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GENETICALLY MODIFIED ORGANISMS: REVISION OF THE CURRENT FEDERAL REGULATION

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Gabriel Galvez, from the Senate Committee on **HEALTH, EDUCATION, LABOR, AND PENSIONS**,

submitted the following

REPORT ON COMMENTS

[To accompany, S. 1043]

The Committee on Health, Education, Labor, and Pensions, (HELP) has analyzed the proposed regulation and the accompanying comments, and recommends that the regulation ought not to pass. The committee is under the impression that the FDA's proposed changes and edits to the current guidelines are insufficient, and will hinder societal progress towards providing safer grocery store products across the United States and the world. As it stands, the guidance does not currently promote the public interest and would not be a suitable replacement of the current FDA guidelines.

PURPOSE

Recently, the Food and Drug Administration (FDA) released a Guidance for Industry (GFI) that aims to classify all genetically modified (GE) plants and animals as "new animal drugs" (NADA) (Regulation of Intentionally Altered Genomic DNA in Animals*,* 2017). The rule plans to place stronger restrictions on genetically modified products, and classify any animal products raised with GE products like corn, feed, or grains as "genetically modified". Through this process of re-classification, the FDA aims to erase the stigma surrounding GE products and label

them as safe for consumers, a problem that has stymied the GE market for decades. This process will supposedly allow the FDA to alleviate the current market failure caused the inundation of information and ease consumers back into the GE market by wooing them with updated product safety standards.

ESTABLISHING THE DEBATE

The debate surrounding GE products is still quite contentious, with both sides bringing excellent arguments to the table. A myriad of comments was posted on www.regulations.gov, a majority of which were the voices of concerned Americans wishing to keep scientific testing out of food. Many firms and a handful of state and federal government agencies also posted their own comments about the issue.

A handful of groups showed support for the FDA's redrafted guidance. One of these groups was the Biotechnology Innovation Organization (BIO), the largest trade association representing biotech companies, scientific interests, and academic centers across the country, including DC's own Georgetown University. BIO holds annual meetings to discuss new findings within the biotech community and discuss the future of science and technology in the workplace. The association is organized into four different sectors that represent the interests of its members and goals – health, the environment, food and agriculture, and emerging companies. BIO, a trade group dedicated to progress within the biotech community, is in favor of the FDA's newly drafted guidance because they believe that it will help promote transparency between the scientific community and the general populace. The guidance, will help clear the murky waters surrounding genetic engineering in the agriculture and meat industries. This will hopefully lead to an increase in consumer trust in GE firms, leading to an increase in revenue.

Another group that supports the FDA's guidance is Exemplar Genetics (EG), a genetic engineering firm that breeds miniature pigs for medical research. Exemplar's miniature pigs are sold to scientific research facilities as to allow researchers to test the effectiveness of medications and currently in development. EG approves of the FDA's proposed guidance because of their obligation to consumer safety – they want to ensure that any GE products they bring to market are safe for human consumption, and cause no risks to human health. Their product helps fine-tune medications not yet ready to be brought to market. Added regulations will allow for more rigorous testing on EG's products, which are important in hypothesis testing. Safer products will reduce the likelihood of producing false-positive or false-negative results in laboratory examples, creating safer products for American consumers.

One last group in favor of the FDA's guidance is the American Farm Bureau Federation (AFBF), a non-profit association that aims to enhance the lives of rural American farmers. AFBF helps farmers across the country by giving them a voice in the political process, teaching children about the farming lifestyle, and empowering other farmers with annual conferences and advocacy programs. The Farm Bureau Federation approves of the FDA's guidance because they that budding industries need regulation, especially the GE industry. A cheaper way to produce fruits and vegetables can ease the burden of agriculture on many farmers across the United

States, but the AFBF wants to ensure that all GE products undergo rigorous scientific regulatory processes to ensure that human and animal welfare will not be threatened.

Other groups, however, don't share the same stances as the previous organizations. These groups want the FDA to drop the proposed regulation because of its vague definitions and general ineffectiveness at regulating the GE market.

One of these groups is AquaBounty (AB), a genetic engineering firm that specializes in aquaculture. AquaBounty grows genetically engineered fish that are designed to reach market size quicker than their non-GE counterparts. AquaBounty currently works with fish like trout and tilapia, but their most notable accomplishment was with salmon. Their *AquAdvantage* prototype was created with an Atlantic salmon that was given the growth genes of a Chinook salmon, allowing it to grow faster in colder waters (Waltz, 2017). AquaBounty disapproves of the FDA's proposed regulation because they believe it provides the FDA with a large claim of regulatory authority over GE products. Their increased regulatory power will increase costs for GE producers, further stifling growth in the economy. They also claim that the FDA's claim to market regulation is not specific enough, making its phrasing too general to be effective. The vague wording in the FDA's recommendation makes compliance incredibly difficult, especially if firms have to keep checking with FDA's policies. AB also uses their comment to insert the claim that the guidance's recommendations aren't based upon any measurable scientific risk.

The second group that wants to amend the FDA's regulatory docket is the Center for Science in the Public Interest (CSPI). The CSPI is a public interest group that has advocated for the improvement of safety and nutritional quality of the domestic food supply. They were the ones to lead country-wide health actions like removing soft drinks from schools and placing calorie labels on menus across the nation (Black, 2017). They create publications about nutrition and food safety, and bring health initiatives to Americas youth through projects that swap school's unhealthy food options and replacing them with healthier choices. The CSPI disputes the FDA's proposed regulation because it doesn't allow for transparency or public participation in the new animal-drug screening process. CSPI argues that input from all sides of the debate ought to be welcomed during testing processes because of how important it is to be able to access information.

The last group to reject the FDA's proposed amendments is the George Washington University Regulatory Studies Center, (the GWRSC). The purpose of the GWRSC is to provide a thoroughly-researched, independent analysis of proposed regulatory policies and release those reports to the public. The GWRSC focuses on researching topics like improving existing institutional practices, providing objective information and suggestions on current regulations, and promoting industry's best practices for others to analyze. The GWRSC, however, objects to the FDA's current guideline proposal because of its failure to address and fix the existing policy on GE products – they believe that a failing model of regulation should not be the basis on which a new wave of regulatory policy is built.

COMMENTS FOR PROPOSED RULE

BIO, Exemplar Genetics, and the American Farm Bureau Federation all support the FDA's current adoptions to the guidance because all three groups agree that the FDA needs to monitor the market and provide transparency for the consumers.

BIO wants to help close any information gaps in the market by supporting the FDA's guidance. BIO recognizes that their success is dependent upon providing clear information about the GE industry, and that any regulation proposed by the government is "critical to maintaining the viability [of the industry] both domestically and internationally" (Glenn, 2008). From the trade group's perspective, it is to their advantage to support a guidance that protects consumers from shady practices. Supporting regulations to ensure clean, healthy products will allow the trade group to earn legitimacy in the eyes of consumers. A trade group that steps up and enforces, or "cracks down" on government regulation internally raises their credibility in the eyes of the consumer.

Exemplar Genetics endorses the FDA's rule because they care about consumer safety and the need to separate their industry from the agriculture and livestock industry. EG states that increased regulatory oversight in the GE product market is important for consumer product safety, but exemptions should be in place for products that already have heavy restrictions, like EG's "mini-swine" (Swart, 2016). EG pushes for less regulation for these heavily regulated products because they believe that the current guidance does an excellent job at protecting consumer safety. They agree, however, that increased safety regulations will ensure that consumers are purchasing the highest-quality GE goods. Exemplar Genetics believes that "genetically engineered animals can benefit animal health, human health, and nutrition," and clear-cut regulation will help cut the red tape that some consumers can't seem to see through (2016).

Lastly, the American Farm Bureau Federation supports the FDA's guidance because of the economic incentive. The AFBF's comment was quite general, addressing multiple positive aspects of GE's in the market and the necessity of increasing consumer acceptance towards GE products. The AFBF's comment has an economic spin – it's quite focused on increasing agricultural productivity and quickly moving foods to commercialization (Maslyn, 2008). The AFBF understands that lowering the cost of our favorite fruits, vegetables, and eventually meat products, many more consumers can suddenly afford these goods, increasing efficiency and the overall economy.

COMMENTS AGAINST PROPOSED RULE

AquaBounty, CSPI, and the GWU Regulatory Studies Center agree that regulation brought about by the FDA will have very little effect on improving consumer safety and ought to be discarded, if not rephrased, at the very least.

The comment left by AquaBounty addresses the FDA's overgeneralization toward all genetically engineered products in the United States. AB is against the FDA's proposed rule change because they believe that their "one-size-fits-all" regulatory standards shouldn't be applied evenly to all GE products because of how different GE products can be. AB understands that the FDA has an obligation to educate consumers and help them avoid taking risks with their

health. However, AB argues that the FDA's proposed alteration to the definition of "DNA Alteration" gives them too much power over GE firms. AB believes that editing this phrase will give the FDA power to call *any* genetic modification innately hazardous, which will further damage the reputation of the industry (Stotish, 2017). AB continues, stating that any further edits to the guidance would not only be inconsistent with Congress' original intent of the New Animal Drug Applications (NADA), but would also worsen human and environmental welfare. AB advises that the FDA ought to continue accepting public comments to help reduce the regulatory burden on the GE industry.

CSPI's comment takes a protectionist approach, arguing that the FDA's proposed regulation will make it difficult for public intervention. CSPI also uses its comment to argue that there are way too many gray areas within the text of the guidance itself, which will confuse many consumers and also cause too much regulatory burden on GE firms. According to the CSPI, the FDA's edits will not adequately address the consumers' needs for transparency or public participation throughout the testing process (Jaffe, 2008). Both the FDA and the CSPI recognize the need for oversight in the GE industry because of how quickly animal products are moving towards commercialization. As it becomes easier and cheaper to create GE animal products, the need for health and safety regulations on those animals becomes ever more necessary.

Lastly, the GWRSC disagrees with the FDA's proposed analysis because of how uncomprehensive it is – their worry stems from the fact that GFI 187 has little scientific basis and will do very little to protect consumers. The GWRSC's comment adopts an immediately unfavorable tone with the proposed regulation, stating that the *existing* policy surrounding GE animals, (modeled after a previous policy), was incredibly outdated and had failed miserably at its job of protecting consumer safety (Lutter and Lewis, 2017). The GWRSC agrees with AquaBounty, stating that the danger of a "one-size-fits-all" approach will be insufficient for future iterations of genetic testing, but also adds the fact that the regulation seems to have no scientific reasoning. A lack of statistical data, econometric conclusions, or *any* quantitative data leads the GWRSC to believe that the document is underdeveloped and unfit for regulatory purposes.

FINAL RECOMMENDATION

We have analyzed the comments left by hundreds of concerned citizens, government agencies, and firms, and reached the conclusion that the FDA's recommendation is too vague and qualitative to achieve any substantial progress in increasing consumer safety. The comments left by the GWRSC, CSPI, and AB have proven that GE products, although contentious, have the power to provide much needed help to producers and consumers economically and personally. AB's criticism of the "one-size-fits-all" generalization approach to GE regulation matches well with CSPI's argument that the guidance causes an undue burden to consumers and producers alike. We want to echo the words of the GWRSC, and offer the suggestion that the FDA ought to utilize a cost-benefit analysis of its review on animal products, and then quantify an amount of risk that might be reduced if achieved. This information will help the general public decide if accepting the benefit of reducing certain health risks is worth the cost of implementing a new set of regulatory standards. We believe that ignoring the FDA's proposal will still allow the FDA to

be at the widely-accepted heuristic of the *one-in-one million* safety standard. Allowing the FDA to adopt the proposed standards will do virtually nothing to reduce the already low-risk activity of accepting GE products. While it is necessary for the FDA to continue to look out for consumer safety in the agricultural and meat-processing industries, we will refuse to accept any recommendations that exclude industry-specific terminology and the ability to accept public insight.

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