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FDA Publicity and Enforcement in the COVID-19 Era

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In his 1973 article, *Adverse Publicity by Administrative Agencies*, Professor Ernest Gellhorn surveys the methods and mechanisms employed by various administrative agencies in the United States and offers suggestions for reform.[1] A significant principle in his work is that agency publicity is important because it serves the dual functions to "inform or warn" and to sanction.[2] The U.S. Food and Drug Administration ("FDA") is one significant utilizer of publicity authority. The FDA's grant of publicity authority is contained in 21 U.S.C. § 375(b), which states:[3]

> Information regarding certain goods. The Secretary may also cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.[4]

Subsequent scholarship has built on Gellhorn's seminal work, focusing on aspects of agency publicity and practices, the legal challenges to agency publicity, the benefits and burdens of publicity, the motivations behind it,

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1. Ernest Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380 (1973).

2. *Id.* at 1382–1418.

3. This is also enacted within the Food, Drug & Cosmetic Act, § 705(b).

4. 21 U.S.C. § 375(b). In furtherance of this statutory provision, the Department of Health, Education and Welfare (now the Department of Health and Human Services) issued Recommendation 73-1, which the United States Food and Drug Administration ("FDA") adheres to in supporting its use of publicity. Adverse Agency Publicity (Recommendation 73-1), 1 C.F.R. § 305.73-1 (1974). The FDA also proposed a rule in 1977 regarding publicity policy, but never finalized it. The FDA has historically faced litigation for use of this publicity authority, although courts have given the agency tremendous discretion in this realm.

the resulting public response and reputational damage, and the evolving scope of activity in this realm. Nearly 50 years after Gellhorn's article, Professor Nathan Cortez revisited Gellhorn's survey methodology and results in a 2011 law review article[5] and a 2015 report to the Administrative Conference of the United States,[6] urging that agencies have moved into an era of "modern publicity" given the range of social media, internet, and other outlets. Within the report, Cortez writes that FDA officials have shifted their views on the use of publicity over time. Cortez notes:

> Wayne Pines, former FDA Chief of Press Relations and Associate Commissioner for Public Affairs, explains that FDA senior leadership has long believed that Congress authorized FDA "to use publicity as an enforcement tool."[7] Current FDA officials stress that FDA no longer views publicity as an enforcement tool.[8]

Global public health emergencies such as the current COVID-19 pandemic provide urgent context to the scope of the FDA's legal authority, including enforcement actions and widespread public health warnings issued through adverse publicity power to counter fraudulent and dangerous product promotion. As has been explored in the legal scholarship, the FDA operates differently than it did in 1973, when Gellhorn published his findings, and now tailors its behavior to the urgency of a given situation.[9] In order to further study how the FDA is pursuing its public health mission in the COVID era, this Article both qualitatively and quantitatively explores recent FDA activity, through the mechanisms of publicity and warning letters, against allegedly violative medical products promoted or advertised for use as a treatment or prevention for COVID-19. The methodology involves scholarly literature review, online searches of the FDA's publicly available materials, analysis of the findings, and discussion of the implications for public health and policy.

Part I of the Article identifies the legal and policy basis of the FDA's authority to take actions utilizing adverse publicity and reviews the prominent scholarly literature discussing its scope. Part II explains the relationship between adverse publicity and enforcement from a historical perspective, noting the evolution of FDA activities in these realms and the use of warning letters to convey information to industry and the general

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5. Nathan Cortez, *Adverse Publicity by Administrative Agencies in the Internet Era*, 2011 BYU L. REV. 1371.

6. NATHAN CORTEZ, ADMIN. CONF. OF THE U.S., AGENCY PUBLICITY IN THE INTERNET ERA (2015).

7. *Id.* at 31 (citing Interview with Wayne Pines, President, Regul. Servs. & Health Care, APCO Worldwide (Jul. 7, 2015) (former FDA Chief of Press Rels. (1975–78) and Assoc. Comm'r for Pub. Affs. (1978–82))).

8. *Id.*

9. *See, e.g.*, Cortez, *supra* note 5; CORTEZ, *supra* note 6; Cortez, *infra* note 74.

public. Part III utilizes a quantitative and qualitative approach to explore the FDA's use of warning letters and publicity in the enforcement of laws and regulations during the COVID-19 pandemic, assessing the breadth of actions undertaken by the agency in the period of January 2020 through June 2020. Part IV offers concluding reflections on the implications of this activity in the context of COVID-19 as it relates to evolving notions of enforcement and adverse publicity.

I. ADVERSE PUBLICITY

A. Authorizing and Defining Adverse Publicity

The statutory provision authorizing publicity is short, neither providing explicit bounds for the term "publicity," nor even using the term. The statute merely states that where, in the opinion of the Secretary, there is a situation involving "imminent danger to health or gross deception of the consumer," the Secretary may "cause to be disseminated information" regarding that situation.[10] The legislative history provides little help in deciphering the scope of this language that has come to be known as the adverse publicity power. A previous draft of the Senate bill that eventually became law granted the Secretary the power to report virtually all proceedings, including initial findings, and to publicize "such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud."[11] Conversely, a third draft included a clause that forbade the release of information specifically naming brands, except in cases of imminent danger or gross consumer deception.[12]

The Administrative Conference of the United States ("ACUS") has issued Recommendation 73-1, which further discusses and guides the use of adverse publicity by federal administrative agencies.[13] Adopted in 1973, the recommendation draws from Gellhorn's findings and is codified in the Code of Federal Regulations.[14] The document, often cited as Recommendation 73-1, refers to "adverse agency publicity" as "statements made by an agency or its personnel which invite public attention to an agency's action or policy and which may adversely affect persons identified

10. 21 U.S.C. § 375 (2018). This authority to the Secretary of Health and Human Services is delegated to the Commissioner of the FDA.

11. S. 1944, 73d Cong. (1933).

12. S. 2800, 73d Cong. (1934). Notably, the accompanying record confirms that the modification of this clause was to avoid pre-judgment censure affecting a particular company or segment of the economy. SEN. REP. NO. 493 (1934).

13. Adverse Agency Publicity (Recommendation 73-1), 1 C.F.R. § 305.73-1 (1974).

14. *Id.*

therein."[15] In a footnote, the ACUS distinguishes publicity from "the mere decision to make records available to the public rather than preserve their confidentiality[,]" as directed by criteria established in the Freedom of Information Act.[16] There is no further elaboration on the scope or format of actions and policy that are used by an agency in this context. The recommendation further emphasizes the potential for serious, and often unfair, injury to the regulated party and rebukes such publicity when "erroneous, misleading or excessive or it serves no authorized agency purpose."[17]

The ACUS recommendation also expressly notes that some agencies utilize adverse publicity as their primary enforcement method and recognizes that such publicity is not typically subject to judicial review.[18] The document also sets forth five standards for agency use of adverse publicity: (1) that the publicity be factual and accurate, avoiding disparaging terms; (2) that publicity relating to regulatory investigations should issue only in limited circumstances (and listing those circumstances); (3) that the publicity should issue only after an agency has taken reasonable precautions to assure the accuracy and verify an authorized purpose; (4) that, where appropriate, the target of the adverse publicity be given advance notice and reasonable opportunity to prepare a response; and (5) that, if the publicity is shown to be erroneous or misleading, the agency issue a retraction or correction.[19]

The Department of Health, Education, and Welfare—now the Department of Health and Human Services ("DHHS")—also codified regulations following the issuance of the ACUS recommendation.[20] These regulations are directly binding on the FDA, as an agency within the DHHS. In the DHHS codification, adverse information is defined as "any statement or release by the Department or any principal operating component made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein."[21] Although parsed into subsections, the substance of the regulations is nearly identical to that of the ACUS recommendation.[22] The legal impact of the DHHS regulation binds the FDA to follow it as law applicable to the agency. In

15. 1 C.F.R. § 305.73-1.
16. § 305.73-1(a) n.1.
17. § 305.73-1.
18. § 305.73-1(b).
19. § 305.73-1.
20. *See generally* Release of Adverse Information to the News Media, 45 C.F.R. §§ 17.1–.7 (1976).
21. § 17.1.
22. §§ 17.1–.7.

1977, the FDA published a notice of proposed rulemaking that described intentions to issue a rule further directing the agency's use of adverse publicity.[23] However, the proposed rule was never finalized.

B. Assessing Adverse Publicity in the Scholarly Literature

The administrative law literature is an extremely useful resource to define the phrase "adverse publicity" as a foundational matter, as well as to compare it with the FDA's practice of issuing warning letters for perceived violations of the statute and regulations. The target audience of each mechanism of communication has traditionally been viewed as distinct and acutely relevant to the issue of whether one versus the other furthers the protection of the public health. On the one hand, adverse publicity targets a broad audience utilizing a range of outlets, including print, social media, and internet. Adverse publicity is wide-ranging in the scope and focus of the message. On the other hand, warning letters are drafted in a templated fashion and targeted directly to an individual or company. Although warning letters are publicly available on the FDA's website, a consumer, medical specialist, or other interested party must actively search for such a communication and be able to comprehend the complexities of the regulations and laws as detailed in the letter. Part II attempts to disentangle the purpose, audience, and intent of adverse publicity as compared to enforcement through warning letters. However, as Part IV will emphasize, the two communications are now typically cross-referenced through electronic means and are no longer completely separate.

On the first page of his seminal article, Professor Ernest Gellhorn defines adverse publicity as "affirmative measures taken by an agency which, by calling public attention to agency action, may adversely affect persons identified in the publicity."[24] He defines the roles of adverse publicity to *inform* the public and regulated parties about the agency's mission, policies, and performance; to *warn* the public of imminent harm; and to *punish* or deter legal violations.[25] However, he does not deem these categorizations mutually exclusive.[26]

Gellhorn considers announcing administrative policy or action to be the primary role of agency publicity.[27] Such publicity brings attention to information that might otherwise be ignored, informs those regulated by the

23. Administrative Practices and Procedures: Publicity Policy, 42 Fed. Reg. 12,436-02 (Mar. 4, 1977).

24. Gellhorn, *supra* note 1, at 1381.

25. *Id.* at 1382.

26. *Id.* at 1382 n.6.

27. *Id.* at 1382. Gellhorn reminds readers that not all publicity is "adverse," especially the informational variety. *Id.* at 1382 n.6.

agency of new policies, aids in administrative efficiency by anticipating questions, and promotes fairness by serving as notice.[28] He contrasts agency announcements with another type of "informational" publicity—agency warnings.[29] Agency warnings can be more controversial, because within a certain context, warnings are desirable and necessary—for example, the threat of serious and imminent physical or economic harm. However, defining the scope of imminent physical or economic harm that justifies the use of adverse publicity can be particularly difficult in practice.[30]

Finally, Gellhorn stipulates that, on occasion, publicity can be used to punish, deter, or force transgressors to negotiate or settle, defining these uses as "sanctions."[31] While Gellhorn notes that agency publicity has, at times, been issued solely for the purpose of injuring or sanctioning the party, more often, sanctions are issued along with information or a warning aimed toward public consumption.[32] Individual types of publicity (e.g., warning letters, press announcements, and talk papers) are not defined. Gellhorn primarily uses "voluntary recalls" as examples of adverse publicity in his FDA-specific analysis.[33]

Professor Lars Noah sees agency "arm-twisting" in licensing, government contracting, and enforcement proceedings.[34] In a 1997 article, he discusses warning letters within his analysis of government contracting.[35] His analysis of adverse publicity, like that of Professor Gellhorn, focuses more on the FDA's authority to compel a "voluntary recall."[36] More recently, Noah criticized 21 U.S.C. § 375(b) for being so ambiguous in scope as to essentially empower the FDA to exercise extrajudicial authority.[37] He cites Professor Gellhorn's strong statement: "Publicity is

28. *Id.* at 1383. Professor Nathan Cortez recognizes these uses in his note, as well. Cortez, *supra* note 5, at 1379–80.

29. Gellhorn, *supra* note 1, at 1383.

30. *Id.* Gellhorn notes that often the harm that results from informational publicity is because it has a "gross" impact—the agency wields publicity like a machete where a scalpel would suffice. *Id.* at 1405.

31. *Id.* at 1382.

32. *Id.*

33. *Id.* at 1407–16.

34. Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 876.

35. *Id.* at 886. Warning letters traditionally advised the addressee that the government purchasing entities had been advised to stop dealing with them until remedial action was taken. This no longer happens.

36. *Id.* at 887; *see also* Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008) (also focusing on the FDA's ability to use publicity to extra-statutorily "encourage" recalls, in addition to licensing contingent on post-market surveillance).

37. Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 128–29 (2014).

quicker and cheaper [than other enforcement measures]; it is not presently subject to judicial review or other effective legal control; and it involves the exercise of pure administrative discretion."[38]

Within his article, Professor Noah also discusses Professor Tim Wu's "Agency Threats."[39] Wu argues that

> [t]hreat regimes . . . are important and are best justified when the industry is undergoing rapid change—under conditions of "high uncertainty." Highly informal regimes are most useful, that is, when the agency faces a problem in an environment in which facts are highly unclear and evolving. . . . Conversely, in mature, settled industries, use of informal procedures is much harder to justify.[40]

He distinguishes public and private agency threats—explicitly categorizing warning letters as a form of private threat.[41] He states "[t]he greatest advantage of a threat regime is its speed and flexibility."[42] Professor Wu refers to an inappropriate use of adverse publicity as a "conviction by press release."[43] Wu writes,

> Threats are not intended as a permanent solution, but rather as part of a longer process. If successful and widely respected, it is possible that a threat may create an industry norm, removing the need for rulemaking at all. Alternatively, a threat regime may be a pilot, as it were, for eventual lawmaking. The law created by rulemaking or adjudication will then benefit from the facts developed under the threat regime.[44]

Professor Nathan Cortez has explored the use of adverse publicity in the internet era, connecting his research with that of Gellhorn. Cortez comments on the sheer range of internet sources utilized by the FDA, stating "[t]he FDA . . . issues adverse or negative publicity in over two dozen different formats, including press releases, warning letters, and a mélange of advisories, alerts, notifications, and updates—not to mention multiple Twitter feeds and the voluminous information it releases on its website."[45] Cortez's research and analysis of internet sources primarily examines "Press Announcements" published on the FDA's website.[46] In his introduction of adverse publicity, Cortez focuses on its specific role in sanctioning firms.[47] He recognizes, and elaborates on, Gellhorn's understanding of sanctions as a way for agencies to amplify statutory enforcement

38. *Id.* at 129 n.173 (quoting Gellhorn, *supra* note 1, at 1424).
39. *Id.* at 124 n.155.
40. Tim Wu, *Agency Threats*, 60 DUKE L.J. 1841, 1842 (2011).
41. *Id.* at 1844.
42. *Id.* at 1851.
43. *Id.* at 1855–57.
44. *Id.* at 1851.
45. Cortez, *supra* note 5, at 1375.
46. *Id.*
47. *Id.* at 1378.

powers.[48] He notes that adverse publicity often precedes or accompanies more traditional or formal enforcement.[49] Cortez, like Gellhorn, defines problematic agency publicity as publicity that is "erroneous, misleading or excessive or it serves no authorized agency purpose."[50] He also characterizes adverse publicity as "a perfect example of what Professor Noah calls extrastatutory 'arm-twisting.'"[51] In the accompanying footnote, Cortez further states, "Professor Noah defines 'arm-twisting' as 'a threat by an agency to impose a sanction or withhold a benefit in hopes of encouraging "voluntary" compliance with a request that the agency could not impose directly on a regulated entity.' This definition encompasses, and Professor Noah thus addresses, adverse publicity."[52]

Later in his article, Cortez stipulates that while "the FDA does not routinely publicize the enforcement actions it initiates—such as issuing a Warning Letter or even signing a consent decree—it does announce a significant number of these actions in press releases, and posts virtually all of them on its website."[53] He further states that, while press releases sound less threatening than warning letters, "both types of documents can constitute a form of punishment against companies that the FDA suspects are violating its regulations."[54] He lists warning letters as a specific form of FDA news announcements (along with media transcripts, press announcements, press releases, and talk papers).[55] However, Cortez later characterizes FDA warning letters as a "passive" form of adverse publicity, in the sense that the FDA posts the information publicly on its website, but does not draw much attention to it.[56] He also states, "[l]ike Warning Letters, which the FDA defines by regulation as informal enforcement actions, the FDA considers adverse publicity to be a statutorily authorized form of informal enforcement."[57] Although never explicitly stated, it seems as though Cortez conceptualizes warning letters as distinct from "adverse publicity."

Professor Cortez's report to the ACUS explicitly addresses the definition of "agency publicity."[58] Cortez first quotes Gellhorn's

48. *Id.* at 1379 ("Agencies also use adverse publicity as a more efficient pressure point to achieve goals authorized by statute.").
49. *Id.*
50. *Id.* at 1382 (citing Adverse Agency Publicity (Recommendation No. 73-1), 1 C.F.R. § 305.73-1 (1974)).
51. *Id.* at 1392.
52. *Id.* at 1392 n.123 (citing Noah, *supra* note 34, at 874).
53. *Id.* at 1408.
54. *Id.* at 1409.
55. *Id.* at 1410.
56. *Id.* at 1411. However, he also notes that the FDA sometimes publicizes warning letters. *Id.*
57. *Id.* at 1414.
58. *See* CORTEZ, *supra* note 6, at 6.

Recommendation 73-1, defining adverse agency publicity as "statements made by an agency or its personnel which invite public attention to an agency's action or policy and which may adversely affect persons identified therein."[59] He notes that, traditionally, the ACUS distinguished adverse publicity from the "mere decision" to make records public.[60] However, in the internet era, the distinction between active and passive disclosure is murky.[61] Cortez states that his previous research was focused on active disclosure, but the ACUS report considers both active and passive disclosures.[62] Furthermore, Cortez writes, "[i]n the past, FDA has used publicity as a regulatory tool, treating both publicity and warning letters as a form of informal enforcement."[63] He discusses warning letters in further detail, clarifying that they are characterized as informal enforcement because, typically, warning letters are used to notify individuals and firms before formal enforcement measures are taken.[64] Cortez quotes the FDA's Regulatory Procedures Manual, which states, "[a] Warning Letter is the agency's principal means of achieving prompt voluntary compliance" with the statute and regulations.[65] Cortez lists warning letters among other forms of publicity,[66] but often refers to them as distinct from "publicity."[67]

Cortez offers that the FDA no longer views publicity as an enforcement tool. Rather, it views publicity as necessary for providing relevant health information to the public, given the FDA's statutorily-mandated mission to promote and protect the public health, and given the broad scope of consumer products the FDA regulates (e.g., drugs, medical devices, foods, and tobacco).[68] This passage recognizes a shift within the FDA toward using publicity to inform and warn the public, rather than those it regulates. Warning letters, themselves, are undoubtedly an enforcement tool. Press announcements about warning letters or the publication of warning letters on the FDA website *could* be viewed as informing or warning the public and, therefore, as adverse publicity.

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59. *Id.* (citing Adverse Agency Publicity (Recommendation No. 73-1), 1 C.F.R. § 305.73-1(a) (1974)).

60. *Id.*

61. *Id.*

62. *Id.* at 7. Cortez specifically references the FDA's warning letter database. *Id.* at 20.

63. *Id.* at 31. This quote is pulled from the same paragraph as the statement "[c]urrent FDA officials stress that the FDA no longer views publicity as an enforcement tool," perhaps suggesting that the FDA now relies exclusively on warning letters to serve that purpose. *Id.*

64. *Id.* at 39.

65. *Id.* at 40; *see also* U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL § 4-1-1 (Mar. 2020), https://www.fda.gov/media/71878/download [https://perma.cc/V3NE-DPYP].

66. CORTEZ, *supra* note 6, at 39.

67. *See, e.g.*, *id.* at 31, 104, 108 (writing consistently "publicity and Warning Letters" or "Warning Letters and accompanying publicity").

68. *Id.* at 31–32.

Cortez provides a comprehensive overview of 21 U.S.C. § 375(b) litigation (as well as actions against other agencies for use of publicity).[69] Only one case involved the use of warning letters.[70] Perhaps coincidently, that same case is also the closest a court has ever come to doing more than simply admonishing the FDA for reckless use of publicity.[71] A more recent case worth highlighting is *Dimare Fresh, Inc. v. United States*, in which tomato producers (whose crop was subject to an FDA warning for salmonella contamination, later discovered to be unfounded) attempted a "takings" argument.[72] However, the court did not adopt the producers' argument, citing familiar counterarguments.[73]

In a subsequent 2018 article, Cortez writes that the goal of disclosure of certain information may not always be to inform, but rather to persuade.[74] He continues, "[a]fter all, is the Surgeon General's Warning on tobacco products meant to tell consumers something they do not already know?"[75] Cortez's work suggests that whether something is effective adverse publicity may depend on the motivation behind the publication and on the audience to whom it is directed. Other scholars have explored the aspect of audience in the context of adverse publicity and tobacco, concluding that

69. *Id.* at app. C: Table of Fed. Cases (1974–2014).

70. *See* Den-Mat Corp. v. United States, No. MJG-92-444, 1992 U.S. Dist. LEXIS 9255 (D. Md. Apr. 24, 1992). Notably, the letters were accompanied by a spokesperson's comments to the media. *Id.* at *3–4.

71. *See id.* at *14 (observing that it would be "inherently unfair" to allow the FDA to use publicity to enforce its determination "without allowing the affected party an opportunity to prove that the FDA's position is wrong"). The court denied the FDA's motion to dismiss; however, there is no record of subsequent case law. CORTEZ, *supra* note 6, at 9. For examples of courts' rather empty condemnations, see *Fisher Bros. Sales, Inc. v. United States*, 46 F.3d 279, 282 (3d Cir. 1995) (ruling in favor of the FDA for fear that extensive tort liability would chill the agency from taking similar action to protect the public's health in the future); *Ajay Nutrition Foods, Inc. v. FDA*, 378 F. Supp. 210, 212, 218 (D.N.J. 1974), *aff'd mem.*, 513 F.2d 625 (3d Cir. 1975) (upholding the FDA's use of publicity, even when the FDA allegedly called health food and dietary supplement manufacturers "quacks" and "faddists"); *United States v. Abbott Lab'ys*, 505 F.2d 565, 571 (4th Cir. 1974) ("[W]e join in the district court's condemnation of this conduct and express our strongest disapproval that highly placed legal officers would make a statement of this import with regard to a pending criminal prosecution, and even more so that the FDA, which had referred the matter to the Department of Justice, would issue a press release containing such prejudicial material."); and *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 34 (D.D.C. 1995) (noting that the FDA's publicity practices allow it to "effectively regulate industry without ever exposing itself to judicial review").

72. Dimare Fresh, Inc. v. United States, 808 F.3d 1301 (Fed. Cir. 2015) (equating the public warning with a quarantine), *cert. denied*, 136 S. Ct. 2461 (2016). In support of their argument in Court of Federal Claims, Plaintiffs cited *Yancey v. United States*, 915 F.2d 1534 (Fed. Cir. 1991) (holding quarantine of undiseased turkey flock was a taking). Dimare Fresh, Inc. v. United States, 118 Fed. Cl. 455, 461 (2014).

73. *Dimare*, 808 F.3d at 1311 (arguing that the warnings were not coercive or binding because they did not prevent the producers from selling their crop—the unfortunate reality that the warnings left the producers without any customers was unpersuasive to the court). The court also raised the familiar counterargument that the FDA should be granted substantial deference in its work to protect the public health. *Id.* at 1310–11.

74. Nathan Cortez, *Regulation by Database*, 89 U. COLO. L. REV. 1, 5 (2018).

75. *Id.*

the FDA's publicity power is virtually ineffective against the Big Tobacco advertising machine.[76]

II. DISENTANGLING ADVERSE PUBLICITY AND ENFORCEMENT

Many theories exist that attempt to explain the FDA's shift away from its view of adverse publicity as an enforcement tool to its utilization of more formal mechanisms, such as warning letters, to urge compliance. For example, one study of the FDA found that as media coverage of the FDA's consumer protection responsibilities became more positive, the agency issued enforcement decisions (warning letters) more slowly, whereas more critical media coverage resulted in quicker action by the FDA.[77] The researchers found that the effect was moderated by media salience—it was only observed during "periods in which press coverage was relatively intense,"[78] such as in time of crisis or national emergency.[79] While an assessment of these theories and relevant supporting evidence is outside the scope of this Article, the discussion informs the quantitative assessments provided in Part III regarding FDA activity in the time of COVID-19.

The FDA has numerous options to carry out the agency's functions authorized by statute. The FDA's traditional command and control regulatory approach to compliance is grounded in applying punitive and deterrent regimes to achieve desired regulatory outcomes. There is rich literature discussing approaches to regulation that supports industry compliance. Ian Ayres and John Braithwaite, for example, have framed a basic approach as "responsive regulation" depicted as an enforcement pyramid with a "range of interventions of ever-increasing intrusiveness (matched by ever-decreasing frequency of use)."[80] Some commentators have characterized the FDA as specifically employing a "coercive approach" to enforcement.[81] In order to achieve regulatory outcomes, the FDA has a range of administrative and enforcement tools at its disposal to monitor and respond to industry behaviors.

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76. Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO ST. L.J. 1053, 1076 n.138 (2017).

77. Moshe Maor & Raanan Sulitzeanu-Kenan, *The Effect of Salient Reputational Threats on the Pace of FDA Enforcement*, 26 GOVERNANCE 31, 31 (2013).

78. *Id.*

79. *See, e.g.*, Sarah Taylor Roller, Raqiyyah R. Pippins & Jennifer W. Ngai, *FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need for Procedural Safeguards to Reduce "Transparency" Policy Harms in the Post-9/11 Regulatory Environment*, 64 FOOD & DRUG L.J. 577 (2009).

80. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 6 (1992).

81. *See generally* Robert L. Glicksman & Dietrich Earnhart, *Coercive vs. Cooperative Enforcement: Effect of Enforcement Approach on Environmental Management*, 42 INT'L REV. L. & ECON. 135 (2015).

The enabling statutes grant the FDA with a variety of mechanisms to address and respond to industry activities. At a general administrative level, the FDA can communicate with consumers, industry, and medical professionals through publicity and outreach. The agency routinely utilizes its website to issue public alerts and share information about products or regulated entities. It also directs letters and electronic communications to medical specialists and pharmacists. Within its broad powers, the FDA can enable product recalls, withdraw a product from the market, remove an approved product indication, and issue a hold on clinical trials. Once a violation is detected, the agency may issue a warning letter or cyber letter, triggering a specific follow-up and close-out process on the part of industry. Inspections of facilities and products are also commonplace, coupled with an official Form 483 identifying observations made by inspectors, and may result in warning letters or legal action. Enforcement may then be effectuated with the assistance of the courts through a seizure action or injunction.

In his 2013 article, *Credible Deterrence: FDA and the Park Doctrine in the 21st Century*, Patrick O'Leary stipulates

> [w]hile warning letters are not technically enforcement actions, in that they are not legally binding on recipients and carry no penalties, [they can be treated] as a form of enforcement due to their frequent use by FDA and the real punitive effect that they can have in terms of negative publicity.[82]

O'Leary also provides a short description of the use of warning letters:

> FDA centers and districts issue warning letters for a wide variety of alleged violations. While they do not constitute final agency action, and do not themselves carry any penalty, they undoubtedly have a negative publicity effect for regulated companies, and allow the agency to communicate its displeasure with a regulated entity openly without committing to a costly enforcement action. While it is unlikely that FDA would consider a warning letter as a substitute for criminal prosecution in a case where the latter could be seriously considered, the widespread use of these letters and their general effectiveness are evidence that FDA's deterrent approach is succeeding, and that the agency's relationship with regulated parties (most of whom are repeat players with no desire to antagonize their regulator unnecessarily) is distinctively asymmetrical.[83]

O'Leary also notes the practical significance of warning letters being available to consumers: "[t]he simple fact of an investigation, warning letter, or some other official suggestion of impropriety can have substantial

82. Patrick O'Leary, *Credible Deterrence: FDA and the Park Doctrine in the 21st Century*, 68 FOOD & DRUG L.J. 137, 155 n.129 (2013).

83. *Id.* at 156.

negative impacts on consumer impressions and employee morale, and can inhibit a company's ability to retain or recruit employees."[84] However, the technical drafting, targeted to an individual or corporate entity, and the need to affirmatively search for the warning letter on the FDA's website, create a barrier to access that does not exist with generally targeted communications through various outlets to the general public. The media may identify such a letter and bring it to the attention of the general public, but for the most part, these letters are not regularly mainstreamed.

The FDA issues thousands of warning letters per year across the spectrum of products that the agency regulates, which includes drugs, biologics, medical devices, food, cosmetics, dietary supplements, tobacco products, veterinary drugs, and radiation-emitting products. The FDA reported that between the period of January 2009 through May 14, 2020, the agency issued a total of 3,141 warning letters: 127 for biologic products; 1,475 for medical device products; and 1,478 for drug products.[85] Those numbers average to approximately 273 warning letters per year: 12 per year for biologics; 128 per year for medical devices; and 128 per year for drugs.[86] In comparison, between the period from March 6, 2020, to June 30, 2020, (roughly four months), the FDA issued 88 warning letters specifically relating to COVID products spanning drug, biologic, and medical device categories.[87] Part III qualitatively and quantitatively assesses the scope and content of those warning letters, which are publicly available on the FDA's website.[88]

The FDA accomplishes dissemination of information directly to the public in various ways, often in tandem with the issuance of a warning letter. These outlets to the public include press releases, either online or in print media, broad-based safety announcements, or topical informational webpages established to address a public health concern or set of products. Over the same four-month period studied for issuance for warning letters, the FDA published 152 press announcements in varying formats. Increasingly, given online modalities and capabilities, the FDA cross-

84. *Id.* at 163.

85. *FDA Dashboard: FDA Compliance Actions*, U.S. FOOD & DRUG ADMIN., https://datadashboard.fda.gov/ora/cd/complianceactions.htm (content current as of May 14, 2020).

86. These averages are based on approximately 11.5 years of data contained in the database (January 2009–May 14, 2020).

87. *Warning Letters*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (content current as of June 22, 2020).

88. The FDA's publicity information regarding warning letters and adverse publicity, as aggregated by the authors, is available in an Excel format through Google Documents. *FDA Publicity and Enforcement in the COVID Era – Raw Data*, https://tinyurl.com/fda-publicity-covid [https://perma.cc/7H4K-T5V6].

references and cross-links industry warning letters with information targeted to the general public through these other online and print outlets.

IV. COVID-19 ENFORCEMENT AND ADVERSE PUBLICITY TRENDS

The current pandemic provides a substantial opportunity to study and scrutinize the FDA's enforcement and publicity response to COVID-19. To accomplish this, the authors of this Article proceeded along several routes of agency communications both to industry and the general public. First, the authors conducted a search of the FDA warning letter database to identify COVID-related communications between January 1, 2020, and June 30, 2020.[89] The methodology was as follows: enter the search term "COVID" in the search field; open and save each letter; and enter into an Excel spreadsheet standardized information, including letter date, issuing FDA Center, product type, legal authority cited, and entity type (e.g., company, individual). Second, the authors searched the FDA Press Announcements webpage for any announcement specific to COVID between January 1, 2020, and July 2, 2020, and similarly saved the results.[90] Upon substantive review of the announcements, the authors characterized the focus of the COVID press announcements, including whether each announcement reported on the issuance of a warning letter or a court decision. Third, the authors searched the webpage entitled "Drug Safety & Availability" to determine whether there were any other COVID-related communications.[91] Initially, the authors selected the link "Drug Safety Communications"[92] and opened each communication listed under the heading "2020" to establish whether any were relevant. After returning to the Drug Safety & Availability page, the authors discovered a searchable "Drug Safety Announcements" section.[93] As with the warning letter methodology, the authors entered the search term "COVID," opened and saved each result, and entered standardized information into a spreadsheet. Due to similarity in function, the authors grouped together the documents identified on the FDA Press Announcement webpage and the specific Drug Safety & Availability webpage as "press announcements" in the description of the findings.

89. Notably, the first warning letter related to COVID-19 was dated March 6, 2020. *Warning Letters*, *supra* note 87.

90. *Press Announcements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-newsroom/press-announcements?page=0 (content current as of May 12, 2020). The first press announcement is dated January 27, 2020. *Id.*

91. *Drug Safety & Availability*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability (content current as of July 13, 2020).

92. *Drug Safety Communications*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications (content current as of July 2, 2020).

93. *Drug Safety & Availability*, *supra* note 91.

In total, the authors identified and assessed 88 warning letters with dates spanning March 6, 2020, to June 30, 2020, and 152 press announcements with dates spanning January 27, 2020, to July 2, 2020. These findings are described below.

A. Warning Letter Findings

The analysis of the warning letters revealed several aspects of the FDA's activity in combating the promotion of unapproved and potentially dangerous products. The Center for Drug Evaluation and Research ("CDER") issued most of the warning letters, by far: 74 out of 88, or 84 percent. The warning letters issued by CDER have been consistent since the declaration of the national emergency in the United States. While fewer in number, the Center for Food Safety and Nutrition ("CFSAN") also issued six letters spread out relatively evenly over the four-month span extending from March through June. In comparison, the Center for Devices and Radiological Health ("CDRH") issued all four of its letters within the same week, close enough in time that the letters were described in a single press announcement.[94] The Center for Biologic Evaluation and Research ("CBER") and the Center for Veterinary Medicine ("CVM") each issued two warning letters. Table 1 depicts the warning letters by issuing Center within the FDA.

94. *Coronavirus (COVID-19) Update: FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Potentially Placing Public Health at Risk*, U.S. FOOD & DRUG ADMIN. (June 17, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-warning-letters-companies-inappropriately-marketing-antibody [https://perma.cc/9KAG-6LRE].

Table 1: Warning Letters by Issuing Center Within the FDA

Issuing Center	**Total Letters**	**Percentage of Total**
Center for Drug Evaluation and Research (CDER)[95]	74	84.09
Center for Devices and Radiological Health (CDRH)[96]	4	4.54
Center for Food Safety and Applied Nutrition (CFSAN)	6	6.82
Center for Biologics Evaluation and Research (CBER)[97]	2	2.27
Center for Veterinary Medicine (CVM)[98]	2	2.27
TOTAL	**88**	**100**

95. One letter was listed as issued by the United States, rather than a particular issuing center; however, it is signed by the director of CDER. U.S. Food & Drug Admin., Warning Letter to Chloroquineonline.com (May 18, 2020) [hereinafter Warning Letter to Chloroquineonline.com], https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/chloroquineonlinecom-607725-05182020 [https://perma.cc/AX2M-U7CD].

96. One CDRH letter was not listed on the warning letter database. U.S. Food & Drug Admin., Warning Letter to KBMO Diagnostics, LLC (June 17, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kbmo-diagnostics-llc-607822-06172020 [https://perma.cc/2XPW-JRV5]. This letter was only found on the "Fraudulent Coronavirus Disease 2019 (COVID-19) Products" page. *See Fraudulent Coronavirus Disease 2019 (COVID-19) Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products (content current as of July 21, 2020). Otherwise the database results (search term: COVID) and the Fraudulent Products page match.

97. This count includes one letter issued by the Office of Biological Products Operations Division II, within CBER. U.S. Food & Drug Admin., Warning Letter to EUCYT Laboratories LLC (June 4, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eucyt-laboratories-llc-607182-06042020 [https://perma.cc/5ZWK-9NHP].

98. The CVM letters were not technically listed under the search term "COVID" on the warning letter database but were included in a COVID-focused press announcement as animal products that the FDA was concerned humans would resort to consuming. *Coronavirus (COVID-19) Update: Daily Roundup April 16, 2020*, U.S. FOOD & DRUG ADMIN. (Apr. 16, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-16-2020 [https://perma.cc/HG2B-P6GW]. After identifying these two letters in the press announcement, the authors accessed them from the same warning letter database as the other letters.

The FDA's online database of warning letters also designates a classification for the product type at issue in each warning letter: drugs, cosmetics, medical devices, biologics, food and beverages, dietary supplements, and animal and veterinary products.[99] Each product category is statutorily defined by Congress and supplemented by FDA policy, and that categorization determines the route to market and applicable legal provisions. Table 2 depicts the FDA's classification of the warning letters by relevant product type, with CDER in bold to highlight the issuance of letters with product categories spanning drugs, food and beverages, and animal and veterinary products. A single warning letter can also contain more than one product classification. The authors identified three examples containing more than one product classification by the FDA, which had the effect of skewing the numbers when compared to Table 1 totals.[100] Like CDER, both CFSAN and CBER issued warning letters addressing multiple product types. This reflects products that were deemed in violation of the statute or regulations by means of their claims pushing the products into another regulatory category. For example, food products that make claims that the product in any way intends to treat, cure, mitigate, or diagnose a disease or condition (i.e., COVID-19) would classify that product as a drug product for legal requirements and enforcement purposes even if otherwise labeled and advertised as food for human or animal consumption.

99. *FDA Publicity and Enforcement in the COVID Era – Raw Data*, *supra* note 88.

100. *See, e.g.*, U.S. Food & Drug Admin., Warning Letter to North Coast Biologics (May 21, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-coast-biologics-607532-05212020 [https://perma.cc/5S38-H4UJ] (including "Biologics" and "Drugs" classifications); U.S. Food & Drug Admin., Warning Letter to Natural Solutions Foundation (May 19, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/natural-solutions-foundation-605748-05192020 [https://perma.cc/YS39-V3XG] (including "Dietary Supplements" and "Drugs" classifications); U.S. Food & Drug Admin., Warning Letter to Savvy Holistic Health dba Holistic Healthy Pet (Apr. 7, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/savvy-holistic-health-dba-holistic-healthy-pet-605915-04072020 [https://perma.cc/J6B2-49Y9] (including "Animal & Veterinary" and "Drugs" classifications).

Table 2: Warning Letters by Product Type

Product Type	**Total**	**Total per Issuing Center**	
Drugs[101]	76	**CDER**	**73**
		CFSAN	2
		CBER	1
Dietary Supplements	3	CFSAN	3
Medical Devices[102]	4	CDRH	4
Biologics	2	CBER	2
Food & Beverages	3	CFSAN	2
		CDER	**1**
Animal & Veterinary	3	CVM	2
		CDER	**1**

101. Two warning letters were not classified at all but were added to this tally based on implicit classification found in the content of each letter. *See* U.S. Food & Drug Admin., Warning Letter to CBD Gaze (May 26, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cbd-gaze-607299-05262020 [https://perma.cc/7PVV-BXL5]; U.S. Food & Drug Admin., Warning Letter to Apollo Holding LLC (May 21, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apollo-holding-llc-607807-05212020 [https://perma.cc/P994-YHBH]. The other 74 warning letters included the explicit FDA classification of "Drugs."

102. One warning letter was not classified at all but was added to this tally based on implicit classification found in the content of the letter. *See* U.S. Food & Drug Admin., Warning Letter to Sonrisa Family Dental dba www.mycovidtest19.com (June 15, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sonrisa-family-dental-dba-www mycovidtest19com-607748-06152020 [https://perma.cc/2J85-6GYM]. The other three warning letters included the explicit classification of "medical devices."

All but three of the 88 warning letters were addressed to a corporate entity.[103] Notably, nine of the warning letters expressly mentioned the use of the Amazon Associates program, where an associate's website advertises, but does not necessarily offer, items for sale. The associate's website instead links to a product's Amazon page for fulfillment. Amazon is copied on all nine warning letters. From a statutory perspective, this is relevant, because prohibited actors under the law include manufacturers, distributors, representatives, and others in the chain of supply of the regulated product.[104] The utilization of the Amazon platform enables more widespread access to the product or information about the product.

Within the warning letters, the FDA relied on a spectrum of legal authorities for alleged violations. In the human drug realm,[105] the most commonly cited trio of legal authority, in 76 of the 88 total letters, included sale of an unapproved drug,[106] general misbranding of a drug,[107] and introduction of an adulterated or misbranded product in interstate commerce.[108] Other legal authority, in addition to this basic trio, includes the additional prohibited act of tampering with a product while held for sale;[109] prescription drug violations;[110] violations of public health emergency;[111] and violations of various subsections of the new drug, misbranding, and adulteration provisions. There were three warning letters that cited a proposed rule regarding an over-the-counter ("OTC") monograph for topical antimicrobial drug products[112] and two proposed rules amending

103. The exceptions included U.S. Food & Drug Admin., Warning Letter to benjaminmcevoy.com (May 14, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/benjaminmcevoycom-607149-05142020 [https://perma.cc/8246-H37C] (regarding a personal blog monetized through the Amazon Associates program); U.S. Food & Drug Admin., Warning Letter to Center for New Medicine/Perfectly Healthy by Connealy MD (May 11, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/center-new-medicineperfectly-healthy-connealy-md-605804-05112020 [https://perma.cc/JR6R -EZ9K] (offering advice from Dr. Connealy herself); U.S. Food & Drug Admin., Warning Letter to North Coast Biologics (May 21, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-coast-biologics-607532-05212020 [https://perma.cc/S9 R4-N94S] (containing evidence of Facebook and LinkedIn posts and comments where individual Johnny T. Stine offered to vaccinate people).

104. Food, Drug, and Cosmetic Act § 301, 21 U.S.C. § 321 (2018).

105. Including those products classified as "Dietary Supplements" in Table 2.

106. *See* 21 U.S.C. § 355(a).

107. *See* § 352.

108. *See* § 331(a), (d). This included introduction of a product in violation of the provisions regarding emergency permits.

109. *See* § 331(k). Thirteen additional letters identified this legal authority.

110. *See* § 353(b)(1).

111. Public Health Service Act § 319, 42 U.S.C. § 247d (2018).

112. Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products, 59 Fed. Reg. 31,402 (proposed June 17, 1994) (to be codified at 21 C.F.R. pts. 333, 369).

the tentative final monograph,[113] as well as the Coronavirus Aid, Relief, and Economic Security ("CARES") Act.[114]

Notably, the Federal Trade Commission ("FTC") co-signed 65 of these 88 warning letters, indicating a strong collaborative effort between the two regulatory agencies to curb unfair and deceptive practices during the pandemic. A total of 58 of the 65 co-signed letters were signed by the director of CDER and the FTC; six of the 65 were signed by the director of CFSAN and the FTC; one of the 65 was signed by the director of CBER and the FTC. As co-signor, the role of the FTC was seemingly to confirm the stance and legal authority of the FDA. Only one letter varied from the others in that it contained additional examples of illegal behavior supplied by the FTC.[115] Those not co-signed by the FTC were either for traditional Chinese medicine or homeopathic remedies, or they were products advertised online through a specific website.[116]

Warning letters for the sale of other types of non-drug products included four letters from CDRH; two of them cite to the definition of device,[117] adulterated device provisions,[118] failure to obtain premarket approval[119] or investigational device status,[120] misbranding provisions,[121] lack of notice to the FDA,[122] introduction of an adulterated or misbranded product into interstate commerce,[123] and tampering with a product while held for sale.[124] Two letters contained additional legal authority regarding misuse of the FDA logo as a specific misbranding violation.[125] There were also two letters relating to biologic products and three relating to a food product, with limited utility to a study of trends.

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113. Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record, 81 Fed. Reg. 42,912 (proposed June 30, 2016) (to be codified at 21 C.F.R. pt. 310); Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record, 80 Fed. Reg. 25,166 (proposed May 1, 2015) (to be codified at 21 C.F.R. pt. 310).

114. The Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. No. 116-136, §§ 3851–56. The provisions relate to procedural aspects regarding tentative final monographs for over-the-counter drug products. *Id.*

115. Warning Letter to Center for New Medicine/Perfectly Healthy by Connealy MD, *supra* note 103.

116. For example, violative products advertised for treatment of COVID-19 were linked to the following websites: https://roidsmall.to/, https://emedkit.com/, Antroids.com, Foxroids.com, https://www.unitedpharmacies.md/, http://chloroquineonline.com/, and http://4nrx.md/.

117. *See* Food, Drug, and Cosmetic Act § 301, 21 U.S.C. § 321(h) (2018).

118. *See* 21 U.S.C. § 351(f)(1)(B).

119. *See* § 360e(a).

120. *See* § 360j(g).

121. *See* § 352(o).

122. *See* § 360(k).

123. *See* § 331(a).

124. *See* § 331(k).

125. *See* § 352(a).

Over half of the warning letters have been resolved in a timely fashion. As of June 30, 2020, 52 addressees had taken corrective action (59 percent of total); 4 additional addressees had taken corrective action prior to the warning letter issuing (64 percent of total, if added to above). However, 32 addressees had not taken corrective action (36 percent of total), including Xephyr, LLC dba N-Ergetics and Genesis II Church, which are now subject to federal court orders, as announced via a press announcement, and discussed below.

Upon closer examination of the letters addressing drug products, an unsurprising trend emerged: more warning letters were issued for certain product types with which the FDA has recently had compliance trouble.[126] For example, 15 warning letters were issued for homeopathic or herbal remedies.[127] Specific products included "Homeopathic Genus Epidemicus,"[128] marketed as a homeopathic medicine for the prevention of COVID-19 symptoms, and boneset tea,[129] marketed to relieve a present infection. Additionally, 9 warning letters were issued for CBD products.[130] More precisely, products like "Restorative Botanicals Ultra High Strength Hemp Oil Supplement"[131] and "NoronaPak"[132] were marketed as regimens to fight off a COVID-19 infection—the latter was claimed to be "pharmacist curated."

The FDA has previously cited its "risk-based approach" to monitoring both of these types of products.[133] Due to the growing popularity of

126. *See, e.g.*, *Statement on the Agency's Efforts to Protect Patients From Potentially Harmful Drugs Sold as Homeopathic Products*, U.S. FOOD & DRUG ADMIN. (Oct. 24, 2019) [hereinafter *Efforts to Protect Patients*], https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-protect-patients-potentially-harmful-drugs-sold-homeopathic-products [https://perma.cc/WF8D-WJDD]; *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd [https://perma.cc/JAH3-9PXN] (content current as of Oct. 1, 2020).

127. *See Warning Letters*, *supra* note 87. Addressees included: Herbal Amy Inc.; Vivify Holistic Clinic; Carahealth; Homeomart Indibuy; Cathay Natural, LLC; Alternative Health Experts LLC DBA Immunization Alternatives; NRP Organics Ltd; Earthley Wellness dba Modern Alternative Mama LLC; Herbs of Kedem; Gaia Arise Farms Apothecary; The Art Of Cure; Dr. Dhole's Sushanti Homeopathy Clinic; Chronic Lyme Treatments; White Eagle Native Herbs; Alternavita. In addition, it may be of note that 11 more letters were issued for essential oil products.

128. U.S. Food & Drug Admin., Warning Letter to Dr. Dhole's Sushanti Homeopathy Clinic (May 4, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-dholes-sushanti-homeopathy-clinic-607348-05042020 [https://perma.cc/9TUJ-ZNJP].

129. U.S. Food & Drug Admin., Warning Letter to Herbal Amy Inc, (Mar. 6, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/herbal-amy-inc-604813-03062020 [https://perma.cc/Y75K-BA7C].

130. *See Warning Letters*, *supra* note 87. Addressees included: CBD Online Store, Indigo Naturals, Native Roots Hemp, NeuroXPF, Project 1600 Inc., CBD Gaze, Apollo Holding LLC, Noetic Nutraceuticals, Nova Botanix LTD d.b.a. CanaBD.

131. Warning Letter to CBD Gaze, *supra* note 101.

132. Warning Letter to Apollo Holding LLC, *supra* note 101.

133. *See* sources cited *supra* note 126.

homeopathic remedies and CBD products in the marketplace, the FDA simply cannot effectively monitor them all; however, the agency's top priority remains protecting the health and safety of the public.[134] At this time, the FDA considers the marketing of these specific types of products as "substitute treatments" for serious or life-threatening diseases to be a significant enough risk to public health to warrant agency intervention.[135] Consequently, in light of the COVID-19 pandemic, the substantial number of warning letters issued for these specific products is unsurprising.

Furthermore, specific product types may have influenced the FDA's decision-making regarding the format, and therefore the audience, of a given publicity statement. The issuance of two different types of publicity for two different types of hand sanitizer provides a strong example. On April 23, 2020, May 7, 2020, and May 28, 2020, respectively, the FDA issued a warning letter for a non-alcohol-based hand sanitizer.[136] Each letter took particular issue with claims of time-specific extended efficacy (i.e., "up to 24 hours of protection!").[137] The FDA stated its concern that the trusting consumer would substitute these products for hand-washing or practicing adequate social-distancing, therefore propagating the spread of COVID-19 and prolonging the pandemic.[138] Contrast these warning letters with a drug safety and availability announcement issued on June 19, 2020, for a methanol-based hand sanitizer.[139] In sharing this communication, the FDA's primary concern was preventing methanol poisoning, which has symptoms including nausea, headache, permanent blindness, seizures, coma, or even death.[140] Ten days later, the FDA updated the announcement

134. *See* sources cited *supra* note 126.

135. *See* sources cited *supra* note 126.

136. U.S. Food & Drug Admin., Warning Letter to Quadrant Sales & Marketing, Inc. (May 28, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/quadrant-sales-marketing-inc-607625-05282020 [https://perma.cc/NDB5-M48Y]; U.S. Food & Drug Admin., Warning Letter to Sanit Technologies LLC dba Durisan (May 7, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sanit-technologies-llc-dba-durisan-606050-05072020 [https://perma.cc/7GRR-Z264]; *see also*; U.S. Food & Drug Admin., Warning Letter to Prefense LLC (Apr. 23, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/prefense-llc-605488-04232020 [https://perma.cc/39CW-86WK].

137. *See* sources cited *supra* note 136.

138. *See* sources cited *supra* note 136; *see also Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns*, U.S. FOOD & DRUG ADMIN. (Apr. 27, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-ensure-availability-alcohol-based-hand-sanitizer-during [https://perma.cc/7S8N-V4XH] (warning consumers about fraudulent and ineffective sanitizer products and containing a hyperlink to the Prefense LLC warning letter).

139. *FDA Advises Consumers Not to Use Hand Sanitizer Products Manufactured by Eskbiochem*, U.S. FOOD & DRUG ADMIN. (June 29, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem [https://perma.cc/3TM2-TADP].

140. *Id.*

to inform the public that the company producing the hand sanitizer had agreed to voluntarily recall its product.[141] However, a few days later, the agency issued a new generalized warning regarding methanol-based hand sanitizers.[142] As of July 20, 2020, the FDA's website listed 75 hand sanitizer products that had tested positive for methanol.[143]

These two types of hand sanitizers were regulated in different ways: non-alcohol-based sanitizer with a warning letter and methanol-based sanitizer with a drug safety and availability announcement. Drug safety and availability announcements tend to be reported much more widely than an average warning letter. For example, the FDA's June 19, 2020, announcement was reported by major media outlets,[144] whereas concerns regarding non-alcohol-based hand sanitizers have been primarily reported by the FDA. Perhaps the seriousness of methanol poisoning influenced the FDA to issue a different, more penetrative form of publicity.

Similarly, the warning letter for Miracle Mineral Solution ("MMS")—comprising chlorine dioxide, which when mixed with citric acid (as instructed) creates a toxic bleach—was the only letter to receive its own press announcement.[145] The FDA had previously warned the public about the dangers of MMS, citing side-effects such as "severe vomiting, severe diarrhea, life-threatening low blood pressure caused by dehydration and acute liver failure."[146] However, starting in March, the addressee Genesis II Church began advertising the COVID-19-fighting properties of MMS across its website, adding to previous claims that the solution can treat "autism, cancer, HIV/AIDS, hepatitis and flu."[147] It is possible that the

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141. *Id.*

142. *FDA Updates on Hand Sanitizers with Methanol*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol [https://perma.cc/K94A-BM79] (refer to July 2, 2020 update).

143. *Id.*

144. *See, e.g.*, Christopher Mele, *F.D.A. Warns of Potentially Toxic Hand Sanitizers*, N.Y. TIMES (Aug. 5, 2020), https://www.nytimes.com/2020/06/22/health/fda-Eskbiochem-toxic-hand-sanitizer-virus.html [https://perma.cc/3EHS-FHQT]; Allen Kim, *These 9 Hand Sanitizers May Contain a Potentially Fatal Ingredient, FDA Warns*, CNN (June 22, 2020, 6:53 PM), https://www.cnn.com/2020/06/22/us/hand-sanitizer-fda-trnd/index.html [https://perma.cc/6T33-JXVG].

145. *Coronavirus (COVID-19) Update: FDA Warns Seller Marketing Dangerous Chlorine Dioxide Products That Claim to Treat or Prevent COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 8, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-seller-marketing-dangerous-chlorine-dioxide-products-claim [https://perma.cc/W2M5-62DL]. As a separate note, this warning letter is unrelated to President Trump's suggestion to kill COVID-19 infection by ingesting bleach. *See Coronavirus: Outcry After Trump Suggests Injecting Disinfectant as Treatment*, BBC (Apr. 24, 2020), https://www.bbc.com/news/world-us-canada-52407177 [https://perma.cc/PQ6K-49CB].

146. *FDA Warns Consumers About the Dangerous and Potentially Life-Threatening Side Effects of Miracle Mineral Solution*, U.S. FOOD & DRUG ADMIN. (Aug. 12, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-about-dangerous-and-potentially-life-threatening-side-effects-miracle-mineral [https://perma.cc/2DXG-98TS].

147. *Coronavirus (COVID-19) Update: FDA Warns Seller Marketing Dangerous Chlorine Dioxide Products that Claim to Treat or Prevent COVID-19*, *supra* note 145.

severe side effects of ingesting MMS, coupled with previous attempts to warn the addressee, resulted in the FDA issuing a press announcement for this warning letter and not for others.

Finally, in addition to four warning letters issued specifically for unapproved "chloroquine" products,[148] the FDA issued several press announcements that discussed the prescription drug hydroxychloroquine ("HCQ"). This comprehensive publicity strategy was reportedly, at least in part, a response to contrary messaging propagated within the executive branch.[149] President Trump repeatedly referred to HCQ as a promising cure for COVID-19, but little to no scientific evidence supported his claim.[150] The President's comments left the FDA in a tricky position—although the agency is authorized to prohibit off-label promotion made by drug manufacturers, it does not have the authority to directly address the President's statements.[151] Ultimately, the FDA decided to release a general press announcement, clarifying that HCQ is only FDA-approved for the treatment of malaria and arthritis.[152] When President Trump later stated that HCQ was "not going to kill anybody" and a man subsequently died from ingesting an aquarium-cleaning product containing "chloroquine," the FDA issued another press announcement advising consumers that chloroquine is not equivalent to HCQ and that any HCQ administration should be under the supervision of a medical professional.[153] On June 15, 2020, the FDA announced that it had revoked HCQ's Emergency Use Authorization for the treatment of COVID-19.[154]

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148. *See* Warning Letter to Chloroquineonline.com, *supra* note 95; U.S. Food & Drug Admin., Warning Letter to 4nrx.md (May 13, 2020), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/4nrxmd-606115-05132020 [https://perma.cc/9FJH-9VBF]; U.S. Food & Drug Admin., Warning Letter to Dr. G's Marine Aquaculture, Inc. (Apr. 15, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-gs-marine-aquaculture-inc-606979-04152020 [https://perma.cc/4PER-XQ9L]; U.S. Food & Drug Admin., Warning Letter to Fishman Chemical of North Carolina, LLC (Apr. 15, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/fishman-chemical-north-carolina-llc-606978-04152020 [https://perma.cc/9F6A-KFLH].

149. *See* Elizabeth Y. McCuskey, *FDA in the Time of COVID-19*, 45 ABA ADMIN. & REG. L. NEWS, no. 3, 2020, at 7–8.

150. *See id.*; *see also* Philip Bump, *Trump and Fox Went All-in on a Coronavirus Silver Bullet. But Maybe the Wrong One*, WASH. POST (Apr. 19, 2020, 6:00 AM), https://www.washingtonpost.com/politics/2020/04/19/trump-fox-went-all-in-coronavirus-cure-what-if-they-picked-wrong-one/ [https://perma.cc/HJ2L-H4Z9].

151. McCuskey, *supra* note 149, at 8.

152. *Id.*

153. *Id.* at 8–9; *see also Coronavirus (COVID-19) Update: Daily Roundup April 16, 2020*, *supra* note 98.

154. *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine*, U.S. FOOD & DRUG ADMIN. (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and [https://perma.cc/F3UX-V5GE].

B. Press Announcement Findings

An analysis of the press announcements identified several important aspects of the FDA's activity in this realm. Of the 152 press announcements reviewed, 96 did not contain any form of adverse publicity regarding an identified company or individual. These published announcements contained information, in the form of hyperlinks, directing consumers to guidance documents, updates on FDA procedures, and announcements of awarded emergency use authorizations for a drug, biologic, or medical device product.[155]

The press announcements that linked to publications on the Drug Safety Communications webpage were the strongest form of adverse publicity reviewed.[156] The "Drug Safety Communications" webpage is housed under the "Drug Safety and Availability" section of the FDA's website.[157] The purpose of the "Drug Safety and Availability" section of the website is to provide information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically-necessary drug products.[158] This section predominantly features a link to the "Drug Safety Communications" webpage, as well as its own searchable list of announcements.[159] During the timeframe analyzed, the searchable list of announcements contained four COVID-19-related publications: two drug safety communications, an advisement on the use of Non-Steroidal Anti-Inflammatory Drugs ("NSAIDs") to soothe COVID-19 symptoms,[160] and a warning issued specifically for hand sanitizer manufactured by Eskbiochem.[161] Unlike the drug safety communications, the other announcements did not have a corresponding press announcement.

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155. For a careful analysis of the scope and impact of the FDA's emergency use authorizations during COVID-19, see Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE L.J.F. 78 (2020).

156. *FDA Updates on Hand Sanitizers with Methanol*, *supra* note 142; U.S. FOOD & DRUG ADMIN., DRUG SAFETY COMMUNICATION: FDA CAUTIONS AGAINST USE OF HYDROXYCHLOROQUINE OR CHLOROQUINE FOR COVID-19 OUTSIDE OF THE HOSPITAL SETTING OR A CLINICAL TRIAL DUE TO RISK OF HEART RHYTHM PROBLEMS (Apr. 24, 2020) [hereinafter FDA CAUTIONS AGAINST USE OF HYDROXYCHLOROQUINE], https://www.fda.gov/media/137250/download [https://perma.cc/Q39X-SLWP].

157. *See Drug Safety Communications*, *supra* note 92; *Drug Safety & Availability*, *supra* note 91.

158. *Drug Safety & Availability*, *supra* note 91.

159. *Id.*

160. *FDA Advises Patients on Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for COVID-19*, U.S. FOOD & DRUG ADMIN. (Mar. 19, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-patients-use-non-steroidal-anti-inflammatory-drugs-nsaids-covid-19 [https://perma.cc/Q6CJ-QAEL].

161. *FDA Advises Consumers Not to Use Hand Sanitizer Products Manufactured by Eskbiochem*, *supra* note 139.

Specifically, the drug safety communications cautioned against the use of HCQ outside the supervision of a medical professional[162] and provided a general warning about methanol-derived hand sanitizers.[163] The fact that these detailed announcements are accessible several places across the FDA's website via various hyperlinks (from a press announcement, from the Drug Safety and Availability page, as well as from the Drug Safety Communications page) suggests the FDA wanted to ensure the public was aware of the adverse effects of using these specific products. However, it is noteworthy that the methanol-derived hand sanitizer communication has since been removed from the Drug Safety Communications webpage, although it is still accessible via the Press Announcement and the Drug Safety and Availability page.[164]

Three press announcements exhibited adverse publicity by discussing warning letters specifically.[165] Across these three publications, a total of 11 warning letters were discussed and hyperlinked. However, an additional 60 warning letters were hyperlinked, among other agency updates, in COVID-19-specific "Daily Roundup" press announcements, which the FDA began publishing each weekday starting on March 23, 2020. Moreover, there were seven press announcements that neither mentioned a drug safety communication nor a warning letter that might also be viewed as the FDA exercising adverse publicity. Two of these publications announced the revocation of an emergency use authorization: one for the use of chloroquine and HCQ to treat COVID-19[166] and one for an inaccurate antibody test.[167] Two other announcements voiced "concerns" regarding test kits—one announcement called out a specific test kit for inaccuracy,[168]

162. FDA CAUTIONS AGAINST USE OF HYDROXYCHLOROQUINE, *supra* note 156.

163. *FDA Updates on Hand Sanitizers with Methanol*, *supra* note 142.

164. *See Drug Safety & Availability*, *supra* note 91.

165. *Coronavirus (COVID-19) Update: FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Potentially Placing Public Health at Risk*, *supra* note 94 (announcing the first medical device warning letters for fraudulent tests); *Coronavirus (COVID-19) Update: FDA Warns Seller Marketing Dangerous Chlorine Dioxide Products that Claim to Treat or Prevent COVID-19*, *supra* note 145; *Coronavirus Update: FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19*, U.S. FOOD & DRUG ADMIN. (Mar. 9, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or [https://perma.cc/7VXK-35SZ] (announcing the first warning letters issued for fraudulent COVID-19 products).

166. *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine*, *supra* note 154.

167. *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chembio Antibody Test*, U.S. FOOD & DRUG ADMIN. (June 16, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test [https://perma.cc/HF9U-P38K].

168. *Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test*, U.S. FOOD & DRUG ADMIN. (May 14, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point [https://perma.cc/7A94-5AKZ].

while the other announcement warned more generally against fraudulent test kits and linked to the FDA's warning letter page.[169] Another announcement assured the public that effective hand sanitizer would be available throughout the pandemic, but also warned that sanitizer can be sold with fraudulent claims, linking to a warning letter issued for a particular non-alcohol-based sanitizer.[170] The final two announcements addressed the FDA's actions to combat fraudulent products in general,[171] including one where the FDA announced the issuance of a consumer update advising consumers to be aware of fraudulent tests, vaccines, and treatments.[172]

Three press announcements mentioned the initiation of litigation related to fraudulent COVID-19 products. These involved three separate legal actions taken by the FDA against products. On April 17, 2020, the FDA publicly announced that federal Judge Kathleen M. Williams for the U.S. District Court for the Southern District of Florida entered a temporary restraining order against Genesis II Church of Health and Healing and individual defendants Mark Grenon, Joseph Grenon, Jordan Grenon, and Jonathan Grenon, for the marketing and sale of MMS products.[173] Ultimately, a permanent injunction was issued against Genesis II Church.[174]

Almost two weeks later, on April 29, 2020, the FDA issued a press announcement stating that "[w]ith support from the FDA's Office of Criminal Investigations and Office of the Chief Counsel, the U.S. Department of Justice announced today that a federal court in Utah has

169. *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits [https://perma.cc/SF6L-PQQY] (linking to the warning letter database generally; note that no specific companies were named).

170. *Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns*, *supra* note 138.

171. *Coronavirus (COVID-19) Update: FDA Continues to Combat Fraudulent COVID-19 Medical Products*, U.S. FOOD & DRUG ADMIN. (May 7, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-combat-fraudulent-covid-19-medical-products [https://perma.cc/F9TZ-G4K4]; *Coronavirus (COVID-19) Update: Daily Roundup, March 24, 2020*, U.S. FOOD & DRUG ADMIN. (Mar. 24, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-24-2020 [https://perma.cc/9ASU-JQYW].

172. *Coronavirus (COVID-19) Update: Daily Roundup, March 24, 2020*, *supra* note 171; *see also Consumer Updates, Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments [https://perma.cc/U5XH-BR6J] (content current as of Sept. 21, 2020).

173. *Coronavirus (COVID-19) Update: Federal Judge Enters Temporary Injunction Against Genesis II Church of Health and Healing, Preventing Sale of Chlorine Dioxide Products Equivalent to Industrial Bleach to Treat COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 17, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-federal-judge-enters-temporary-injunction-against-genesis-ii-church [https://perma.cc/6RF5-SSD3]; *see also* United States v. Genesis II Church of Health & Healing, No. 1:20cv21601, 2020 U.S. Dist. LEXIS 70031 (S.D. Fla. Apr. 17, 2020); *supra* notes 146–48 and accompanying text.

174. Order of Permanent Injunction, United States v. Genesis II Church of Health & Healing, No. 1:20cv21601 (S.D. Fla. July 9, 2020).

entered an injunction halting the sale of various silver products, promoted as treatments for COVID-19."[175] The publication contained a hyperlink to a more detailed announcement originating from the Department of Justice.[176] In this case, the court issued a temporary restraining order against defendant Gordon Pedersen and his companies, My Doctor Suggests LLC and GP Silver LLC. This order was closely followed by an order to freeze all of the defendant's assets.[177] On June 26, 2020, the court entered a final consent order.[178] The consent order, among other things, required the defendant to issue refunds to eligible customers and to post explicit disclaimers on his websites disavowing the ability of his products to treat COVID-19.[179]

Finally, on May 14, 2020, the FDA announced that a federal judge entered a temporary restraining order against Xephyr LLC, also blocking the sale of silver products.[180] A preliminary injunction was entered by the court on May 27, 2020.[181] As of July 20, 2020, a final decision was still pending.

IV. CONCLUDING REFLECTIONS ON FDA'S COVID ENFORCEMENT AND PUBLICITY

The global COVID-19 pandemic has forced the FDA to respond in myriad ways to support innovation in product development as well as to protect the public health, including the issuance of warning letters and the use of adverse publicity. This moment in public health history has provided a narrow and discernable timeframe to study the mechanisms by which the

175. *Coronavirus (COVID-19) Update: Daily Roundup April 29, 2020*, U.S. FOOD & DRUG ADMIN. (Apr. 29, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-april-29-2020 [https://perma.cc/8NPQ-76TM].

176. *Court Orders Halt to Sale of Silver Product Fraudulently Touted as COVID-19 Cure*, U.S. FOOD & DRUG ADMIN. (Apr. 29, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/court-orders-halt-sale-silver-product-fraudulently-touted-covid-19-cure [https://perma.cc/BYV6-VD9D]. In the press release Assistant Attorney General Jody Hunt is quoted: "[w]e work closely with our partners at the Food and Drug Administration and will move quickly to shut down schemes that promote and sell unlawful products during this pandemic." *Id.*

177. Temporary Restraining Order and Order to Show Cause Why a Preliminary Injunction Should Not Issue, United States v. My Dr. Suggests, LLC, No. 2:20cv00279 (D. Utah Apr. 28, 2020); Order Freezing Assets, United States v. My Dr. Suggests, LLC, No. 2:20cv00279 (D. Utah Apr. 28, 2020).

178. Consent Order and Final Judgment, United States v. My Dr. Suggests, LLC, No. 2:20cv00279 (D. Utah June 26, 2020).

179. *Id.* at 3–6.

180. *Coronavirus (COVID-19) Update: Federal Judge Enters Temporary Injunction Against Xephyr LLC Doing Business as N-Ergetics, Preventing Sale of Colloidal Silver Products for COVID-19*, U.S. FOOD & DRUG ADMIN. (May 14, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-federal-judge-enters-temporary-injunction-against-xephyr-llc-doing [https://perma.cc/U49Q-F86G]; *see also* Order Granting Temporary Restraining Order, United States v. Xephyr LLC, No. 6:20-cv-00140 (E.D. Okla. May 14, 2020).

181. Order of Preliminary Injunction, United States v. Xephyr LLC, No. 6:20-cv-00140 (E.D. Okla. May 27, 2020).

agency monitors and reacts to industry behaviors as they relate to the protection of consumers. This analysis also provides an opportunity to engage with the existing scholarship on the agency's use of adverse publicity as distinct (or not) from enforcement activity. Based on these findings, the authors offer a few modest reflections connecting the literature and current FDA practices.

First, as a foundational matter, the FDA promotes transparency through the utilization of timely publication and updating of information on its website, as well as providing the means for the public to search the agency website and databases. Much has changed since Gellhorn's 1973 publication regarding how agencies communicate information and how the general public is able to access that information. The observations presented by Cortez in his scholarship on adverse publicity—that the FDA employs a vast array of communications to inform and warn the public—are supported by these findings, as well.

Second, the information the FDA provides on its website is interconnected through electronic hyperlinks within the different resources. For example, most warning letters (80 percent) were linked in a press announcement, and many were among a miscellaneous Daily Roundup of COVID-19 news. In addition, each warning letter contained a link to a page on the FDA website specifically listing fraudulent COVID-19 products.[182] Once a company is listed as an entity with fraudulent products, its name is not removed from the list (although an asterisk will be placed next to its name if it has taken corrective steps). As noted in Part III, drug safety communications were linked both in press announcements and on the Drug Safety and Availability landing page. Generally speaking, the more serious the violation or safety risk to the public, the more often the messaging was cross-referenced and hyperlinked. Presumably, overlapping publicity reinforced the FDA's messaging across its website, allowing the information to reach wider and more diverse audiences.

Third, whether passive publicity or something more, the COVID-19 warning letters effectively employed Gellhorn's original five standards for agency use of adverse publicity as codified in the ACUS Recommendation 73-1. The information in each warning letter was factual and accurate. Also, the warning letters provided several specific examples of violative behavior, often with quoted text or links to the webpage of the addressee, and did not contain disparaging terms.[183] The warning letters were issued

182. *Fraudulent Coronavirus Disease 2019 (COVID-19) Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products (content current as of July 7, 2020).

183. *See* Ajay Nutrition Foods, Inc. v. FDA, 378 F. Supp. 210, 218 (D.N.J. 1974). For example, no letter contained the terms "quack," "faddist," or any other term conveying a value judgment. *See id.*

for a stated specific purpose: to prevent the spread of misinformation during the COVID-19 pandemic. Each warning letter contained a paragraph explaining why it was sent. In addition, the warning letters contained several statutes authorizing action by the FDA. Each warning letter notified the addressee that it had 48 hours to either (a) provide a plan for corrective action or (b) explain to the FDA, via a COVID-specific email address, why its content did not violate the cited statutes. While this aspect of the letters is largely reflective of general FDA protocol regarding warning letters, it specifically addresses concerns about the lack of response mechanisms available to targets of agency publicity. Finally, the FDA instituted means to communicate the corrective action taken by and the compliance of addressees. Although the FDA has not been publishing retractions, it has been marking warning letters that resulted in corrective action on its website with an asterisk.

Last, and relatedly, it is unclear how certain warning letters were resolved when not resolved through official closeout procedure. During the timeframe under study, 36 percent of addressees of warning letters did not take timely corrective action in response to the letter according to the FDA's website; yet, according to the FDA's press announcements, the FDA has only pursued legal action against two of the addressees.[184] Perhaps the agency reached agreement with entities in some other manner, the closeout information had not been timely updated on the website, or the FDA contemplated or initiated legal action after our study. Arguably, an unresolved warning letter has served the purpose of informing or warning the public, with or without official sanctions following the warning letter itself.

184. *See Coronavirus (COVID-19) Update: Federal Judge Enters Temporary Injunction Against Genesis II Church of Health and Healing*, *supra* note 173; *Coronavirus (COVID-19) Update: Federal Judge Enters Temporary Injunction Against Xephyr LLC Doing Business as N-Ergetics*, *supra* note 180. The third press announcement with reference to a court decision regards a case with defendants not subject to an FDA warning letter.