IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	No. C 10-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

DEFENDANTS' REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs' Brief in Support of Resistance to Defendants' Revised Motion to Dismiss and Motion for Summary Judgment ("Resistance") (DR[1] 61) neither identifies any genuine issue of material fact nor shows that defendants are not entitled to judgment as a matter of law. In this Reply, defendants respond to the only issue unique to plaintiffs' Resistance: application of the statute of limitations, 28 U.S.C. § 2401(a).[2]

First, plaintiffs are clearly not bringing an "as-applied" challenge to the Regulations. In their Motion for Summary Judgment, defendants established that plaintiff Wagoner, the only plaintiff to even claim to have been subject to the application of the PHSA Regulation, relied solely on conclusory allegations that were rebutted by

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[1] "DR" refers to the docket report.

[2] Virtually all of plaintiffs' arguments in the Resistance were also raised in their contemporaneously-filed Motion For Summary Judgment (DR 57). Defendants respond to all overlapping arguments in their Brief in Resistance to Plaintiffs' Motion for Summary Judgment ("Resistance Brief"), which is incorporated by reference herein.

the sworn testimony from FDA and the State of Georgia. *See* Defs.' Combined Br. (DR 50) at 19-21. Plaintiffs' Resistance fails to raise any genuine dispute that it was any agency other than the Georgia Department of Agriculture that brought an enforcement action against Mr. Wagoner in 2009. Mr. Wagoner's subjective belief — unsupported by any objective facts showing that he was the target of an FDA enforcement action — is not enough to overcome the sworn declarations from both FDA and Georgia to the contrary. *See Gallagher v. Magner*, 619 F.3d 823, 838 (8th Cir. 2010) ("[U]nsupported and conclusory allegations cannot defeat summary judgment."). Indeed, plaintiffs' assertions they are bringing a "pre-enforcement challenge" should settle any further argument over whether FDA has ever applied the regulations against them. *See* Pls.' Resist. at 8, 10. Plaintiffs' challenge is clearly a facial one.[3]

Second, plaintiffs' cases do *not* support the proposition a substantive challenge under the Administrative Procedure Act ("APA") can be raised at any time, but show rather that a rule may be challenged only within *six years of promulgation* (on procedural or substantive grounds) *or* within *six years of agency action* applying the rule to plaintiffs in particular (on substantive grounds). *See Functional Music, Inc. v. F.C.C.*, 274 F.2d 543, 546 (D.C. Cir. 1958) ("[T]he statutory time limit . . . does not foreclose subsequent examination of a rule where properly brought before this court for review of

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[3] In an effort to counter defendants' claim that plaintiffs are bringing a facial challenge to the regulations, plaintiffs state they are challenging FDA's "underlying legal authority to issue these rules in the first place." *See* Pls.' Resist. at 12. This characterization of their claims merely underscores that plaintiffs are bringing a classic *facial* challenge. *See, e.g.*, *Air Transport Ass'n v. Dep't of Trans.*, 613 F.3d 206, 216 (D.C. Cir. 2010) ("In a facial attack the [plaintiff] argues the DOT lacked authority to promulgate [the challenged regulation].") Plaintiffs are also plainly wrong in asserting that, merely because the law "applies" to them, they can bring an "as-applied" challenge. *See* Pls.' Resist. at 52.

further Commission action applying it.") (emphasis added); *NRDC v. Evans*, 232 F. Supp. 2d 1003, 1024 (N.D. Cal. 2002) ("Under *Wind River*, plaintiffs are time-barred from challenging the regulation itself, but are not time-barred from challenging *the application of that regulation to them . . . .*") (emphasis added); *Utu Utu Gwaitu Paiute Tribe of Benton Paiute Reservation v. Dep't of Interior*, 766 F. Supp. 842, 845-46 (E.D. Cal. 1991) (permitting a substantive as-applied challenge to a regulation regarding EAJA attorney's fees more than six years after regulation was promulgated, but *only after* an agency denied plaintiffs' application for attorney fees and expenses).

Plaintiffs' collection of cases under the Hobbs Act make the very same point. *See Public Citizen v. Nuclear Regulatory Com'n*, 901 F.2d 147, 149-53 (D.C. Cir. 1990) (allowing a challenge to an agency's original policy only after the agency reconsidered and republished an amended policy in the Federal Register); *Commonwealth Edison Co. v. U.S. Nuclear Regulatory Com'n*, 830 F.2d 610, 614 (7th Cir. 1987) ("[I]ndirect challenges to the rule brought *when the rule is applied* to a particular individual are within the court's jurisdiction.") (emphasis added); *Tri-State Motor Transit Co. v. Interstate Commerce Comm'n*, 739 F.2d 1373, 1374 (8th Cir. 1984) (allowing a challenge to the ICC's underlying policy statement only after the ICC granted unrestricted motor carrier operations to a competitor based on that policy); *State of Texas v. United States*, 730 F.2d 409, 415 (5th Cir. 1984) ("When an agency applies a previously adopted rule in a particular case, the Hobbs Act does not bar judicial review of the substance of the rule . . . .").

Third, plaintiffs are plainly wrong that *their own violations of the law* can toll the statute of limitations under the "continuing violations" doctrine. *See* Pls.' Resist. at 10-

11. Again, plaintiffs' own cases make clear that the statute of limitations in an APA challenge hinges upon the timing of final agency action and the date relief was sought, and not upon any continuing actions *by plaintiffs*. *See, e.g.*, *Izaak Walton League of Am., Inc. v. Kimbell*, 588 F.3d 751, 759 (8th Cir. 2009) (noting plaintiffs alleged the continuing violation was caused by the U.S. Forest Service's failure to implement quotas). Further, for a continuing violation theory to apply, "new overt acts must be more than the unabated inertial consequences of the initial violation." *Midwestern Mach. Co. v. Nw. Airlines, Inc.*, 392 F.3d 265, 270 (8th Cir. 2004).

Fourth, plaintiffs' argument that "FDA at no time cites to any case that holds the proscriptions of 28 U.S.C. 2401 apply to a declaratory judgment action" and "[c]onsequently, 28 U.S.C. 2401 cannot bar Plaintiff's claims,"[4] (Pls.' Resist. at 12-13), is demonstrably incorrect. *See* Defs.' Combined Br. at 13-14 (citing five declaratory judgment actions in which courts recognized 28 U.S.C. § 2401 applied). Declaratory judgment actions are as subject to the statute of limitations as any other form of action. Were this not true, the statute of limitations would become a nullity as plaintiffs would only have to seek a declaratory judgment to avoid the limitation.

Conclusion

For the reasons stated above, in defendants' motion for summary judgment, and in defendants' accompanying Resistance Brief, plaintiffs have not demonstrated any

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[4] Plaintiffs also cite the declaratory judgment action *Abbott Labs. v. Gardner*, 387 U.S. 136, 143 (1967). However, *Abbott Labs*. did not address § 2401, presumably because, unlike in the instant case, the district court challenge in *Abbott Labs* was filed, briefed, and decided within ten months of final promulgation of the rules in June 1963. *See Abbott Labs. v. Celebrezze*, 228 F. Supp. 855, 858 (D. Del. 1964).

genuine issue of material fact and defendants are entitled to judgment as a matter of law.

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CERTIFICATE OF SERVICE

I certify that I electronically served a copy of the foregoing document to which this certificate is attached to the parties or attorneys of record, shown below, on July 1, 2011.

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