

09-5006-cr (L) 10-750-cr (CON)

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

UNITED STATES OF AMERICA,

Appellee,

v.

ALFRED CARONIA, PETER GLEASON,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK,
JUDGE ERIC N. VITALIANO

SUPPLEMENTAL BRIEF OF APPELLANT ALFRED CARONIA

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INTRODUCTION

Defendant-Appellant Alfred Caronia files this supplemental brief in response to the Court's questions regarding the impact of *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), on this case, and the prejudicial errors in the district court's jury instructions and verdict sheet.

In *Sorrell*, the Court struck down Vermont's "Prescription Confidentiality Law," which prohibited the use of physician prescribing records by pharmaceutical companies in their marketing. 131 S. Ct. at 2662-63. Critical to the Court's holding, the Vermont law imposed content and speaker-based burdens on truthful speech promoting prescription drugs. *Id.* at 2663-64. The law disfavored only certain speakers (pharmaceutical manufacturers) and only certain types of speech (pharmaceutical marketing). *Id.* at 2663. Due to this discriminatory treatment, the Court held that it must apply "heightened judicial scrutiny," *id.* at 2664, and that the Vermont law could not survive that scrutiny, *id.* at 2667-72.

The same analysis applies to Caronia's criminal conviction under the regulatory regime of the Food and Drug Administration ("FDA"). That regime engages in content (and, indeed, viewpoint) discrimination, because it prohibits manufacturers from encouraging doctors to prescribe approved drugs for off-label uses but permits them to discourage such off-label prescriptions. And the regime engages in speaker discrimination, because it applies only to pharmaceutical

manufacturers and their agents. Indeed, the burdens in this case are even more severe. While *Sorrell* arose out of a *civil* suit seeking injunctive relief against a law that authorized “civil remedies,” *id.* at 2660-62, this case resulted in a *criminal* conviction. See 21 U.S.C. §§ 331(a), 333(a)(1), 352(f)(1). What is more, Justice Breyer’s dissent in *Sorrell* specifically referenced the FDA’s regime at issue here, suggesting that the majority’s analysis called into question the FDA’s ability to “control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products.” 131 S. Ct. at 2678 (Breyer, J., dissenting). In short, *Sorrell* confirms that the Court should overturn Caronia’s conviction as a violation of the First Amendment.

ARGUMENT

I. ***SORRELL* PROVES THAT THE FDA’S CONTENT AND SPEAKER-BASED SPEECH BURDENS VIOLATE THE FIRST AMENDMENT.**

The Vermont law struck down in *Sorrell* imposed content and speaker-based burdens on truthful speech promoting prescription drugs. *Id.* at 2663-64. These burdens, the Court concluded, “justif[ied] application of heightened scrutiny.” *Id.* at 2667. Whether those content and speaker-based burdens require “heightened scrutiny” different from the typical commercial-speech test, or simply a rigorous application of it, such burdens are forbidden absent a persuasive “neutral justification” for the discriminatory treatment. Since the ban on off-label promotion underlying Caronia’s conviction imposes content and speaker-based

burdens without a valid “neutral justification,” it violates the First Amendment. In response to the Court’s request, this section first explains the standard of review for these content and speaker-based burdens and then explains why the FDA’s regime impermissibly imposes such burdens.

A. Content And Speaker-Based Burdens On Truthful Speech Are Presumptively Unconstitutional.

1. Prohibitions on truthful speech that discriminate based on content and speaker are subject to heightened scrutiny.

Sorrell clarifies that restrictions on truthful speech that discriminate based on content and speaker are presumptively invalid, whether those restrictions impose burdens on political speech, commercial speech, or any other kind. That result follows from first principles. The First Amendment is premised on the belief “that ‘information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.’” *Sorrell*, 131 S. Ct. at 2671 (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)). Thus, “above all else, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content.” *Police Dep’t of Chi. v. Mosley*, 408 U.S. 92, 95 (1972). It also means that government may not restrict the expression of certain speakers, because “[s]peech restrictions based on the identity

of the speaker are all too often simply a means to control content.” *Citizens United v. FEC*, 130 S. Ct. 876, 899 (2010). Instead, “[t]he First Amendment protects speech and speaker,” *id.*, demanding “heightened scrutiny” when the Government discriminates against either. *Sorrell*, 131 S. Ct. at 2664 (“strict scrutiny applies to regulations reflecting ‘aversion’ to what ‘disfavored speakers’ have to say”) (quoting *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 658 (1994)).

To avoid this heightened scrutiny for a “selective ban” on certain speech or speakers, the Government must proffer a “neutral justification” unrelated to the message conveyed. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429-30 (1993). And several alleged “neutral” justifications are *per se* invalid. The Government may not rely on the “justification” that the speaker’s expression is “uttered for a profit.” *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989). “While the burdened speech results from an economic motive, so too does a great deal of vital expression.” *Sorrell*, 131 S. Ct. at 2665. Nor may the Government justify a ban on a message simply because, in its view, the message will adversely affect its audience. *Linmark Assocs., Inc. v. Willingboro Twp.*, 431 U.S. 85, 96-97 (1977); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 375 (2002). “[T]he fear that people would make bad decisions if given truthful information cannot justify content-based burdens on speech.” *Sorrell*, 131 S. Ct. at 2670-71 (internal quotation marks omitted).

Significantly, *Sorrell* holds that “[c]ommercial speech is no exception” to these principles. 131 S. Ct. at 2664. To be sure, “[t]he right of citizens to inquire, to hear, to speak, and to use information to reach consensus is a precondition to enlightened self-government.” *Citizens United*, 130 S. Ct. at 898. But “[a] consumer’s concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.” *Sorrell*, 131 S. Ct. at 2664 (internal quotation marks omitted). And “[t]hat reality has great relevance in the fields of medicine and public health, where information can save lives.” *Id.* Thus, “strict scrutiny,” *id.* (citing *Turner Broad.*, 512 U.S. at 658), should apply to content and speaker-based burdens on truthful commercial speech when the Government bases those burdens on “a difference of opinion” with the message conveyed, rather than on any “neutral justification,” *Sorrell*, 131 S. Ct. at 2672.

“[H]eightedened judicial scrutiny” in these circumstances makes sense. *Id.* at 2664. Content and speaker-based bans on *truthful* commercial speech bear no relation to the underlying rationale for giving the Government more leniency to regulate that kind of speech. The “typical” neutral justification for “why commercial speech can be subject to greater governmental regulation than noncommercial speech” is the concern for fraudulent or misleading statements in commercial transactions. *Discovery*, 507 U.S. at 426. Where, however, the Government “nowhere contends that [the commercial speech] is false or

misleading within the meaning of th[e] Court’s First Amendment precedents,” *Sorrell*, 131 S. Ct. at 2672, this neutral justification for avoiding strict scrutiny with respect to commercial speech falls away. *Cf. Discovery*, 507 U.S. at 426-27.

Indeed, even before *Sorrell*, the Court had held that “the First Amendment imposes . . . a ‘content discrimination’ limitation upon a State’s prohibition of proscribable speech,” like obscenity or defamation. *R.A.V. v. City of St. Paul*, 505 U.S. 377, 387 (1992). Thus, while the Government may freely ban *all* “fighting words,” strict scrutiny applies to a *content-based* ban on “fighting words” that invoke anger on the basis of “race” or “religion,” rather than “political affiliation” or “union membership.” *Id.* at 391 (“The First Amendment does not permit [the Government] to impose special prohibitions on those speakers who express views on disfavored subjects.”).

Sorrell proves that the same principle applies to commercial speech. The Government may enact commercial-speech regulations under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Yet strict scrutiny applies if the Government fails to give a neutral justification for a content-based ban that prohibits the use of physician prescribing records in marketing, but not in, for example, “educational communications.” *Sorrell*, 131 S. Ct. at 2663. Any other rule would absurdly apply a less demanding First Amendment standard to content-based burdens on commercial speech that the

Government may regulate only under the *Central Hudson* test than to content-based burdens on types of speech that the Government may ban entirely.

2. Content and speaker-based prohibitions are equally invalid under the traditional commercial-speech test.

Even assuming that the traditional *Central Hudson* test applies to content and speaker-based burdens on truthful speech, *Sorrell* at least proves that those types of speech burdens will not survive that test. The test requires, among other things, that the Government assert a substantial interest and prove that its prohibition directly advances that interest. *W. States*, 535 U.S. at 367. As already indicated in Caronia’s reply brief (Appellant’s Reply Br. 19-26) and the Washington Legal Foundation brief (WLF Br. 18-21), a content and speaker-based prohibition on truthful commercial speech will not meet these requirements.

To begin with, content and speaker-based bans typically rest, not on substantial interests, but “on the offensive assumption that the public will respond ‘irrationally’ to the truth.” *W. States*, 535 U.S. at 375 (internal quotation marks omitted). But “[t]he First Amendment directs [courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” *Id.* Thus, the United States cannot restrict the advertising of beneficial compounded drugs out of “fear that [such] advertising . . . would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway.” *Id.* at 374. Indeed, the Government may

not even be able to restrict advertising that will stimulate demand for admittedly harmful products. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996) (plurality opinion). Instead, “[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.” *Va. State Bd.*, 425 U.S. at 770.

In addition, the discriminatory nature of content and speaker-based burdens shows that the Government lacks truly legitimate interests and that its prohibition is “too narrow to advance [them].” *Sorrell*, 131 S. Ct. at 2669. For example, the United States’ “unwillingness to adopt a single national policy” with respect to gambling advertising both called into question the legitimacy of its interest in “alleviating the societal ills” from gambling and showed that its selective ban would not advance that interest. *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 186-94 (1999). Likewise, while Cincinnati had “admittedly legitimate interests” relating to “esthetics” on its sidewalks, its *selective* ban on *commercial* newsracks did not advance that interest because other newspapers were “equally unattractive.” *Discovery*, 507 U.S. at 424-25.

Sorrell applied these same rules. To justify its content and speaker-based burdens, Vermont argued that it had a substantial interest in “reduc[ing] healthcare costs” by encouraging the use of generic drugs and in ensuring “physician confidentiality.” *Sorrell*, 131 S. Ct. at 2668. As for reduced costs, the state did not

seek to achieve its goal directly (by requiring the prescription of generic drugs) but indirectly (by keeping people in the dark about brand-name alternatives). This it could not do. “[T]he State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements.” *Id.* at 2671. As for physician privacy, “Vermont made prescriber-identifying information available to an almost limitless audience” and so the marketing limit did not “advance the State’s asserted interest.” *Id.* at 2668-69.

B. Caronia’s Conviction For Promoting Truthful, Off-Label Uses Of An Approved Drug Suffers From The Same Content And Speaker-Based Defects As The Statute Invalidated In *Sorrell*.

1. Caronia’s conviction rests on the same content and speaker-based burdens struck down in *Sorrell*. The FDA’s ban on off-label promotion applies *only* to manufacturers and their agents, not independent doctors or any other person. FDA, *Legal Status of Approved Labeling of Prescription Drugs; Prescribing for Uses Unapproved by the FDA*, 37 Fed. Reg. 16503, 16504 (Aug. 15, 1972); WLF Br. 2-5, 15 n.3. Thus, “[t]he explicit structure of the [FDA’s regime] allows [off-label promotion] to be . . . [made] by all but a narrow class of disfavored speakers.” *Sorrell*, 131 S. Ct. at 2668. The regime also imposes a content-based ban. Because it applies only to off-label promotion, 37 Fed. Reg. at 16504, it “disfavors” “speech with a particular content,” *Sorrell*, 131 S. Ct. at 2663. Worse still, it is “aimed at a particular viewpoint,” *id.* at 2664—that doctors

should prescribe drugs for off-label uses. It freely permits speech (by manufacturers or anyone else) to *discourage* those prescriptions.

As in *Sorrell*, the “neutral” justifications that the Government has proffered in this litigation for these content and speaker-based restrictions cannot avoid “heightened judicial scrutiny.” 131 S. Ct. at 2664. Here, the Government does not justify its commercial-speech ban with “typical” fraud concerns. *Discovery*, 507 U.S. at 426. Rather, it justifies the discrimination out of concern that, if doctors find the promotion “too persuasive,” *Sorrell*, 131 S. Ct. at 2671, they will prescribe drugs for off-label uses and thereby obviate the need for manufacturers to go through the FDA approval process. U.S. Br. 64-68. This it cannot do. As in *Sorrell*, the Government “seeks to achieve its policy objectives through the indirect means of restraining certain speech” rather than the direct means of banning off-label uses. *Id.* at 2670. But the FDA may not “burden the speech of [manufacturers] in order to tilt public debate in a preferred direction” against lawful, off-label prescriptions for approved drugs. *Id.* at 2671.

In short, the similarities between the statute in *Sorrell* and the FDA’s present regime are striking. As Justice Breyer noted, “the same First Amendment standards that apply to Vermont” also “apply to similar regulatory actions taken . . . by the . . . Food and Drug Administration.” *Id.* at 2675-76 (Breyer, J., dissenting). He correctly recognized that the Court’s holding necessarily restricts

the FDA's ability to "control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products." *Id.* at 2678.

2. In fact, enforcement of the FDA's regime here represents a markedly greater violation of the First Amendment. *First*, the Vermont law did not restrict marketing, but only the use of what the Supreme Court assumed to be "a mere commodity" (physician prescribing records). *Id.* at 2667. Here, by contrast, the FDA has repeatedly noted that it directly prohibits off-label promotion. *See* 37 Fed. Reg. at 16504. And the jury was told that manufacturers were not permitted to promote off-label uses (Trial Tr. at 921), as the trial court also conclusively determined prior to trial, *see United States v. Caronia*, 576 F. Supp. 2d 385, 391-92 (E.D.N.Y. 2008). Such promotion is "indisputably a form of 'commercial speech' for purposes of the First Amendment." *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 282 (2d Cir. 2010) (Livingston, J., dissenting).

At the least, *Sorrell* removes all doubt that the Court must reject the Government's argument that it evades all First Amendment scrutiny because it prohibits only "conduct." U.S. Br. 47-57. Vermont made a similar argument—that "sales, transfer, and use of prescriber-identifying information are conduct, not speech." *Sorrell*, 131 S. Ct. at 2666. "[E]ven assuming" that to be true, the Court still applied "heightened scrutiny" due to Vermont's content and speaker-based discrimination. *Id.* at 2667.

Here, even assuming (contrary to the FDA guidance and jury instructions) that the FDA does not directly *outlaw* speech promoting off-label uses, it still “imposes a speaker- and content-based *burden* on [that] protected expression” by treating such speech as *partial* grounds for criminal prosecution, “and that circumstance is sufficient to justify application of heightened scrutiny.” *Id.* (emphasis added). The Act treats a drug as unlawfully “misbranded” if its labeling lacks “adequate directions for use.” 21 U.S.C. § 352(f)(1). And the Government conclusively deems an approved drug’s directions inadequate if it “is marketed for an unapproved use.” FDA, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs* § III (Jan. 2009). Off-label promotion, therefore, automatically subjects a manufacturer to criminal penalties, and constitutes the dividing line between lawful and unlawful conduct. *Cf. W. States*, 535 U.S. at 370 (striking down, as violation of First Amendment, government’s use of advertising to “draw a line” between lawful drug compounding from unlawful drug manufacturing). But, again, even assuming promotional speech is not *the* touchstone or *exclusive* means of demonstrating unlawful off-label use or intent, it nonetheless is *a* (typical) means of doing so—and therefore, under *Sorrell*, burdens such speech sufficiently to trigger heightened scrutiny.

Indeed, this case shows just how burdensome the speech ban is. Caronia’s conviction rests on two meetings with a confidential government informant, Dr. Steven Charno. During the first, Dr. Charno himself sought to illicit “off label” promotion from Caronia. During the second, Caronia merely introduced Dr. Charno to Dr. Peter Gleason, who promoted the drug for off-label uses based on his experienced medical judgment.

Second, the Vermont law merely prohibited pharmaceutical companies from accessing information that other entities possessed as a result of government regulation. *Sorrell*, 630 F.3d at 286 (Livingston, J., dissenting). But the FDA’s ban on off-label promotion prohibits companies ““from conveying information that [they] already possess[],””*id.*—namely, their studies and statistics. Since “manufacturers have superior access to information about their drugs,” *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009), the restriction represents an onerous burden on the “free flow of commercial speech” in the critical “fields of medicine and public health,” *Sorrell*, 131 S. Ct. at 2664 (internal quotation marks omitted).

Third, the Vermont ban on the use of physician prescribing records in *all* marketing did not dictate the message that companies could convey or discriminate on viewpoint; it only made the marketing “more difficult and less effective.” *Sorrell*, 630 F.3d at 294 (Livingston, J., dissenting). Here, the FDA engages in that viewpoint discrimination, approving some marketing messages (that drugs should

not be used for unapproved uses) while prosecuting others (that drugs should be used for unapproved uses). *Sorrell* thus shows that Caronia's conviction for the truthful, off-label promotion of an approved drug violates the First Amendment.

II. THE DISTRICT COURT'S INSTRUCTION ON THE CONSPIRACY COUNT WAS ERRONEOUS BECAUSE IT OMITTED A MENS REA REQUIREMENT AND FOR OTHER REASONS.

The jury verdict sheet impermissibly failed to reference the mens rea requirement for Caronia's conspiracy conviction and treated elements that the Government needed to prove as already established facts. Caronia submitted several requests to charge on September 30, 2008, October 9, 2008, and October 15, 2008. In each request, Caronia specifically requested mens rea jury instructions on both the conspiracy and the misbranding charges. In a letter to the Court dated October 15, 2008 (A83) Caronia objected to the *malum prohibitum* charge and the verdict sheet both of which led to the confusion concerning Count One (a) and (b) of the verdict sheet. Moreover, Caronia objected to the declarative statements in the verdict sheet, which stated as a matter of fact (a) that Xyrem "was misbranded." As a result of these defects, the guilty verdict on Count (1)(a) of the verdict sheet was inconsistent with the acquittal on Count (1)(b) and Count 2.

In Rule 29 motions (GA 392-401) Caronia strenuously argued for a directed verdict as to the conspiracy charges and renewed that application after the verdict. GA 511. After trial, additional objections were interposed to the verdict sheet.

GA 391; *see also* GA 472, lines 15-25. The district court, over the objection of the defense with respect to its charge and verdict sheet, stated:

THE COURT: Right, the four different questions, not counts. These are interrogatories to the jury; two interrogatories on Count One, two interrogatories on Count Two asking specific questions of the jury so that there's no confusion as to what they find.

The reason I did it really is because of the problem that Mr. Liotti was putting his finger on earlier, which is that there are varying mens rea elements, particularly in Count Two where the misbranding charge, as principle, has virtually a nonexistent mens rea and the branding charge as aider and abettor has an unlawful mens rea.

Thus, while addressing the disparities between *malum in se* and *malum prohibitum* charges, the Court did not resolve the conflict in its charge and exacerbated the problem in its verdict sheet.

III. THE CHARGE AS A WHOLE WAS IMPROPER; CARONIA DID NOT WAIVE ERRORS IN THE CHARGE AND THE ERRORS WERE NOT HARMLESS.

Caronia never waived errors in the charge or the verdict sheet and clearly the errors were not harmless. (*See* Appellant's Opening Br. 18-33; Appellant's Reply Br. 2-9).

CONCLUSION

For the foregoing reasons, Appellant Alfred Caronia respectfully requests that this Court overturn his conviction in this case.

Date: August 29, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2011, I filed the foregoing Supplemental Brief via email and UPS overnight delivery with the Clerk of the United States Court of Appeals for the Second Circuit. I also certify that I served two copies of this Brief via email and UPS overnight delivery on:

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SUPPLEMENTAL APPENDIX

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA

v.

ALFRED CARONIA,

CR -06-229 (S-1) (ENV)

Defendant.

-----X

Defendant's Request to Charge

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To best facilitate the Court's determination in this matter, the Defendant has responded and addressed only those areas of concern in the Government's Request to Charge.

Request No. 2

The defendant requests page 3, paragraph 2 of the Government's proposed charge be amended to state:

“Under Title 21, United States Code, Section 331(a), it is a federal crime to introduce, or to deliver for introduction, into interstate commerce a drug that is misbranded. Under Title 21, United States Code, Section 331(k), it is also a federal crime to alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or the doing of any other act with respect to, a drug if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.”

Title 21, United States Code, Section 331(a), (k).

CONSPIRACY- Definition

The defendant requests page 3, paragraph 3 of the Government's proposed charge be amended to state:

“You should understand that a conspiracy is an offense separate from the commission of any offense that may have been committed. That is because the formation of a conspiracy, of a partnership for criminal purposes, or a combination or agreement of two or more persons to join together to accomplish some unlawful purpose, is in and of itself a crime. Thus, if a conspiracy exists, even if it should fail in achieving its purpose, it is still punishable as a crime. The essence of the charge of conspiracy is an understanding between or among two or more persons, who are

not government agents, that they will act together to accomplish a common objective that they know is unlawful.”

Callanan v. United States, 364 U.S. 587, 81 S. Ct. 321, (1961) ; Pereira v. United States, 347 U.S. 1, 74 S. Ct. 358, (1954); Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008).

FIRST ELEMENT- EXISTENCE OF AGREEMENT

The defendant requests page 4, paragraph 2 of the Government’s proposed charge be amended to state:

“The first element that the government must prove beyond a reasonable doubt to establish the offense of conspiracy is that two or more persons, at least two of whom are not government agents, entered into the unlawful agreement charged in the information. Government agents may have discussed the conspiracy with alleged conspirators, but the agents are trying to prevent crime and there can be no mutual assent between a conspirator and a government agent to commit a crime.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008); Iannelli v. United States, 420 U.S. 770 (1975).

SECOND ELEMENT- MEMBERSHIP IN CONSPIRACY

The defendant requests page 6, paragraph 2 of the Government’s proposed charge be amended to state:

“If you are satisfied that the conspiracy charged in the indictment existed, you must next ask yourselves who the members of that conspiracy were, remembering that no government

agents can be conspiracy members. In deciding whether the defendant whom you are considering was, in fact, a member of the conspiracy, you should consider whether the defendant knowingly and willfully joined the conspiracy. Did he voluntarily participate in it with knowledge of its unlawful purpose and with the specific intention of furthering its business or objective as an associate or worker?"

Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008);

Iannelli v. United States, 420 U.S. 770 (1975).

The defendant requests page 8, paragraph 2 of the Government's proposed charge be amended to state:

"I also want to caution you that mere knowledge or acquiescence, without participation, in the unlawful plan is not sufficient. Moreover, the fact that the acts of a defendant, without knowledge, merely happen to further the purposes or objectives of the conspiracy, does not make the defendant a member. More is required under the law. What is necessary is that the defendant must have participated with knowledge of at least some of the purposes or objectives of the conspiracy and with the intention of aiding in the accomplishment of those unlawful ends. What the government must prove beyond a reasonable doubt, in order to bring the defendant into the conspiracy, is that the defendant knew the purpose and the object of the conspiracy, and knowing that, he willfully participated in the conspiracy and he helped further the business of the conspiracy, and in doing so, he did it deliberately, intentionally, not inadvertently, negligently, innocently, but willfully. Knowledge of the existence and goals of a conspiracy does not, without more, make one a conspirator; the defendant must also have a stake in the venture. The defendant must have agreed to participate in an unlawful scheme, with knowledge of its essential

nature.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-6 (Matthew Bender 2008);

United States v. Cianchetti, 315 F.2d 384, 588 (2d Cir. 1963); United States v. De Biasi, 712

F.2d 785 (2d Cir.) , cert. denied, 464 U.S. 962 (1983) ; United States v. Rosenblatt, 554 F.2d 36 (2d Cir. 1977).

THIRD ELEMENT- COMMISSION OF OVERT ACT

The defendant requests page 9, paragraph 3 of the Government’s proposed charge be amended to add:

“You must also find that the overt act occurred while the conspiracy was still in existence.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-7 (Matthew Bender 2008)

FOURTH ELEMENT- COMMISSION OF OVERT ACT IN FURTHERANCE OF THE CONSPIRACY

The defendant requests page 10, paragraph 2 of the Government’s proposed charge be amended to state:

“The fourth, and final, element which the government must prove beyond a reasonable doubt is that the overt act was committed for the purpose of carrying out the unlawful agreement. In order for the government to satisfy this element, it must prove, beyond a reasonable doubt, that at least one overt act was knowingly and willfully done, by at least one conspirator, in furtherance of some object or purpose of the conspiracy, as charged in the information. In this regard, you should bear in mind that the overt act, standing alone, may be an innocent, lawful act.

Frequently, however, an apparently innocent act sheds its harmless character if it is a step in carrying out, promoting, aiding or assisting the conspiratorial scheme. You are therefore instructed that the overt act does not have to be an act which, in and of itself is criminal or constitutes an objective of the conspiracy.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-8 (Matthew Bender 2008)

The defendant requests page 11, paragraph 1 of the Government’s proposed charge be omitted.

Success of the Conspiracy Immaterial and Impossibility of Success of Conspiracy

The defendant requests page 12-13 of the Government’s proposed charge be amended to state:

“It is not a defense to a conspiracy charge that the object of the conspiracy could not be achieved because of circumstances that the conspirators did not know about. Thus, you may find the defendants guilty of conspiracy even though it was impossible for them to carry out their plan successfully.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-10 (Matthew Bender 2008)

Request No. 3

COUNT ONE: CONSPIRACY TO MISBRAND

The defendant requests page 16 of the Government’s proposed charge be amended to state:

“...Intent is determined by such persons' expressions or may be shown by the circumstances

surrounding the distribution of the drug. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put. The manufacturer is not permitted to promote uses for a drug that have not be cleared by the Food and Drug Administration....”

21 Code of Federal Regulations 201.128

“It is the responsibility of the corporation and its corporate agents to uphold the highest standard of foresight and vigilance. You must find Mr. Caronia is a responsible corporate agent if, by reason of his position in the corporation, he had the responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. You must consider if the failure to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link to the act. You must consider what prompts the imposition of his duty, and the scope of his duty, provide the

measure of culpability. If you find Alfred Caronia to be a responsible corporate agent, you may find him criminally accountable for "causing" violations of the Act. If you also find that Mr. Caronia was unable to prevent or correct the violation because he did not know the violation was going to occur, or he knew about the violation and he was not in a position to correct the violation, you must not find him criminally liable for the act. It is Mr. Caronia's burden to establish evidence that he did not cause the violations, but this does not alter the Government's ultimate burden of proving beyond a reasonable doubt the defendant's guilt, including his power, in light of the duty imposed by the Act, to prevent or correct the prohibited condition."

United States v. Park, 421 U.S. 658, 673-674 (1975).

Request No. 4

Misbranding

The defendant requests page 21-22, of the Government's proposed charge have the following added:

"The duty imposed on responsible corporate agents is one that requires the highest standard of foresight and vigilance, but the Food and Drug Act, in its criminal aspect, does not require that which is objectively impossible. You must find Mr. Caronia is a responsible corporate agent if, by reason of his position in the corporation, he had the responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. You must consider if the failure to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link to the act. You must consider what prompts the imposition of his duty, and the scope of his duty, provide the measure of culpability. If you find Alfred Caronia to be a responsible corporate

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Request No. 12

Entrapment

The defendant requests page 32, paragraph 2 of the Government's proposed charge have the following added:

"The government must prove beyond a reasonable doubt that the defendant was not induced or persuaded to commit the offense by law enforcement officers or their agents."

Conclusion

The Defendant respectfully requests that the Court include the foregoing instructions in its charge to the jury."

Dated: September 30, 2008
Garden City, New York

/s/ Jennifer L. McCann
Jennifer L. McCann (JM4098)
Law Offices of Thomas F. Liotti
Attorneys for Defendant, Caronia
600 Old Country Road, Suite 530
Garden City, NY 11530

CC: AUSA Martin Coffey

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X

UNITED STATES OF AMERICA

v.

ALFRED CARONIA,

CR -06-229 (S-1) (ENV)

Defendant.

-----X

Defendant’s Amended Request to Charge

Law Offices of Thomas F. Liotti
Attorneys for Defendant, Caronia
600 Old Country Road, Suite 530
Garden City, NY 11530
(516) 794-4700

To best facilitate the Court's determination in this matter, the Defendant has responded and addressed only those areas of concern in the Government's Request to Charge.

Request No. 2

The defendant requests page 3, paragraph 2 of the Government's proposed charge be amended to state:

“Under Title 21, United States Code, Section 331(a), it is a federal crime to introduce, or to deliver for introduction, into interstate commerce a drug that is misbranded. Under Title 21, United States Code, Section 331(k), it is also a federal crime to alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or the doing of any other act with respect to, a drug if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.”

Title 21, United States Code, Section 331(a), (k).

CONSPIRACY- Definition

The defendant requests page 3, paragraph 3 of the Government's proposed charge be amended to state:

“You should understand that a conspiracy is an offense separate from the commission of any offense that may have been committed. That is because the formation of a conspiracy, of a partnership for criminal purposes, or a combination or agreement of two or more persons to join together to accomplish some unlawful purpose, is in and of itself a crime. Thus, if a conspiracy exists, even if it should fail in achieving its purpose, it is still punishable as a crime. The essence of the charge of conspiracy is an understanding between or among two or more persons, who are

not government agents, that they will act together to accomplish a common objective that they know is unlawful.”

Callanan v. United States, 364 U.S. 587, 81 S. Ct. 321, (1961) ; Pereira v. United States, 347 U.S. 1, 74 S. Ct. 358, (1954); Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008).

FIRST ELEMENT- EXISTENCE OF AGREEMENT

The defendant requests page 4, paragraph 2 of the Government’s proposed charge be amended to state:

“The first element that the government must prove beyond a reasonable doubt to establish the offense of conspiracy is that two or more persons, at least two of whom are not government agents, entered into the unlawful agreement charged in the information. Government agents may have discussed the conspiracy with alleged conspirators, but the agents are trying to prevent crime and there can be no mutual assent between a conspirator and a government agent to commit a crime.”

Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008);

Iannelli v. United States, 420 U.S. 770 (1975).

SECOND ELEMENT- MEMBERSHIP IN CONSPIRACY

The defendant requests page 6, paragraph 2 of the Government’s proposed charge be amended to state:

“If you are satisfied that the conspiracy charged in the indictment existed, you must next ask yourselves who the members of that conspiracy were, remembering that no government

agents can be conspiracy members. In deciding whether the defendant whom you are considering was, in fact, a member of the conspiracy, you should consider whether the defendant knowingly and willfully joined the conspiracy. Did he voluntarily participate in it with knowledge of its unlawful purpose and with the specific intention of furthering its business or objective as an associate or worker?"

Modern Federal Jury Instructions, Section 19.01, Instruction 19-2 (Matthew Bender 2008);

Iannelli v. United States, 420 U.S. 770 (1975).

The defendant requests page 8, paragraph 2 of the Government's proposed charge be amended to state:

"I also want to caution you that mere knowledge or acquiescence, without participation, in the unlawful plan is not sufficient. Moreover, the fact that the acts of a defendant, without knowledge, merely happen to further the purposes or objectives of the conspiracy, does not make the defendant a member. More is required under the law. What is necessary is that the defendant must have participated with knowledge of at least some of the purposes or objectives of the conspiracy and with the intention of aiding in the accomplishment of those unlawful ends. What the government must prove beyond a reasonable doubt, in order to bring the defendant into the conspiracy, is that the defendant knew the purpose and the object of the conspiracy, and knowing that, he willfully participated in the conspiracy and he helped further the business of the conspiracy, and in doing so, he did it deliberately, intentionally, not inadvertently, negligently, innocently, but willfully. Knowledge of the existence and goals of a conspiracy does not, without more, make one a conspirator; the defendant must also have a stake in the venture. The defendant must have agreed to participate in an unlawful scheme, with knowledge of its essential

nature.”

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United States v. Cianchetti, 315 F.2d 384, 588 (2d Cir. 1963); United States v. De Biasi, 712

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COUNT ONE: CONSPIRACY TO MISBRAND

The defendant requests page 16 of the Government’s proposed charge be amended to state:

“...Intent is determined by such persons' expressions or may be shown by the

circumstances surrounding the distribution of the drug. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put. The manufacturer is not permitted to promote uses for a drug that have not be cleared by the Food and Drug Administration....”

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Entrapment

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"The government must prove beyond a reasonable doubt that the defendant was not induced or persuaded to commit the offense by law enforcement officers or their agents."

Additional Proposed Charges

Missing Witness Not Equally Available to Defendant

The defendant requests following charge be read to the jury with regard to witnesses who were not produced by the Government including: Robert Weaver, Pam Stahl, Mark Perrin, Ron Mercado, Dr. Blank, Geoffrey Kaiser:

"You have heard evidence about a witness who has not been called to testify. The

defense has argued that the witness could have given material testimony in this case and that the government was in the best position to produce this witness.

If you find that this uncalled witness could have been called by the government and would have given important new testimony, and that the government was in the best position to call him, but failed to do so, you are permitted, but you are not required, to infer that the testimony of the uncalled witness would have been unfavorable to the government.

In deciding whether to draw an inference that the uncalled witness would have testified unfavorably to the government, you may consider whether the witness' testimony would have merely repeated other testimony and evidence already before you.”

Modern Federal Jury Instructions, Section 6.04, Instruction 6-5 (Matthew Bender 2008);

United States v. Erb, 543 F.2d 438 (2d Cir. 1976) ; *United States v. Dixon*, 536 F.2d 1388 (2d Cir. 1976).

Good Faith

The defendant requests following charge be read to the jury:

“Good faith is an absolute defense to the charges in this case. A statement made with good faith belief in its accuracy does not amount to a false statement and is not a crime. This is so even if the statement is, in fact, erroneous. The burden of establishing lack of good faith and criminal intent rests upon the prosecution. A defendant is under no burden to prove his good faith; rather, the prosecution must prove bad faith or knowledge of falsity beyond a reasonable doubt.”

Modern Federal Jury Instructions, Section 8.01, Instruction 8-1 (Matthew Bender 2008); *Cheek v.*

United States, 498 U.S. 192, 111 S. Ct. 604, 112 L. Ed. 2d 617 (1991) ; *Durland v. United States*, 161 U.S. 306, 16 S. Ct. 508, 40 L. Ed. 709 (1896) ; *United States v. Ballard*, 322 U.S. 78, 64 S. Ct. 882, 88 L. Ed. 1148 (1944) .

Conclusion

The Defendant respectfully requests that the Court include the foregoing instructions in its charge to the jury.”

Dated: October 9, 2008
Garden City, New York

/s/ Jennifer L. McCann
Jennifer L. McCann (JM4098)
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CC: AUSA Martin Coffey