# 17-3745-cv(L), 17-3791-cv(CON)

# United States Court of Appeals

*for the*

# Second Circuit

FEDERAL TRADE COMMISSION, PEOPLE OF THE STATE OF NEW YORK, by Barbara D. Underwood, Attorney General of the State of New York,

*Plaintiffs-Appellants,*

– v. –

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation, QUINCY BIOSCIENCE, LLC, a limited liability company, PREVAGEN, INC., a corporation, DBA Sugar River Supplements, QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company, MARK UNDERWOOD, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC and Prevagen, Inc., MICHAEL BEAMAN, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc.,

*Defendants-Appellees.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

**BRIEF *AMICI CURIAE* FOR COUNCIL FOR RESPONSIBLE NUTRITION AND CONSUMER HEALTHCARE PRODUCTS ASSOCIATION IN SUPPORT OF APPELLEES AND AFFIRMANCE**

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. Civ. P. 26.1, *amici curiae* Council for Responsible Nutrition and Consumer Healthcare Products Association state that they have no parent corporations and that no publicly held corporations own 10% or more of their stock.

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## STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

The Council for Responsible Nutrition ("CRN") is a leading trade association for the dietary supplement industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements. CRN represents more than 150 companies worldwide that manufacture dietary ingredients or dietary supplements, or supply services to those customers. CRN members manufacture popular national brands, as well as the store brands marketed by major supermarket, drug store, and discount chains.

The Consumer Healthcare Products Association ("CHPA") is a 137-year-old, member-based national trade association that represents the leading manufacturers and marketers of over-the-counter medicines and dietary supplements. CHPA members' products provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. The association provides leadership and guidance on regulatory and scientific issues to Congress; state legislatures; and federal, state, and international government agencies.

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici curiae* state that no counsel for any party authored this brief in whole or in part, and no person or entity other than *amici curiae* made a monetary contribution to the preparation or submission of the brief. All parties consent to the filing of this *amicus* brief.

Both CHPA and CRN have a special interest in this case because it involves the appropriate legal standard for substantiating dietary supplement claims. The Federal Trade Commission ("FTC") and the Attorney General of the State of New York ("NYAG) (collectively, "the government") have based this lawsuit on a novel and improper reading of the law. If the government were to prevail and impose this new standard, it would directly and adversely affect not only the defendants here, but the entire dietary supplement industry, including members of CRN and CHPA. While CRN and CHPA recognize that defendants' brief touches upon some of these issues, that brief is focused primarily upon showing that the defendant cannot be held liable under the Federal Trade Commission Act ("FTC Act") and New York law (which substantially tracks the FTC Act) with regard to the particular product at issue. That brief therefore does not fully represent the interests of the broader dietary supplement industry in guarding against a wholesale change in the governing substantiation standard. CRN and CHPA's interest is not with any specific company or product. Rather, CRN and CHPA's compelling interest is in making clear that the government's asserted legal standard is novel, erroneous, and inconsistent with statute, agency guidance, and decades of government practice.

Moreover, given CRN and CHPA's active involvement and engagement with the U.S. Congress, the FTC, and the U.S. Food and Drug Administration

("FDA") throughout the development, promulgation, and implementation of the foundational law governing the regulation of dietary supplements and the agencies' guidance documents regarding claim substantiation, CRN and CHPA believe they offer an important perspective to the Court as it considers the merits of the underlying case.

## SUMMARY OF ARGUMENT

The government's Complaint is premised on a novel legal standard that is irreconcilable with the governing statute, FTC and FDA guidance, and over 20 years of precedent. The government alleged that defendants' dietary supplement claims were unsubstantiated because, even though defendants relied on a randomized clinical trial ("RCT"), they lacked positive results from the primary end points in that RCT. This legal standard is fundamentally flawed because dietary supplements are not drugs and drug-level RCTs are not required under the law at all. Accordingly, the Complaint's premise that dietary supplement claims must be supported by a RCT *that yields particular results* has no basis in the governing law and is made of whole cloth. Merely alleging that a manufacturer failed to have positive results from a drug-level RCT does not state a plausible claim for relief.

For over 20 years, Congress, the FTC, and the FDA have made clear that supplements are not regulated like drugs and that evidence other than a drug-level

RCT can be considered in substantiating dietary supplement claims. *See* Dietary Supplement Health & Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.); FTC, *Dietary Supplements: An Advertising Guide for Industry* (issued Nov. 1998), http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry/ ("FTC Guidance"). Clinical trials are not necessary—much less clinical trials with particular results—and even animal and *in vitro* studies can be considered. FTC Guidance at 10. To this day, the agency has never repudiated this guidance, and the industry continues to rely on it.

Supplement companies follow the law and FTC guidance and rely on many different modes of research to substantiate claims. Drug-level clinical trials are not required and not typically done in the industry.

Unfortunately this is not the first time the FTC has attempted to impose a drug-level substantiation standard for dietary supplements that is irreconcilable with the statute and agency guidance. Fortunately, like the district court below, courts have universally rejected the FTC's attempt to raise the standard without proper notice and procedures. For example, in *United States v. Bayer Corp.*, No. 07-01(JLL), 2015 WL 5822595 (D.N.J. Sept. 24, 2015), the FTC attempted to require that Bayer's dietary supplement claims be supported by drug-level RCTs. The district court denied the government's contempt motion, holding that the

"[FTC] Guidance specifically refutes the [substantiation] standard the Government is seeking to impose." *Id.* at *14. Based on the statements in the Guidance, the court concluded that "competent and reliable scientific evidence does not require drug-level clinical trials." *Id. See also FTC v. Garden of Lif*e, 845 F. Supp. 2d 1328, 1334-35 (S.D. Fla. 2012), *aff'd in part, vacated in part,* 516 F. App'x 852 (11th Cir. 2013) (rejecting FTC's RCT standard for dietary supplements); *see also Basic Research, LLC v. FTC,* No. 2:09-cv-0779, 2014 WL 12596497 (D. Utah Nov. 25, 2014) (same).

In accordance with these principles, the district court below properly recognized that the government's attempt to use litigation to impose a novel, heightened substantiation standard on a dietary supplement fails to state a viable legal claim.

If the government were to prevail in holding defendants, retroactively, to this newly-minted standard, it would have disastrous ramifications not only for defendants, but also for the entire dietary supplement industry. The industry would face confusion as to the appropriate substantiation standard for non-disease dietary supplement claims. Contrary to the express codified purposes of DSHEA, dietary supplement companies could no longer make claims that provide consumers with important and truthful information about dietary supplements and health benefits. *Amici* therefore urge this Court to affirm the district court's dismissal of the

Complaint and reject the government's latest attempt to impose a standard on dietary supplements that Congress has not enacted and the agency has not promulgated in a rulemaking.

## ARGUMENT

### I. THE LAW AND GUIDANCE THAT GOVERN DIETARY SUPPLEMENTS DO NOT REQUIRE DRUG-LEVEL RCTs, MUCH LESS RCTs THAT YIELD PARTICULAR RESULTS.

Prevagen is a dietary supplement, not a drug. *See* FTC Br. at 2 ("Quincy sells Prevagen, a dietary supplement"); NYAG Br. at 1 ("Defendants sell Prevagen, a dietary supplement"). Although one would never know it from the government's Complaint or briefs, dietary supplements are not regulated like drugs. Rather, they are subject to fundamentally different regulatory frameworks and different substantiation requirements. The government's entire lawsuit is predicated on its attempt to impose a substantiation standard on dietary supplements that neither Congress nor the FTC has established.

#### A. Congress Provided That Dietary Supplements Can Be Marketed And Sold Without Following The Stringent Requirements Imposed On Drugs.

Recognizing the health benefits and low safety concerns of dietary supplements, Congress enacted the DSHEA, Pub. L. No. 103-417, sec. 8, § 413(c), 108 Stat. at 4331-32 (codified at 21 U.S.C. § 350(b)) to create a new regime for FDA's regulation of dietary supplements so that they will not be regulated like drugs. In enacting DSHEA, Congress emphasized that "dietary supplements are

not drugs." S. Rep. No. 103-410, at 19-20, 33 (1994). The Food, Drug, and Cosmetic Act ("FDCA") defines a drug, in part, as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). A "dietary supplement," in contrast, is any non-tobacco product "intended to supplement the diet," *id.* § 321(ff), and cannot claim to diagnose, cure, mitigate, treat, or prevent a disease. *Id.* § 343(r)(6)(C) (requiring disclaimer for statements about dietary supplements); *see* JA21-36 (Compl. ¶ 27) (noting presence of the required disclaimer in illustrative Prevagen ads).

One of Congress's primary goals in enacting DSHEA was to "assure citizens have continued access to dietary supplements and information about their benefits." S. Rep. No. 103-410, at 17. Congress expressly found that "there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health," that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements," and that "the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products . . . to consumers." Pub. L. No. 103-417, § 2(7), (8), (13), 108 Stat. at 4326.

Accordingly, whereas new drugs must be pre-approved by the FDA, *see* 21 U.S.C. § 331(d); *id.* § 355(a), and traditionally must be supported by rigorous

randomized, placebo-controlled, double-blind clinical trials,[1] dietary supplements need not. As long as the supplement is not marketed as a drug—*i.e.*, is "not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," *id.* § 343(r)(6)(C)—it is not regulated like a drug.

Unlike drugs, the substantiation requirement for dietary supplements making structure-function[2] claims, is that they must be "truthful and not misleading." *Id.* § 343(r)(6)(B). Notably, the law does not require the type of human clinical research that is required for drugs for supplements. Congress recognized in DSHEA that the traditional model for evaluating drugs is not appropriate or necessary because "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare." Pub. L. No. 103-417, § 2(14), 108 Stat. at 4326.[3]

Congress further recognized that drug-level clinical trials may be infeasible for dietary supplements. The health benefits of dietary supplements—which can

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[1] *See* 21 C.F.R. § 314.126; FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last updated Nov. 24, 2017).

[2] DSHEA defines structure/function claims as those which "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [or] characterize[] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6)(A).

[3] The government does not contend that there are any safety concerns related to Prevagen.

include the maintenance of healthy body functions, the mitigation of conditions associated with natural states such as aging and pregnancy, and the treatment of symptoms not characteristic of a specific disease—are incredibly wide ranging and not always capable of being evaluated by specific endpoints through randomized, double-blind clinical studies. Accordingly, by declining to require drug-level RCTs to substantiate dietary supplement claims, Congress limited barriers to the supplement industry's ability to make truthful and scientifically valid claims about its products.

### B. Longstanding FTC and FDA Guidance Establish A Flexible Approach To The Substantiation Of Dietary Supplement Claims And Do Not Require Drug-Level RCTs.

Consistent with the statute, the FTC and FDA have long recognized that the substantiation standard for dietary supplements is lower and more "flexible" than the drug-level standard. Neither agency requires drug-level RCTs for dietary supplements, and neither agency requires a particular type of RCT results.

Both the FTC and the FDA have issued guidance to industry that a dietary supplement manufacturer should have "competent and reliable scientific evidence" to support its claims. *See, e.g.*, FTC Guidance at 3; FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008), http://www.fda.gov/food/

guidanceregulation/guidancedocumentsregulatoryinformation/ucm073200.htm ("FDA Guidance").

The purpose of the FTC Guidance is to clarify for the dietary supplement industry "how long-standing FTC policies and enforcement practices relate to dietary supplement advertising." FTC Guidance at 1. Since it was issued in April 1998, the dietary supplement industry has relied extensively upon this guidance, and related FTC case law, to ensure that claims made for dietary supplements are substantiated by competent and reliable scientific evidence. In particular, the FTC Guidance defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 9.

The FTC Guidance makes clear that this standard is *not* the drug standard. RCTs are *not* required. Instead, the FTC Guidance states that the "competent and reliable scientific evidence" standard is "flexible" and there is "*no fixed formula* for the number or type of studies required" to substantiate a claim, *id.* at 3, 9 (emphasis added); that the necessary evidence depends on a number of factors, including the type of claim and the relevant area of study, *id.* at 10; and that there "is no set protocol for how to conduct research that will be acceptable under the

FTC substantiation doctrine," *id.* at 12. Although "well-controlled human clinical studies are the most reliable form of evidence[,]" they are not necessary, and animal and *in vitro* studies, research explaining the biological mechanism underlying the claimed effect, and epidemiological evidence can all qualify as "competent and reliable scientific evidence." *Id.* at 9, 10.

The FDA Guidance is modeled on and intended to complement the FTC Guidance. FDA Guidance (FDA "intends to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach."). Like the FTC Guidance, the FDA Guidance provides for significant flexibility in substantiating claims made on dietary supplements. FDA states that "*there is no pre-established formula* as to how many or what type of studies are needed to substantiate a claim" and recognizes that randomized, double blind, clinical trials "may not always be possible, practical, or ethical." *Id.* (emphasis added).

### C. Courts Have Rejected The FTC's Recent Attempts To Impose A Drug-Level Substantiation Standard On Dietary Supplements.

Apparently unhappy with the statute and its own guidance, the FTC began to demand drug-level RCTs for dietary supplements.

Initially, under the threat of litigation and millions of dollars in penalties, a number of companies agreed to this RCT standard *going forward* through consent decrees with the FTC. *See e.g.*, *FTC v. Iovate Health Sciences USA, Inc.*, No. 10-CV-587, slip op. at 7 (W.D.N.Y. July 29, 2010) ("competent and reliable scientific

evidence [under this section] shall consist of at least two adequate and well-controlled human clinical studies"); *United States v. Jason Pharm., Inc.*, No. 12-CV-01476, slip op. at 3, 6 (D.D.C. Sept. 17, 2012) ("competent and reliable scientific evidence shall consist of at least one Adequate and well-controlled human clinical study" which is defined as a study of certain size and length where participants are "randomly assigned to a treatment and a control group"); *The Dannon Co.*, No. C-4313, slip op. at 3 (F.T.C. Jan. 31, 2011) ("competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies" of the product). Of course, these settlements only bind the parties that agreed to a standard that exceeds what DSHEA and the FTC Guidance require.

Fortunately, when the FTC has tried to impose this drug-level standard on companies in court—without an agreement—courts have rejected the FTC's attempt to unlawfully raise the standard for dietary supplement claims. Indeed, courts have uniformly rejected the agency's attempts to impose higher substantiation requirements for dietary supplements than those set forth in the FTC Guidance.

For example, in *United States v. Bayer Corp.*, No. 07-01(JLL), 2015 WL 5822595 (D.N.J. Sept. 24, 2015), the FTC alleged that Bayer marketed a probiotic dietary supplement unlawfully because it lacked drug-level RCTs for its claims.

Following trial, the district court rejected the government's claims, holding that the "[FTC] Guidance specifically refutes the [substantiation] standard the Government is seeking to impose." *Id.* at *14. Based on the statements in the Guidance, the court concluded that "competent and reliable scientific evidence does not require drug-level clinical trials, and the Government cannot try to reinvent this standard through expert testimony." *Id.*

Two other district courts, confronted with similar attempts by the FTC, also rejected the argument that the "competent and reliable scientific evidence" standard requires drug-level RCTs. *See Garden of Life*, 845 F. Supp. 2d at 1334-35 (when a consent decree incorporates the "competent and reliable scientific evidence" standard, the FTC cannot retroactively redefine it through expert testimony and thereby "read additional requirements into the Consent Decree"); *Basic Research*, 2014 WL 12596497, at *13 (rejecting FTC's attempt to require RCTs because by "requir[ing] a level of substantiation that exceeds the requirements of the [consent decree]," the government failed the "expectation of reasonableness.").

## II. THE DISTRICT COURT PROPERLY DISMISSED THE COMPLAINT, WHICH IS A FURTHER ATTEMPT TO USE LITIGATION TO IMPOSE A NOVEL AND UNLAWFUL STANDARD.

This lawsuit is the FTC's most recent attempt to use litigation to impose a substantiation standard for dietary supplement claims that far exceeds the

requirements in DSHEA and the agency's own guidance. Here the FTC is trying to raise the standard even higher because it admitted that the defendant *does have an RCT*. The FTC is now demanding positive results from primary end points in that drug-level RCT. The district court correctly dismissed the Complaint because its entire premise is wrong: neither the law nor agency guidance require dietary supplement claims to be substantiated by an RCT. The FTC therefore cannot state a claim under the FTC Act by alleging that a company fails to have a gold-plated RCT.

The government's entire Complaint is based on the premise that defendants' dietary supplement claims were unsubstantiated because they lack positive results from primary end points in a gold standard drug-level clinical trial. *See, e.g.*, JA40 (Compl. ¶ 37) (alleging violation of FTC Act because Prevagen advertising claims were "false or misleading, or were not substantiated"); JA41 (Compl. ¶ 43) (alleging violation of New York law because Prevagen advertising claims were "false or misleading, or were not substantiated"); JA42 (Compl. ¶ 45) (same). Although the FTC conceded that a "double-blind, placebo-controlled human clinical study" was conducted on Prevagen, the FTC alleged that the study was insufficient because it "failed to show a statistically significant improvement in the treatment group over the placebo group" *as a whole*. JA37 (Compl. ¶ 28). As the district court noted, however, "statistically significant results were observed

between the experimental and control groups" among two subgroups in multiple cognitive tasks measured in the study. SA5. The FTC simply alleged that those results were not good enough.

But the district court was correct to dismiss the Complaint on these allegations. An RCT is not required at all, so surely nit-picking the RCT that did exist does not state a valid legal claim under this regulatory regime. The government cannot hold defendants to a substantiation standard that has no foundation in either DSHEA or the FTC's Guidance that comprehensively addresses that very issue. As the courts in *Bayer*, *Garden of Life*, and *Basic Research* correctly recognized, neither DSHEA nor the FTC Guidance require that dietary supplement advertising claims be substantiated by drug-level RCTs.

The fact that the government has alleged violations of the FTC Act and state law, rather than DSHEA, does not change this conclusion. The core issue in this case is the proper standard for substantiating dietary supplement claims, and it is DSHEA (an amendment to the FDCA) and the FTC Guidance that establish that substantive standard. Moreover, the FTC and FDA have long sought to harmonize their approach to the substantiation of claims made for dietary supplements, and the FTC (and New York) should not require a type and degree of evidence for advertising claims that is not equivalent to that required by the FDA for label claims.

The FTC attempts to sidestep the fact that it is seeking to impose a novel, heightened substantiation standard by asserting that this case is just about the federal pleading standards and whether the district court properly applied them. *See, e.g.,* FTC Br. at 21 ("This case is a classic example of a district court violating basic principles governing motions to dismiss."). The FTC argues, relatedly, that whether the advertising claims at issue were properly substantiated "can be properly assessed only after the development and consideration of a full record" and "is a quintessential matter for expert opinion and analysis." *Id.*

But this is misdirection. The pleading standard is modest, to be sure, but plaintiffs are required to plead a viable legal theory to defeat a motion to dismiss and move on to discovery. Here they have not done so. The agency cannot rest on a legal theory that is rejected by the governing statute and guidance.

Nor can the government's eagerness to put on experts save its case. While the definition of "competent and reliable scientific evidence" "looks to the view of experts in the relevant field," *Bayer*, 2015 WL 5822595, at *14, the case law is clear that the FTC cannot change the substantiation standard through hired experts. *See id.*; *Garden of Life*, 845 F. Supp. 2d at 1334-35; *Basic Research*, 2014 WL 12596497, at *13.

Indeed, the *Bayer* court expressly rejected the government's attempt to pursue an enforcement action "on the basis of a lone expert who propose[d] a

standard that was not disclosed to industry until the day the government" initiated its action. *Bayer*, 2015 WL 5822595, at *14; *see also id.* (government cannot "reinvent [the substantiation] standard through expert testimony"). Similarly, the *Garden of Life* court held that the FTC cannot "read additional requirements" into a consent decree by retroactively redefining the term "competent and reliable scientific evidence" through expert testimony. 845 F. Supp. 2d at 1334-35. And the *Basic Research* court rejected as unreasonable the FTC's attempt to use "its expert" to "require[] a level of substantiation that exceeds the requirements of [a consent decree]." *Basic Research*, 2014 WL 12596497, at *13.

The FTC can only change the law by asking Congress to pass a new statute. It can only change its guidance by revoking its existing guidance and promulgating a new standard for the industry though proper notice and comment rulemaking with the participation of all stakeholders. *See, e.g.*, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995) (rulemaking under the Administrative Procedure Act is required when an agency "adopt[s] a new position inconsistent with any of the [agency's] existing regulations"); *Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 240-41 (D.C. Cir. 1992) (invalidating agency directives that "adopt[ed] a new construction of an old rule" because the agency failed to conduct notice-and-comment rulemaking).

What the FTC cannot do is introduce a novel standard in litigation through purported experts, and then apply it retroactively to a company that lacked fair notice of the standard. The district court properly rejected the government's attempt to do so here.

## CONCLUSION

*Amici* respectfully request that the Court affirm the judgment of the district court.

Respectfully submitted,

/s/ Benjamin M. Mundel

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Date: June 6, 2018

## CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the length limitations of Local Rule 29.1(c) because it contains 3889 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), and that it complies with the typeface requirements of Fed. R. App. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it was prepared using Microsoft Word 2010 in 14 point Times New Roman type.

/s/ Benjamin M. Mundel
Benjamin M. Mundel

**CERTIFICATE OF SERVICE**

I certify that on June 6, 2018, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Benjamin M. Mundel
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