



November 26, 2018

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls; Draft Guidance for Industry and FDA Staff; Docket No. FDA-2018-D-1752

Dear Commissioner Gottlieb,

The undersigned consumer and food safety groups appreciate the opportunity to comment on the Food and Drug Administration (FDA)'s draft guidance titled *Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls*.¹ The draft guidance is an important step forward, ushering in a policy change that will provide consumers with key information needed to protect themselves and their families from serious health risks.

However, the draft guidance falls short by focusing on too narrow a range of foods and failing to clearly identify the sets of circumstances under which retail consignee² lists will be made available during recalls, particularly for packaged foods and foods sold in restaurants. We urge the FDA to commit to publishing a list of retail consignees for any recall that triggers a public warning, and to advise that such a list be included in all public warnings drafted by industry. The final version of the guidance should also establish criteria for publishing the names of restaurants covered in recalls.

¹ U. S. Food and Drug Administration. Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls; Draft Guidance for Industry and FDA Staff, September 2018. Accessed at: <www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM621668.pdf> [Hereinafter: The Draft Guidance]

² In the draft guidance, the agency uses the term "retail consignee" to refer to "retail establishments that, based on information available to FDA, have received or otherwise possess recalled food and that sell food products directly to consumers, traditionally meant to be consumed away from the establishment." The Draft Guidance, *see supra*, footnote 1.

I. The Draft Guidance is an Important Step Forward

The draft guidance announces an important shift in agency thinking. As FDA Commissioner Scott Gottlieb confirmed in his statement announcing the draft guidance, “[t]he agency has not traditionally released lists of specific retailers where recalled foods may have been purchased. This is because certain supply chain information is confidential between the supplier and retailer.”³ While the FDA has long acknowledged that it could disclose such confidential information when “necessary to effectuate a recall,”⁴ in practice the agency almost never invoked that authority.⁵ This policy prevented the agency from releasing information about retailers selling potentially harmful product—information that is key to protecting consumers.

Under the draft guidance, the agency has announced that its “goal is to collect, compile, and make public retail consignee lists for those food recalls where publicizing this additional information will be of the most use to help consumers identify recalled food and to determine whether that food is in their possession as effectively and quickly as possible.”⁶ In doing so, the agency will “primarily focus” on “those recalls where there is a reasonable probability that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals (i.e., Class I recalls).”⁷ The agency “may also publicize retail consignee lists for some Class II food recalls, particularly where FDA has issued a public warning or where there is an association with an outbreak of a foodborne illness.”⁸

The draft guidance further specifies that the agency will commit to publishing retail consignee lists where two conditions are both met: first, “the food is not easily identified as being subject to a recall from its retail packaging (or lack thereof);” and second, “the food is likely to be available for consumption (i.e., given its shelf life or perishability, it may still be in the consumer’s possession).”

This language commits the agency to publishing retailer lists for Class I and some Class II recalls only where 1) the food is not easily identified by its retail packaging and 2) the food is still in the consumer’s possession (i.e. unexpired). While the agency says it “will also consider publicizing retail consignee lists in other recall situations that do not meet both of these criteria,” it does not outline a clear rule for taking such action, saying only that it might post retail consignee lists if “the agency determined that providing such information would help prompt consumers who may

³ U.S. Food and Drug Administration. Statement from FDA Commissioner Scott Gottlieb, M.D., on new FDA commitment to disclose retailer information for certain food recalls to improve consumer safety. September 26, 2018. Accessed at: <www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621692.htm>

⁴ Caitlin Dewey. “Why the FDA hides the names of grocery stores that sell contaminated food.” *The Washington Post*, March 13, 2017, https://www.washingtonpost.com/news/wonk/wp/2017/03/13/fda-says-soynut-butter-couldmake-your-child-sick-who-sold-it-thats-a-trade-secret/?utm_term=.bc80ed3769b4.

⁵ Although the agency has on at least one occasion published the names of restaurants that served recalled food, as we discuss below.

⁶ The Draft Guidance, *see supra*, footnote 1.

⁷ *Ibid.*

⁸ *Ibid.* A Class II recall is a situation in which “use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.” 21 CFR § 7.3(m)(2).

have received or purchased such recalled food to consider whether they possess the recalled product.”⁹

Consumer and food safety groups have long advocated for the FDA to publish retail consignee lists, which would align FDA practices with those of the U.S. Department of Agriculture (USDA). Since 2008, USDA has published the full lists of retailers involved in recalls of meat and poultry for all Class I recalls.¹⁰ The undersigned consumer and food safety groups supported section 206 of the 2011 FDA Food Safety Modernization Act (FSMA), which directed that the FDA shall “consult the policies of the [USDA] regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public.”¹¹ The FDA has indicated that the draft guidance serves as a response to that FSMA requirement.¹²

In August 2017, the undersigned groups joined in a public letter urging the FDA to begin disclosing retail consignee lists as soon as possible.¹³ In the letter, we pointed out reasons why retail consignee disclosures are generally “necessary to effectuate a recall.”¹⁴ The draft guidance recognizes one such reason: helping consumers to identify a recalled food. Retail consignee lists also serve a broader public awareness function. Knowing that a particular store or restaurant sold a recalled product may prompt a consumer to check the freezer or pantry for that product, perhaps weeks or months after the recall, enhancing the effectiveness of the recall and providing an added measure of consumer protection.

The FDA’s failure to publish retail consignee lists has resulted in consumers lacking critical information during recalls. In the summer of 2017, for example, four different brands of papayas were recalled in relation to an outbreak of *Salmonella* that caused over 250 infections in 25 states, with 79 hospitalizations and two deaths.¹⁵ The FDA posted the names of the papaya farms, brand names, and in some cases the codes on the bulk boxes received at grocery stores.¹⁶ Yet the agency did not provide information that would have been far more useful to consumers: the names of the stores that sold the recalled fruit. Instead, the agency unhelpfully advised consumers to contact their own grocery store to determine if it had sold papayas that were part of the recall.¹⁷

Immediately following the announcement of the papayas recall, Center for Science in the Public Interest (CSPI) filed a Freedom of Information Act request with the FDA to obtain the names of

⁹ The Draft Guidance, *see supra*, footnote 1.

¹⁰ *See* Final Rule: “Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls,” 73 Fed. Reg. 40,939 (July 17, 2008).

¹¹ 21 U.S.C. § 350l(g)(2).

¹² The Draft Guidance, *see supra*, footnote 1.

¹³ Letter from Food Safety Advocates to Scott Gottlieb Regarding FDA Retail Consignee Disclosure Policy, August 22, 2017. Accessed at: <<https://advocacy.consumerreports.org/wp-content/uploads/2017/08/Food-Safety-Advocates-Letter-to-Commn-Gottlieb-re-FDA-Retail-Consignee-Disclosure-Policy-8-22-17.pdf>>

¹⁴ *Ibid.*

¹⁵ U.S. Food and Drug Administration. FDA Investigates Multiple Salmonella Outbreak Strains Linked to Papayas, November 4, 2017. Accessed at: <www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm568097.htm>

¹⁶ *Ibid.*

¹⁷ *Ibid.*

retailers who distributed the recalled papayas.¹⁸ The FDA acknowledged that it had 451 pages of responsive information, but denied the request to reveal the store names, citing exemptions for “trade secret and confidential information.”¹⁹ CSPI’s timely appeal to obtain that information remains pending.

The undersigned groups therefore welcome the proposed guidance, which signals that the agency will no longer withhold retail consignee lists in recalls where this information may be helpful for consumers. In particular, we support the agency’s declared intention to consistently publish retailer consignee lists for all cases in which a food is not easily identified by its packaging (or lack thereof). Such food can include papayas and much other fresh produce, as well as nuts, grains and other agricultural products sold in bulk. Retailer names and locations are essential to facilitating a consumer-level recall of such products, because consumers frequently have little way of identifying these products other than by the store where they were purchased.

II. FDA Should Expand its Policy to All Public Warnings

While the draft guidance represents a step forward, it also falls short in several ways. Importantly, the scope of the draft guidance is narrower than the current USDA policy, which provides for publication of retail consignee lists for all Class I recalls.²⁰ The FDA has not clearly stated it will seek to publish retail consignee lists for all Class I recalls. Instead, as we note above, it has committed to publishing the subset of Class I and some Class II recalls for which a food is 1) not easily identified by its retail packaging and 2) likely to remain in consumer’s possession.

Yet publication of retail consignee lists is important even for foods with detailed packaging, as this information would help ensure that the public warning notifying consumers of the recall reaches its intended audience. Most consumers do not subscribe to the FDA’s email listserv or regularly visit the FDA website, and instead learn of recalls through national or local media. Recall messages are more likely to be amplified through local media if a local retailer is identified in the public warning for the recall. Similarly, social media users may be more likely to open and share warnings if a store is identified where they or members of their network are likely to shop. Consumers hearing the name of their own local store may also be more likely to take note of the recall and check to see if they have recalled product in their possession. Retailer consignee lists therefore serve as an important tool to help amplify communications around recalls, increasing the number of consumers who will hear about the recall and take action.

We urge the agency to expand the draft guidance by indicating that it will request publication of the names of retail consignees in all cases in which a food company has issued a public warning related to the recall. As the FDA has recently emphasized, public warnings are for urgent

¹⁸ Center for Science in the Public Interest (CSPI). Watchdog Group Asks FDA to Disclose Retailers of Papayas Implicated in *Salmonella* Outbreak, September 7, 2017. Accessed at: <<https://cspinet.org/news/watchdog-group-asks-fda-disclose-retailers-papayas-implicated-salmonella-outbreak-20170907>>.

¹⁹ *Ibid.*

²⁰ See Final Rule: “Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls,” 73 Fed. Reg. 40,939 (July 17, 2008).

situations to alert the public that a product being recalled “presents a serious hazard to health.”²¹ The agency generally recommends public warnings for recalls likely to be classified as Class I recalls, as well as “for some urgent Class II recalls that, while not rising to Class I hazards, still present a serious hazard to health.”²² Given the level of health threat inherent in recalls that require a public warning, consumers should have access to retailer information as part of all such recalls.

The FDA has long had legal authority to expand its policy to cover all public warnings, based on regulations providing for the disclosure of confidential commercial information “to the extent necessary to effectuate [a recall].”²³ Disclosure of retailer names should be considered necessary to effectuate a recall in all cases where the recalled food has been distributed to consumers, because this information helps better target the recall announcement towards its intended audience. Failure to include these names could mean some consumers fail to receive recall communications and identify products within their possession that might be implicated, preventing them from fully effectuating the recall.

Collection and publication of retail consignee lists by the FDA is also necessary to effectuate recalls because it allows public officials and others to verify that recalls have been effectively carried out. Unfortunately, previous experience shows that foods subject to recall often remain available to consumers long after a public warning goes out. For example, recalled I.M. Healthy soy nut butter was still available for sale by online retailer Amazon.com half a year after the product was linked to an *E. coli* outbreak and recalled by federal officials.²⁴ In 2010, the Association of Food and Drug Officials conducted a survey of its members in which it sought to identify obstacles to recall efforts. Half of state agency survey respondents indicated that the FDA’s “inability to share distribution information” was an obstacle to participating in audit checks to ensure that recalled products had actually come off shelves.²⁵ If retail consignee lists were routinely collected and published as part of every public warning, it would be easier for state officials to verify that recalls have been effectively carried out. Similarly, local media, watchdog groups, and individual consumers would be able to check store shelves for recalled product as an additional safeguard.

While the FDA has authority to collect and disclose retail consignee lists directly, it may also do so indirectly by advising that this information be included in public warnings prepared by industry. The FDA recently provided advice to industry on crafting these warnings in its draft guidance titled *Public Warnings and Notification of Recalls Under 21 CFR Part 7*, which was circulated for public comment on January 17, 2018.²⁶ Section 3 of that draft guidance, titled

²¹ U.S. Food and Drug Administration. Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Draft Guidance for Industry and FDA Staff, January 17, 2018. Accessed at: www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf

²² *Ibid.*

²³ 21 CFR § 20.91.

²⁴ Beach, C. Amazon Today Removed Nut Butter Recalled in March for *E. coli*. *Food Safety News*, September 5, 2017. Accessed at: www.foodsafetynews.com/2017/09/amazon-today-removed-nut-butter-recalled-in-march-for-e-coli/#.WcoDt0yZPV0.

²⁵ Association of Food and Drug Officials. AFDO Recall Survey 2010. Accessed at: <http://www.afdo.org/page-1186469>

²⁶ U.S. Food and Drug Administration. Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Draft Guidance for Industry and FDA Staff, January 17, 2018. Accessed at: www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf

“What information should be contained in a public warning?” does not instruct recalling firms to provide retail consignee lists as a standard part of all public warnings. Instead, it says that this information may be necessary “in some cases,” and includes a footnote indicating that supply chain distribution data “may be [Confidential Commercial Information].” We urge the agency to amend this guidance to make clear that retailer consignee lists generally will be required as part of all public warnings moving forward. This will help to ensure that retailer names are always made available, regardless of whether the public warning is drafted by the FDA or members of industry.

The FDA has indicated that “[i]dentifying retail consignees can be a time-consuming process that often involves obtaining information from multiple entities throughout a supply chain.”²⁷ Yet the effort needed to compile such lists would likely diminish over time, particularly if the agency makes clear that recalling firms are expected to produce retail consignee lists as a standard part of food recalls. Many members of the food industry are already exploring new recordkeeping systems, including those based on block-chain technology, which make it easier to obtain vital supply chain information in case of a recall or other food safety event.²⁸ These systems are also capable of using security features to easily and securely maintain protections for confidential commercial information, which can then be instantaneously unlocked in the event this information is needed to effectuate a recall.²⁹

A policy requiring consignee lists for all recalls would have the potential to accelerate the adoption of this new technology throughout the supply chain. Manufacturers that adopt better supply chain practices could thereby reduce the resources needed to carry out recalls. Likewise, retailers that adopt such practices could avoid being mistakenly implicated in recalls. Better supply chain information would also have the benefit of facilitating swifter traceback in the event of an outbreak of foodborne illness.³⁰ All of this benefits industry as a whole by helping federal officials target recalls more narrowly, allowing consumers to continue buying with confidence those foods that are free of health risks.

III. The FDA Should Reserve Aggregate Data for Rare Exceptions

The draft guidance indicates that the agency may provide aggregate information in some cases (e.g., “all Grocery ABC stores nation-wide”³¹). While summaries may be appropriate under certain circumstances, there are also cases involving large and diverse outbreaks in which individual store names and addresses can be valuable. For example, if a product was shipped to a variety of stores in multiple regions, consumers and local reporters may rely on store names and

²⁷ The Draft Guidance, *see supra*, footnote 1.

²⁸ Radocchia, S. Three Innovative Ways Blockchain Will Build Trust in the Food Industry. *Forbes*, April 26, 2018. Accessed at: <<http://www.forbes.com/sites/samantharadocchia/2018/04/26/3-innovative-ways-blockchain-will-build-trust-in-the-food-industry/#15c51bf12afc>>.

²⁹ For example, blockchain technology has the capacity to encrypt every entry, making it secure from other users. Retailers, processors and suppliers can then develop specific protocols for unlocking specific supply chain information in the event of a recall or outbreak traceback. Wasik, R. Enhancing food safety with blockchain technology. *Food in Canada*, February 22, 2018. Accessed at: <<http://www.foodincanada.com/opinions/enhancing-food-safety-blockchain-technology/>>.

³⁰ Banker S, Blockchain Gains Traction in the Food Supply Chain. *Forbes*, July 25, 2018. <www.forbes.com/sites/stevebanker/2018/07/25/blockchain-gains-traction-in-the-food-supply-chain/#1f161ccd1cf9>.

³¹ The Draft Guidance, *see supra*, footnote 1.

addresses to discern whether stores in their neighborhood or region were affected. We therefore encourage the agency to make the provision of detailed information the default and clearly delineate specific circumstances under which aggregate data would be more appropriate, so that providing an aggregate summary can be the exception, rather than the rule.

IV. The FDA Should Establish a Policy for Restaurants

We encourage the FDA to clarify the circumstances under which it intends to publish the names of restaurants during recalls. The current version of the draft guidance excludes restaurants, indicating that “[m]ost restaurants and similar entities are not considered retail consignees under this policy because identifying them would not enable consumers to recognize recalled food in their possession.”³² We disagree with this exclusion. First, consumers may well have taken food home from a restaurant for later consumption. Even if they have not, they may still benefit from knowing they have recently eaten at a restaurant implicated in a recall, as this information could allow them to seek early appropriate medical treatment and avoid spreading an illness to others.

Patients with many types of foodborne illness contracted in restaurants can benefit from early identification and appropriate medical treatment. This can include diverse methods ranging from administering equine-derived antitoxin in cases of botulism to prophylactic vaccination for hepatitis A.³³ Accurate diagnosis is important because treatment for similar symptoms may vary: antibiotics are helpful in reducing the risk of complications for *Campylobacter*, *Shigella*, and some *Salmonella* and *E. coli* infections, but will increase the risk of severe complications for STEC *E. coli* infections.

Early identification can also help prevent the spread of disease by causing sick individuals to delay a return to work, school, or daycare, where they can spread the disease to others. Daycare centers, in particular, have been a tragic source of secondary *E. coli* O157:H7 infection, as children and caregivers with this disease may initially believe they carry harmless diarrhea and return to infect others.³⁴ At least one high-profile death in the 1990s was traced back to a child who had contracted *E. coli* O157:H7 as part of a restaurant outbreak, but whose symptoms were mild enough to continue to attend daycare.³⁵ Had his family learned earlier of the outbreak, additional infections could have been prevented.

The FDA has previously recognized the value of publishing restaurant names during recalls, and posted the names of restaurants in at least one prior outbreak of hepatitis A infection, allowing patrons of these establishments to identify the potential exposure and consult with their

³² The Draft Guidance, *see supra*, footnote 1.

³³ American Medical Association, et al. Diagnosis and Management of Foodborne Illness. *MMWR*. 2004;53(RR04):1-33. Accessed at: <www.cdc.gov/mmwr/preview/mmwrhtml/rr5304a1.htm>.

³⁴ Field C. Deadly *E. Coli* Outbreak at Daycare Began with Teacher, Lawsuit Alleges. *WYFF News 4*, August 13, 2015. Accessed at: <www.wyff4.com/article/deadly-e-coli-outbreak-at-daycare-began-with-teacher-lawsuit-alleges/7016695>; Associated Press. *E. Coli* Kills 1, Sickens 3 at Day Care. April 10, 2010. Accessed at: <www.cbsnews.com/news/e-coli-kills-1-sickens-3-at-day-care/>.

³⁵ Reuters. 17-Month-old is 3rd Child to Die of Illness Linked to Tainted Meat. *The New York Times*. February 22, 1993. Accessed at: <www.nytimes.com/1993/02/22/us/17-month-old-is-3d-child-to-die-of-illness-linked-to-tainted-meat.html>.

physicians on the need for prophylaxis.³⁶ The FDA also named McDonald's in a recent multi-state outbreak of *Cyclospora* infection linked to salads sold at that restaurant chain, and instructed consumers with symptoms to contact their healthcare provider to receive care.³⁷

We urge the FDA to expand its draft guidance by committing to publish restaurant names in all recalls for which a public warning has been issued. At a minimum, the agency should collect and publish the names of restaurants in cases where early interventions could be effective in altering the course of treatment (e.g., prophylactic vaccination for hepatitis A), as well as recalls involving pathogens that can easily spread to others through person-to-person contact (e.g., *E. coli* O157:H7).

V. Conclusion

The undersigned groups support the FDA's draft guidance as an important step forward for transparency and public health. We urge the agency to expand the scope of the guidance in order to be most effective for consumers. In particular, we urge the agency to publish retail consignee lists in all cases where a public warning is issued, and to advise that such lists be included in all public warnings that are drafted by industry. We also urge the agency to make detailed information the norm, aggregating only for clearly-delineated exceptions. Finally, we encourage the agency to include restaurants within the scope of its policy.

Thank you for your consideration. We urge you to incorporate our recommendations into the final version of the guidance.

Sincerely,

Center for Foodborne Illness Research and Prevention
Center for Science in the Public Interest
Consumer Federation of America
Consumer Reports
Food and Water Watch

³⁶ U.S. Food and Drug Administration. FDA Investigates Findings of Hepatitis A Linked to Frozen Tuna. June 8, 2017. Accessed at: <www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm561199.htm>.

³⁷ U.S. Food and Drug Administration. FDA Investigation of a Multistate Outbreak of Cyclospora Illnesses Linked to Fresh Express Salad Mix Served at McDonald's Ends, September 12, 2018. Accessed at: <www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm613513.htm#Symptoms>.