Consumer Federation of America

October 25, 2023

Commissioner Robert Califf
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Modernizing Recalls of FDA-Regulated Commodities (Docket No. FDA-2023-N-2393)

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV

Dear Commissioner Califf:

On behalf of Consumer Federation of America, I am writing in response to the U.S. Food and Drug Administration's ("FDA") request for comments regarding modernizing recalls of FDA-regulated commodities. CFA is an association of over 250 non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. We commend FDA for soliciting public comment on this topic of vital importance, and for holding a public meeting to allow stakeholders, including representatives and survivors of foodborne illness, to share their perspectives.

As I noted in my oral comments at the hearing, modernizing food recalls involves many complex and difficult policy questions. Fortunately, at least one step towards modernization has a proven pedigree and robust public support: publishing the names and locations of retailers selling recalled foods. Consumer and food safety groups have long advocated for the FDA to publish lists of retail consignees of foods subject to class 1 recalls, consistent with the policy that the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has implemented since 2008.[1] In November of 2018, FDA issued a draft guidance titled Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls.[2] That draft guidance improved upon past policy by clarifying that FDA would publish the identities of retailers selling certain recalled foods, namely: 1) foods not easily identified by retail packaging (or lack thereof) and 2) foods determined to likely still be in the consumer's possession. However, the guidance continued to perpetuate the myth that FDA lacks legal authority to identify retail consignees in class 1 recalls. Specifically, the guidance states that "in some recalls, identifying 'retail consignees' may reveal

[1] U.S. Department of Agriculture, Food Safety and Inspection Service. "Availability of lists of retail consignees during meat or poultry product recalls." Fed. Reg. 73 (2008), pp. 40939-40948.
[2] Letter from Food Safety Advocates to Scott Gottlieb Regarding Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls, November 26, 2018. Accessed at: https://consumerfed.org/testimonial/food-safety-advocates-urge-greater-transparency-in-fda-recall-disclosure-policy/

confidential business relationships between suppliers and customers which may be confidential commercial information (CCI), the disclosure of which is restricted by law and FDA regulation."[3]

This is not true. As consumer advocacy groups have explained previously, neither federal law nor FDA regulations prevent the agency from disclosing retail consignees. Retail consignee information does not fall under Exemption 4 of FOIA or FDA's related regulations.[4] According to federal case law, "commercial or financial matter is confidential for purposes of the [FOIA] exemption if disclosure of the information is likely either (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained."[5] Neither of these conditions hold with respect to retail consignee information. First, because the Federal Food, Drug, and Cosmetic Act authorizes FDA to require submission of retail consignee information, [6] "there is presumably no danger that public disclosure will impair the ability of the Government to obtain this information in the future."[7] Second, disclosing the names and locations of retailers of recalled food products would not harm the competitive position of businesses, as FSIS explained in its 2008 rulemaking, "because of the complex food distribution system in the United States," which obscures the relationship between any given list of retail consignees and the recalling firms' customer list.[8]

Yet even if FDA maintains that FSIS has misinterpreted the FOIA statute and that a list of places that sold recalled goods is "confidential commercial information," the agency may still release the information pursuant to the Food Safety Modernization Act (FSMA).[9] In particular, FSMA authorizes the FDA to release information about where a recalled product is sold by directing the

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[3] Food and Drug Association. (2020). *Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls.* https://www.fda.gov/media/116401/download.

[4] 5 U.S.C.A. § 552(b)(4); 21 C.F.R. 20.61 ("Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.").

[5] *Critical Mass Energy Project v. Nuclear Reg. Commn*., 975 F.2d 871, 873 (D.C. Cir. 1992) *citing National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C.Cir.1974) (internal quotations omitted).

[6] *See, e.g.,* 21 U.S.C. §350f(d), (e)(9) (requiring food companies to submit a report to FDA on recalled foods that includes "[t]he contact information for parties directly linked in the supply chain"; 21 U.S.C. §350f(f) ("the Secretary may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include . . . any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food."); 21 U.S.C. § 350*l*(b)(1) (describing FDA's authority to order a mandatory recall).

[7] *Nat'l Parks & Conservation Ass'n*, 498 F.2d at 770.

[8] FSIS, *supra* note 4, at 40942-43 ("FSIS, however, in considering the application of Exemption 4, has determined that the names and locations of retail consignees of recalled meat and poultry products compiled by the Agency do not constitute confidential commercial information because the disclosure of this information will not impair the Agency's ability to obtain necessary information in the future and will not cause substantial harm to the competitive position of any business.").

[9] "The mere fact that information falls within a FOIA exemption does not of itself bar an agency from disclosing the information." *Bartholdi Cable Co., Inc. v. F.C.C.*, 114 F.3d 274, 281 (D.C. Cir. 1997) (holding that challenged Federal Communications Commission regulation could provide for disclosure of materials exempt under FOIA Exemption 4 to the extent that policy considerations favoring non-disclosure were outweighed by factors favoring disclosure.)

agency to determine what information is "necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food," and to publish that information "on the Internet website of the Food and Drug Administration."[10] The names and locations of retailers of recalled products are absolutely "necessary to enable a consumer" to take action that would protect themselves and their families in response to a recall, as consumers may lack information about a product beyond knowing the store at which the product was purchased.[11] This information can serve to prevent illness long after a recall is announced in the case of foods that may be held in freezers or pantries for months or even years after purchase. Additionally, the information may prompt a consumer to seek medical attention for a serious foodborne illness, rather than take a "wait-and-see" approach.

Again, FSIS has disclosed retail consignees of meat and poultry products subject to Class 1 recalls since 2008, and that agency's experience suggests that FDA will benefit from adopting a similar policy. The FSIS policy has led to greater transparency. According to a 2020 research study, "the proportion of recalls with retailer information increased over time," from 17% of recalls in 2010 to 89% of recalls in 2015, "which suggests that policy compliance improved."[12] By contrast, a 2018 Inspector General's report notes that "FDA did not always assign audit checks consistent with the audit check levels in the audit plan" in part because "the consignee distribution lists that FDA obtained from recalling firms were not always complete or accurate." [13] As a result, the Inspector General recommended that FDA "take steps to . . . ensure the completeness and accuracy of consignee distribution lists."[14] One sure fire way to improve the completeness and accuracy of these consignee distribution lists is to publicize them.

Aligning FDA's retail consignee disclosure policy with FSIS', and abandoning the myth that Congress has not given FDA the same authority as FSIS, would generate other benefits. Information about retail consignees of recalled foods could help to generate local media coverage of recalls, and increase the odds of recall information reaching a consumer. Publicizing retail consignee lists would also facilitate collaboration with state regulatory partners. According to a survey of Association of Food and Drug Official members, FDA's "inability to share distribution information" poses a frequent obstacle to recall efforts.[15] Similarly, the state and local public health officials have complained that "the inability of local health departments to see distribution lists in order to conduct recall audit checks at the retail level leaves public health at risk."[16]

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[10] 21 U.S.C. §350f(f)-(h).
[11] *Id.*
[12] Yu, J., Hooker, N.H. (2020). Assessing the Impact of Retailer Disclosure on the Effectiveness of U.S. Meat and Poultry Recalls. *Journal of Food Protection, 83(12).*
https://www.sciencedirect.com/science/article/pii/S0362028X22103583
[13]Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process, 115th Cong.(2018) (testimony of Gloria L. Jarmon).
https://oig.hhs.gov/documents/testimony/53/20180119_-_Jarmon_Testimony.pdf
[14] *Id.*
[15] Association of Food and Drug Officials. (2022). *Recall Modernization: Accelerated Partnering for Effective Recalls*. AFDO-Recall-Whitepaper-Executive-Report-4.22.pdf
[16] *Id.*

Conclusion

Protecting public health involves many tough trade-offs. Recalls are expensive. Potentially effective means of identifying consumers of recalled goods, such as using credit card data, implicate serious privacy concerns. Risk communication must navigate a complex array of diverse audiences, interests, and levels of sophistication. Publishing retail consignee lists represents a rare opportunity to promote public health with little downside. FDA should enact a policy now requiring food companies to submit, for publication on the FDA website and elsewhere as the agency sees fit, lists of retail consignees of food and beverage products under FDA jurisdiction subject to a Class 1 recall.

Thank you for your consideration of these comments,

Thomas Gremillion
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Consumer Federation of America