UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR BIO-INTEGRITY,

et al.

Plaintiffs,

v. Docket No. 98-1300(CKK)

DONNA SHALALA,

et al.

Defendants.

PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS

CROSS-MOTION FOR SUMMARY JUDGMENT ON ALL COUNTS

Introduction

In this case, the plaintiffs challenge the Food and Drug Administration's (FDA) actions in creating a regulatory system that allows for the marketing of an unlimited number of genetically engineered foods without premarket safety testing or labeling [1]. See 57 Fed. Reg. 22984 (May 29, 1992). The plaintiffs maintain that, in taking these actions, FDA has violated, *inter alia*, the Administrative Procedure Act (APA), 5 U.S.C. § 551, *et seq.*, the National Environmental Policy Act (NEPA), 42 U.S.C. § 4321, *et seq.*, the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 301, *et seq*., and the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb, *et seq*. In promulgating each of the above named statutes, Congress was cognizant of what this Circuit has called "the unrepresentative nature of an administrative agency."[2] Therefore, these laws, in whole

or in part, are designed to ensure continued public participation and scientific input in potentially "unrepresentative" agency decision-making processes. Throughout the promulgation and application of their 1992 regulation [3] on genetically engineered foods, the agency has demonstrated a consistent and regrettable pattern of violating these statutes and thereby insulating their decision making from public accountability and from the public participation and scientific input (both in and outside the agency) required by those laws.

At the outset, the agency published a proposed rule and a request for comments which they now claim are exempt from the APA's notice and comment rulemaking. By claiming this exemption, the agency attempts to shield itself from its illegal action of not meaningfully responding through a final rule to the thousands of negative comments they received. Without a doubt, not responding to these comments was more convenient for the agency and the regulated industry; the defendants, however, have therefore egregiously violated the purpose and requirements of the APA.

Next, acting against the detailed NEPA instructions of its own scientific staff [4] and its prior regulations, [5] the agency declared that its action was "categorically excluded" from NEPA. This illegal action effectively blocked the notice and comment and other relevant public and scientific participation in agency decision making which is the basis of the NEPA review process for major federal actions. This meant that the agency did not ensure that it was as informed as possible about human health or environmental impacts of its actions prior to coming to a decision, which is precisely the principal purpose of NEPA.

Moreover, in its rule, the agency summarily granted "generally recognized as safe" (GRAS) status to genetically engineered foods, which allowed for the commercialization of such foods without premarket safety testing. They granted this GRAS status despite the scientific views of many of the agency's own experts and those of numerous scientists outside the agency who had commented on the rule. The agency thus failed to seek out, or find, the consensus on this issue legally required by the FFDCA and the agency's own regulations. Finally, the agency did not reach out to the religious community on this sensitive issue to ensure that their regulation did not adversely impact the free expression of various religious denominations and beliefs. Consequently, the defendants have violated RFRA and the constitutional protection for religious Free Exercise.

The defendants, apparently unable to resist ad hominem arguments, have accused the plaintiffs of filing this case for a number of unsavory purposes, including "fear mongering." See Defs' Opp. at 1. They also make seemingly innumerable claims of agency discretion for their decision making due to this case's purportedly "complex scientific" nature. In reality, the plaintiffs are not driven by any nefarious purpose. As noted, they merely seek the Court's redressing of the agency's actions in illegally shutting out the scientific and public input from their decision making. The majority of the plaintiffs' claims do not involve complex science, but rather involve clear questions of law and fact which have been reviewed by numerous courts in similar circumstances. For example, as an initial step in addressing the agency's illegal action, the plaintiffs ask the

court to hold that the 1992 regulation is a substantive rule and to remand it back to the agency for timely and full compliance with the APA's notice and comment regulations. They also seek the Court's ruling that this is a major federal action required to undergo the full public and scientific input mandated by NEPA. The plaintiffs further ask the court to arrive at the factual conclusion that, given the extraordinary difference of scientific opinion about the safety of the new components in these genetically engineered foods, the agency did not have the legally required scientific consensus to declare them to be GRAS. It is important to emphasize that neither the plaintiffs nor the Court bears the burden of arriving at the scientific conclusion that these foods are unsafe or dangerous. The Court merely must look at the obvious scientific controversy over these foods and conclude that the agency has failed to meet its burden to establish that it had obtained a scientific consensus on the safety of these foods.

Similarly, the plaintiffs ask the Court to remand the labeling decision back to the agency and order them to require appropriate labeling under RFRA and the First Amendment so that individuals from a number denominations and beliefs can avoid these foods and thereby fully practice their religions. No complex science is required for this decision. Admittedly, the request by the plaintiffs that the Court remand the rule back to the agency with a finding that the new genes, promoters, vector and antibiotic marker systems are "material" for purposes of labeling under the FFDCA is more scientific in nature. However, the Court need only determine that the genetically engineered changes alter the physical or functional properties of the food and affirm that information about such changes is information that the reasonable person wishes to have [6].

In sum, the defendants issued a substantive rule allowing the unfettered marketing of untested, unlabeled genetically engineered foods that is 1) in violation of the APA's notice and comment procedures; 2) illegally excluded from NEPA review; 3) devoid of the scientific consensus legally necessary to determine that genetically engineered foods are GRAS; 4) without labeling that reveals material facts to the reasonable consumer; and 5) unduly burdensome to numerous individuals' free exercise of religion. Accordingly, the defendants' actions are arbitrary, capricious, an abuse of discretion, and not in accordance with law, and the plaintiffs are entitled to summary judgment on all counts.

Argument

I. PROMULGATION OF THE 1992 RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT (APA).

When an agency promulgates a substantive rule, the Administrative Procedure Act ("APA") requires that , *inter alia*, it 1) issue a public notice of proposed rulemaking describing the substance of the proposed rule; 2) offer the public an opportunity to submit written comments; and 3) publish a final rule which meaningfully responds to such comments and states the basis and purpose of the rule. 5 U.S.C. §553 (b),(c),(d). It is

undisputed that the defendants in promulgating the 1992 Rule ran roughshod over these requirements, including, among other violations, misrepresenting this proposed rule as a "statement of policy," and twice soliciting comments (resulting in the submission of thousands of comments) and then failing to respond to those comments through the issuance of a final rule. The defendants defend their violations of the APA by claiming that the 1992 Rule is either a "general statement of policy" or an "interpretive rule," or perhaps both, and thus is exempt from the notice and comment rulemaking requirements under the APA. Defs.' Opp. at 2-14.

A. The Defendants Fail to Show "Good Cause" or "Need" For Their Violations of the APA.

The APA requirements violated by the defendants embody an important policy objective. They are designed to ensure public participation in agency decision making that affects the public interest [7]. Chamber of Commerce of the United States v. Department of Labor, 174 F.3d 206, 211 (1999). Given the important public policy objectives of the APA, courts have narrowly and cautiously applied the exceptions claimed by the defendants. See American Hosp. v. Bowen, 834 F.2d 1037, 1044 (D.C.Cir. 1987). This Circuit has specifically held that exemptions should be recognized only where the requirement for public participation is overcome by "good cause" or where the "need is too small to warrant" public participation. Batterton v. Marshall, 648 F. 2d 694, 704 (1980); See also Chamber of Commerce, 174 F.3d at 211(". . . we apply §553 (b)(3)(A) with an eye toward balancing the need for public participation in agency decisionmaking with the agency's competing interest in 'retaining latitude in organizing [its] internal operations."). The defendants make numerous semantic arguments about why the 1992 Rule should not be subject to APA notice and comment requirements. However, they do not adequately address the public interest balancing test articulated by this Circuit. See Batterton, 648 F. 2d at 703 ("Analysis that improves upon semantic play must focus on the underlying purposes of the procedural requirements at issue.").

The defendants also make no showing whatever of "good cause" as to why they violated the APA. More specifically, they give no explanation for why they twice called for comments and then never even responded to the thousands which were submitted, or why they never published a final rule that meaningfully responded to the comments they received. In weighing the need for a substantive rule, this Circuit has recently emphasized the importance of agency responsiveness to public comments, especially in cases such as the current one in which agency decisions which have a significant effect on the public. See Chamber of Commerce, 174 F. 3d at 212 (". . . [agency action] will affect the safety practices of thousands of employers. The value of ensuring that the [agency] is well-informed and responsive to public comments before it adopts a policy is therefore considerable.")(emphasis added).

The defendants have also failed to make a colorable argument that the need for public involvement in the issue of the regulation of genetically engineered foods was "too small" to warrant compliance with APA requirements. See Batterton, 648 F. 2d at 704. Far from being "too small," it is difficult to imagine a scenario in which the need for the APA's "underlying purpose" of public participation in agency decision making would be greater than in the current case. Although the agency now minimizes the rule as merely a discretionary "general statement of policy," thousands of commenters -- consumers, scientists and public interest organizations -- understood the significance and function of the 1992 Rule. See Defs.' Opp. at 2. They understood that the rule allowed genetically engineered foods into the marketplace without labeling and pre-market safety testing, and, through their comments to the agency, opposed such a rule. Pls.' Mot. 45-46, 53-54; A.R. at 19591, 19593. The agency denied these thousands of commentors the APA required consideration of their views, and let the 1992 Rule stand as a new regulatory system for genetically engineered foods. As a result of the agency's refusal to meaningfully respond to public comments in a final rule, millions of American consumers are being denied a choice in deciding whether to purchase or consume genetically engineered foods, a choice that polls show the public overwhelmingly wants. They are also being denied the protection of mandatory premarket safety testing for such foods.

In sum, the defendants have failed to apply the proper balancing test articulated by this Circuit for allowing exemptions to the APA. They denied the public its APA-mandated role in agency decison making and have shown neither "good cause" for doing so nor that the the need was somehow "too small" to warrant the public's participation in their decision making.

B. The 1992 Rule is a Substantive Rule That Makes Dispositive Findings and Creates Binding Norms.

Throughout their opposition, the defendants continue to mischaracterize their 1992 Rule as a mere "general statement of policy" or "interpretive rule." Defs.' Opp. at 2. In unsuccessfully attempting to fit their broad regulatory system for genetically engineered foods into these narrow exemptions to APA rulemaking, the defendants rely heavily on their own characterization of the rule as a "statement of policy," and on several passages in the rule that are framed in precatory or permissive language. See Defs.' Opp. at 5-10. However, the agency's characterization of the 1992 Rule, and the rule's admittedly often obfuscatory language, are an insufficient basis for the defendants' claim. Courts routinely "look behind the particular label applied by the agency to challenged action in order to discern its real intent and effect." Batterton , 648 F. 2d at 705. Further, this Circuit has been wary of purported "policy statements" that are really "rules in masquerade" and which are designed to avoid public participation in agency decision making as mandated by the APA. See United States Tel. Ass'n v. FCC, 28 F. 3rd 1232, 1234, 1235 (D.C. Cir. 1994). The function of the rule, not 'the clothing it wore" is the deciding factor as to whether it is a substantive rule. Id. As recently summarized by this Circuit, the question of whether a rule is substantive or not is a "functional not formal" question. Chamber of Commerce, 174 F.3d at 212.

1. The 1992 Rule Has a Practical Effect.

Under this standard, the central focus of judicial review is a rule's practical effect, not its formal characteristics. Id. If a rule "grants rights, imposes obligations, or produces significant effects on private interests," then these practical effects make it a substantive rule. American Hosp., 834 F. 2d at 1047. When finally addressing the functional nature of the 1992 Rule, the defendants claim that the 1992 Rule is not a substantive policy because "it creates no 'binding' norms of any kind, nor does it make dispositive scientific findings." Defs.' Opp. at 2. The defendants are wrong. The 1992 Rule makes numerous scientific findings and creates binding norms, including determining the GRAS and labeling status of genetically engineered foods. As such, it is, and functions as, a substantive rule rather than as a general statement of policy or interpretive rule. Id. Moreover, as will be discussed *infra*, the 1992 Rule further functions as a substantive rule because it effectively amends a prior legislative rule, namely FDA's own regulations requiring that GRAS determinations be accomplished solely through notice and comment rulemaking. American Mining, 995 F.2d at 1112 (noting that a rule is a substantive rule if it effectively amends a prior legislative rule).

In granting unilateral GRAS status to food additives in genetically engineered foods, the 1992 Rule made both dispositive scientific findings and created regulatory norms which have affected, and continue to affect, food producers and the public. It is undisputed that the range of genetic material, and therefore the expression products, that can be introduced into foods through genetic engineering now and in the future is almost infinite. See FDA Docket No. 90A-0416. Nevertheless, the 1992 Rule makes the broad and dispositive finding that this "almost infinite" number of food additives that can be added to genetically engineered foods "do not raise a safety concern as a component of food." 57 Fed. Reg. at 22990. Based on this dispositive (even if completely unfounded) finding, the 1992 Rule then creates in the very next sentence a regulatory norm: "In regulatory terms, such material is presumed to be GRAS." Id. Contrary to the defendants' claim that the 1992 Rule contains no dispositive findings and creates no rules, it is difficult to imagine a more compelling example of a dispositive finding and resulting norm. This provision, which grants producers of genetically engineered foods the right to market their food under an unprecedented blanket GRAS affirmation and denies the public this important pre-market protection, demonstrates that the 1992 Rule is a substantive rule which grants rights and "produces significant effects on private interest." American Hosp. Ass'n, 834 F. 2d at 1047.

Similarly, in determining whether genetically engineered foods should be labeled, the 1992 Rule also makes multiple dispositive findings on the "materiality" of the changes in genetically engineered foods:

[F]DA believes that the new [genetic engineering] techniques are an extension at the molecular level of traditional methods and will be used to achieve the same goals as traditional plant breeding. The agency is not aware of any information showing that . . . . as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." 57 Fed. Reg. at 22991.