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How Monitoring Food is Protecting People

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Senior Capstone

Philosophy and Applied Ethics

Research Essay

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Senior Project Proposal

Name and Concentration - Grace Sugden, Philosophy and Applied Ethics

Project Focus - How effective are food safety regulations and enforcement agencies in preventing foodborne illnesses? I chose this topic as the focus for my paper since I find outbreaks of foodborne illnesses interesting, as well as the processes for preventing them. Also, the FDA approved label has been around the food industry for a long time, yet I don't know what it means to be FDA approved.

Direct Alignment - This project aligns with the Common Theme since it had a direct focus on the food industry, its practices and policies. My theme aligns with my ethics concentration due to the FDA's moral responsibility to protect people and disclose what is being consumed by people.

Purpose - My project's primary purpose is to determine what the FDA's role in the food industry is and how effective the practices of producers are in preventing contaminants being spread. I hope to accomplish a greater understanding of the processes of the FDA and feel more secure in the foods we eat being the safest as possible.

Title - How Monitoring Food is Protecting People.

Working Summary - The food we consume is thought to be safe, yet we have next to no role in the creation of our store or restaurant food. The processes controlling food production are a mystery to most people, yet we only apply scrutiny to the system once contaminated food outbreak strikes. By looking at the FDA and their processes, light can be shed on how outbreaks are prevented and stopped from happening again.

Sources - To complete my project, I am going to need substantial information about the FDA and its processes. I want to look at where the funding comes from, who its supporters and

opponents are, and what other agencies are a part of examining our food. I also need to find a producer's insight on what it's like to deal with these processes and their perspective on the policies in place.

My primary sources are going to come from the FDA website and their documents. My secondary sources are going to be journals and studies about how outbreaks are managed and how things have changed over the years.

Next Steps - My steps for meeting the project's expectations are going to start by timing my assignments properly. I won't want to start too close to other projects so by starting early I can do small pieces instead of a large chunk. By using my free time between classes I can slowly start collecting sources and write when inspiration strikes. The hardest part of the project I predict is going to be working from my draft to my final project. I am not the best at revising the work I have already done, but I plan on using my classmates to help me find where I need to work on.

Timeline - Annotated Bibliography, due March 12, start on March 1 by accumulating sources, First Draft, due April 4, start on March 15 by using annotated bibliography to start writing around my quotes, Senior Project Title and Abstract, due April 21, start on April 10 by summarizing the main points of my current draft, Final Paper and Portfolio, due April 28, start on April 24.

How Monitoring Food is Protecting People

Introduction

While the issue of food safety has always been a concern for humanity, what that looks like has changed drastically over time. Instead of trying to judge if a stream has safe drinking water, consumers are now faced with deciding which preservatives and pesticides they expose themselves to. With the multitude of United States agencies tasked with protecting the public, standards and quality control processes should be transparent and efficient. Since the creation of the Bureau of Chemistry, numerous acts have been passed that regulate ingredients, processing procedures, and minimize contamination risks. When a spoiled product enters the food web, there are stages of recall responses to limit harm to consumers and track down the present error. By examining the processes in place to protect consumers from harm, we can determine if our current system is effective or if changes need to be made. By looking at the governing aspects of our food protective agencies, we can uncover potential reasons why our system isn't as effective as it is on paper. While completing these evaluations, a conclusion will be made about if the shortcomings of the FDA are a result of a broken system or typical errors expected of such a large organization.

Influential Acts

The government's role in protecting our food started in 1862 when President Abraham Lincoln established the Bureau of Chemistry as part of the United States Department of Agriculture. At the time, food products were not required to state what ingredients they contained and could advertise themselves with terms like "miracle cure" without repercussions. To combat this, the Food and Drugs Act of 1906 was passed. This act mandated that labels have

their ingredients and effects listed and established the Bureau of Chemistry as the enforcer of food standards in the US. With this new power, the Bureau of Chemistry completed investigations, inspections, and analyses of food and drug products to check for violations. When violations were discovered, the Bureau had the authority to take legal action against the offenders by issuing warnings, seizing products, and pursuing criminal prosecutions. This Act is an important start to food regulations as today consumers can see a variety of labels on the shelves. There are symbols put on food that is kosher, gluten free, sugar free, organic and FDA approved. In an environment of so many labels, consumers are left unsure of what is required to earn such a label. When a label says a product is certified, very rarely is there immediate knowledge of what it takes to earn these standards, but with the Food and Drugs Act passed, consumers can feel assured it is monitored.

The Federal Meat Inspection Act, enacted at the same time as the Food and Drugs Act, primary goal was to regulate the safety and quality of meat and meat products. There are three key points of the act: Livestock must go through a mandatory inspection both before and after slaughter to ensure only healthy animals enter the food supply. Meat processing facilities must be subject to regular inspection to maintain sanitary standards and prevent contamination, and each meat product must pass inspection by USDA inspectors to verify its safety. The act also mandates that once a meat product has been inspected it must be labeled “Inspected and passed” and sealed to be considered properly handled. In 1957, the Poultry Products Inspection Act was passed. This act came to be since “unwholesome, adulterated, or misbranded poultry products … are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, … as well as injury to consumers,”(Poultry Products Inspection Act). Since poultry is a large portion of the meat consumers eat, the health and

wellbeing of the birds before slaughter is crucial to keeping consumers safe. Disabled or dying birds pose a risk of passing illnesses and contaminants throughout the slaughterhouse and therefore are not allowed to be slaughtered for human consumption. Similar to the Federal Meat Inspection Act, there are also strict regulations on what is deemed “Inspected and passed” as well as prohibitions against forging or tampering with these labels.

The Egg Products Inspection Act of 1970 was created since “eggs and egg products are an important source of the Nation's total supply of food… in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed,”(Egg Products Inspection Act). Important requirements from this act include pasteurization of eggs, proper labeling of eggs or products that contain eggs, and sanitary operation of processing facilities.

The FDA regulates pesticides on food through the Federal Food, Drug, and Cosmetic Act of 1938. This Act regulates the use of pesticides, including setting a standard for their use in food and additional protections for children under 2. The FDA and Environmental Protection Agency work together to register pesticides and when they are used, determine what are safe amounts of residue on food, and to identify when a pesticide is incorrectly used. Through the same act, antibiotics for animals are regulated and evaluated for safety. Due to risks of antibiotic resistance and residue in food products, the use of antibiotics is heavily restricted.

The Food Safety Modernization Act serves to bolster preventive measures to reduce the risk of foodborne illnesses. Two key rules under FSMA are the Produce Safety Rule and the Preventive Controls for Human Food Rule. The Produce Safety Rule has several key requirements. One of these requirements is to have grazing or working livestock receive the same consideration for contamination as wild animals currently receive. The Preventive Controls for Human Food Rule “requires food facilities to have a food safety plan in place that includes an

analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards," (FSMA Final Rule for Preventive Controls for Human Food). Through sampling and testing, farm inspections and water quality checks, the FDA is able to enforce both rules. These US regulations are also enforced on foreign produce entering the country.

Government behind the FDA

The FDA is supervised through a combination of legislative oversight, executive branch authority, and internal agency procedures. The FDA operates under the authority of the Department of Health and Human Services. Since the FDA is part of the executive branch, Congress holds hearings and has the power to pass laws that affect the FDA's authority, funding, and responsibilities. The head of the FDA is a Presidentially sworn in Commissioner who receives backing from the US Senate. The current Commissioner of the Food and Drug Administration is Dr. Robert Califf, who was sworn into his position in February 2022. Dr. Califf is a recognized cardiovascular expert who has a long history of clinical trials and other research projects. As Commissioner, Dr. Califf is "committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health,"(Office of the Commissioner). The Commissioner of Food and Drugs, along with senior leadership, oversees the implementation of these procedures and ensures that they are followed consistently across the agency. Within the FDA, there are various offices and centers responsible for specific areas, such as the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Each of these centers has its own set of regulations, policies, and procedures for evaluating and regulating products within its jurisdiction. The FDA is also subject to oversight by external bodies, such as the Government

Accountability Office and the Office of Inspector General within the Department of Health and Human Services. These entities conduct audits, investigations, and evaluations to ensure that the FDA is fulfilling its regulatory responsibilities effectively and efficiently.

As previously stated, the FDA reports to Congress, but specifically goes through the Office of Legislation. The Office of Legislation has a multitude of duties, but is primarily responsible for ensuring that Congress is up to date with regulatory actions and works with other agencies like the Department of Health and Human Services. Another valued task for the Office of Legislation consists of needing to "provide essential information and guidance on relevant Congressional actions to FDA Leadership and advises them in advance of hearings and other key engagements,"(Office of the Commissioner). Some of their daily responsibilities include advising the Commissioner of the FDA, preparing members of the FDA to testify in front of Congress, and monitoring legislation that could impact the FDA. Erin O'Quinn is the current Acting Associate Commissioner for Legislative Affairs, the head of the Office of Legislation. After working ten years on Capitol Hill, O'Quinn achieved "a Master of Public Health and Master of Social Work from the University of North Carolina at Chapel Hill where she focused on Maternal and Child Health and Policy and Management,"(Office of the Commissioner).

Evaluating the Effectiveness of Preventative Measures

In 1981, the Food Safety and Inspection Service was officially established as a separate agency within the USDA. This move came in response to the growing need for a dedicated overseer of the inspection of meat, poultry, and egg products. The FSIS bore the responsibility of enforcing laws passed by Congress, such as the Federal Meat Inspection Act, the Poultry Products Inspection Act of 1957, and the Egg Products Inspection Act of 1970. The FSIS has

implemented modernized inspection techniques, adopted science-based approaches to risk assessment, and enhanced collaboration with stakeholders across the food industry.

The presence of antibiotics in meat presents risks to human health, animal welfare, and the environment, with one of the primary concerns being the development of antibiotic-resistant bacteria, which can occur when animals are routinely administered antibiotics for growth promotion or disease prevention. These resistant bacteria can persist in the animals' guts and may be transmitted to humans through the consumption of contaminated meat, leading to infections that are difficult to treat. Furthermore, the use of antibiotics in livestock can contribute to the spread of antibiotic resistance in the environment, as antibiotic residues can enter soil and water sources through manure and runoff, potentially impacting ecosystems and human health. Additionally, the indiscriminate use of antibiotics in animals can disrupt the balance of beneficial bacteria in their guts, affecting animal health and potentially altering the nutritional quality of meat. Regulatory oversight is crucial to monitor antibiotic use in livestock and ensure that antibiotic residues in meat are within safe limits. Efforts to promote responsible antibiotic usage in livestock farming, along with initiatives to reduce unnecessary antibiotic use and improve regulatory measures, are essential for mitigating these risks and preserving the effectiveness of antibiotics for both human and animal health.

The Food and Drug Administration's Foodborne Illness Risk Factor Trend Analysis Report from 1998 to 2008 highlights improvements in certain risk factors within the food industry, with eight out of nine facility types showing significant improvement in at least one area. However, despite these advancements, areas still exist for betterment. The study showed the areas needing revision were improved by a maximum of 5% in the span of ten years. To have compliant rates in the low 80% range shows the FDA tolerates performance lower than the ideal.

This leads to the conclusion that the United States' regulatory agencies are not effective enough in maintaining the strict standards expected when it comes to food preparation.

Upon the 2008 mandate by the FSIS to publish a list of retailers for meat and poultry recalls, focus has been given to the recall system and its effectiveness. While recalls are important procedures to limit the consumption of harmful food, the process and participation have both been lacking. Recalls in the US are a process initiated by manufacturers or government agencies when identifying products that pose risks to public health or safety. It typically begins with the detection of a potential hazard, often through consumer reports, routine monitoring, or testing. Then, the responsible party conducts an investigation to determine the severity of the problem and assess potential risks to consumers. The severity of recalls is divided into three categories. Class I is for the most severe issues, where the possibility of death is high. Then there is Class II and Class III, when the chance for harm is remote or unlikely. If the need for a recall is confirmed, the responsible party notifies the appropriate authorities and formulates a remedy plan, which may involve repairing, replacing, or refunding affected products. A public announcement is then made, sharing details about the recall, including the product and danger posed. Consumers affected by the hazardous product are informed through methods such as advertising, mail, or store notices. Government agencies monitor compliance throughout the process, ensuring that consumers are adequately informed and protected. Once the recall is completed and the hazard is addressed, a final report is issued, officially closing the recall. Despite having this system in place, issues still arise when trying to contact consumers. Due to the time it takes for reports to be made, if a product is already in the hands of consumers, little can be done to ensure more people do not suffer negative consequences from the defective product.

Another recall of note occurred in 2018. Due to contaminated romaine lettuce from Yuma, Arizona, the US faced a significant foodborne outbreak that stemmed from E. coli O157:H7. The outbreak, which affected multiple states across the country, resulted in a total of 210 reported illnesses, with 96 hospitalizations and 5 fatalities. The outbreak drew widespread attention and concern, prompting swift action from health authorities. Through investigations and trace back efforts, health officials were able to pinpoint that "the available information indicates that romaine lettuce from the Yuma growing region is the source of the current outbreak of E. coli O157:H7 infections, and was supplied to restaurants and retailers through multiple processors, grower/shipper companies, and farms,"(Center for Food Safety and Applied Nutrition). The incident underscored the challenges associated with ensuring the safety of fresh produce. It also highlighted the importance of collaboration between government agencies, industry stakeholders, and public health organizations in safeguarding the food supply chain and protecting public health. This event spurred discussions around improving food safety practices and traceability measures to prevent similar outbreaks in the future.

A more recent recall was in February of 2022 for infant formula potentially contaminated with *Cronobacter.* The contamination sadly resulted in the death of two infants and two hospitalizations. Shockingly, "the first infant illness was reported to federal health officials in September [2021]. Inspectors were not sent to the plant to investigate until late January [2022]" (Bottemiller). This setback in the investigation delays the closure for families suffering from the contaminant and allows for tampering of evidence and the negligent behavior to continue. The CDC estimates that each year roughly 48 million people get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. These numbers could have been greatly reduced if proper

oversight had been upheld. Without strict investigations, contamination will continue to repeat at an unchecked rate.

The FDA's Shortcomings

Stephen Ostroff has been acting commissioner of the FDA twice, and he is not satisfied with the current running of the organization. "There are a lot of things that languish," Ostroff said. "We don't have that imperative and that pressure to actually make things happen on the food side of the Food and Drug Administration." While COVID vaccines were streamlined, any worthwhile legislation to regulate food has been slow going at best. The most recent movement to get calorie totals on menus was stalled in the face of the pandemic and shows no signs of life. With a one billion-dollar budget for food, it is surprising to learn that most goes towards inspections, which is contradictory to the fact that the number of inspections taking place has been decreasing over the years. In addition, the structure of the FDA is not conducive to a flourishing workplace. Among other administrative shortcomings, "The extremely different leadership styles of the two top officials only adds to the structural dysfunction – and the situation is confusing for those trying to work with the agency. Who is actually making decisions?"(Bottemiller). Without knowing who is in charge or who is enforcing protocol, it leaves the few employees the FDA has without a clear purpose. The fact that "the center charged with overseeing the vast majority of the country's food supply has roughly the same number of staff as it did a decade ago" should be considered an emergency (Bottemiller). By having so few workers available, there is no guarantee that the food being distributed is upholding the standards federal acts have put in place.

A total of 68 people were confirmed to have been infected with *Salmonella* Typhimurium back in 2022 due to Alfalfa Sprouts grown in Nebraska. In late November and

early December of 2022, over 1,400 pounds of sprouts were distributed. 10 people were hospitalized from this outbreak, but since the strain was responsive to antibiotics, there were no deaths. On May 10, 2023, a warning letter from the FDA was sent to Sun Sprouts, the grower responsible for the outbreak. The contents of the warning letter critiqued the grower for not testing their irrigation water, not sanitizing the food preparation surfaces and there was a lack of supervisors with FDA food safety training. The FDA required a response in 15 days on what the farm was going to do to address the errors in processing, citing "Failure to adequately address this matter may result in legal action by the FDA without further notice, including, without limitation, seizure and/or injunction," (Office of Regulatory Affairs). While this recall seems to show the FDA properly responding to a food illness outbreak, it raises questions as to how the grower Sun Sprouts was allowed to have three major errors in their production process. Instead of regular inspections having caught these oversights, 68 people had to become ill to spark scrutiny.

In 2011, there was a listeria outbreak seemingly coming from cantaloupes. An FDA investigation started on September 8th by collecting cantaloupes from suspected outbreak locations. By September 11th there were confirmed listeria results coming from locations where ill people reported buying their cantaloupes. After the FDA released a statement advising against the farm's cantaloupes, environmental samples taken and produced were tested, they were all testing positive for listeria. September 22nd saw the FDA completing an environmental assessment of Jensen Farms, the organization responsible for the fruit. However, despite several tests, stating that Jensen Farms had contamination in their produce, they only received a warning letter from the FDA stating what the failures were and what needed to be resolved. From this outbreak, there were 147 people sick from eating contaminated food sold at their grocery stores.

While 143 people were hospitalized, “in total, 33 deaths from outbreak-associated cases of listeriosis have been reported to CDC. In addition, one woman pregnant at the time of illness had a miscarriage”(Centers for Disease Control and Prevention). Ten additional deaths occurred in people who were infected with listeria, but were not able to have their cause of death primarily listed as listeria. The FDA’s actions in this case show a sluggish approach to regulations that mean more outbreaks like this are possible. Out of 39 swabs taken, 13 had listeria. These swabs tell us that this outbreak was not a coincidence but a severe lack of standards where an outbreak was only a matter of time. Without close supervision by the FDA to ensure health standards are met farms are reliant on self-regulation instead of years of research and legislature.

Not only are the FDA’s infrequent inspections for contaminations lacking, but “the proportion of recalled product recovered decreased from 1994 to 2016, with no product recovered in 12% of all recalls,” (Yu). For a recall to be successful, several factors must be in line. To start, consumers have to be aware that a recall is occurring. This alone is a major struggle with systems not being able to reach every customer who purchased the product. Next the customer must identify that their product is part of the recall. Once they make this realization a consumer has to become concerned enough about the recall to bother with returning the product. In cases where the recall is Class II or III, the urgency of participating in a recall may not be present. With this knowledge it seems difficult to ensure customer participation, but “a 2008 national survey of U.S. consumers revealed that 59% of respondents had searched for a recalled product in their home,” (Yu). This data suggests that there is an error in how recall information is presented to consumers. The information might not be as widely spread as needed to have an effective recall. Another issue could be the labels used might be too difficult for consumers to understand. The best-by date is sometimes used to identify products, alongside the

lot number. To expect consumers to know this knowledge could lead to less participation. An easier code could simplify the process and comfort consumers, knowing they ensure their food safety.

Healthy Living Programs

Healthy People is a national initiative focused on enhancing the health and well-being of US consumers and is updated every ten years. Federal government, states, local communities, and private organizations use the goals and objectives that have been scientifically informed to track progress and address health issues.. The FDA plays a key role in advancing food safety and nutrition within Healthy People's national objectives. Objectives for Healthy People 2030 encompass health conditions, behaviors, populations, settings, systems, and social determinants of health. The program strives to encourage a healthy lifestyle where preventable illnesses are minimal, achieve health equity, and promote healthy development through all stages of life.

The plan of action to reach the 2030 goals is to provide tools for the public and see how it improves health and wellness, to set national goals to guide policies and programs, as well as to better the health of people of all ages alongside the communities they live in. Changes made in the last four years include the increase of accredited public health agencies, the increase of Medicaid coverage for quitting tobacco, and the increase in the number of children who receive developmental screenings. With six years remaining in this cycle, there are hopes of increasing the vegetable, fruit and whole grain consumption of children two years and over, and increasing participation in school breakfast programs. By having these programs in place, the FDA can work towards building a healthier nation beyond just looking at individual food products. Looking at health from a holistic approach allows for the root of the issue to be found and addressed instead of just treating the symptoms of a broken system.

People in the United States surpass the recommended sodium intake by 50%, which elevates the likelihood of heart attacks and strokes. Packaged and restaurant foods contribute to about 70% of sodium intake, presenting a challenge for individuals aiming to lower their sodium consumption. As an initial measure towards reducing sodium in the food chain, the FDA introduced voluntary targets for the food industry in October 2021, covering a wide array of processed, packaged, and prepared foods. Believing that healthy eating habits are best started and maintained at a young age, the FDA rolled out the Maternal and Infant Health and Nutrition effort. This initiative gives updated guidelines on consuming seafood, better nutrition requirements for baby formula, and provides accessible information on making safe eating choices. “After trans fat was required to be declared on the Nutrition Facts label in 2006, trans fat was reduced by almost 80% in the food supply”(FDA’s Nutrition Initiatives), the FDA is moving forward with initiatives to redefine what the ‘healthy’ label on foods means. The hope is to push manufacturers to make new recipes to earn the ‘healthy’ label on their products. With this movement, there will also be a ‘healthy’ symbol made so foods can more readily be recognized. Another aspect of this initiative is to give consumers access to nutrition facts when shopping online. Since the COVID-19 pandemic saw a rise of online shopping, ensuring that the same information is readily available is crucial to keeping consumers in the know about their food choices.

The Future of the FDA

The FDA has been criticized publicly for allocating budget unequally to favor the Drug side of the administration while neglecting Food and maintenance responsibilities. On March 11, 2024, the FDA announced its request for the 2025 presidential budget to provide over $7 billion to enhance food safety operations. This budget request is over 7% higher than the previous year's

budget and aims to modernize the lacking FDA infrastructure. $15 million are dedicated to the investigation of the root causes of food illness outbreaks and the FDA's initiatives to fight diet related diseases. $43 million will be dedicated to modernizing the FDA's labs and increasing inspections at points of entry to limit contamination. The largest chunk of the $7 billion is slated towards staff salaries and adapting to the current cost of living, estimated to cost $114 million. The budget request is also paired with legislative proposals. Three key proposals are to "support innovation and competition, such as creating a new regulatory category of animal food additives… Enhance supply-chain resiliency for drugs, medical devices, and foods, including with respect to addressing supply disruptions… Provide new authorities to help ensure the safety of foods, including infant formula, medical foods, and foods marketed for infants and young children,"(Office of the Commissioner).

By 2030 the FDA plans to bring a 'New Era' of food safety to light to adapt to modernization in the food production industry. What this Era would bring is a new traceability system, smarter tools for prevention and outbreak responses, and a new food safety culture. Tech traceability will manifest as a possible adoption of a strong traceability system for food safety oversight. For the new prevention and outbreak responses, the FDA is potentially going to outsource for safety inspections. The FDA states a plan to "Increase the use of reliable third-party audits to help ensure safer food… for example, with respect to inspections of both imported and domestically produced foods." (Center for Food Safety and Applied Nutrition). This change implies that the FDA is knowledgeable about the lack of supervision they have been providing and due to lack of workers, may need additional parties to do it instead. The new food safety culture is an exciting plan revolving around getting more public interest in food safety. The plan for building this culture is to launch a social marketing plan and bring chefs, bloggers

and celebrities together around their food safety agenda. Creating influencers for the movement is a genius idea to spread the news about how our food arrives at our table. Too often are people ignorant as to the processes protecting them from dangerous food. These changes brought on by the 'New Era' are sparked by the FDA's perspective, stating "Our world is evolving at a breakneck pace. With this evolution comes new technologies, ranging from new digital tools to new sources of food ingredients," (Center for Food Safety and Applied Nutrition). While adapting to change is never easy, this new Era could bring back to life the backbone of the food industry.

Conclusion

This study on the FDA and the key acts that shape these decisions show that the foundation of the Food and Drug Administration is solid. With the restrictions placed upon ingredients and what animals can be slaughtered, there is a limited risk for sickly animals to bring infection into the food system. In addition, with the structure of the US government behind the FDA there is clear supervision and monitoring for actions taken by the FDA in place so new regulations can be tailored to what is needed to protect consumers. While there are numerous errors shown in the FDA's operations, with an adapted approach to recalls and investigations, producers will be forced to adhere to the strict standards currently in place. Hopefully with the larger budget the FDA can reinvigorate the food inspection system and increase supervision over producers. With programs and upgrades, this could be the start of a healthier, more informed market of consumers. With a strong foundation to build upon, the possibility of a better FDA is hopeful and well within reach.

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