

No. 21-5170

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

MARK MCAFEE; FARM-TO-CONSUMER LEGAL DEFENSE FUND,
Plaintiffs-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Defendant-Appellee,

On Appeal from the United States District Court
for the District of Columbia, No. 19-3161

**BRIEF OF THE WESTON A. PRICE FOUNDATION,
FARM AND RANCH FREEDOM ALLIANCE, RED ACRE
CENTER, FOOD FREEDOM FOUNDATION,
NATIONAL HEALTH FREEDOM COALITION, AND
NATIONAL HEALTH FREEDOM ACTION AS *AMICI CURIAE*
IN SUPPORT OF APPELLANTS AND REVERSAL**

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**CERTIFICATE AS TO PARTIES,
RULINGS, AND RELATED CASES**

The following information is provided pursuant to D.C. Circuit Rule 28(a)(1).

A. Parties and *Amici*

All parties, intervenors, and *amici curiae* appearing before this Court are listed in the Brief of Appellants, except for Pacific Legal Foundation, the Weston A. Price Foundation, Farm & Ranch Freedom Alliance, Red Acre Center, Food Freedom Foundation, National Health Freedom Coalition, and National Health Freedom Action, which are *amici curiae* in support of the Appellants.

B. Ruling Under Review

An accurate reference to the rulings at issue appears in the Brief of Appellants.

C. Related Cases

As stated in the Brief of Appellants, this case has not previously come before this Court or any other, and there are no related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Dated: January 14, 2022

/s/ Marisa C. Maleck _____

Marisa C. Maleck

Counsel for Amici Curiae

**STATEMENT REGARDING CONSENT TO FILE
AND SEPARATE BRIEFING**

In accordance with Circuit Rule 29(b), counsel represents that all parties have consented to the filing of this *amicus* brief.*

In accordance with Circuit Rule 29(d), counsel certifies that this separate brief is necessary to provide a discussion of raw butter's unique properties and the regulatory landscape resulting from the federal ban. This coalition of *amici* consists of raw dairy advocates who have witnessed first-hand the raw butter ban's consequences. Counsel for these *amici* anticipate that this is the only brief that will address these topics.

* No party's counsel authored this brief in whole or in part, and no one other than *amici* and their counsel contributed money that was intended to fund preparing or submitting the brief. *See* Fed. R. App. P. 29(4)(E).

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, the Weston A. Price Foundation, Farm & Ranch Freedom Alliance, Red Acre Center, Food Freedom Foundation, National Health Freedom Coalition, and National Health Freedom Action are non-profit, tax exempt organizations. These organizations have no parent corporation, and no publicly held company has 10% or greater ownership in them.

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GLOSSARY

FDA	Food & Drug Administration
<i>Pub. Citizen II</i>	<i>Pub. Citizen v. Heckler</i> , 653 F. Supp. 1229 (D.D.C. 1986)

INTEREST OF *AMICI CURIAE*

Amici are a coalition of organizations committed to advocating for consumers' free choice as to what foods they may consume. They have a particular interest in this case because the raw butter ban directly implicates Americans' right to choose their food.

The Weston A. Price Foundation is a non-profit, tax-exempt charity dedicated to improving human health through nutrient-dense whole foods and the vital fat-soluble activators found exclusively in animal fats. It supports movements that contribute to this objective including accurate nutrition instruction, organic and biodynamic farming, pasture-feeding of livestock, community-supported farms, and honest and informative labeling. The Weston A. Price Foundation regularly advocates for legalizing raw milk products.

The Farm & Ranch Freedom Alliance is a national 501(c)(4) non-profit organization that supports independent family farmers and protects a healthy and productive food supply for American consumers. The Farm & Ranch Freedom Alliance promotes common sense policies for local diversified agricultural systems, including access to farm-fresh products.

The Red Acre Center is a nonprofit in Utah that works to promote and protect farmers, small rural and farms, and the right to food choice.

The Food Freedom Foundation, started in 2015, is a 501(c)(3) nonprofit that works to provide grants supporting sustainable family farms and artisan food producers. Their objective is to promote a fair and independent farm-to-a-consumer ecosystem that preserves and enhances the environment and its natural resources.

The National Health Freedom Coalition is an educational nonprofit. Along with its sister grassroots lobbying organization, National Health Freedom Action, the National Health Freedom Coalition works to ensure freedom of choice in healthcare, both for patients and practitioners.

INTRODUCTION

Raw butter is as American as apple pie. Since the founding, it has been an essential part of American life—not only as a culinary staple but as a vital part of this country’s burgeoning post-Revolution economy. In the early days of the United States, raw butter was an essential part of farm production, providing “a commodity for use in the family” and

supplemental income to farmers.¹ Colonial-era laborers in Philadelphia ate thirteen pounds of raw butter per year.² In 1796 alone, the United States exported 2.5 million pounds of it.³ Raw butter even has links to America's time-honored tradition of free speech. In 1766, it was the subject of the first-ever documented protest on an American campus, now known as the "Great Butter Rebellion."⁴

Even outside the United States, humans have been using and eating raw butter for thousands of years. It "is one of the oldest as well as one of the most universal articles of diet."⁵ Hindu populations were eating it as early as 2000 B.C.⁶ The Greeks and Romans used it as a

¹ Joan M. Jensen, *Butter Making and Economic Development in Mid-Atlantic America from 1750 to 1850*, 13 *Signs* 813, 816 (1988).

² *Id.* at 815.

³ *Id.* at 816.

⁴ Nicole Jankowski, *Spread The Word: Butter Has An Epic Backstory*, NPR (Feb. 24, 2017, 9:00 AM), <https://www.npr.org/sections/thesalt/2017/02/24/515422661/spread-the-word-butter-has-an-epic-backstory>.

⁵ Edward Sewell Guthrie, *The Book of Butter* 1 (1918).

⁶ *Id.*

remedy for skin injuries.⁷ And, in the 1600s, the Irish stored their raw butter in peat bogs, possibly to hide it from invaders or to enhance its flavors.⁸

Despite raw butter's undeniable contributions and importance to society, the federal government bans its sale in interstate commerce. For the reasons set forth in Appellant's Brief, and in this brief, this Court should reverse that decision.

SUMMARY OF THE ARGUMENT

Amici agree with Appellant's brief that this ban should be overturned. They write separately to detail how, far from protecting consumers, FDA's ban unreasonably constrains them.

I. The ban lacks a reasonable justification. Since 1992, the Food & Drug Administration (FDA) has required butter sold in interstate commerce to be pasteurized because of a single district court decision that did not even discuss raw butter. *Pub. Citizen v. Heckler (Pub. Citizen II)*, 653 F. Supp. 1229, 1241 (D.D.C. 1986). *Public Citizen II* addressed FDA regulations on fluid milk—a product entirely distinct from raw butter.

⁷ *Id.*

⁸ *Id.* at 3.

Raw butter's unique qualities make it safe for consumption while retaining the benefits of being raw. For this reason, FDA and the district court erred when it determined that *Public Citizen II* extended to raw butter.

II. Though raw butter has only been illegal for a relatively short period of time compared to its long history of human consumption, the impact on consumers and dairy producers is substantial. Raw butter producers cannot sell out-of-state without risking criminal prosecution. Consumers are constrained as well. Americans who choose to eat raw butter—whether because of health concerns or taste preference—either cannot get it or must travel out-of-state to find it (again, possibly risking criminal prosecution if they transport it across state lines).

Underscoring the absurdity of the ban, raw butter has a better safety track record than many other legally available foods that can be sold in interstate commerce. For example, the FDA permits romaine lettuce to be sold in interstate commerce, despite causing regular outbreaks with devastating consequences, like permanent injury and death. FDA can protect the public health without a categorical ban. This Court should reverse.

ARGUMENT

I. **Raw butter is lower risk than raw milk, and *Public Citizen II* should not extend to it.**

Americans may choose to consume raw butter for a variety of reasons. Some consumers don't want to consume pasteurized dairy products as pasteurization kills natural vitamins.⁹ For example, studies show that raw dairy products have higher levels of vitamins A, B, C, and D.¹⁰ Moreover, recent European studies suggest a connection between drinking raw milk and asthma and allergy prevention.¹¹

⁹ See, e.g., Anna Haug, Arne T. Høstmark, & Odd M. Harstad, *Bovine Milk in Human Nutrition—a Review*, 6 *Lipids in Health & Disease* 1, 10 (2007) (“Proteins and peptides are heat sensitive, and their bioactivity may be reduced by pasteurisation of milk. Heating of milk may also result in the formation of potentially harmful new products i.e. when carbohydrates in milk react with proteins.”).

¹⁰ See, e.g., P.J. Kilshaw, P.J., L.M. Heppell, & J.E. Ford, *Effects of Heat Treatment of Cow's Milk and Whey on the Nutritional Quality and Antigenic Properties*, 57 *Archives of Disease in Childhood* 842, 842 (1982) (“Severe heat treatment of skimmed milk . . . destroyed all the vitamin B12, about 60% of the thiamin and vitamin B6, 70% of the ascorbic acid, and about 30% of the folate.”).

¹¹ See Josef Riedler et al., *Exposure to Farming in Early Life and Development of Asthma and Allergy: a Cross-Sectional Survey*, 358 *Lancet* 1129, 1129 (2001) (“Long-term and early-life exposure to stables and farm milk induces a strong protective effect against the development of asthma, hay fever, and atopic sensitization.”); Michael R. Perkin & David P. Strachan, *Which Aspects of the Farming Lifestyle Explain the*

Other reasons for buying raw dairy abound. Some may find the taste is better than pasteurized butter. Still others buy it to support local dairies in their communities. And for many, consuming raw butter is a personal choice, made in the best interest of themselves and their families.

FDA's categorical ban on raw butter strips them of that choice. 21 C.F.R. §§ 1240.3(j), 1240.61(a). You would be forgiven for believing that, before the FDA banned raw butter in interstate commerce (which is legal in some form in most states), it engaged in extensive research and factfinding specifically about raw butter. You would be wrong.

The federal raw butter ban is the product of a single district court case that *did not even discuss raw butter*. *Pub. Citizen II*, 653 F. Supp. at 1241. The administrative record in *Public Citizen II* is also devoid of research, discussion, or commentary on its safety because FDA limited

Inverse Association With Childhood Allergy?, 117 J. Allergy & Clinical Immunology 1374, 1374 (2006) (“Unpasteurized milk might be a modifiable influence on allergic sensitization in children.”); M. Waser et al., *Inverse Association of Farm Milk Consumption With Asthma and Allergy in Rural and Suburban Populations Across Europe*, 37 Clinical & Experimental Allergy 661, 661 (2006) (“Our results indicate that consumption of farm milk may offer protection against asthma and allergy.”).

its analysis to fluid milk products. Doc. 18 at 6. Yet in 1992, six years after *Public Citizen II*, FDA extended its ban to raw butter for the first time, despite—as Appellant McAfee points out—lacking the statutory authority to do so. 21 C.F.R. §§ 1240.3(j), 1240.61(a); *see also* McAfee Br. at 47 (citing 41 U.S.C. § 262(g)).

But raw butter is not raw milk. Unlike raw milk, raw butter’s unique properties make it inherently low risk. In fact, there has been no foodborne-illness outbreak linked to commercially-produced raw butter in recent history. JA103 (Citizen Pet. at 10) (discussing the CDC’s Foodborne Outbreak Online Database, which has compiled data on foodborne illnesses since 1998).

This is not surprising. Evidence suggests raw butter is likely safe for consumption even without pasteurization, while retaining the benefits of being raw. JA105 (Citizen Pet. at 12). When it is properly prepared in a commercial setting, pathogen growth is “rare.” *Id.* And when pathogens are present, the counts are not significant enough to cause illness. *Id.*

Butter is a bad vehicle for pathogen growth. JA105–06 (Citizen Pet. at 12–13). When butter hardens, small droplets of water form in the fat.

JA105 (Citizen Pet. at 12). Bacteria grow in these droplets but cannot spread because of the fat surrounding them. JA106 (Citizen Pet. at 13). In commercially produced raw butter, these water droplets become too small to allow bacterial growth. *Id.* Additionally, other factors like butter's acidic pH, the practice of refrigerating butter, and for salted butters, the dispersion of salt, restrict bacterial growth. *Id.*

If raw butter is as dangerous as FDA insists, then you might assume all 50 states ban it too. Not so. Thirteen states have legalized the sale or distribution of raw butter.¹²

You might also assume that states ban the sale of its higher risk cousin, raw milk.¹³ But most states have rejected the findings of *Public*

¹² Alaska (Alaska Stat. § 17.20.15); Arizona (Ariz. Rev. Stat. § 3-606(A)(2)); California (Cal. Food & Agric. Code §§ 37161–63, 37192); Idaho (Idaho Code Ann. § 37-1101; Idaho Admin. Code r. 02.04.13.020); Kansas (Kan. Stat. Ann. § 65-784); Maine (Me. Rev. Stat. Ann. tit. 7, § 2902-B); New Hampshire (N.H. Rev. Stat. Ann. § 184:84(V)); Montana (2021 Mont. SB 199); North Carolina (N.C. Gen. Stat. § 106-266.35(d)); North Dakota (N.D. Cent. Code § 4.1-25-40); Tennessee (Tenn. Code Ann. § 53-3-119; Tenn. Att'y Gen. Op. No. 12-04); Utah (Utah Code Ann. § 4-3-502, 503); Wyoming (Wyo. Stat. Ann. § 11-49-103).

¹³ For 50-state surveys examining raw milk laws, see Farm-to-Consumer Legal Defense Fund *Raw Milk Nation – Interactive Map* (Aug. 12, 2021), <https://www.farmtoconsumer.org/raw-milk-nation-interactive-map/>; *Raw-Milk Laws State-by-State*, Britannica ProCon.org (Feb. 2, 2018), <https://milk.procon.org/raw-milk-laws-state-by-state/>.

Citizen II. Thirty-five states have expressly legalized the sale or distribution of raw milk through statute, regulation, court decision, or written policy. Ten states permit the outright retail sale of raw milk to consumers.¹⁴ Seventeen states permit consumers to purchase raw milk directly from the farm (though some states only allow this under very limited circumstances).¹⁵ Eight states allow herd-share agreements,

¹⁴ California (Cal. Food & Agric. Code §§ 3591–93); Connecticut (Conn. Gen. Stat. §§ 22-172, 167, 133), Idaho (Idaho Code Ann. § 37-1101; Idaho Admin. Code r. 02.04.13); Maine (Me. Rev. Stat. Ann. tit. 7, §§ 2910, 2902-B); New Hampshire (N.H. Rev. Stat. Ann. § 184:30-a); New Mexico (N.M. Stat. Ann. § 25-8-1); Pennsylvania (7 Pa. Code § 59.302); South Carolina (S.C. Code Ann. Regs. 61-34); Utah (Utah Code Ann. § 4-3-503); Washington (Wash. Admin. Code § 246-215-041).

¹⁵ Arkansas (Ark. Code. Ann. § 20-59-248); Illinois (Ill. Admin. Code tit. 77, § 775.55); Kansas (Kan. Stat. Ann. §§ 65-771(cc), 784, 789); Massachusetts (Mass. Gen. Laws Ann. ch. 94, § 13; 330 Mass. Code Regs. 27.01 *et seq.*); Minnesota (Minn. Stat. Ann. § 32D.20); Mississippi (Miss. Code Ann. § 75-31-65) (farm sales legal but limited to incidental sales of goat milk only); Missouri (Mo. Rev. Stat. § 196.935); Montana (2021 Mont. SB 199); Nebraska (Neb. Rev. Stat. Ann. § 2-3969); New York (N.Y. Comp. Codes R. & Regs. tit. 1, § 2.3); Oklahoma (Okla. Stat. tit. 2, § 7-406, 417); Oregon (Or. Rev. Stat. §§ 621.012, 076); South Dakota (S.D. Codified Laws § 39-6-3); Texas (25 Tex. Admin. Code § 217.31); Vermont (Vt. Stat. Ann. tit. 6, § 2777); Wisconsin (Wis. Stat. Ann. § 97.24); Wyoming (Wyo. Regs. Dep't of Agric. Wyo. Food & Safety ch. 3: AGR-FSF § 3-8(g)).

where a consumer purchases an interest in a herd and then receives the resulting dairy products.¹⁶

In California, the sale of raw dairy and raw dairy products (including raw butter) has always been legal. Since 2001, Organic Pastures Dairy Company in California has sold over 2 million pounds of raw butter, without a single case of foodborne illness connected to these sales. JA104 (Citizen Pet. at 11). In a state that rigorously regulates food safety standards—for example, banning bacon from hog farmers who do not meet minimum pig-spacing requirements¹⁷—the continued legality of raw butter supports that it can be safely consumed.

All this data points to one conclusion: FDA must do more than rely on *Public Citizen II* to justify a blanket ban on raw butter. *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015) (“[A]n agency

¹⁶ Alaska (Alaska Admin. Code. tit. 18, §§ 32.010, 060); Colorado (Colo. Rev. Stat. § 25-5.5-117); Michigan (Mich. Dep’t of Agric. & Rural Dev., Food & Dairy Div., Policy No. 1.40, Fresh Unprocessed Whole Milk (Mar. 12, 2013)); North Carolina (N.C. Gen. Stat. § 106-266.35); North Dakota (N.D. Cent. Code Section § 4.1-25-40); Ohio (Ohio Rev. Code Ann. § 917.02, 04, 09); Tennessee (Tenn. Code Ann. § 53-3-119); West Virginia (W. Va. Code § 19-1-7).

¹⁷ *Nat’l Pork Producers Council v. Ross*, 6 F.4th 1021, 1025 (9th Cir. 2021), *petition for cert. filed* (U.S. Sept. 29, 2021) (No. 21-468).

cannot fail to consider an important aspect of the problem or offer an explanation that runs counter to the evidence before it.” (cleaned up)).

Consumers should be able to make choices about how to feed themselves and their families. And if FDA is going to ban a food for safety reasons, then it should do so only after a thorough and extensive investigation. FDA has failed to do this for raw butter to the detriment of consumers.

II. Banning the interstate sale of raw butter creates a parade of absurdities.

FDA’s categorical ban presents significant consequences for dairy farmers and raw dairy consumers. Ostensibly, a California raw dairy farmer can be prosecuted for selling raw butter to a New Jersey consumer. A Maryland mom who drove to Pennsylvania to pick up some raw butter for her family could also face prosecution. Even if the government promises to exercise prosecutorial discretion for this banal act, the public should not be forced to rely on the government’s “*noblesse oblige*.” Cf. *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (quoting *United States v. Stevens*, 559 U.S. 460, 480 (2010)) (discussing how due process forbids vague regulations that allow the government to choose who to prosecute).

The ban's absurdity only grows when compared to other foods which have produced several devastating outbreaks. Consider romaine lettuce. From 2009 to 2018, there were 40 *E. coli* outbreaks linked to leafy greens—54% of outbreaks connected to a specific leafy green were from romaine. Sara G. Miller, *Leafy greens were linked to 40 E.coli outbreaks in a decade. Most involved romaine*, NBC News (Sept. 16, 2020, 1:01 PM).¹⁸ In 2018, 197 people in 35 states got sick from tainted romaine lettuce. Jan Hoffman, *Four More People Die From Tainted Romaine Lettuce*, N.Y. Times (June 1, 2018).¹⁹ Twenty-six people “developed a type of kidney failure called hemolytic uremic syndrome.”²⁰ Five people died.²¹

¹⁸ <https://www.nbcnews.com/health/health-news/leafy-greens-were-linked-40-e-coli-outbreaks-decade-most-n1240178#:~:text=Leafy%20greens%20are%20a%20common,brunt%20of%20the%20blame%3A%20romaine.>

¹⁹ <https://www.nytimes.com/2018/06/01/health/romaine-ecoli-outbreak-deaths.html>.

²⁰ Julia Jacobs, *Officials Identify a Source in the Romaine Lettuce E. Coli Outbreak*, N.Y. Times (July 1, 2018), <https://www.nytimes.com/2018/07/01/us/romaine-lettuce-e-coli-nyt.html>.

²¹ *Id.*

Other foods are equally dangerous to romaine, and more dangerous than raw butter. In 2009, 714 people got sick and nine people died because of peanut butter.²² In 2006, three people died and 31 suffered kidney failure because of baby spinach.²³ In 2011, 33 people died because of contaminated cantaloupe.²⁴ None of these products is illegal to sell in interstate commerce. In fact, all are readily accessible at your nearest grocery store.

Compare that with raw butter, which has no documented outbreaks resulting in death or permanent injuries related to its commercial sale in recent history. JA105 (Citizen Pet. at 12). Yet raw butter is totally banned.

²² CDC, *Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008-2009 (FINAL UPDATE)*, CDC.gov (May 11, 2009), <https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html>.

²³ CDC, *Multistate Outbreak of E. coli O157:H7 Infections Linked to Fresh Spinach (FINAL UPDATE)*, CDC.gov (Oct. 6, 2006), <https://www.cdc.gov/ecoli/2006/spinach-10-2006.html>.

²⁴ CDC, *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado (FINAL UPDATE)*, CDC.gov (Aug. 17, 2012), <https://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html>.

FDA is using a shotgun where a scalpel would suffice. Instead of an outright ban on raw butter, FDA should treat it the way it treats other foods—by permitting its sale and using regulatory powers to control outbreaks if they occur. For example, FDA can issue public safety alerts if food may be contaminated. 21 U.S.C. § 375(b). In more serious scenarios, FDA has the authority to enter and inspect establishments where food is being manufactured or produced. 21 U.S.C. § 374. FDA can also demand a mandatory recall if “there is a reasonable probability that an article of food . . . is adulterated” and the food will “cause serious adverse health consequences.” 21 U.S.C. § 350l(a). Additionally, FDA has the power to stop distribution and transport of adulterated or misbranded food by: (1) obtaining an injunction; (2) obtaining a seizure order from a court; and (3) administratively detaining food. 21 U.S.C. §§ 332, 334(a), (h). These safeguards are more than adequate to protect the public in the event of a raw butter outbreak. If this is sufficient to protect the public from far deadlier foods, then surely FDA could use it to ensure safe raw butter.

Setting aside what FDA can do, other protections exist too. States have the authority to regulate the production and sale of raw butter. For

example, in California, raw butter sales are legal, but the farm must obtain a license after inspection, but before starting commercial production. Cal. Food & Agric. Code § 33222. Like FDA, state regulatory agencies have the power to detain and seize foods suspected of being adulterated or misbranded. Likewise, the threat of civil litigation (like a class action if there is an outbreak) should encourage small dairy farmers to follow strict safety protocols.

If this Court affirms the district court, American dairy farmers may continue to be at risk of criminal prosecution for the simple act of selling raw butter. Or worse still, for transporting raw butter across state lines for a family dinner. FDA's ban makes Americans no safer than they are from a host of more risky, but legal, foods. This Court should reverse.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's judgment.

Respectfully submitted,

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Pursuant to Federal Rule of Appellate Procedure 32(g), I certify that this brief complies with the type-volume limitation of Rules 29(a)(5) and 32(a)(7)(B) because it contains 3,210 words, excluding the parts exempted by Rule 32(f) and Circuit Rule 32(e)(1).

I further certify that this brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because the brief was prepared in 14-point Century Schoolbook font using Microsoft Word ProPlus 365.

Dated: January 18, 2022

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CERTIFICATE OF SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I certify that on January 18, 2022, I caused a copy of this document to be served on all registered counsel via CM/ECF.

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