UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 10-CR-253

CONRAD E. LEBEAU,

Defendant.

THE UNITED STATES OF AMERICA'S RESPONSE TO DEFENDANT CONRAD E. LEBEAU'S "APPELLATE BRIEF" [DOC NO. 98]

INTRODUCTION

The United States of America, by and through its attorneys, James L. Santelle, United States Attorney for the Eastern District of Wisconsin, and Gordon P. Giampietro, Assistant United States Attorney, respectfully submits this brief in response to Defendant Conrad E. LeBeau's ("LeBeau") December 28, 2012, "Appellate Brief." Doc. No. 98.

ARGUMENT

I. This Court should summarily adopt Magistrate Judge Callahan's disposition of LeBeau's many arguments.

Magistrate Judge Callahan properly resolved LeBeau's many legal arguments and, accordingly, there is no reason to disturb the judgment. Moreover, LeBeau's

plea agreement specifically preserved his legal arguments for appeal pursuant to Rule 11(a)(2) of the Federal Rules of Criminal Procedure. The United States respectfully requests that this Court summarily adopt the reasoning set forth in Magistrate Judge Callahan's decisions dated September 21, 2011, December 7, 2011, and May 29, 2012. *See* Doc. Nos. 41, 51, and 71. The Seventh Circuit can then decide whether to re-affirm in the criminal context what, two decades ago, it held in the civil context. *See United States v. Vital Health Prods., Ltd.*, 786 F. Supp. 761, 772 (E.D. Wis. 1992), *aff'd, United States v. LeBeau*, 985 F.2d 563 (7th Cir. 1993). While there is not a perfect overlap between the cases, LeBeau has long-known of the Food and Drug Administration's ("FDA") interpretation of the Federal Food Drug and Cosmetic Act ("FDCA") as it relates to unapproved new drugs. He rejects it, of course, but it does not come as a surprise to him.

In response to LeBeau's arguments before this Court, the United States incorporates herein, but will not repeat, its pleadings submitted to Magistrate Judge Callahan. *See* Doc. Nos. 37, 45, 68, and 76. Suffice it to say, LeBeau's arguments have been fully-litigated and Magistrate Judge Callahan's reasoning is both compelling and comprehensive. There is no good reason to spill more ink before this case reaches the court of appeals.

II. The Second Circuit's decision in *Caronia* does not undermine Magistrate Judge Callahan's First Amendment analysis.

The only aspect of LeBeau's appeal that requires a response is his First Amendment argument based on a recent Second Circuit decision, *United States v. Caronia*, 2012 WL 5992141 (2d Cir. 2012). Doc. No. 98, Appellate Brief, pages 22-24. Although Magistrate Judge Callahan properly rejected LeBeau's First Amendment argument (Doc. No. 41, pages 7-9), *Caronia* was not decided until well-after his decision. Nothing in *Caronia* calls into doubt Magistrate Callahan's First Amendment analysis.

In *Caronia*, the Second Circuit overturned the 21 U.S.C. § 331(a) misdemeanor conviction of a pharmaceutical salesman because the government's trial statements, and the district court's jury instructions, treated the promotion of off-label uses for an FDA-approved product as criminal activity. *Id*. at *25 ("The district court record thus confirms overwhelmingly that Caronia was, in fact, prosecuted and convicted for promoting Xyrem off-label.") and *29 ("the government's theory of prosecution identified Caronia's speech alone as the proscribed conduct").

The Second Circuit's decision in *Caronia* must be limited to its unusual facts and does not (nor could it) undermine the First Amendment cases cited by Magistrate Judge Callahan: *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980); and *Whitaker v. Thompson*, 353 F.3d 947 (D.D.C.

2004); and *Wisconsin v. Mitchell*, 508 U.S. 476 (1993). Specifically, as would be expected, *Caronia* applied *Central Hudson* to determine whether the commercial speech at issue - a salesman's promotion of the off-label use of an approved drug – was protected by the First Amendment. *Id*. at *11-15. Under *Central Hudson*, a restriction on commercial speech is analyzed under a four-part test: (1) the speech must not be misleading and must concern lawful activity; (2) the government's interest in regulating the speech must be substantial; (3) the regulation must directly advance the government's asserted interest; and (4) the regulation must be narrowly drawn and no more extensive than necessary to serve that interest. *Caronia*, * 2 (citations omitted).

The Second Circuit held that the government could not justify its prosecution of Caronia, a salesman, under the third and fourth prongs of *Central Hudson.* Specifically, the Second Circuit held that precluding the class of salesmen from truthful statements about an approved product, would not advance the FDA's interest in preserving the efficacy and integrity of the drug approval process. *Caronia*, *13. The Second Circuit also found the prohibition to be more extensive than necessary to achieve the government's interest. *Id*. at * 14. The Second Circuit specifically limited its holding to "FDA-approved drugs for which off-label use is not prohibited. . . ." *Id*. at * 15.

In this case, the very first prong of the *Central Hudson* test, alone, distinguishes LeBeau from Caronia. Caronia's speech was truthful and concerned the lawful off-label use of an approved drug. *Id*. at * 13. Here, of course, LeBeau admitted in the plea agreement that he shipped in interstate commerce Perfect Colon Formula # 1, and that it is an unapproved new drug. Doc. No. 58, Plea Agreement, ¶ 5. To be sure, LeBeau has preserved multiple arguments challenging the law, but Perfect Colon Formula #1, unlike the drug in *Coronia*, is not an approved new drug under the FDCA.

Indeed, the Second Circuit in *Caronia* specifically noted this fact in distinguishing its holding from the District of Columbia Circuit's decision in *Whitaker, supra;* a case cited by Magistrate Judge Callahan in rejecting LeBeau's First Amendment challenge. *Caronia*, * 13, n. 11 (distinguishing *Whitaker* because the product, saw palmetto extract, was an unapproved new drug that made disease claims); Doc. 41, 9/21/11 Decision and Order, page 8.

For this reason, *Caronia*, decided after Magistrate Judge Callahan issued his decision, does make LeBeau's First Amendment argument any better. If anything, *Caronia* confirms that LeBeau, like Whitaker, may not invoke the First Amendment to protect disease claims made in the marketing of an unapproved new drug.

CONCLUSION

For all the foregoing reasons, the judgment dated August 7, 2012, should not be disturbed.

Dated at Milwaukee, Wisconsin, this 24th day of January 2013.

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