UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST and NATIONAL CONSUMERS LEAGUE, Plaintiffs, v. DR. TOM PRICE, Secretary of the Department of Health and Human Services; DR. SCOTT GOTTLIEB, Commissioner of the United States Food and Drug Administration; and the UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	)	Civil Action No. 1:17-CV-1085 (EGS)

JOINT MOTION FOR STAY

Plaintiffs Center for Science in the Public Interest ("CSPI") and National Consumers League ("NCL") (collectively, "Plaintiffs") and Defendants Dr. Tom Price, Dr. Scott Gottlieb, and the United States Food and Drug Administration ("FDA") (collectively, "Defendants" or, together with Plaintiffs, "the Parties") jointly and respectfully request that the Court stay all deadlines in this case until the earlier of either May 7, 2018 or the occurrence of one of the triggering events identified in paragraph 8 below. A stay of litigation will serve judicial economy and preserve the Parties' resources by potentially allowing for resolution of this case without litigation.

As required by LCvR 7(m), the Parties have conferred and jointly state as follows:

1. On December 1, 2014, FDA published a final rule requiring chain restaurants and similar retail food establishments to disclose calorie contents and other health information for standard menu items ("Menu Labeling Rule"), with a compliance deadline of December 1, 2015.

2. After subsequent extensions, on December 30, 2016, FDA published a final rule "to clarify and confirm that the compliance date for the [Menu Labeling Rule] is May 5, 2017." FDA, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date*, 81 Fed. Reg. 96,364, 96,364 (Dec. 30, 2016). On May 4, 2017, FDA published an interim final rule extending the Menu Labeling Rule's compliance deadline until May 7, 2018 ("Interim Final Rule"), which is the subject of this litigation.

3. Although the Interim Final Rule was issued without a prior opportunity for public comment, FDA sought post-promulgation comments on the extension and "how [FDA] might further reduce the regulatory burden or increase flexibility while continuing to achieve [FDA's] regulatory objectives to provide consumers with nutrition information so that they can make informed choices for themselves and their families." FDA, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date, Request for Comments*, 82 Fed. Reg. 20,825, 20,827 (May 4, 2017).

4. On June 7, 2017, Plaintiffs commenced this action by filing a complaint for declaratory and other relief against Defendants, alleging that the Interim Final Rule was promulgated in violation of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*.

5. On August 14, 2017, Defendants moved to dismiss the complaint on the grounds that Plaintiffs lack standing or, alternatively, that Plaintiffs' claims are not ripe.

6. On August 25, 2017, the Court granted the Parties' joint motion for a scheduling order, directing Plaintiffs to file either their opposition to Defendants' motion to dismiss or an amended complaint no later than September 19, 2017.

7. Also on August 25, 2017, Dr. Gottlieb issued a press release (attached hereto as Exhibit A), concerning the Menu Labeling Rule. In this release, Dr. Gottlieb stated that FDA "[has] issued detailed regulations addressing what information should be provided in menus at restaurant chains and similar retail establishments, as well as when and how that information should be provided," and that the most recent round of feedback on the regulations helped FDA by "further inform[ing] our approach to implementing the menu labeling provisions." Dr. Gottlieb announced that FDA "will provide additional, practical guidance on the menu labeling requirements by the end of this year . . . [to] address concerns that were raised about challenges establishments faced in understanding how to meet their obligations under the new regulations." Dr. Gottlieb explained that this guidance "should allow covered establishments to implement the requirements by next year's compliance date."

8. The Parties recognize Dr. Gottlieb's stated intent to maintain the Menu Labeling Rule's current compliance date of May 7, 2018 and to address the aspects of the Menu Labeling Rule on which the agency sought and received comment through guidance. To allow FDA adequate time to prepare this guidance, the parties have conferred and have agreed that:

a. On or before December 31, 2017, FDA will use its best efforts to confirm in a Federal Register publication that the Menu Labeling Rule's compliance date is May 7, 2018;

b. The parties jointly and respectfully request that Plaintiffs' complaint and Defendant's motion to dismiss be held in abeyance until May 7, 2018 or until the earliest of one of the following events occurs:

i. FDA announces by rule, guidance, public statement, publically-available document, or otherwise that the Menu Labeling Rule's compliance deadline could be or will be extended beyond May 7, 2018;

ii. FDA fails to confirm on or before December 31, 2017, in a Federal Register publication that the Menu Labeling Rule's compliance date is May 7, 2018; or

iii. FDA fails to publish draft or final menu labeling guidance as referenced in Dr. Gottlieb's August 25 press release by December 31, 2017.

9. Upon the occurrence of any event set forth in Paragraph 8(b) above, the Parties will confer, may file a notice that the stay is lifted, and, if necessary, may jointly seek a status conference to set a revised briefing schedule, including an opportunity for Plaintiffs to file an amended complaint (if desired). Plaintiffs may move for expedited consideration of the case, and Defendants agree not to oppose expedited consideration.

10. If, after May 7, 2018, the stay has not been not lifted by the occurrence of an event in paragraph 8(b), the case will be dismissed. All parties agree to bear their own costs and attorneys' fees.

11. The parties agree that neither this agreement nor the underlying litigation precludes FDA employees from communicating in an open and transparent manner with

employees of CSPI or NCL about the development or substance of the planned Menu Labeling guidance, in the same manner, and subject to the same restrictions and procedures, as FDA would with any other member of the public.

12. In the event that the Court denies this Motion, the Parties request that the Court extend the briefing deadlines on Defendants' pending motion to dismiss and permit the Parties to submit a joint scheduling proposal for briefing on the motion to dismiss.

WHEREFORE, the Parties respectfully request that the Court grant their joint motion for stay pursuant to the conditions set forth above.

Respectfully submitted this 15th day of September 2017.

/s/ Peter Lehner
PETER LEHNER*
ALEXIS ANDIMAN*
Earthjustice
48 Wall Street, 19th Floor
New York, NY 10005
T: (212) 845-7376
E: plehner@earthjustice.org
aandiman@earthjustice.org

/s/ Seth L. Johnson
SETH L. JOHNSON
D.C. Bar No. 1001654
Earthjustice
1625 Massachusetts Avenue, N.W., Suite 702
Washington, D.C. 20036
T: (202) 667-4500
E: sjohnson@earthjustice.org

Counsel for Plaintiffs

* Admitted *pro hac vice*.

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

ETHAN DAVIS
Deputy Assistant Attorney General

ANDREW E. CLARK
Assistant Director
Consumer Protection Branch

/s/ Daniel E. Zytnick
DANIEL E. ZYTNICK
DC Bar No. 998138
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
T: (202) 598-8337
E: Daniel.E.Zytnick@usdoj.gov

OF COUNSEL:

JEFFREY S. DAVIS
Acting General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Administration

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

BARBARA J. ALKALAY
Associate Chief Counsel, Litigation
U.S. Dept. of Health & Human Services
Office of the General Counsel
10903 New Hampshire Ave.
White Oak 31, Room 4422
Silver Spring, MD 20993-0002
T: 301-348-3085
E: Barbara.Alkalay@fda.hhs.gov

Counsel for Defendants