KPMG

Regulatory Alert

Regulatory Insights

September 2025

MAHA Commission Strategy Report

KPMG Regulatory Insights:

- ***Broad Impacts:*** *Although the report title and strategy are directed toward children's health, the initiatives impact multiples industries/sectors (e.g., agriculture, healthcare, technology) and will thus have potentially wide-reaching corporate as well as federal funding impacts.*
- ***Wide-Ranging Initiatives:*** *More than 120 initiatives spanning a wide variety of areas including food (e.g., labelling, additives/dyes), nutrition (e.g., dietary guidelines, labelling), technology (e.g., data sharing, AI applications, "precision agriculture"), and marketing/advertising.*
- ***Accelerating Innovation:*** *Looks to continue to development of health-focused technologies, including AI applications, through research/studies, policy reforms, incentives, and public/private collaboration.*
- ***Increasing State Activity:*** *Expect a continued increase in state legislative and regulatory activity, including labelling, food additives, ultra-processed foods, and marketing/sales practices.*

The Make America Healthy Again Commission (MAHA Commission), chaired by the U.S. Health and Human Services (HHS) Secretary, has issued its Make Our Children Healthy Again Strategy report outlining initiatives to approach/address childhood chronic disease. As directed by Executive Order 14212, this report is based on the MAHA Commission's previously released report, the Make Our Children Healthy Again Assessment. Although the reports are titled/directed toward children's health, the initiatives impact multiple industries/sectors, including agriculture, healthcare, pharmaceuticals, and technology.

More than 120 initiatives in the Strategy Report are organized into four distinct categories:

1. "Advancing Research" (e.g., chemicals, nutrition, microplastics, AI)
2. "Realigning Incentives" (e.g., policy reforms, "deregulation," and "structural improvements")
3. "Increasing Public Awareness" (e.g., campaigns, guidelines)
4. "Fostering Private Sector Collaboration" (e.g., farming solutions, educational programs)

In a separate but related release, the President issued a memorandum directing the HHS Secretary to take action to ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of prescription drugs.

1. Advancing Research: Topics include:

Topic	Regulatory Agencies	Description
Whole-Person-Health Research	NIH	— Launch an "Whole-Person-Health" approach to chronic disease prevention research including discovery science and intervention strategies that promote wellness, resilience, and optimal health, including metabolic health, at all stages of life.
Real World Data Platform (RWDP)	NIH	— Link multiple datasets (e.g., claims information, electronic health records, and wearables data) into a single integrated dataset for researchers to conduct chronic disease studies.
New Approach Methodologies (NAMs)	EPA, FDA, and NIH	— Expand the use of NAMs to enable earlier predictive insights through the use of human-relevant models (e.g., organoids, computational simulations, and real-world data integration).
Cumulative Exposure	EPA, USDA, and NIH	— Develop research and evaluation frameworks for cumulative chemical exposure across chemical classes, focusing on using and developing NAMs and computational tools.
Vaccine Injury	HHS, NIH/NIAID	— Investigate potential injuries using data collection and analysis, including through a vaccine injury research program at NIH Clinical Center.
Water and Air Quality	EPA, USDA, NIH, and other relevant federal partners	— Assess ongoing evaluations of water contaminants and update guidance and prioritization of certain contaminants. — Study air quality impacts and utilize existing research programs to improve data collection and analysis.
Microplastics and Synthetics	HHS, NIH, and EPA	— Complete an evaluation of the risks and exposures of microplastics and synthetics, including in common products such as textiles.
Prescribing Patterns & Impact on Mental Health	HHS (ACF, SAMHSA, FDA, NIH, and CMS)	— Form a mental health diagnosis and prescription working group to evaluate prescription patterns for selective serotonin reuptake inhibitors, antipsychotics, mood stabilizers, stimulants, and other relevant drugs. — Assess therapeutic harms and benefits of current diagnostic thresholds, overprescription trends, and evidence-based solutions that can be scaled to improve mental health.
Nutrition	HHS, FDA, USDA, and AHA	— Conduct "high-quality" nutrition research and ingredient assessments, including dietary patterns supporting metabolic health. — Utilize the FDA and NIH Joint Nutrition Regulatory Science Program.
Repurposed Drugs	NIH and FDA	— Jointly investigate strengthening the use of repurposed drugs for the treatment of chronic disease. — Harmonize authorization processes through collaborative clinical trial designs to achieve FDA approval.
Precision Agricultural Technology	USDA and EPA	— Prioritize research and programs to aid growers' adoption of "precision agricultural technology" to potentially decrease pesticide volumes, improve the soil microbiome, and increase financial benefit for growers.
Artificial Intelligence	HHS, NIH, and OSTP	— Prioritize research into the integration of AI to potentially assist in earlier diagnosis, personalized treatment plans, real-time monitoring, and predictive interventions. — Develop evidence-based and AI-driven approach to research and clinical trials on pediatric cancer and serve as a model for research in other critical areas.

2. Realigning Incentives: Topics include:

Topic	Regulatory Agencies	Description
Policy reforms		
Dietary Guidelines for Americans (DGAs)	USDA and HHS	— Update 2025-2030 DGAs in alignment with science, data, and health recommendations. — Reform future DGA processes, including structure/membership of the advisory committee.
Food Dyes	FDA and USDA	— Advance and implement policies to limit or prohibit the use of petroleum-based food dyes (FD&C certified colors) in all food products approved in the U.S.; USDA to apply this framework to food served through Federal nutrition programs. — Develop research and policies to support domestic agriculture production of plants used as natural color sources. — Expedite review and approval of color additive petitions for colors from natural sources and explore flexibility with the use of “no artificial color” and other labeling claims.
Post Market Review of Chemical Additives in Food	FDA	— Continue to develop and implement enhanced evidence-based systematic processes for post-market assessment of chemicals - including food additives, color additives, “Generally Recognized as Safe" (GRAS) substances, and contaminants.
Ultra-Processed Foods	USDA, HHS, and FDA	— Develop a U.S. government-wide definition for “Ultra-Processed Food” (UPF)
Nutrition Labeling	FDA	— Consider revisions to the proposed Front-of-Pack Nutrition Information rulemaking based on comment feedback.
GRAS Reform	FDA	— Update regulations to reform the GRAS designation by implementing a mandatory GRAS notification program and increasing consumer transparency with respect to substances found in the nation’s food supply.
Direct-to-Consumer (DTC) Pharma Advertising	FDA, HHS, FTC, DOJ	— Increase oversight and enforcement for potential violations of DTC prescription drug advertising laws. — Prioritize “most egregious” violations including by social media influencers and DTC telehealth companies.
Direct Marketing Guidelines	HHS, FTC	— Explore the development of potential industry guidelines to limit the direct marketing of certain “unhealthy” foods, including by evaluating the use of misleading claims and imagery.
Conflicts of Interest	FDA, EPA, USDA, HHS, NIH	— Ensure transparency in user-fee processes. — Require public reporting of research grants. — Require advisory committee members to recuse themselves from matters that will have a direct and predictable financial effect on their financial interests. — Establish public databases for disclosure of financial relationships. — Establish a publicly accessible researcher payment database tracking health industry payments to researchers. — Mandate annual disclosures by research applicants.

Deregulation		
Agriculture Deregulation	USDA, EPA	— Streamline organic certification processes. — Eliminate barriers for Community Supported Agriculture programs and direct-to-consumer sales. — Reduce regulatory compliance requirements for small farms (e.g., streamline/digitize USDA application processes).
Food Deregulation	FDA, USDA	— Actions to include: — Remove restrictions on whole milk sales in schools and eliminate mandatory reduced-fat requirements in federal nutrition programs. — Eliminate zoning restrictions preventing mobile grocery units from serving food deserts. — Fast-track grocery store permits for underserved areas.
Government Data for Research	HHS	— Revise policies for sharing de-identified government datasets to improve research without compromising privacy.
Structural improvements		
Agency Restructuring	HHS, EPA, and NIH	— HHS reorganization to create the Administration for a Healthy America (AHA) to coordinate and lead the Federal government's response to the chronic disease crisis. — EPA will refocus research initiatives using the Office of Applied Sciences and Environmental Solutions. — NIH launch of the: — Office of Research Innovation, Validation, and Application to develop, validate, and scale NAMs, and serve as an interagency coordination hub. — Office of Research Innovations, Planning, and Analysis (ORIPA) to look to improve disease-specific portfolio analysis, research prioritization, innovation, and Meta-Science, with an initial focus on increasing the chronic disease portfolio.

3. Increasing Public Awareness: Topics include:

Topic	Regulatory Agencies	Description
School Campaigns	USDA, HHS, ED, and the PCSFN	— Work with states on a Make American Schools Healthy Again awareness campaign that provides tools on best practices (e.g., increasing physical activity and improving nutrition options).
Using Data Tools Focused on Children	EPA	— Expand the America's Children and the Environment tool to compile and track data on quantifiable indicators for key factors relevant to the environment and children's health.
President's Task Force on Environmental Health Risks and Safety Risks to Children	HHS and EPA	— Leverage the existing Task Force to share information, coordinate efforts and develop interdepartmental strategies to protect and promote environmental health and safety.
Dietary Guidelines (DGAs)	USDA, HHS	— Launch education campaigns that highlight whole foods, minimize highly processed foods and added sugars, and emphasize nutrition through "food for health" initiatives.
Alcohol, Controlled Substances, Vaping and THC Impact	The Surgeon General	— Launch initiatives to educate on the impact of alcohol, controlled substances, vaping, and THC.
Illegal Vapes	FDA and ATF	— Increase enforcement on illegal vaping products. — Increase awareness of unapproved vaping products.

4. Fostering Private Sector Collaboration: Topics include:

Topic	Regulatory Agencies	Description
Community-Level Transformations	HHS	— Leverage available funding to help drive community-led initiatives aimed at measurably reducing chronic disease (e.g., local school leadership, pediatric care teams, and "local health navigators").
Whole, Healthy Foods	HHS, USDA, ED, VA, and DOD	— Improve access to "whole, healthy foods" in government-funded nutrition programs and meals.
Eating Healthy at Restaurants	HHS and USDA	— Work with restaurants to increase education and awareness of age-appropriate healthy food options, consistent with DGAs.
Soil Health and Stewardship of the Land	USDA and EPA	— Promote and incentivize farming solutions in partnership with the private sector that focus on soil health and land stewardship– including programs and practices related to: — The Environmental Quality Incentive Program and Conservation Stewardship Program. — Pollinator management, forage, and habitat. — Prescribed Grazing, Soil Health Systems, and Water Management.
Precision Agriculture	USDA and EPA	— Launch a partnership with private sector innovators to ensure continued investment in approaches and technologies for more "targeted and precise" pesticide application methods (e.g., targeted drone applications, computer-assisted targeted spray technology, robotic monitoring).

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