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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY and CENTER FOR ENVIRONMENTAL HEALTH, *Plaintiffs*, v. ALEX M. AZAR II, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORMAN E. SHARPLESS, M.D., ACTING COMMISSIONER OF FOOD AND DRUGS;[1] and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Case No.: 4:18-cv-06299-YGR **CONSENT DECREE**

[1] Norman E. Sharpless, M.D. became Acting Commissioner of Food and Drugs on April 5, 2019. By operation of Fed. R. Civ. P. 25(d), Dr. Sharpless is automatically substituted as a party for former Commissioner of Food and Drugs, Scott Gottlieb, M.D.

WHEREAS, this case comes before the Court upon the Joint Stipulation for Entry of Consent Decree ("Stipulation") of Plaintiffs Center for Food Safety and Center for Environmental Health and Defendants Alex M. Azar II, Secretary of U.S. Department of Health and Human Services; Norman E. Sharpless, M.D., Acting Commissioner of Food and Drugs; and U.S. Department of Health and Human Services. Plaintiffs and Defendants are collectively referred to as the "Parties."

WHEREAS on January 4, 2011, Congress enacted the Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (FSMA). This statute set deadlines for the Food and Drug Administration (FDA) to (1) designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health (Section 204(d)(2)(A) of FSMA), and (2) publish a notice of proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold such foods (Section 204(d)(1) of FSMA). This statute also required FDA to publish the list of the foods designated as high-risk on the FDA's website at the time the agency promulgates the final rule establishing recordkeeping requirements for facilities that manufacture, process, pack, or hold high-risk foods (Section 204(d)(2)(B) of FSMA). Plaintiffs filed this action on October 15, 2018, alleging that FDA violated FSMA and the Administrative Procedure Act (APA) by failing to meet the statutory deadlines and to complete the other actions identified in the previous two sentences, and seeking declaratory and injunctive relief requiring FDA to take the actions described in the statute pursuant to a court-ordered timeline;

WHEREAS Defendants neither admit nor deny the allegations in the Complaint;

WHEREAS the Parties agree that resolution of this matter without further litigation is in the best interest of the Parties and the public, and that entry of this Consent Decree is the most appropriate means of resolving this action.

NOW, THEREFORE, upon consent of the Parties, and upon consideration of the mutual promises contained herein,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

I. GENERAL TERMS

1. This Consent Decree applies to, is binding upon, and inures to the benefit of the Parties (and their successors, assigns, and designees).

2. The Parties to this Consent Decree understand that Alex M. Azar II and Norman E. Sharpless, M.D., were sued in their official capacities as Secretary of the United States Department of Health and Human Services (HHS), and Acting Commissioner of Food and Drugs, respectively, and that obligations arising under this Consent Decree are to be performed by HHS and FDA, and not Alex M. Azar II or Norman E. Sharpless, M.D. in their individual capacities.

II. DEFINITIONS

3. Whenever terms listed below are used in this Consent Decree, the following definitions shall apply:

a. "Complaint" means the complaint filed in this case by the Center for Food Safety and the Center for Environmental Health on October 15, 2018, to initiate this case.

b. "Consent Decree" means this document.

c. "FDA" means the United States Food and Drug Administration and/or Defendant in this action, Norman E. Sharpless, M.D., Acting Commissioner of Food and Drugs, or his duly authorized representative.

d. "HHS" means Defendant in this action, the United States Department of Health and Human Services and/or Defendant in this action, Alex M. Azar II, Secretary of the United States Department of Health and Human Services, or his duly authorized representative.

e. "Plaintiffs" means the Center for Food Safety and the Center for Environmental Health.

f. "Party" means either Plaintiffs or Defendants.

g. "Parties" shall collectively refer to Plaintiffs and Defendants.

III. SCHEDULE FOR FDA ACTION

4. The Parties agree to the following schedule for FDA action. Except as otherwise specified below, the dates provided are dates by which FDA will submit documents to the Office

of the Federal Register for publication, rather than the dates by which the documents will be published.

a. Designation of the list of high-risk foods required by FSMA Section 204(d)(2)(A)

September 8, 2020

b. Recordkeeping requirements for the designated high-risk foods as required by FSMA Section 204(d)(1)

Proposed rule: September 8, 2020

Final rule: November 7, 2022

c. Publication on the FDA website of the list of high-risk foods required by FSMA Section 204(d)(2)(B)

Upon publication of the Final rule in the Federal Register

IV. SEEKING EXTENSIONS AND FAILURE TO COMPLY WITH SCHEDULE

5. FDA agrees in good faith to complete the actions in the above schedule and shall make every effort to meet or precede these dates. Nothing in this Consent Decree shall be construed as precluding FDA from satisfying the above schedule by dates earlier than those set forth in this document.

6. If despite FDA's best efforts (meaning commitment of agency time, money, energy, and resources that FDA reasonably anticipates will result in meeting the schedule in this Consent Decree), FDA believes good cause exists to seek an extension of the schedule, any date in the schedule set forth above may be extended by written agreement of the Parties and notice to the Court. The Parties agree to negotiate in good faith to reach a mutually agreeable outcome with respect to any such extension of the schedule, as the circumstances may warrant.

7. In the unlikely event that FDA believes an extension of the schedule set forth in this Consent Decree is necessary and the Parties are unable to agree to the terms of the extension, as a measure of last resort FDA may seek modification of the schedule in accordance with the procedure specified below.

a. FDA shall file a motion requesting modification of any date established by this Consent Decree at least thirty days before the date at issue. In such a motion, FDA

shall have the burden to show good cause and/or exceptional circumstances warranting the delay, and address the effect of the delay on the public health and safety, among other relevant considerations. Any motion to modify the schedule established in this Consent Decree shall be accompanied by a motion for expedited consideration. In the event that circumstances arise less than thirty days before the specific deadline that make compliance with that deadline unfeasible, FDA may move to shorten the time required by this paragraph and shall have the burden to show good cause and/or exceptional circumstances warranting the shortened time.

b. FDA shall provide notice to Plaintiffs of its intent to file a motion to modify any date established by this Consent Decree as soon as reasonably possible, and in any event no later than a week prior to the filing of its motion unless good cause and/or exceptional circumstances warrant a shortened notice period.

c. FDA bears the burden of demonstrating that modification of the schedule is warranted.

8. In the event that FDA has failed to meet the schedule established in this Consent Decree, Plaintiffs' first remedy shall be a motion to enforce the terms of this Consent Decree. FDA retains all rights to defend against such a motion.

V. DISPUTE RESOLUTION AND MODIFICATIONS

9. In the event of a disagreement among the Parties concerning the interpretation or performance of any aspect of this Consent Decree including compliance with the schedule as explained above, the dissatisfied Party shall provide the other Party or Parties with written notice of the dispute and a request for negotiations. The Parties shall confer within twenty-one days of the written notice, or such time thereafter as is mutually agreed, in order to attempt to resolve the dispute. In the event that the Parties are unable to resolve the dispute, a Party may file with the Court a motion to enforce the Agreement and/or to compel performance, or a motion to modify this Agreement in accordance with Federal Rule of Civil Procedure 60(b). Any modification shall be effective upon the filing and entry of an order granting such a motion with the Court.

VI. CONTINUING JURISDICTION

10. The Court shall retain jurisdiction for the purposes of overseeing compliance with the terms of this Consent Decree; resolving any disputes arising under this Consent Decree; resolving any motions to modify the terms of this Consent Decree; issuing such further orders or

directions as may be necessary or appropriate to construe, implement, modify, or enforce the terms of this Consent Decree; resolving all claims regarding attorneys' fees and costs as they relate to the Consent Decree; and granting any further relief as the interests of justice may require. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375 (1994). Except as otherwise stated in this Consent Decree, the Parties retain all procedural and other rights related to such proceedings.

VII. EFFECTIVE DATE

11. This Consent Decree shall be effective upon the date of its entry by the Court. If for any reason the Court does not enter this Consent Decree as executed by the Plaintiffs and Defendants, all terms set forth herein are null and void.

VIII. TERMINATION OF CONSENT DECREE AND DISMISSAL OF CLAIMS

12. This Consent Decree shall terminate without further judicial action upon the occurrence of the last FDA action under Paragraph 4 of this Consent Decree.

IX. NOTICE AND CORRESPONDENCE

13. Any notice required or made with respect to this Consent Decree shall be in writing and shall be effective on the date that notice is delivered by electronic mail unless the sender learns that it did not reach the person to be served. For any matter relating to this Consent Decree, the contact persons are:

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Upon written notice to the other Parties, any Party may designate a successor contact person for any matter relating to this Consent Decree.

X. RELEASE BY PLAINTIFFS AND RESERVATION OF RIGHTS

14. Plaintiffs agree that upon entry by the Court, this Consent Decree shall constitute full satisfaction and shall serve as a release of all their claims in *Center for Food Safety v. Azar*.

15. Plaintiffs further release, discharge, and covenant not to assert any and all claims, causes of action, suits, or demands of any kind in law or in equity that they may have had, or may now have, against Defendants upon the same transactions or occurrences as those at issue in the Complaint.

16. Nothing in this Consent Decree shall limit Plaintiffs' rights to assert the claim pleaded in Plaintiffs' Complaint and make any legal or factual assertions necessary to support a claim, in the event that the Parties are before the Court pursuant to Paragraphs 5–8 ("Extensions ") or Paragraph 9 ("Dispute Resolution and Modification"). Nor shall anything in this Consent Decree be construed to limit Defendants' arguments in favor of modifying the schedule established in this Consent Decree or concerning any Dispute Resolution or Modification.

17. Nothing in this Consent Decree shall waive or limit Plaintiffs' rights to challenge, in a separate lawsuit, the merits of any final agency action taken by FDA pursuant to this Consent Decree (or any final agency action taken by FDA implementing FSMA), including but not limited to claims relating to whether FDA's final action complies with FSMA, the Administrative Procedure Act, and other applicable laws.

18. This release does not encompass any claims by Plaintiffs related to this action, pursuant to the Equal Access to Justice Act, for their fees and costs in this matter, which shall be resolved pursuant to a separate, concurrent agreement entered by this Court.

XI. MUTUAL DRAFTING AND CONSTRUCTION

19. It is expressly understood and agreed that this Consent Decree was jointly drafted by the Parties. Accordingly, the Parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Consent Decree.

XII. EFFECT OF CONSENT DECREE

20. This Consent Decree shall not constitute an admission or evidence of any issue of fact or law, wrongdoing, misconduct, or liability on the part of any Party. The Parties agree that this Consent Decree was negotiated in good faith and that this Agreement constitutes a settlement of claims that were denied and disputed by the Parties.

XIII. SCOPE OF CONSENT DECREE

21. Except as expressly provided in this Consent Decree, none of the Parties waives or relinquishes any legal rights, claims, or defenses it may have. Nothing in this Consent Decree shall be construed to confer upon the Court jurisdiction to review any decision, either procedural or substantive, to be made by FDA pursuant to this Consent Decree, except for the purposes of determining FDA's compliance with this Consent Decree. Nothing in this Consent Decree shall be construed to make any non-Party a third-party beneficiary of this Consent Decree. Nothing in this Consent Decree alters or affects the standards for judicial review of any final FDA action.

XIV. COUNTERPARTS

22. This Consent Decree may be executed in any number of counterpart originals, each of which will be deemed to constitute an original agreement, and all of which shall constitute one agreement. The execution of one counterpart by any Party shall have the same force and effect as if that Party had signed all other counterparts.

XV. ENTIRE AGREEMENT

23. This Consent Decree is the entire agreement between the Parties in this case. All prior conversations, meetings, discussions, drafts, and writings of any kind are specifically superseded by this Consent Decree.

XVI. APPLICABLE LAW

24. This Consent Decree shall be governed by and construed under the laws of the United States.

XVII. COMPLIANCE WITH OTHER LAWS

25. This Consent Decree requires FDA to take certain actions by a date certain, as described above. No provision of this Consent Decree shall constitute or be interpreted as permitting or requiring FDA to take any action in contravention of any law or regulation, either substantive or procedural.

XVIII. REPRESENTATIVE AUTHORITY

26. Each undersigned representative of the Parties to this Consent Decree certifies that he or she is fully authorized by such Party to enter into and execute the terms and conditions of this Consent Decree and to legally bind such Party to this Consent Decree. By signature below, the Parties consent to entry of this Consent Decree. Signature on a counterpart or authorization of an electronic signature shall constitute a valid signature.

For Plaintiffs:

Date: June 7, 2019

/s/ George Kimbrell

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For Defendants:

Date: June 7, 2019

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ENTERED AND DATED this 11th day of June, 2019.

United States District Court Judge