Statement for the Record of

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Before the House Committee on Oversight and Government Reform

"Restoring Trust to FDA: Rooting Out Illicit Products."

April 9, 2025

Chairman Comer, Ranking Member Connolly and members of the committee, thank you for this opportunity to testify. My name is Richard A. Williams, and I am retired from the Food and Drug Administration after serving for 27 years. I am currently the Chairman of the Board for the Center for Truth in Science and a Senior Affiliated Scholar with the Mercatus Center. I am also the author of *Fixing Food: An FDA Insider Unravels the Myths and the Solutions*.

In *Reputation and Power,* Daniel Carpenter said, "Over the late twentieth century, few regulatory agencies of any sort, in any nation, possessed or exercised the power of the Food and Drug Administration. … The regulatory power stems in large measure from a reputation that inspires praise and fear.[i]

I saw this regularly during my time at the FDA. When Congress threatened to take governance of seafood away from FDA and give it to USDA in the 90s, FDA implemented a huge regulatory program (HACCP) for seafood. When I suggested that it was not going to make seafood safer, the answer was, "It doesn't matter, we are doing this to keep seafood at FDA." When, after a year of trying to find some health or safety benefits for a rule to regulate dietary supplements and failing, I was told we had to regulate dietary supplements because, "We have to get them somewhere." It wasn't about safety; it was about power.

I see it on the other side as well. When addressing hundreds of small business owners in Atlanta about the then upcoming food labeling regulations, I ended my presentation and asked for questions or comments. Not one hand went up. I ended the conference and immediately was surrounded by participants. They explained to me that they didn't want to give me their name or their company's name for fear that they would be targeted by the FDA. I was dismayed by the obvious fear of the FDA.

Rather than using its regulatory authority to exercise the maximum amount of control over a massive amount of the economy, the FDA must refocus on regaining the trust of the

American people. To do so, the FDA needs to take advantage of advances in technology and focus on their programs that achieve real results. We have been increasing funding for food safety and nutrition for decades and not getting the results consumers should expect. It is time to demand results but results, such as making food safer, have not been demanded of FDA.

Each year, FDA presents budget requests that describe new challenges but never discusses how they have used previous budgets to make food safer or how nutrition has improved. I discuss below how FDA resisted the change required under the Bush Administration's Performance Assessment's Rating Tool (PART) that would have required such results.

In addition to making the United States more competitive in world trade, particularly against our enemies, the answer is to reshape the FDA's culture and programs. This will require the agency to focus on research and sharing information on best practices, encouraging invention and innovation, rethinking their approach to regulations, and focusing on targeted risk-based compliance.

These sweeping cultural changes within the agency and Congressional oversight of FDA's outcomes will do much to restore America's faith in the FDA.

Research and Information Sharing

The FDA needs to be reoriented to be an information agency first, and an enforcement agency second. Ensuring that accurate information is readily available is one of the FDA's most important tools when it comes to minimizing harm and improving food safety. This level of transparency is also critical to building trust.

Back in the early 2000s, CFSAN (now the Human Foods Program) epidemiologists did a deep dive into the root causes of one particular foodborne disease outbreak. Coming up with the original cause of the outbreak, they posted the cause of the outbreak on the FDA website. A food industry executive later told me how food producers all around the country pounced on that solution to see if it applied to their own process. It had an immediate impact and where applicable, companies changed their practices. To the best of my knowledge, FDA has not followed up with similar investigations of outbreaks, at least not sharing them this way. Companies don't want to poison their customers, recall a product, or end up in a courtroom. Starting with root cause investigations, FDA can help to gather information not readily available to consumers and stakeholders and make it freely available on the web.

Creating an easily accessible, central location for vetted information doesn't require the FDA to issue new regulations. But this change could empower food producers to proactively take steps to ensure food safety. Shared information would not be guidance or legally enforceable in any sense. However, with that information, companies could, on their own, determine whether the information applies to their products.

FDA should also be available for consultations to help where asked. One group to benefit from this kind of help will be small businesses who do not have large research and regulatory staffs. The United Kingdom, when implementing a shortened form of Hazard Analysis Critical Control Points (HACCP) for small businesses, started a program where the first visit was always to help, not inspect.

FDA also needs better science to identify actual risks that need to be addressed in regulations and enforcement. In 2016, FDA decided to include fruits and vegetables that had never had a food safety outbreak.[ii] Ignoring their own risk assessment, they decided to include those that had never had an outbreak to be precautionary because, as was explained to me by an FDA official in 2019, "anything could happen at any time."

Another example is given by FDA's focus on food and color additives in the last several years that results from conservative risk assessments and failure to pay attention to alternative risks.[iii]

When we test additives with high dose animal studies, giving rodents 700 or 800 times the amount that humans normally eat, about half[iv] of all natural and synthetic foods are found to "cause cancer" in rodents.[v] That does not establish causation, and it is amazing that the founding principle of toxicology from Paracelsus is so often ignored:

"*What is there that is not poison? All things are poison and nothing is without poison. "Solely the dose determines that a thing is not a poison*."

It's not only the lack of risk of the additive, removing them from the market ignores the downside of these policy choices. The question that should be asked is, "what will replace substances removed from the market?" When something is regulated so that the price goes up, or they are removed from the market entirely, something will take its place. It's called risk/risk trade-offs. For example, synthetic red food dyes banned because of high-dose animal studies will be replaced by carmine. Carmine is a natural red food dye made from crushed up beetles that live on prickly pear cactus, in other words "beetlejuice." And, of course, it is a chemical. Carmine is also an allergen for some causing delayed allergic reactions although, like synthetic red food dyes, it appears to be perfectly safe.[vi] Carrageenan is a "natural food additive from seafood that has side effects on gut health and inflammation.[vii]

FDA, perhaps in petitions from activist organizations, also uses results from the International Agency for Research on Cancer (IARC). IARC's assessment does not include the risks associated with exposure: meaning it ignores the probability of getting cancer at actual levels of exposure. This has resulted in everything they have examined being called a cancer-causing agent except for one. As for food and color additives, as Walter Willett recently noted, "rigorous regulations are in place to ensure that these substances do not pose risks to human health."

Too frequently, regulations are not supported by the best science. Examples of using poor science include selecting only those studies that support the regulation (cherry-picked), conservative risk assessments, using correlation instead of causation,[viii] or ignoring risk tradeoffs.[ix] Using poor science is an easy way for the FDA to erode Americans' trust.[1]

Another issue is ignoring science for the sake of slogans. Regulatory programs such as FDA's "Closer to Zero" is an example of ignoring evolutionary and toxicological science.[x] "Closer to Zero" is a program to reduce exposure to children from arsenic, lead, cadmium and mercury as close to zero as possible.

Over the course of evolution, our bodies have developed repair mechanisms such that, for the millions of times we are assaulted daily through air, water, food and other exposures, we repair the damage over 99.99 percent of the time (although these mechanisms decline in efficiency as we age). Not only do we repair almost all chemical and microbiological assaults, but in the case of all radiation and over half of all chemicals, low doses provide medicinal benefits – called hormesis. Cadmium, included in FDA's Closer to Zero program, exhibits hormetic properties. Another example is sulforaphane, a phytochemical that protects against oxidative stress at low doses.[xi] There are many synthetic chemicals that are hormetic, but this principle has been marginalized in current risk assessment practices.[xii]

Ignoring thresholds and hormesis based on well-established biological mechanisms has led to regulations and enforcement that are both unnecessary and, given trade-offs, potentially harmful.

With better science, including risk/risk analysis, fewer regulations should show that their benefits exceed costs, resulting in fewer regulations.

Encouraging Invention and Innovation

Precision Health

[1] Unfortunately, too often regulatory economists are forced to use cherry-picked or weak science to generate benefits for regulations.

Health scientists are beginning to realize that "one-size-fits-all" does not work for health. Some foods may have hormetic responses for one person while being toxic for another. Most foods that are allergenic for some are perfectly safe for others. In nutrition, some people lose weight on a low-fat diet, others gain.[xiii] Even twins respond differently to food.[xiv] Precision health also includes medicine where a disease shared by many may have different molecular causes for individuals. Human variability includes genetics, epigenetics, age, sex, health conditions, environment, microbiomes and, for behavior change, preferences.

This kind of variation means, in some cases, we cannot try and protect some people from exposure that theoretically may be harmful when they aren't helpful to others or actually harm them. For nutrition, it means that there are most likely zero diets that will work for everyone. Precision health ultimately will help us all to live longer. FDA should incorporate this science into all of their regulatory activities.

New Technologies

Another way that the FDA hurts their credibility with the American people is lagging behind in implementing technical solutions to improve food safety. FDA has finally engaged in tech-enabled traceability of food but there is so much more they should be considering.[xv] For example, smart packaging[xvi] using nanomaterial biosensors can either alert consumers to a spoiled food or even kill growing pathogens.[xvii] Smart devices can connect food processing machines to allow centralized monitoring.[xviii] New designs for production machines can remove places where pathogens grow or make them easier to clean. Robots and other automation can be used in restaurants to prepare food or to clean plants - eliminating error-prone or sick humans. New food preservation technologies, like hydrostatic pressure, ultraviolet radiation, pulsed UV light and hydrostatic pressure can be used to treat foods including those that are sold as "fresh."

Foods produced in factories, not farms, are much less likely to be contaminated with pathogens. These include, for example, foods produced with precision fermentation or in indoor farms. Genetically modified foods deliver higher yields, are drought resistant, use fewer pesticides and can produce healthier foods to feed a growing world population.

These are the solutions that will drive food safety, not more regulation.

Rethinking FDA's Approach to Regulation

Achieving maximum control over firms drives many FDA actions. The result is a huge mixed bag of regulations - some that are effective and many that are not. Some were produced at the behest of larger companies actively trying to put smaller ones at a competitive

disadvantage and, as I've previously mentioned, some regulations are based on weak scientific support.

Besides better science, some process changes may help eliminate bad regulations.

Most regulations should be preceded by an advanced notice of proposed rulemaking (ANPR) where the agency identifies a problem and suggests one or more possible solutions. This ensures that the agency is not committed to any particular course of action prior to receiving comments. If, after that, they identify a course of action that will result in a major regulation, there should be a pilot program, where feasible, to determine whether the regulation is likely to be effective.

At the proposal stage, the regulation should include: 1) an outcome goal; 2) an explanation of how that goal will be achieved; 3) the time necessary to achieve the goal; and 4) a Regulatory Impact Analysis, including a risk/risk Analysis.

As with formal rules, stakeholders should have a chance to object to them prior to being enacted.

This process should result in regulations being rare and, when implemented, have a much better chance of being effective.

Current regulations and programs should be reviewed, under the auspices of a Congressional agency, to determine which ones are outdated, duplicative or not effective.[xix] If a regulation or program is not successful in improving outcomes, it is simply a costly burden on the public.

An example of an outdated program is food standards: recipe standards that govern about half of all foods in the United States. Do we really need to ensure that ice cream is at least ten percent milkfat, that reflects how "mother used to make" them in the 1930s?[xx]

Since food labeling has failed to stop the growth of obesity and chronic disease, should FDA continue to tinker with it? Currently, every manufacturer of low acid canned foods must submit paperwork on every food, in every size container. Is it still necessary?[xxi]

With these regulatory and program reforms in place, the 800 pages of the FDA Investigations Operations Manual could probably be shortened considerably.[xxii] A simplified manual will make it easier for agency staff to focus on the critical processes that Americans rely on to keep food safe.

Recent reorganization efforts to modernize FDA's food program should be examined to see if they eliminated ineffective programs.[xxiii]

Targeted, Risk-Based Compliance

With fewer regulations that effectively address existing resources, resources should be freed up to do more and more effective inspections.

When I started at FDA in 1980, I was told "We are cops." It's a role FDA cannot shirk and will always be important. To do so effectively, they must have risk-based inspections including both domestic and international foods. Internationally, we should focus on those who are intentionally trying to do us harm by poisoning our food[xxiv] or who are trying to gain a competitive advantage by undermining American companies.[xxv] The later harm may occur by influencing regulatory agencies,[xxvi] investing in tort trials, [xxvii] or stealing technology (e.g., stealing GM seeds).[xxviii] Improved information sharing would also allow the FDA to help American consumers stay informed of potential threats.

Addressing these threats will be strengthened if FDA shares best practices, science, and issues found with foreign suppliers with consumers and manufacturers. Such sharing is likely to be more effective than regulations and inspection.

Accountability and Oversight

In addition to the cultural changes I've outlined above, Congressional oversight is key to ensuring that the FDA regains public trust.

There are three products of government programs: inputs, outputs and outcomes. For food safety:

- Inputs are the number of people who worked on regulations or inspections;
- Outputs are the number of regulations and inspections; and,
- Outcomes are the reduction in the number of cases or deaths from foodborne diseases reduced.

Outcomes are what consumers and taxpayers who fund this activity care about. Unfortunately, an agency's success is too often measured by their inputs or outputs. In 2007, President George W. Bush attempted to address this issue with an Executive Order[xxix] called the Program Assessment Rating Tool (PART) to assure accountability in federal agencies. It was done in conjunction with the Government Performance and Results Act.

The Executive Order required agencies to have outcome goals and to track and report their progress. Agencies, including FDA, fought this requirement, as failure to comply with the E.O. was to be directly tied to reduced agency funding. I was briefly tasked with creating outcome measures for the foods program until the Deputy Center Director found out we would be required to actually achieve a health benefit by reducing consumption of trans fatty acids. The measure was changed to making people aware that trans fatty acids exist.[xxx] The program was discontinued by the next administration in 2009.

For FDA's food safety program, the outcome goal is simple, reducing the number of illnesses and deaths from food. Bring PART back and ensure that a Congressional committee charged with overseeing the budget uses the results of outcome-based goals to establish agency budgets.

Additional Areas of Oversight for Congressional Consideration

- Operation Stork Speed – Two problems have plagued infant formula: failure to maintain a plant free of pathogens resulting in shortages and high prices that affect low-income consumers. To ensure a consistent supply and that infant formula prices remain low, Congress should make sure FDA's policies encourage new competitors.[xxxi] More producers will ensure that supply disruptions, such as occurred recently, will not happen again. Also, more competitors will help to keep prices down so that less well-off consumers do not end up trying to extend infant formula with water, a danger to infants who rely on this sole source of nutrients.

- Pathogens

  In terms of food making people sick, the biggest problem is still pathogens. After years of increased funding, the rates of foodborne disease are about the same. Unfortunately, the Hazard Analysis Critical Control Points or HACCP has, so far, not appeared to make much difference. It made no difference in the first mandated version for seafood because there were no critical control points for raw seafood like oysters. However, as mentioned above, knowing more about root causes could make a difference. Artificial intelligence may also help with predicting likely areas of outbreaks. Another step forward can be making foods in sanitary environments, like precision fermentation. Also, more targeted, risk-based inspections of plants and facilities could help.

- Single Food Agency
  Recognizing it will upset the committee structures in Congress, there is still a great opportunity to clean up enabling laws (e.g., get rid of food standards, get rid of visual observation of meat preparation) by pulling together FDA's Human Food Program, USDA's FSIS, and pesticides from EPA. This would allow greater prioritization of resources, end duplicative or confusing inspections, and perhaps reduce overall expenditures.

- Nutrition

  No evidence I have found shows that existing government tools including food labels, the Food Guide Pyramid and the Dietary Guidelines have been effective. We are eating more, getting heavier and chronic diseases have been increasing. If Congress continues to fund FDA's work on nutrition, it must hold the FDA responsible for improving health outcomes. Creating new foods will help but so will devices that will monitor what we eat, keep track of all of the relevant factors such as biomarkers and dietary preferences, and will make recommendations on what to eat. The problem for these devices is that they will fall under the restrictions of FDA's onerous medical device rules. See, for example, US Medical Devices; Choices and Consequences."[xxxii]

Summary

In every budget season, FDA presents challenges, and the only question is how much should the budget be increased? There are new challenges but a change in FDA's culture of trying to control everything can lead to better management with existing funds.

New challenges include discovering which, if any, of the various forms of microplastics and PFAS chemicals that occur in food or bottled water are dangerous. There are also food issues from China and other countries that are harming American consumers. The use of new technologies like blockchain for traceback and artificial intelligence to help predict food safety weaknesses, perhaps using data from critical control points, needs further exploration. If artificial intelligence can be used for drug approvals, it should also be applicable to food additive approvals.[xxxiii] New foods created with precision fermentation and genetic modification offer exciting nutrition possibilities but should be evaluated for food safety challenges.

Better science can identify real risks and separating risks from hazards (terminating the precautionary approach) will help to reduce the rate of new regulations. Reducing the rate of new regulations, the stock of existing regulations, and eliminating outdated programs such as food standards can free up resources to meet new challenges. Both pre-market approvals and regulatory programs should be examined to see where new food and food technologies are being strangled by overly precautious rules.

Importantly, in an increasingly competitive international trade market, FDA can help to encourage new companies that are more competitive for both imports and exports by having fewer, more effective rules.

The FDA will never be able to improve Americans' health outcomes if they are not seen as an effective and trustworthy agency. To help consumers eat safer food and American businesses compete, FDA must shift its focus to public health, rather than simply amassing power.

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