UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 10-CR-253

CONRAD E. LEBEAU,

Defendant.

MEMORANDUM IN OPPOSITION TO DEFENDANT'S REQUEST FOR A REVIEW UNDER RULE 58

INTRODUCTION

The United States files this memorandum in response to Defendant's two related requests for a review pursuant to Fed. R. Crim. P. 58(g). R. 111, 113.[1] As this Court is aware, Rule 58 of the Federal Rules of Criminal Procedure creates a right "of appeal" to a district judge in misdemeanor criminal cases. *See United States v. Smith*, 992 F.2d 98 (7th Cir. 1993). Review by the district judge is jurisdictional; that is, an appeal to the Seventh Circuit is unavailable without review by the district judge. *Id.* at 99. While the Seventh Circuit has questioned the wisdom of this procedural "scheme," it is required. *Id.* at 100.

The rule itself offers little guidance with respect to the scope of Rule 58 proceedings in the district court. The Fourth Circuit has held that the district judge acts as an appellate court, giving appropriate deference to the magistrate judge. *See United*

[1] "R." followed by a number indicates a docket entry in this case.

States v. Cathey, 2015WL 4036036, * 1 (4th Cir. 2015) (internal citation omitted). In light of this limited "appellate" role, it is the position of the United States that this Court, like an appellate court, should not entertain new evidence or new arguments. Rather, review should be limited to the arguments that the defendant preserved in his conditional plea agreement. *See* R. 58 (¶ 25).

The Defendant makes legal arguments that fall primarily into three categories: (1) that the definition of "drug" found in the Federal Food, Drug, and Cosmetic Act ("FDCA") is overbroad, (2) that the Defendant's crime of introducing an unapproved new drug into interstate commerce in violation of 21 U.S.C. § 331(d), represents an unconstitutional restriction on Defendant's commercial speech rights under the First Amendment, and (3) that it would have been "impossible" for the Defendant to avoid committing this offense. Defendant's contentions are without legal merit, and this Court should reject them in their entirety.

More broadly, the Defendant has requested that this Court review *all* of Magistrate Judge Callahan's decisions spanning the long life of this case. Specifically, Defendant references three of Magistrate Judge Callahan's major decisions. R. 41, 51, 71. While the Government acknowledges that Defendant's Conditional Plea Agreement provides him with the opportunity to appeal certain legal issues such as those enumerated above (R. 58 (¶ 25)), Defendant has not provided any rationale for departing from the numerous, well-reasoned decisions made by Magistrate Judge Callahan throughout this case. In short, Defendant asks for a wholesale review but fails to explain how the magistrate judge erred at any stage of this proceeding. Whether this Court reviews these

decisions *de novo* or with deference, they are based on sound legal reasoning and should not be disturbed.

DISCUSSION

I. The term "drug" is neither overly broad nor vague.

The Defendant pleaded guilty to the distribution of an unapproved new drug in interstate commerce, a crime under 21 U.S.C. §§ 331(d), 355, and 333(a)(1). The Defendant acknowledged and agreed in his Plea that the government could have demonstrated at trial beyond a reasonable doubt that his product (Perfect Colon Formula) qualified as a drug. [2] As he has before, the Defendant argues that the definition of "drug" found in the FDCA is overbroad because it reaches products that the Defendant believes

[2] Mr. LeBeau now implies (1) that he did not intend his product to treat food allergy; and (2) that he does not consider the treatment of food allergy to be the treatment of a disease. R. 113 (pp. 5-6) (questioning whether a disease claim for Perfect Colon Formula was intended). This is confusing. For a start, Mr. LeBeau was not charged with "intending to make a disease claim for a product" but rather distributing a drug (meaning, a product that he intended to be used to treat disease). Mr. LeBeau does not deny that his product was intended to treat food allergy but does now assert, possibly, that he didn't intend to break the law. As Magistrate Judge Callahan clearly discussed with the Defendant prior to the entry of his plea, the Defendant's knowledge that he was breaking the law is not an element of the offense at issue. *See* R. 71 (pp. 6-7) (Defendant quoted from the record to state "under the law…you don't have to have a state of mind being guilty, or even knowingly violate the law. That's the way the law is. So under the law I'm guilty."). To the extent that Mr. LeBeau is questioning whether he intended his product to treat food allergy and whether food allergy is a disease state, these factual assertions are contradicted by the factual basis of his plea agreement. For example, the Defendant admitted that Perfect Colon was among the four products for which he made "disease claims" that would have been used as evidence of his intended use for those products. R. 58 (¶ 5) ("Offense Conduct") ("The defendant admits to these facts and that these facts establish his guilt beyond a reasonable doubt:…Selected for purchase were products for which the defendants made 'disease claims'…that use of the product, Perfect Colon Formula #1, 'reduces food allergies.'"). The Defendant also acknowledged and agreed that "[i]f this case were to proceed to trial, FDA experts would testify that Perfect Colon Formula #1 is a new drug…" R. 58 (¶ 5). Further, FDA regulations define "disease" to include "damage to an organ, part, structure, or system of the body such that it does not function properly (*e.g.*, cardiovascular disease), or a state of health leading to such dysfunctioning (*e.g.*, hypertension)…" 21 C.F.R. § 101.93(g). To the extent that the Defendant is now arguing factually that food allergy is not a qualifying disease state, the Defendant has already admitted that the Government could have met its factual burden in this case beyond a reasonable doubt. Although the Plea Agreement provides Defendant the ability to appeal specific legal issues, he cannot now walk back the factual admissions that form the basis for his guilty plea, voluntarily and knowingly entered. *See* R. 71, 8 (denying Mr. LeBeau's motion to withdraw his guilty plea "when the record clearly demonstrates that the plea was entered knowingly, voluntarily, intelligently, and with a full appreciation of the consequences of such plea.").

should not be considered drugs. R. 58 (¶ 25). It is the Defendant's position that this represents a regulatory "over-reach" by the FDA. *Id*.

The simple answer to Defendant's objection is that Congress chose to define "drug" in a very specific way to include "articles *intended for use* in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B) (emphasis added). As this definition suggests, whether a product is a "drug" under the law turns on that particular product's intended use. *See* 21 U.S.C. § 321(g)(1); *United States v. Bowen*, 172 F.3d 682, 686 (9th Cir. 1999); *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 333 (2d Cir. 1977).

Despite Defendant's contentions about what the law ought to be, the express language of the FDCA and interpreting case law make it clear that any article which is intended to diagnose, cure, mitigate, treat, or prevent disease is a "drug" under the law. *See* 21 U.S.C. § 321(g)(1)(B). Under the FDCA, any article -- including an article commonly thought of as a food -- when sold for the purpose of disease treatment – is properly considered a drug within the meaning of the law. Some longstanding examples include peppermint tea leaves, mineral water, and honey.[3] *United States v. 250 Jars of U.S. Fancy Pure Honey*, 218 F. Supp. 208 (E.D. Mich. 1963) (finding honey to be a drug based on claims made in newspaper leaflet and booklet claiming that honey was panacea for various ailments), *aff'd*, 344 F.2d 288 (6th Cir. 1965) (honey affirmed as a drug due

[3] Additional examples include, but are not limited to, *United States v. 3 Cartons * * * 'No. 26 Formula GM etc.*,' 132 F. Supp. 569, 573-74 (S.D. Cal. 1952) (therapeutic purpose for animal heart held to bring it within the definition of drug); *United States v. Millpax, Inc.*, 313 F.2d 152, 154 (7th Cir. 1963) (intended use proved by form "disclaimer letter" and magazine testimonials implying that iron tonic was cancer cure); *United States v. Cruez*, 144 F. Supp. 229 (E.D. Ill. 1956) (herb tonic formula and cold salve sold to cure, mitigate and treat arthritis, diabetes, ulcers and swollen ankles).

to intended use as "a panacea for various diseases and ailments"); *United States v. Hohensee*, 243 F.2d 367, 370 (3d Cir. 1957) (peppermint tea leaves found to be a drug due to intended use for treatment of, *e.g.*, gall stones, colic, flatulence, headache, rheumatism, high blood pressure, arthritis); *Bradley v. United States*, 264 F. 79, 80-82 (5th Cir. 1920) (mineral water was considered a drug where the product was marketed as a substance that "possesses certain elements or ingredients which are curative, or at least alleviative, for the diseases named in the label" and where it was "recommended in the treatment of Bright's Disease, Diabetes, Dropsy . . . Indigestion, Kidney and Bladder troubles").

Indeed, Mr. LeBeau is no stranger to this settled construction of the FDCA, because his own "White Birch Mineral Water" and "Licorice Root Tea" were determined by this Court to be drugs in 1992, a decision affirmed by the Seventh Circuit. *United States v. Vital Health Prods., Ltd.*, 786 F. Supp. 761, 772 (E.D. Wis. 1992); *United States v. Lebeau*, 985 F.2d 563 (7th Cir. 1993) ("White Birch Mineral Water" and "Licorice Root Tea" reported to possess curative powers for arthritis, cancer, general warts, stomach ulcers, AIDS, cancer, chronic infection, and detoxification).

Against this legal backdrop, the Defendant continues to insist that the definition of a drug is overly broad simply because that definition encompasses his product (Perfect Colon Formula) as he intended it to be used, even though Congress has mandated FDA pre-approval for all new drugs in order to protect the public from products of unknown safety and efficacy. *See* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application

filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."); 21 U.S.C. § 331(d) (Making the introduction of a drug in violation § 355 a "Prohibited Act"); 21 U.S.C. 333(a)(1) (Criminalizing the commission of a Prohibited Act under § 331). As Magistrate Judge Callahan pointed out, Mr. LeBeau's position is best understood not as a legal challenge to the statute as written but a public policy preference Mr. LeBeau wishes Congress had adopted:

> To the extent that LeBeau is arguing that Congress did not intend to include God-made things as "drugs" under the Federal Food, Drug, and Cosmetic Act, there is no need for the court to rummage through legislative history and the isolated remarks of legislators from the early 20th century in order to give effect to that Act. The language of the Act is clear and unambiguous and, as such, is to be given its clear meaning. If, as LeBeau maintains, certain food stuffs were not intended by the 1906 Congress to be potentially included as "drugs" under the definition of that term in the Food and Drug Act, his argument misses the mark because, as previously noted, he is not charged with a violation of the Food and Drug Act of 1906. Rather, he is charged with a violation of the FDCA. And, to the extent that he is making a similar argument with respect to that particular Act, his remedy is to have Congress amend the FDCA to reflect his view of how the FDCA should read. It is not for this court to amend the law as written. That would constitute political action; it would not constitute judicial action. Stated another way, LeBeau should be presenting this argument on how the law should read to his elected federal representatives, not to this court.

R. 41 (pp. 6-7) (Magistrate Judge Callahan denying one of Defendant's motions to dismiss).

To the extent that the Defendant is arguing that it was unclear to him why his product is encompassed by this definition, his argument can best be understood as a challenge to the law on vagueness grounds. "The prohibition of vagueness in criminal statutes 'is a well-recognized requirement, consonant alike with ordinary notions of fair

play and the settled rules of law,' and a statute that flouts it 'violates the first essential of due process.'" *Johnson v. United States*, 135 S. Ct. 2551, 2556-57 (U.S. 2015) (quoting *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926)). But unconstitutional vagueness only exists when the law "forbids no specific or definite act" and "leaves open . . . the widest conceivable inquiry, the scope of which no one can foresee and the result of which no one can foreshadow or adequately guard against." *United States v. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921). Once lawmakers provide "clear notice that a reasonably ascertainable standard of conduct is mandated . . . it is for [the defendant] to insure that his actions do not fall outside the legal limits." *United States v. Powell*, 423 U.S. 87, 92 (1975).

Whatever LeBeau claims to have believed about the curative properties of his product, his choice to distribute a product of unknown efficacy and safety without FDA pre-approval does not mean that the FDCA fails to create a "metric for decision" that permits informed choices, particularly given that the law expressly prohibits the distribution of unapproved new drugs in interstate commerce. *United States v. Caputo*, 517 F.3d 935, 941 (7th Cir. 2008); *see also United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986).

Given the specificity of the FDCA's legal requirements at issue in this case, it is no surprise that courts have consistently rejected vagueness challenges to the FDCA. *See, e.g., General Nutrition, Inc.*, 638 F. Supp. at 564 (rejecting vagueness challenge to the term "new drug" and noting that "this court is unaware of any case holding any provision of the [FDCA] void for vagueness in any circumstance."); *United States v.*

Travia, 180 F. Supp. 2d 115, 125 (D. D.C. 2001) (rejecting vagueness challenge in prosecution involving nitrous balloons sold in parking lot of a rock concert); and *United States v. Marcen Labs., Inc.*, 416 F. Supp. 453, 455 (S.D.N.Y. 1976), *aff'd*, 556 F.2d 562 (2d Cir. 1976) (table) (rejecting vagueness challenge to the definition of "new drug").[4]

In short, it is one thing for Mr. LeBeau to disagree with the explicit terms of the statute as a matter of policy, but quite another to prevail on a legal argument that the scope of the law is unconstitutionally broad or vague.

II. The use of Defendant's speech as evidence of his intent does not infringe his First Amendment Rights.

In *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), the Supreme Court made clear that the First Amendment does not prohibit the use of a defendant's speech as evidence of an element of motive or intent. *Id.* at 489; *see generally Church of Scientology v. Richardson*, 437 F.2d 214, 218 (9th Cir. 1971) (holding that religious literature could constitutionally be considered in determining the intended use of a product and that there was no First Amendment infringement). And when this concept from *Wisconsin v. Mitchell* was recently applied in the FDCA context -- to a purported dietary-supplement peddler much like LeBeau -- the D.C. Circuit made it clear that the use of speech as evidence to establish the intended use of a drug does not infringe the First Amendment's protection:

> Assuming that the government may condition the sale of drugs on passage through the elaborate testing that the statute requires (an assumption that

[4] A more extensive response to Defendant's vagueness argument can be found in the Government's response to his earlier motion (R. 37 (pp. 16-23)) and Magistrate Judge Callahan's rejection of Defendant's vagueness argument R. 41 (p. 7).

> Whitaker doesn't question), the key step is the FFDCA principle that classification of a substance as a "drug" turns on the nature of the claims advanced on its behalf. That principle, in turn, rests on the idea that claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose--and, therefore, as evidence whether the product is or is not a drug. *See, e.g., Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980). The question is whether this use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid. In fact, the First Amendment allows "the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." *Wisconsin v. Mitchell*, 508 U.S. 476, 489, 124 L. Ed. 2d 436, 113 S. Ct. 2194 (1993) (upholding use of speech to determine that defendant selected battery victim because of his race, for purposes of statutory sentence enhancement). *Thus it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that Whitaker's proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug.*

Whitaker v. Thompson, 353 F.3d 947, 953 (D.C. Cir. 2004) (emphasis added). Defendants' objection is identical to that addressed and rejected by the D.C. Circuit in *Whittaker*. For the reasons articulated in *Whittaker*, the use of LeBeau's speech as part of the evidentiary basis for his guilty plea does not raise a First Amendment free-speech concern.

In support of his First Amendment position, Mr. LeBeau points the court to two cases: *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 565 (U.S. 1980) and *United States v. Caronia*, 703 F.3d 149 (2d Cir. N.Y. 2012). The test articulated in *Central Hudson* is inapposite because the law at issue in this case – the prohibition on the introduction of an unapproved new drug – does not restrict speech but rather restricts the distribution of a drug of unknown safety and efficacy. Distributing such a drug product is not an act of speech. Mr. LeBeau's reliance on *Caronia* is

similarly misplaced. Even putting aside the distinguishing fact that *Caronia* involved the distribution of an FDA-approved drug product that could legally be distributed, *Caronia* provides no shield for Mr. LeBeau because that case involved the (highly unusual) prosecution of a pharmaceutical executive in which "the government's theory of prosecution identified Caronia's speech alone as the proscribed conduct." *Caronia*, 701 F.3d at 162. According to the Second Circuit, the district court's jury instruction also erroneously "left the jury to understand that *Caronia's speech was itself the proscribed conduct*." *Id.* at 161 (emphasis added). Such is simply not the case for Mr. LeBeau, whose plea agreement rests on the admitted and agreed fact that he distributed an unapproved new drug in interstate commerce, not the criminalization of any speech on his part.

While he is entitled to say whatever he wishes, Mr. LeBeau is not allowed under the law to sell unapproved new drug products in interstate commerce, which is precisely what he has admitted in his plea agreement that he did. And when Mr. LeBeau made the choice to ship his wares in interstate commerce, his speech about those products rightly became evidence of the use he intended for those products. As such, Mr. LeBeau's First Amendment rights have not been abridged, and his arguments here should (again) be rejected.[5]

[5] A more extensive briefing of the government's response to Mr. LeBeau's First Amendment arguments occurred below (R. 37 (pp. 12-14)). Magistrate Judge Callahan also rejected the Defendant's argument in the context of a motion to dismiss (R. 41 (pp. 7-9)).

III. Mr. LeBeau confuses the doctrine of impossibility with the valid exercise of Congressional power to restrict the sale of potentially harmful drugs

Most of Mr. LeBeau's submission focuses on his "core arguments about the Doctrine of Impossibility." Doc. No. 113 at 6. By this, Mr. LeBeau means that it is impossible for him to obtain FDA approval for his product through the New Drug Approval process for financial reasons and because his products are not patentable. Even if these assertions were factually true,[6] these obstacles would not excuse Mr. LeBeau's crime.

To clarify, the doctrine of impossibility, at common law, "distinguished between legal and factual impossibilities, providing that the former is a defense and that the latter is not." *United States v. Tykarsky*, 446 F.3d 458, 465 (3d Cir. 2006). But Mr. LeBeau is not referring to a now-archaic defense for inchoate crimes when he refers to his impossibility defense. Instead, he simply means that the law makes it "impossible" for him to do what he wants to do: sell his unapproved new drug products without first getting those drugs approved by FDA and without facing a legal sanction. [7]

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[6] Acknowledging that it might be extremely difficult for Mr. LeBeau to get a drug product approved, if his products were truly the promising cures for food allergy and other diseases that he believes them to be, others in his position have found financial backing to conduct the clinical research needed to prove that a drug is safe and effective to the FDA. Doing so is not "impossible," particularly if the scientific basis for the safety and efficacy of one's drug product is as sound as Mr. LeBeau's professed belief in his formulae appears to be. Further, Mr. LeBeau is simply incorrect that a patent is required in order to submit a New Drug Application. For a more complete explanation of why a patent is not required for an NDA, please see the government's briefing of this argument (R. 45 (pp. 8-9)) and Magistrate Judge Callahan's rejection of this argument R. 51 (p.4).

[7] Mr. LeBeau does not appear to be suggesting at this time that Congress does not have the authority to regulate the distribution of drug products in interstate commerce. Such a suggestion would be incorrect. Congress' exercise of Commerce Clause power to restrict the movement of unapproved new drugs in interstate commerce easily falls within both the first and second categories of permissible regulation identified by the Supreme Court in *United States v. Lopez*, 514 U.S. 549, 558 (1995).

Perhaps Mr. LeBeau's "impossibility" argument is better understood as an attempt to articulate a necessity or justification defense. Such a defense to a charged crime can sometimes lie if the defendant can prove four elements:

> (1) that defendant was under an unlawful and present, imminent, and impending threat of such a nature as to induce a well-grounded apprehension of death or serious bodily injury, (2) that defendant had not recklessly or negligently placed himself in a situation in which it was probable that he would be forced to choose the criminal conduct, (3) that defendant had no reasonable, legal alternative to violating the law, a chance both to refuse to do the criminal act and also to avoid the threatened harm, and (4) that a direct causal relationship may be reasonably anticipated between the criminal action taken and the avoidance of the threatened harm.

United States v. Luker, 395 F.3d 830, 832-33(8th Cir. 2005) (quotations and internal citations omitted). In general terms, this defense may be available to excuse otherwise criminal conduct only when a defendant can demonstrate, among other things, that he was incapable of avoiding the commission of a crime.

A simple review of the elements needed for this defense demonstrates that it is unavailable to excuse Mr. LeBeau's conduct. At all times, he was perfectly capable of complying with the prohibition on the introduction of unapproved new drugs into interstate commerce. He states in his motion that, as a result of this prosecution, he has stopped selling his violative products. R. 113 (p. 4) ("so I closed the business down and dissolved Vital Health Products Ltd…"). Thus, if the Court takes him at his word, Mr. LeBeau has personally demonstrated that compliance with the law is possible. He just believes that noncompliance is *preferable* and would like the court to rewrite federal law

or excuse his violation of it. This Court should decline to do so and should reject his "impossibility" defense.

CONCLUSION

For the foregoing reasons, all of Mr. LeBeau's legal arguments should be rejected, Magistrate Judge Callahan's rulings below should be upheld, and Mr. LeBeau's guilty plea should remain undisturbed.

Dated at Milwaukee, Wisconsin, this 11th day of August 2015.

Respectfully submitted,

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