing debate about their health effects, the broader issue is the overall diet of American children. He pointed to alarming rates of insulin resistance and diabetes in teenagers, arguing that the entire food system—including school lunches—needs scrutiny. He proposed a pilot program for school districts to transition to healthier food options, recognizing that many schools want to make changes but lack the resources or guidance to do so.

C. Red Dye #3

Senator Tuberville also questioned Dr. Makary about Red Dye # 3. Senator Tuberville questioned why Red Dye #3 dye is banned in cosmetics due to cancer concerns but still permitted in food. This is the same point that Senator Tuberville made in December 2024 before the Senate HELP Committee in December 2024. Senator Tuberville emphasized that Europe has stricter regulations on food dyes and suggested that the U.S. is 20 years behind in addressing such risks.

Dr. Makary agreed that U.S. additive policy does not make sense and pointed out that while the Biden Administration has announced a ban on Red Dye # 3, it will not take effect until 2027 or 2028. ***We believe Dr. Makary has signaled a potential interest in accelerating the compliance deadline for removing Red Dye #3 from foods and food products by January 15, 2027, and possibly moving it earlier.*** Dr. Makary concluded by reiterating his commitment to ensuring FDA prioritizes science-driven, transparent, and common-sense decision-making.

D. Food Safety Inspection & State/Local Funding

Senator Murkowski raised concerns about food safety inspections, noting that state and local governments handle a significant portion of the workload—conducting 60% of food processing inspections, 90% of produce safety inspections, and 100% of retail food inspections. She asked whether Dr. Makary would commit to maintaining federal funding for these contracts, arguing that they are cost-effective and efficient. While Dr. Makary did not make a firm commitment, he stated that he was open to reviewing the issue.

II. Drugs, Vaccines, and the Evidence-Based Approach

The Hearing focused heavily on a range of topics related to drugs, vaccines, and the importance of an evidence-based safety approach to medical products. Overall, Dr. Makary relied repeatedly upon guiding principles of "trust in science, transparency, and common sense."

Democrats and Republicans voiced concerns regarding FDA's recent cancellation of a meeting to select influenza strains for the 2025-2026 flu season. Dr. Makary *did not* commit to reinstating the meeting but did say he would review FDA's decision.

Dr. Makary affirmed that "vaccines save lives" during the Hearing but, consistent with Secretary Kennedy, did not recommend them for the current measles outbreak. In a nod to anti-vaccine advocacy, he discussed the role of nutrition in reducing severity.

On mifepristone, Democrats voiced their support for the longstanding findings of safety and efficacy, while Republicans criticized the drug widely used in medical abortions and its accessibility through telemedicine. Dr. Makary repeatedly stated that he has no preconceived plans and will conduct a thorough review of the data alongside FDA scientists. While Democrats expressed their concerns about potential political interference, Dr. Makary said he was committed to independent scientific review.

III. Staffing, FDA Organization, and DOGE Concerns

Dr. Makary addressed staffing and organizational concerns at FDA. Specifically, Democrats expressed concerns around probationary staff dismissals and otherwise arbitrary firings. Senator Alsobrooks (D-MD) asked Dr. Makary if he was aware of DOGE's recommendations to close buildings, such as FDA buildings in the White Oak Campus in Maryland which houses the Commissioner's office. Dr. Makary was also questioned about the recent layoffs at FDA, the need for inspectors and scientists, and how the agency could review food ingredients if it had fired the reviewers.

In response, Dr. Makary said that he is committed to reviewing personnel decisions, ensuring inspectors and scientists have adequate resources, and assessing recent layoffs, particularly in areas such as food safety. He emphasized strategic staffing rather than arbitrary firings and pledged to evaluate FDA facility closures.

IV. Commitment to Transparency

Transparency has been the narrative for Secretary Kennedy, MAHA, and now, for Dr. Makary during the Hearing. Senator Kim (D-NJ) questioned Dr. Makary's commitment to transparency in light of Secretary Kennedy's recently released notice, "Policy on Adhering to the Text of the Administrative Procedure Act," where HHS announced it would no longer put certain agency decisions out for public comment and may be more likely to rely upon a "good cause" exemption to forego public comment altogether.[2] Dr. Makary did not defend this seeming undermining of the commitment to transparency other than to emphasize, "I believe in the law."

[2] The Statement was published on March 3, 2025, and is effective immediately, 40 Fed. Reg. 11029. In the Statement, HHS rescinded its longstanding policy of employing notice-and-comment processes for matters relating to agency management or personnel and to public property, loans, grants, benefits, or contracts, even though the Administrative Procedures Act (APA), § 553(a)(2) exempts these matters from public notice and comment requirements. Further, the Statement also rescinds the prior HHS commitment to only use "sparingly" the APA

Throughout the Hearing, Dr. Makary repeatedly emphasized his commitment to transparency and independent decision-making in his nomination hearing. He claims to support "radical transparency" in food labeling and advisory committees, advocating for public involvement to enhance trust in regulatory decisions.

V. Dr. Makary's Personal Ties, Knowledge, and Fitness

Dr. Makary reassured lawmakers that his nomination process was thorough; he emphasized his independence and public service, particularly in improving children's health and restoring trust in FDA. On conflicts of interest, Dr. Makary stated he has divested from or would divest from all financial and professional ties that could create biases.

Dr. Makary was questioned by Democrats on whether, if appointed as Commissioner, he would recuse himself on matters involving former clients and employees if they came before him at FDA. In response, Dr. Makary said he can promise to be committed to abiding by all the guidance of the Office of Government Ethics (OGE). Dr. Makary also defended his previous work in reducing unnecessary medical procedures but pledged to maintain full transparency regarding past affiliations.

VI. Other Topics

Other topics were discussed during the Hearing. Below, we highlight some, but not all, of those topics. *Please contact us if you would like any additional information on these topics or others that may have been discussed.*

- E-Cigarettes and Vapes: On nicotine and vaping, Dr. Makary said that he recognized the influx of illegal flavored vapes from China. He also said he recognized that these products often target children and that we need better enforcement from FDA and the U.S. Department of Justice (DOJ).
- Electronic Labeling: When questioned on whether to replace paper package inserts for prescription drugs and medical devices with electronic labeling, Dr. Makary would not commit to the elimination of paper labeling. However, he also was not necessarily opposed to electronic labeling but did note that seniors might need and prefer paper rather than electronic information about their drugs and other medical products.
- Biosimilar Competition and Generic Drug Approvals: Dr. Makary expressed support for the expedited pathway for biosimilars and for generic drugs, emphasizing the importance of transparency and market competition to lower costs. He backed moving certain drugs, such as Naloxone and EpiPens, to over-the-counter (OTC) status to drive pricing reforms. He suggested that over-prescribing was linked to higher healthcare costs.

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exemption that permitted an agency to dispense with prior notice-and-comment for "good cause." The Statement, thus, reduces the matters that would be subject to prior notice and public comment and would seemingly be counter to the commitment of Dr. Makary and Secretary Kennedy to "radical transparency."

- Regulatory Flexibility for Rare Diseases, Clinical Trial Diversity, and Drug Shortages: Dr. Makary agreed that FDA should tailor regulatory approaches based on the condition and expressed willingness to review policies that promote inclusivity in clinical trials. He supported the use of Real World Evidence and more use of and reliance upon data developed in other countries. He acknowledged FDA's role in addressing drug shortages but noted that the issue extends beyond the agency.
- Healthcare Costs: Dr. Makary agreed that rising costs are unsustainable and linked them to chronic disease prevention, particularly in children. He stressed the need for a shift toward addressing root causes, such as unhealthy diets, and rebuilding public trust in health institutions.
- Technology and AI: Dr. Makary noted the potential of AI in assisting drug review processes, monitoring post-approval data, and improving medical device assessments.

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Next Steps

Senate HELP could vote as soon as next week on a recommendation for Dr. Makary's confirmation. If Senate HELP votes favorably to report Dr. Makary to the full Senate for consideration, he must garner at least 51 votes in the Senate to be confirmed. Based upon the Hearing today, it appears he will likely be confirmed.

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OFW will continue to monitor issues pertaining to FDA. Please let us know if you have any questions.

OFW: KSK