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' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TODISMISS OR, ALTERNATIVELY, FOR SUMMARY JUDGMENT

Introduction

Plaintiffs filed this case challenging FDA's actions on genetically engineered foods on May 27, 1998. The complaint was amended on July 24, 1998, and again on September 14, 1998. On September 28, 1998, defendants filed their Answer to Plaintiffs' 2nd Amended Complaint. The parties filed cross-motions for summary judgment on June 1, 1999. Plaintiffs now file their Opposition to Defendants' Motion to Dismiss Or, Alternatively, for Summary Judgment.

In their Motion, defendants claim that their actions on genetically engineered foods fall within agency discretion and are subject only to deferential review by this Court. Defs.' Mot. to Dismiss Or, Alternatively, for Summ. J. (Defs' Mot.) at 2. Defendants also assert that their actions do not substantially burden religious beliefs and therefore do not violate the First Amendment or the Religious Freedom Restoration Act (RFRA), nor should their actions be subject to analysis under the National Environmental Policy Act (NEPA). Id.

As plaintiffs demonstrate below, defendants' claims are misinformed and without legal basis.

From the outset, defendants have misunderstood the effect of their "Statement of Policy: Foods Derived From New Plant Varieties," 57 Fed. Reg. 22984 (May 29, 1992) (1992 Policy). Although this policy grants significant rights to the industry, substantially reduces the agency's discretion, and has palpable effects on the industry and the public, defendants continue to make the legally inconsistent claim that it is exempt from the APA's notice and comment provisions. It is undisputed that defendants failed to comply with these provisions, including the failure to answer thousands of public comments demanding premarket safety testing and labeling of genetically engineered foods. Defs.' 2nd Amend. Ans. ¶ 121. Defendants also promulgated the 1992 Policy without performing the necessary NEPA analysis, despite the fact that their own scientists had outlined the need for extensive environmental and human health analysis under NEPA. This violation of NEPA allowed defendants to continue to implement their policy without the required input and oversight of the public and policy makers. Defs.' 2nd Amend. Ans. ¶¶ 128, 157. Defendants also failed to observe the applicable requirements of the Federal Food, Drug and Cosmetic Act (FFDCA) and the agency's own regulations in deciding without the necessary scientific evidence that the novel materials inserted into plants through genetic engineering and the expression products resulting therefrom were "generally recognized as safe" (GRAS). Further, defendants failed to require the labeling of foods developed through genetic engineering, even though such foods have been materially changed from their conventionally produced counterparts and despite the countless requests from commenters who want to avoid being unknowingly exposed to foods that they deem religiously objectionable.

Standard of Review

A. Motion to Dismiss

When considering a motion to dismiss, "the Court accepts as true the factual allegations of the complaint and draws from them all reasonable inferences favorable to the plaintiff."United Parcel Serv., Inc. v. International Bhd. Of Teamsters , 859 F. Supp. 590, 593 (D.D.C. 1994). The plaintiff's complaint must also be read liberally, Dixon v. Ford, 1997 Dist. Lexis 263, *7 (D.D.C. 1997), and the plaintiff "must be given every favorable inference that may be drawn from his allegations of fact." Washington Legal Found. v. Kessler, 880 F. Supp. 26, 31 (D.D.C. 1995). Dismissal is not granted if the court finds that any of the facts in support of plaintiff's claim would entitle the plaintiff to relief. Id.

B. Motion for Summary Judgment

Under Fed. R. Civ. P. 56(c), summary judgment is properly granted if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of

law. In resolving a summary judgment motion, all reasonable inferences that can be drawn from the facts placed before the Court must be drawn in favor of the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). The non-moving party can defeat a motion for summary judgment by responding with some factual showing to create a genuine issue of material fact. Harding v. Gray, 9 F.3d 150, 154 (D.C. Cir. 1993). The non-movant will meet this burden of showing that a dispute about material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Laningham v. Dep't of the Navy, 813 F.2d 1236, 1241 (D.C. Cir. 1987) (per curiam) (citing Anderson, *supra*).

Argument

- **COUNT I (D): Defendants' 1992 Policy Required Notice and Comment Rulemaking**

Defendants contend that their 1992 Policy was not a substantive rule requiring an APA notice and comment rulemaking under 5 U.S.C. § 551, et seq. More specifically, they assert that the 1992 Policy is either a general statement of policy or an interpretative rule and falls under one or both of the two exceptions to APA's rulemaking requirements. 5 U.S.C. § 553(b)(A); Defs' Mot. at 10. Congress intended the exceptions now claimed by defendants to be "narrow ones." American Hosp. v. Brown, 834 F.2d 1037, 1044 (D.C. Cir. 1987).[(1)] Here, the 1992 Policy's content, the agency's own admissions, and the manner in which the rule has been applied demonstrate that it does not fit either of the two narrow exceptions claimed by defendants, but rather is a substantive rule subject to the APA notice and comment requirements.

A. The 1992 Policy is Not a General Statement of Policy

In prior pleadings, defendants have made the contradictory assertion that the 1992 Policy is both "an interpretive rule and a statement of policy." See Pls.' Mot. for Summ. J. ("Pls.' Mot.") at 11, 12.[(2)] In their Memorandum, defendants now make the misguided claim that the 1992 Policy is a general policy statement. Defs'. Mot. at 10.

This Circuit has established a two-prong test for determining whether an agency action is a statement of policy or substantive rule. Pls'. Mot. at 12-13 and cases cited thereto. Defendants do not address the first prong of this test, namely, that a policy statement may not create "any rights or obligations" on those regulated. Troy Corp. v. Browner, 120

F.3d 277, 287 (D.C. Cir. 1997). Here, the producers of genetically engineered foods have been officially granted the right to market their foods without premarket safety testing or labeling a right that they would not have had but for the findings and rulings in the 1992 Policy. Under this prong alone, the 1992 Policy is revealed to be a rule which binds the agency. Id.

Defendants do address the second prong of this Circuit's test, however, which asks whether a policy statement leaves an agency and its decision makers "free to exercise discretion." Troy Corp. 120 F.3d at 286. Defendants concede that the 1992 Policy makes a finding and a subsequent "presumption" that substances introduced into genetically engineered foods are GRAS, a finding that would constitute a substantive rule. Defs.' Mot. at 10-11. However, defendants allege that this GRAS finding is in reality a "rebuttable" presumption that the agency will reexamine on a case-by-case basis for each genetically engineered food. Defs'. Mot. at 11. They further allege that this case-by-case regulatory review of each genetically engineered food constitutes discretion required of a non binding statement of policy. Id.,citing , *inter alia*, Panhandle Producers and Royalty Owner's Ass'n v. Economic Regulatory Admin, 822 F.2d 1105, 1111 (D.C. Cir. 1987).

This assertion of legal discretion is, however, little more than a ruse. In reality, the 1992 Policy leaves the agency with no legally binding discretion about the unilateral granting of GRAS for substances in genetically engineered foods or, for that matter, about the agency's decision not to require food additive review. Far from mandating a case-by-case review, the 1992 Policy only suggests to producers of genetically engineered foods that they may engage in an informal, completely voluntary consultation process with the agency if the producers so choose. The 1992 Policy concedes that "such consultations are not legally required." 57 Fed. Reg. 22984, 22989. The unilateral granting of GRAS certification to substances in genetically engineered food is therefore not legally rebuttable by the agency on a case-by-case basis, but rather may be examined solely at the voluntary request of food producers. Given that defendants only review genetically engineered foods at the discretion of producers, dozens or even hundreds of genetically engineered foods could be, and may currently be, marketed without the agency even knowing of such foods, much less examining their GRAS status on a case-by-case basis. This voluntary, informal consultation process is clearly distinguishable from the discretion involved in the mandatory case-by-case regulatory system evident in Panhandler and the other cases cited by defendants. Defs' Mot. at 11.

Defendants confirmed the complete abdication of their discretion to impose premarket safety testing on genetically engineered foods in a 1995 communication with the government of Canada. There, they admitted that under the "U.S. system" of regulation for genetically engineered foods, including the unilateral granting of GRAS certification, producers can market their genetically engineered products at "at any time" without even notifying FDA. A.R. at 37659. In these cases, they would only be subject to postmarket regulation if the foods later cause illness or other problems. Id. This regulatory decision, in addition to the consistent approval by the agency of dozens of genetically engineered foods subsequent to 1992, reveal that the agency has removed all legally mandated § 409

premarket approval for genetically engineered foods, in and instead will rely solely on § 402(a)(1) post-market enforcement.

Therefore, the 1992 Policy fails as a statement of policy under both prongs of this Circuit's tests. It grants significant and unprecedented rights to the regulated industry, and retains for FDA no legally cognizable discretion to alter those rights on a mandated case-by-case basis.

B. The 1992 Policy Is Not An Interpretive Rule.

Defendants also make the somewhat contradictory claim that their 1992 Policy is an interpretive rule. Defs. Mot. at 12 (citing Truckers United for Safety v. Federal Highway Admin., 139 F.3d 934 (D.C. Cir. 1998)). They then wrongly assert that the 1992 Policy survives scrutiny as an interpretive rule under the American Mining test. Id., citing American Mining Congress v. MIne Safety and Health Admin., 995 F.2d 1106 (D.C. Cir. 1993). This test requires a finding that a rule is substantive if it alters an agency's statutorily granted ability for enforcement or alters other agency action involving the conferring of benefits or ensuring the performance of duties." American Mining 995 F.2d at 1108-12. As this Circuit later explained, this factor is "another way of asking whether the disputed rule really adds content to the governing legal norms." Syncor Int'l., 127 F.3d at 96.

Examined in this light, it is clear that, in the 1992 Policy, defendants altered-indeed abdicated-their enforcement powers with regard to premarket safety testing of genetically engineered foods and the labeling of such foods. As discussed *supra*, subsequent to the 1992 Policy, FDA cannot ensure that the requirements of the FFDCA are met because it effectively abandoned its authority to monitor and approve genetically engineered foods before they are introduced into commerce. Because the 1992 Policy profoundly alters the manner in which the agency enforces and ensures performance of duties under § 409 and other regulatory provisios including those involving labeling, it is a substantive rule under the threshold prong of the American Mining test.

Defendants also attempt to distinguish the line of cases that establish that a legislative action such as the 1992 Policy is a substantive rule. Defs.' Mot. at 12, n. 4. Defendants argue that this Circuit's decision in Syncor Int'l is limited to circumstances in which the agency causes a significant change in past enforcement practice. Id. As a case directly on point, Syncor Int'l shows that defendants are in error. In that case, plaintiffs Syncor International Corporation and others sued FDA and the Department of Health and Human Services for failing to promulgate their 1995 Nuclear Pharmacy Guideline through a notice and comment rulemaking. Id. As in the present case, defendants claimed that the Guideline was merely a general statement of policy on enforcement and an interpretive rule. Syncor Int'l., 127 F.3d at 93. The Court explained that, in the case of interpretive rules:

The legal norm is one that Congress has devised; the agency does not purport to modify that norm, in other words, to engage in lawmaking. . . . That is why we have said that 'the

distinction between an interpretative rule and substantive rule . . . likely turns on how tightly the agency's interpretation is drawn linguistically from the actual language of the statute.' Syncor Int'l., 127 F.3d at 94, citing Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579, 588, n.6 (1997).

This is precisely the situation at hand. The intent and effect of defendants' 1992 Policy was to replace the statutory presumption that a food additive is unsafe unless tested or shown to be GRAS with a unilateral agency finding that the numerous GE derived substances introduced into foods now and in the future "are presumed to be GRAS."[(3)] Defs.' Mot.at 10-11. Defendants' actions are tantamount to lawmaking and thus require notice and comment rulemaking.

The Syncor Int'l. court also explained that the Guideline was a substantive rule because it "drew a boundary to the agency's regulatory reach." Id. at 96. Defendants have limited their discretion with the 1992 Policy because they no longer have any premarket control over the safety of genetically engineered foods and their ingredients.

Defendants also attempt to distinguish the instant case from this Circuit's per curiam holding that FDA's action levels for unavoidable food contaminants were substantive rules. Community Nutrition Inst. v. Young, 818 F.2d 943 (D.C. Cir. 1987). Once again, FDA claimed that it had issued nothing more than "nonbinding statements of agency enforcement policy" that "do not bind courts, food producers or the FDA." Id. at 945-6. There, as here, plaintiffs countered that FDA's actions "restrict enforcement discretion to such a degree as to constitute legislative rules." Id. The effect of the 1992 Policy on genetically engineered foods is to limit the agency's discretion because, while the FFDCA provides two methods for the agency to ensure the safety of food additives-§ 409 premarket approval and § 402(a)(1) postmarket enforcement-the agency explicitly stated in its 1992 Policy that it would rely almost solely upon its § 402(a)(1) authority to address unsafe food additives:

If the producer begins to market the ingredient based on the producer's independent determination that the substance is GRAS and FDA subsequently concludes the substance is not GRAS, the agency can and will take enforcement action to stop distribution of the ingredient and foods containing it on the ground that such foods are or contain an unlawful food additive.[(4)] 57 Fed. Reg. at 22969.

After applying the test used in American Bus Assoc. v. United States, 627 F.2d 525 (D.C. Cir. 1975), the Community Nutrition court concluded that the FDA's policy statement was binding:

But the fact that action levels do not completely bind food producers as would a more classic legislative rule (where the only issue before the court would be if the agency rule were in fact violated) is not determinative of the issue. For here, we are convinced that FDA has bound itself. . . And this type of cabining of an agency's prosecutorial discretion can in fact rise to the level of a substantive, legislative rule."[(5)] Community Nutrition, 818 F.2d at 948.

C. The 1992 Policy is a Substantive Rule

Courts have consistently found that when rules have "palpable effects on the regulated industry and the public" they are not interpretive rules, but rather are substantive rules requiring notice and comment. Natural Resources Defense Council v. EPA, 683 F.2d 752, 762 (3rd Cir. 1982). This common sense approach underscores the policy objectives of the APA which are to ensure full analysis and critique by interested parties and the agency on regulations which affect industry and the public. American Medical Ass'n v. Reno, 57 F. 3d 1129, 1134 (D.C. Cir. 1995). The 1992 Policy has had "palpable effects on the regulated industry and the public in general" because, *inter alia*, it has made a finding that novel genetic material, viral vectors, promoters , antibiotic markers and other substances added to genetically engineered foods, now and in the future, are presumed to be GRAS and that all the various materials added to foods pursuant to genetic engineering are not "material" for purposes of requiring labeling. See generally 57 Fed. Reg. 22984. The palpable effect of the 1992 rule on the industry is that it has been freed to introduce into commerce dozens of genetically engineered foods without mandatory pre-market safety testing or labeling. The palpable effect of the rule on the public is that they are unknowingly consuming unlabeled genetically engineered foods that have not been subject to mandatory safety testing by regulators, even though over 80% of the public desire such testing and/or labeling and thousands have communicated this desire to the agency. Pls.' Mot. at 52.

In addition, defendants' own statements further indicate that the 1992 policy is substantive. In 1992, FDA Commissioner David Kessler characterized the 1992 Policy as establishing a "standard of care to help plant developers ensure that the products they develop meet safety standards of the [FFDCA]." See Subcomm. on Agric, Rual Dev., FDA, and Related Agencies, 103d Cong (Apr. 20, 1993). In the same year, FDA Biotechnology Coordinator James Maryanski stated in an interview that the 1992 rule "establishes a standard of care" for those producing genetically engineered foods. Food and Drug Administration, Genetically Engineered Foods: Fears and Facts (1993) (visited June 21, 1999) <http://www.fda.gov/bbs/topics/consumer/cons00191.html>. The creation of such standards is a hallmark of substantive rules. Vietnam Veterans of America v. Secretary of the Navy, 843 F.2d 528, 537 (D.C.Cir. 1988) . Thus, the 1992 Policy is a substantive rule for which notice and comment is required. Defendants' failure to comply with these APA requirements renders the rule invalid.

II. Plaintiffs Challenge Defendants Construction and Implementation of the FFDCA, Not the Agency's Enforcement Discretion

As part of their attempt to shield the 1992 Policy from judicial review, defendants assert that the 1992 Policy is not reviewable by this Court because it is solely an "enforcement action" and not a substantive rule. Defs.' Mot. at 13-14. Defendants' attempt to transform the 1992 Policy from a regulatory rule to an ad hoc enforcement action completely mischaracterizes the issue at hand. Before enforcement discretion can even become an issue,the agency must determine its duties under the relevant authorizing statute, or statutes. In that process, the agency has discretion only to the extent that the statute is unclear or does not apply to a particular issue. When the intents of Congress is clear , "the court , as well as the agency must give effect" to that intent. Chevron U.S.A. Inc v. NRDC, 467 U.S. 837, 842-43 (1984).

In this case, the duties of the agency under the FFDCA, APA, NEPA and RIFRA are clear. As fully described in plaintiffs Memorandum in Support of Summary Judgement and in the current Opposition, plaintiffs maintain that in promulgating the 19