UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, et al.,

Plaintiffs,

v.

MARGARET A. HAMBURG M.D.,

Defendant.
/

No. C 12-4529 PJH

ORDER RE CROSS-MOTIONS FOR SUMMARY JUDGMENT

The parties' cross-motions for summary judgment came on for hearing before this court on March 27, 2013. Plaintiffs appeared by their counsel George Kimbrell, and defendant appeared by her counsel Gerald Kell. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS plaintiffs' motion and DENIES defendant's motion as follows.

BACKGROUND

This is an action brought by plaintiffs Center for Food Safety and Center for Environmental Health against Margaret Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration ("FDA"), pursuant to the Administrative Procedures Act ("APA"), 5 U.S.C. § 551, et seq. Plaintiffs seek declaratory and injunctive relief regarding the failure of the FDA to promulgate final regulations by mandatory deadlines contained in the FDA Food Safety and Modernization Act of 2010 ("FSMA"), Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of 21 U.S.C. § 301 et seq., as amended).[1]

[1] The complaint also asserted claims against Jeffrey Zients, Acting Director of the Office of Management and Budget ("OMB"). Those claims were dismissed on January 14, 2013, pursuant to stipulation of the parties.

Congress enacted the FSMA – which was signed into law on January 4, 2011 – to modernize food safety laws and regulations by mandating science-based standards and controls; by providing the FDA with greater authority to prevent and address food safety hazards by taking steps to prevent them from occurring; by strengthening the FDA's inspection and enforcement powers; and by improving coordination among federal, state, and foreign food safety agencies. See H.R. Rep. No. 111-234 (2009) at 35-40.[2] To this end, Congress directed the FDA to promulgate new regulations in seven areas, within 18 months of the effective date of the FSMA.

The seven major food safety regulation areas, and the implementation dates listed in the legislation, are as follows:

(1) regulations with regard to establishing science-based minimum standards for conducting hazard analysis, documenting hazards, implementing preventing controls, and documenting implementation of preventive controls, as required by 21 U.S.C. § 350g(n)(1) (regulations to be promulgated "[n]ot later than 18 months after January 4, 2011" – or July 4, 2012);

(2) regulations with regard to (a) activities that constitute on-farm packing or holding of food not raised or consumed on such farm or another under the same ownership for purposes of § 415 of the Food, Drug, and Cosmetic Act; and (b) activities that constitute on-farm manufacturing or processing of food not consumed on that farm or on another farm under common ownership for purposes of § 415, as required by provision that the FDA must clarify activities included as part of definition of "facility," pursuant to 21 U.S.C. § 350d note ("notice of proposed rulemaking" to be published in Federal Register "[n]ot later than 9 months after date of enactment" – or by October 4, 2011 – with final rules to be adopted 9 months after close of comment period);

(3) regulations establishing science-based minimum standards for safe

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[2] H.R. Rep. No. 111-234 relates to the Food Safety Enhancement Act, which was passed by the House of Representatives on July 30, 2009. The FSMA, which was passed by the Senate and the House in December 2010, resulted from negotiations regarding the Senate version of the bill.

production and harvesting of fruits and vegetables, as required by 21 U.S.C. § 350h (notice of proposed final rulemaking to be published by January 4, 2012, with final regulation to be adopted within one year after close of final comment period);

(4) regulations to protect against intentional adulteration of food subject to FSMA, as required by 21 U.S.C. § 350i(b), in consultation with Secretary of Homeland Security and Secretary of Agriculture (regulations due "[n]ot later than 18 months after January 4, 2011" – or July 4, 2012);

(5) regulations regarding FDA requirement that shippers, carriers by motor vehicle or rail, receivers, and other persons engaged in transportation of food use sanitary transportation practices to ensure that food is not transported under conditions that might render it adulterated, as required by 21 U.S.C. § 350e(b) and note (regulations due by July 4, 2012);

(6) regulations regarding foreign supplier verification program, as required by 21 U.S.C. § 384a(c) (final regulations due by January 4, 2012);

(7) regulations ensuring the neutrality and independence of third-party audits, as required by 21 U.S.C. § 384d(c)(5)(C) (final regulations due by July 4, 2012).

In the complaint, which was filed on August 29, 2012, plaintiffs allege that certain proposed and final regulations have not been issued within the time frame set forth in the FSMA. Plaintiffs seek a judicial declaration that the FDA has violated the FMSA and the APA by failing to issue the regulations by the statutory deadlines, and continues to be in violation of the FMSA and the APA for failing to promulgate the regulations. Plaintiffs also seek an order ordering the FDA to issue the regulations as soon as reasonably possible, according to a court-ordered timeline. In addition, plaintiffs request that the court retain jurisdiction over the case to ensure compliance with the order.

Each side now seeks summary judgment. The issues to be decided are whether the FDA has "unlawfully withheld" or "unreasonably delayed" action in violation of the APA by failing to promulgate the FMSA regulations by the statutory deadlines, and whether the court must grant plaintiffs the relief they seek.

DISCUSSION

A. Legal Standard

A party may move for summary judgment on a "claim or defense" or "part of . . . a claim or defense." Fed. R. Civ. P. 56(a). Summary judgment is appropriate when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Id.

As a general matter, district courts are empowered by the APA to review agency action, and have federal question jurisdiction over such claims pursuant to 28 U.S.C. § 1331. For a court to review agency action pursuant to the APA, there must be "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. "Agency action" also includes a "failure to act." 5 U.S.C. § 551(13).

In a "failure to act" case, a court can "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). Judicial review is appropriate if the plaintiff makes a showing of "agency recalcitrance . . . in the face of clear statutory duty or . . . of such a magnitude that it amounts to an abdication of statutory responsibility." ONRC Action v. Bureau of Land Mgmt., 150 F.3d 1132, 1137 (9th Cir. 1998) (citation and quotation omitted).

In Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55 (2004), the Supreme Court explained that a "failure to act" within the meaning of the APA is the failure of the agency to issue an "agency rule, order, license, sanction or relief." Id. at 62. That is, judicial review of a failure to act under § 706(1) "is properly understood to be limited . . . to a discrete action" such as "the failure to promulgate a rule or take some decision by a statutory deadline." Id. at 63.

However, even discrete agency action cannot be compelled under § 706(1) unless that action is "demanded by law." Id. at 65. Statutory goals that are "mandatory as to the object to be achieved" but leave the agency with "discretion in deciding how to achieve" those goals are insufficient to support a "failure to act" claim because such discretionary actions are not "demanded by law." Id. at 66.

The sole remedy available under § 706(1) is for the court to "compel agency action," such as by issuing an order requiring the agency to act, without directing the substantive content of the decision. Thus, "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take." Id. at 64.

B. The Parties' Motions

The FDA regulates more than $400 billion worth of domestic and imported food and hundreds of thousands of registered food facilities. Its responsibilities in the food area generally cover almost all domestic and imported food (except for meat, poultry, eggs, tolerance for pesticide residues in food, and requirements for public drinking water). The FDA argues that the regulations that it was directed to promulgate under the FMSA are novel and complex, and the complexity is increased by the need to build a cohesive system of regulatory controls integrating different regions and countries, as well as different food types, and also coordinate with other regulations (such as regulations relating to small businesses) and other federal and state agencies.

The FDA contends that during the period that it has been working on the new regulations, it has also continued to monitor the food industry, and to exercise its pre-existing authority regarding food safety under the Federal Food, Drug, and Cosmetic Act (including responding to outbreaks of food-borne illnesses, developing non-FMSA related guidance documents and rulemaking, and overseeing the safety of imported foods as they enter the country).

To carry out this complex and difficult task, the FDA first established an implementation committee, which in turn established six implementation teams, with a number of working groups under those teams. The working groups were assigned the hands-on responsibility for developing the regulations, reports, guidance, and processes required by FMSA.

The FDA asserts that even with this organizational structure specifically directed at the expedited implementation of the FSMA, the aggressive timelines set forth in the statute

have proven to be unachievable. In addition, because promulgating the new regulations requires the participation and input of individuals with specific expertise – writers, subject matter experts, regulatory counsel, attorneys, economists, program managers, and operations specialists – and because the FDA employs only a limited number of such individuals (particularly those having the relevant subject matter expertise), the FDA has found it difficult to staff the simultaneous development of such a large number of major rules in the same general subject area.

For this reason, the FDA determined that it needed to prioritize, and decide which regulations to develop first. It initially selected four rules that would be in the "first wave" – Preventive Controls for Human Food; Produce Safety Standards; Foreign Supplier Verification Program; and Preventive Controls for Animal Food. These rules were selected because they are foundational for other rules and offer the most public health benefits. The rules placed in the "second wave" are Intentional Adulteration, Sanitary Transport, and Accredited Third Parties.

The FDA contends that it has been working diligently to develop the required regulations. Briefly, with regard to the "first wave," the FDA submitted draft proposed rules to OMB for review in November and December 2011. According to the FDA, the review process for all four rules is "ongoing." As for the "second wave," the FDA determined with regard to Intentional Adulteration that it would benefit for more information and ideas as to how to implement this novel requirement before engaging in rulemaking, and thus developed a draft Notice of Proposed Rulemaking which is currently undergoing review within the FDA. With regard to Sanitary Transport, the FDA asserts that it has developed draft codified and preamble language, which is currently undergoing review within the FDA. With regard to Accredited Third Parties, the FDA contends that it sent a draft proposed rule to OMB in November 2012, and review remains ongoing.

In addition, after the FDA filed the present motion, it issued two complex and major proposed rules – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," and "Standards for Growing, Harvesting,

Packing, and Holding of Produce for Human Consumption" – which set out extensive new proposals for preventing problems that can cause foodborne illness. The FDA asserts that these proposals are concrete steps taken to implement three of the seven statutory requirements identified in plaintiffs' complaint.

The FDA concedes that FMSA provides specific deadlines for the promulgation of the regulations, but argues that because the issue under the APA is whether it has "unreasonably delayed" in issuing the regulations, the matter that needs to be resolved is the reasonableness of the FDA's administrative timeline. The FDA asserts that it has responded to FMSA by making its implementation a top priority, but still has not been able to complete rules of such magnitude and complexity within the statute's timeframes.

The FDA agrees that these regulations are important to public health and safety, but argues that is just as important that any regulations that are promulgated be carefully developed, given the scope and magnitude of what is called for by the statute. The FDA argues that a particular administrative timetable should be evaluated under the six-factor test set forth in Telecommunications Res. & Action Ctr. v. F.C.C., 750 F.2d 78 (D.C. Cir. 1984) ("TRAC").[3]

In their motion, plaintiffs submit that the FSMA resulted from Congress' recognition of the prevalence and severity of the food-borne illness problem, and argue that it was because of the need to remedy this problem that Congress instructed the FDA to act quickly to promulgate the needed regulations. Plaintiffs contend that without regulations to give it effect, FMSA cannot reduce the dangers to consumers of food-borne illnesses. They contend that because the FDA has not complied with the statutory deadlines set by

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[3] Under the TRAC test, the court should consider (1) whether the time agencies take to make decisions is governed by a "rule of reason" that governs the analysis; (2) whether Congress provided a timetable in the statute; (3) whether the delays have more or less of an impact on human health and welfare (as opposed to simply having an impact in the area of economic regulation; (4) whether expediting agency action would have an effect on agency actions of a higher or competing priority; (5) the nature and extent of the interests prejudiced by the delay; and (6) whether there is any impropriety "lurking behind agency lassitude" (although such a finding is not essential to a determination that agency action has been unreasonably delayed). See id. at 80; see also cited in Brower v. Evans, 257 F.3d 1058, 1068 (9th Cir. 2001).

Congress, the issue under the APA is failure to act.

Plaintiffs disagree with the FDA's argument that the court should apply the TRAC balancing test to this case. They contend that the TRAC test applies only where the issue is whether a delay is unreasonable in the absence of express Congressional deadlines. Here, however, because Congress included mandatory deadlines in the FMSA, plaintiffs argue that the FDA cannot be excused for its per se violation of the law (failing to meet those deadlines).

Plaintiffs contend that the court should grant their motion as a matter of law because the FDA has failed to comply with the mandatory FMSA deadlines. Specifically, plaintiffs seek an order declaring that the FDA has not complied with the deadlines proscribed by FSMA; and compelling the FDA to promulgate and finalize the required regulations by dates certain – including issuing the rules, providing notice and opportunity for comment, and issuing final regulations.

Plaintiffs suggest that the court could either order the parties to stipulate to deadlines; or order the FDA to provide the court with "expedited dates," and then afford plaintiffs an opportunity to oppose the FDA's proposed deadlines. In addition, plaintiffs request that the court retain jurisdiction to ensure that the FDA complies with the court-mandated schedule, and to ensure that the FDA complies with additional upcoming FSMA deadlines.

The court finds that given that the FDA has admittedly failed to comply with the mandatory rulemaking schedule, declaratory relief is proper. As noted above, plaintiffs seek a judicial declaration that the FDA has violated the FMSA and the APA by failing to promulgate the FMSA regulations by the statutory deadlines. The FDA asserts that the court should evaluate this case under the TRAC factors, in order to determine whether it has violated the APA by unreasonably delaying the promulgation of the regulations. However, because the FMSA includes specific deadlines, the failure to comply with those deadlines constitutes a "failure to act" under the APA. See Forest Guardians v. Babbitt, 174 F.3d 1178, 1189-90 (10th Cir. 1999). Moreover, where Congress has specifically

provided a deadline for performance by an agency, "no balancing of factors is required or permitted." Biodiversity Legal Found. v. Badgley, 309 F.3d 1166, 1177-78 & n.11 (9th Cir. 2002).[4]

The question with regard to injunctive relief is less straightforward. Plaintiffs seek an order compelling the FDA to complete the rulemaking process by a date certain. That is, they contend that having found that the FDA has violated the FMSA and the APA by failing to complete the regulations by the statutory deadlines, the court is required to issue an order compelling the FDA to act.

The APA provides that a court "shall" compel unlawfully withheld agency action. See 5 U.S.C. § 706. The question is whether the court has any discretion in this regard. In Forest Guardians, the Tenth Circuit held that where a statute requires action by a date certain, and the plaintiffs proceed under § 706, the courts lack discretion not to grant injunctive relief. Id., 174 F.3d at 1190. However, in In re Barr Labs., Inc., the D.C. Circuit held that courts maintain discretion not to compel agency action even where deadlines are mandatory. Id., 930 F.2d 72, 74 (D.C. Cir.1991).

The Ninth Circuit addressed this issue in Biodiversity, concluding that "a statutory violation does not always lead to the automatic issuance of an injunction." Id., 309 F.3d at 1177. "[W]hen federal statutes are violated, the test for determining if equitable relief is appropriate is whether an injunction is necessary to effectuate the congressional purpose behind the statute." Id. The court looked at the Endangered Species Act (the statute at issue in the case) to determine whether equitable relief was proper, and found that it was, because effectuating Congress' clear intent of protecting endangered species required compelling compliance with the ESA.

Here, the parties are in agreement that the "purpose" of the FMSA is to protect human health by ensuring that the food supply is safe from contaminants. Plaintiffs contend that the regulations are essential to that purpose, and the FDA counters that the

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[4] The court appreciates the FDA's attempt to distinguish Biodiversity, but finds the Ninth Circuit's ruling to be unambiguous and its reasoning unassailable.

issuance of the required regulations on a rushed or hurried basis would not help protect human health and safety. Given that the parties are essentially in agreement as to the purpose of the FMSA, the question becomes whether the court should grant injunctive relief, and if so, what form that relief should take.

Beyond the evident purpose of the FMSA – to ensure the safety of the food supply – Congress also intended that the implementing regulations be promulgated and finalized by a date certain. The dates set for completion of the regulations in the seven areas identified in the complaint have passed. However, that does not mean that the FMSA now should be interpreted as granting the FDA total discretion in deciding when to finalize the regulations. While the FMSA vests the FDA with discretion regarding the substance of the mandated regulations, endless delay does not serve any purpose of the FMSA. At a minimum, it seems clear that by setting deadlines, Congress signaled its intention that the process be closed-ended, rather than open-ended. Thus, the court finds that imposition of an injunction imposing deadlines for finalization of the regulations would be consistent with the underlying purposes of the FMSA.

Nevertheless, the FDA is correct that the purpose of ensuring food safety will not be served by the issuance of regulations that are insufficiently considered, based on a timetable that is unconnected to the magnitude of the task set by Congress. The court issues the following order in the hope that the parties will themselves arrive at a mutually acceptable schedule. It will behoove the parties to attempt to cooperate on this endeavor, as any decision by the court will necessarily be arbitrary.

The parties are hereby ORDERED to meet and confer, and prepare a joint written statement setting forth proposed deadlines, in detail sufficient to form the basis of an injunction. The joint statement shall be submitted no later than May 20, 2013. After reviewing the statement, the court will determine whether any further written submissions would be helpful or necessary.

As for the request for discovery, the only disputed "facts" here relate to the question whether the FDA's delay was unreasonable. Given the ruling that the action is one to

compel agency action unlawfully withheld – not to compel agency action unreasonably delayed – and the fact that the court finds the TRAC factors inapplicable to that analysis, the question whether discovery should be permitted falls by the wayside.

CONCLUSION

In accordance with the foregoing, plaintiffs' motion for summary judgment is GRANTED and defendant's motion is DENIED. Plaintiffs' request for declaratory relief is GRANTED, and the court hereby declares that defendant has violated the FMSA and the APA by failing to promulgate the FSMA regulations by the statutory deadlines. Plaintiffs' request for injunctive relief is also GRANTED. The scope of such relief will be determined following the parties' May 20, 2013 submission or such other submissions as deemed warranted.

IT IS SO ORDERED.

Dated: April 22, 2013

PHYLLIS J. HAMILTON
United States District Judge