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20 **UNITED STATES DISTRICT COURT**  
21 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

22 CENTER FOR FOOD SAFETY and CENTER  
23 FOR ENVIRONMENTAL HEALTH,

24 *Plaintiffs,*

25 v.

26 ALEX M. AZAR II, SECRETARY OF U.S.  
27 DEPARTMENT OF HEALTH AND HUMAN  
28 SERVICES; NORMAN E. SHARPLESS, M.D.,  
ACTING COMMISSIONER OF FOOD AND  
DRUGS;<sup>1</sup> and U.S. DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

*Defendants.*

) Case No.: 3:18-cv-06299

) **CONSENT DECREE**

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27 <sup>1</sup> Norman E. Sharpless, M.D. became Acting Commissioner of Food and Drugs on April  
28 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.

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

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

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

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

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

27 IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:  
28

1 **I. GENERAL TERMS**

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

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

10 **II. DEFINITIONS**

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

- 13
- 14 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.
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- 16 b. “Consent Decree” means this document.
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- 18 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.
- 19
- 20 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.
- 21
- 22 e. “Plaintiffs” means the Center for Food Safety and the Center for Environmental  
Health.
- 23
- 24 f. “Party” means either Plaintiffs or Defendants.
- 25
- 26 g. “Parties” shall collectively refer to Plaintiffs and Defendants.

26 **III. SCHEDULE FOR FDA ACTION**

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

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

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

4 September 8, 2020

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

7 Proposed rule: September 8, 2020

8 Final rule: November 7, 2022

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

11 Upon publication of the Final rule in the Federal Register

12 **IV. SEEKING EXTENSIONS AND FAILURE TO COMPLY WITH SCHEDULE**

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

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

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

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

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

- 6 b. FDA shall provide notice to Plaintiffs of its intent to file a motion to modify any date  
7 established by this Consent Decree as soon as reasonably possible, and in any event  
8 no later than a week prior to the filing of its motion unless good cause and/or  
9 exceptional circumstances warrant a shortened notice period.
- 9 c. FDA bears the burden of demonstrating that modification of the schedule is  
10 warranted.

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

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14 **V. DISPUTE RESOLUTION AND MODIFICATIONS**

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

24 **VI. CONTINUING JURISDICTION**

25 10. The Court shall retain jurisdiction for the purposes of overseeing compliance with  
26 the terms of this Consent Decree; resolving any disputes arising under this Consent Decree;  
27 resolving any motions to modify the terms of this Consent Decree; issuing such further orders or  
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1 directions as may be necessary or appropriate to construe, implement, modify, or enforce the  
2 terms of this Consent Decree; resolving all claims regarding attorneys' fees and costs as they  
3 relate to the Consent Decree; and granting any further relief as the interests of justice may  
4 require. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375 (1994). Except as  
5 otherwise stated in this Consent Decree, the Parties retain all procedural and other rights related  
6 to such proceedings.

7 **VII. EFFECTIVE DATE**

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

11 **VIII. TERMINATION OF CONSENT DECREE AND DISMISSAL OF CLAIMS**

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

14 **IX. NOTICE AND CORRESPONDENCE**

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

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21 George A. Kimbrell  
22 Center for Food Safety  
23 2009 NE Alberta St., Suite 207  
24 Portland, OR 97211  
25 gkimbrell@centerforfoodsafety.org  
26 (971) 271-7372

27 Daniel K. Crane-Hirsch  
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1 Julie B. Lovas  
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3 United States Department of Health and Human Services  
4 10903 New Hampshire Avenue, WO 31-4520  
5 Silver Spring, MD 20993  
6 julie.lovas@fda.hhs.gov  
7 (301) 796-8575

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

10 **X. RELEASE BY PLAINTIFFS AND RESERVATION OF RIGHTS**

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

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

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

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

28 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.

1 **XI. MUTUAL DRAFTING AND CONSTRUCTION**

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

6 **XII. EFFECT OF CONSENT DECREE**

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

11 **XIII. SCOPE OF CONSENT DECREE**

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

19 **XIV. COUNTERPARTS**

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

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

5 **XVI. APPLICABLE LAW**

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

8 **XVII. COMPLIANCE WITH OTHER LAWS**

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

13 **XVIII. REPRESENTATIVE AUTHORITY**

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

2 Date: June 7, 2019

/s/ George Kimbrell

3 GEORGE A. KIMBRELL (*admitted Pro Hac*  
4 *Vice*)  
5 RYAN D. TALBOTT (*admitted Pro Hac Vice*)  
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10 **For Defendants:**

11 Date: June 7, 2019

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13 Assistant Attorney General  
14 DAVID M. MORRELL  
15 Deputy Assistant Attorney General  
16 GUSTAV W. EYLER  
17 Director  
18 ANDREW E. CLARK  
19 Assistant Director  
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21 /s/ Daniel K. Crane-Hirsch  
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5 Silver Spring, MD 20993-0002

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8 ENTERED AND DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2019.

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11 \_\_\_\_\_  
United States District Court Judge  
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