UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, et al.,

Plaintiffs,

v.

MARGARET A. HAMBURG, M.D.,

Defendant.
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No. C 12-4529 PJH

ORDER

Before the court is the motion of defendant Margaret A. Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration ("the FDA") for an order amending the order and judgment issued on June 21, 2013. Having read the parties' papers and carefully considered their arguments, the court hereby rules as follows.

Plaintiffs Center for Food Safety, and Center for Environmental Health brought this action against the FDA in August 2012, asserting claims for declaratory and injunctive relief, seeking to compel the FDA to issue regulations implementing the federal Food Safety Modernization Act ("FSMA"). When Congress enacted the FSMA, it included as part of the statute certain deadlines for promulgating regulations in seven specific areas. The FDA missed all the deadlines, although it has published proposed rules in four of the seven areas, and anticipates publishing a proposed rule in a fifth area in November 2013. On April 22, 2013, the court issued an order granting plaintiffs' motion for summary judgment and denying the FDA's motion. See Center for Food Safety v. Hamburg, __ F.Supp. 2d __, 2013 WL 1741816 (N.D. Cal. Apr. 22, 2013). The court granted plaintiffs' request for declaratory relief, and declared that the FDA had violated the FSMA and the APA by failing to promulgate the regulations by the statutory deadlines. The court also granted plaintiffs' request for injunctive relief, and ordered the parties to meet and confer, and to prepare a

joint written statement setting forth proposed deadlines, in detail sufficient to form the basis of an injunction. The parties were unable to reach agreement, and thus submitted competing proposals.

The court reviewed the proposals, and on June 21, 2013, issued an order granting injunctive relief. With regard to any regulations not yet been published in the Federal Register, the court ordered the FDA to publish all proposed regulations by November 30, 2013. The court directed that the close of the comment period would be no later than March 31, 2014, and that all final regulations would be published in the Federal Register no later than June 30, 2015. Also on June 21, 2013, the court issued a final judgment.

On July 19, 2013, the FDA filed a motion seeking reconsideration of the June 21, 2013 order as to two of the seven areas – intentional adulteration (or intentional contamination), and sanitary transport – or, in the alternative, an order staying the judgment as to those two areas pending a decision by the Solicitor General as to whether to authorize an appeal in this case.

Where, as here, a ruling has resulted in final judgment or order, a motion for reconsideration may be construed either as a motion to alter or amend judgment pursuant to Federal Rule of Civil Procedure 59(e), or as a motion for relief from judgment pursuant to Federal Rule 60(b). School Dist. No. 1J Multnomah County v. AC & S, Inc., 5 F.3d 1255, 1262 (9th Cir. 1993).

Rule 59(e) provides that any "motion to alter or amend a judgment shall be filed no later than 28 days after entry of the judgment." Because specific grounds are not listed in the Rule, the district court has considerable discretion in granting or denying the motion. Allstate Ins. Co. v. Herron, 634 F.3d 1101, 1111 (9th Cir. 2011). In general, a motion under Rule 59(e) "should not be granted, absent highly unusual circumstances, unless the district court is presented with newly discovered evidence, committed clear error, or if there is an intervening change in the controlling law." Herbst v. Cook, 260 F.3d 1039, 1044 (9th Cir. 2001) (citation and quotation omitted); see also Herron, 634 F.3d at 1111 (amending a judgment may be appropriate where necessary to correct factual or legal errors, or in light

of newly discovered evidence, manifest injustice, or an intervening change of law).

Under Rule 60(b), the court may relieve a party from a final judgment or order for mistake, inadvertence, surprise, or excusable neglect; newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b); fraud, misrepresentation, or misconduct by an opposing party; the judgment is void; the judgment has been satisfied, released, or discharged; or is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or any other reason that justifies relief. Fed. R. Civ. P. 60(b).

The FDA contends that it is unable to complete the proposed rules in the remaining two areas (intentional adulteration and sanitary transport) by November 30, 2013, because of the complexity of the issues, the amount of work required, and other reasons it previously argued in its motion for summary judgment. The FDA also argues that reconsideration is warranted because it was never given the opportunity before the court issued the injunction to respond to the schedule proposed by plaintiffs in response to the court's April 22, 2013 order.

The FDA has submitted a declaration from Michael R. Taylor, the FDA's Deputy Commissioner for Foods and Veterinary Medicine, detailing the reasons the FDA cannot comply with the court's schedule with regard to the two remaining areas. Mr. Taylor states that the FDA anticipates publishing the sanitary transport proposed rule by January 31, 2014 – 60 days after the deadline set by the court. He also asserts, however, that the FDA cannot publish the intentional adulteration proposed rule until the second half of 2015, and that it projects releasing the final rule during the second half of 2017.

According to Mr. Taylor, the intentional adulteration rule will require additional time to issue because the prevention of intentional contamination is an area the FDA has not previously regulated, as preventive controls against intentional contamination have always been voluntary. Mr. Taylor asserts that the FDA must develop criteria where preventive controls are appropriate, and must also develop an initial draft Advanced Notice of Proposed Rulemaking (ANPRM) – which it asserts is undergoing review within the FDA at

this time. Part of the purpose of the ANPRM, according to Mr. Taylor, is to ask industry for information about how vulnerability is currently assessed and what measures are currently in place to guard against intentional adulteration.

Plaintiffs oppose the motion, arguing that the FDA has not met the standard for Rule 59(e) motions, as the motion does not assert any manifest errors of law or fact, does not present newly discovered and previously unavailable evidence, does not claim that the motion is necessary to prevent manifest injustice, and does not allege any change in controlling law. Moreover, plaintiffs assert, the FDA is mainly attempting to relitigate matters that it previously litigated in the cross-motions for summary judgment.[1] Plaintiffs also argue that the FDA has not presented adequate grounds for staying the judgment.

Plaintiffs are willing to accept a 60-day extension on the deadline for publication of the sanitary transport proposed rule – to January 31, 2014 – although they also request that the comment period end date be extended 30 (not 60) days – from March 31, 2014, to April 30, 2014 – and that the date for the final rule deadline remain June 30, 2015.

However, they contend that there is no justification for the additional extension requested for the intentional adulteration rule. They claim that it is not true that the FDA has never worked on issues involving food safety vulnerability, as the FDA stated in its 2007 Food Protection Plan that it had devoted "significant resources" over the previous six years to address what it called "food defense – defending the food supply against deliberate attack."

Plaintiffs also contend that the FSMA intentional contamination regulations are to be based on vulnerability assessments using systems the FDA has already developed, and that the FDA maintains a website detailing tools and educational materials regarding intentional contamination, and regularly holds workshops on food security awareness and

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[1] A motion for reconsideration "may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation." Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co., 571 F.3d 873, 880 (9th Cir. 2009) (quotation and citation omitted); see also Herron, 634 F.3d at 1112.

defense, and publishes expert reports on the subject.

As for the FDA's argument that it was not allowed an opportunity to respond to the plaintiffs' proposed deadlines, plaintiffs contend that this assertion is without merit, as each side submitted a proposed schedule, and the court did not adopt either one, but instead reviewed all the papers and structured its own schedule, which was set forth in the June 21, 2013 order granting injunctive relief.

Plaintiffs assert further that the need to publish an ANPRM before the proposed rule can be published is not a proper ground for a Rule 59(e) motion, and that in any event, a pre-publication ANPRM is not required by the APA or the FSMA. Plaintiffs assert that the FDA appears to use ANPRMs only rarely, and that a draft proposed rule can serve the same function as an ANPRM. In any event, they assert, where health and safety are involved, the issuance of an ANPRM instead of a rule is the least responsive course short of inaction, and an agency should not be permitted to slow down the rulemaking process by adding an unnecessary step.

Finally, plaintiffs argue that the FDA's alternative request for a stay pending appeal should be denied. First, they assert that a stay motion properly falls under Federal Rule of Civil Procedure 62, but that Rule 62 applies only to cases where an appeal has actually been taken. Here, they note, no appeal has been filed.

Second, plaintiffs contend that the FDA has failed to make the required showing. A district court may stay an injunction while an appeal from the order granting the issuance of the injunction is pending. Fed. R. Civ. P. 62(c). The factors regulating the issuance of a stay under Rule 62(c) are whether the applicant has made a strong showing that he is likely to succeed on the merits; whether the applicant will be irreparably injured absent a stay; whether issuance of the stay will substantially injure the other parties interested in the proceeding; and where the public interest lies. Hilton v. Braunskill, 481 U.S. 770, 776 (1987); see also Leiva-Perez v. Holder, 640 F.3d 962, 964 (2011). "The first two factors of [this] standard are the most critical." Nken v. Holder, 556 U.S. 418, 434 (2009).

In reply, the FDA reiterates that it cannot meet the November 30, 2013 deadline for

promulgating a proposed intentional adulteration rule because it first needs to issue an ANPRM to obtain substantive public input to inform its formulation of the proposed rule. Moreover, the FDA argues, information relevant to an accurate cost/benefit analysis is not readily available in the public arena, in part because so much of it is sensitive and proprietary. The FDA contends that plaintiffs' argument that an ANPRM is unnecessary because it is not legally required misses the point – which is that the FDA needs to issue an ANPRM because it does not currently have the information it needs to formulate a proposed rule.

The FDA contends that its efforts towards the creation of voluntary standards does not provide a sufficient basis to support the promulgation of mandatory rules, as it is neither feasible nor necessary for every entity to implement all the voluntary measures that the FDA has suggested, and the FDA needs input from various companies to reasonably balance the risks of adulteration against the burdens of taking preventive measures.

The FDA adds that if the court is "reluctant to amend the order without appointing a date certain," it should set deadlines for promulgating the proposed and final rules that are consistent with the timeline outlined by the FDA. Otherwise, the FDA wants the court to stay the case pending the Solicitor General's decision whether to file a notice of appeal.

The motion is GRANTED in part and DENIED in part. As an initial matter, the court agrees with plaintiff that the FDA has not met the standard for amending the judgment under Rule 59(e) (or under Rule 60(b)). Nevertheless, given plaintiffs' agreement to extend the deadline for publication of the proposed sanitary transport rule 60 days, to January 31, 2014, the court will amend the order and judgment to that extent. In addition, however, the court will add an additional 60 days to the comment period for this rule, extending the deadline to May 31, 2014. The deadline for publication of the final rule remains unchanged.

As for the extension requested for promulgation of the intentional adulteration rule, the court finds that the motion must be DENIED. The court understands the FDA's position, and is in sympathy with it, but remains of the opinion that the dispute here is

between the FDA and Congress. This court is unwilling to grant extension after extension, or to permit the FDA to continually delay publication of this rule, in the face of the clear Congressional directive that this be a closed-end process.

The court finds further that the FDA has not met the standard for seeking a stay pending appeal under Rule 62(c). "The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion." Nken, 556 U.S. at 433-34. Here, the FDA has not addressed the required factors. Moreover, in view of the fact that no notice of appeal has been filed, any request for a stay is premature.

The date for the hearing on this motion, previously set for August 28, 2013, has been VACATED.

IT IS SO ORDERED.

Dated: August 13, 2013

PHYLLIS J. HAMILTON
United States District Judge