UNITED STATES OF AMERICA, -against- ANTONIO QUINONES, also known as "Tony,"ALFRED VALDIVIESO, MICHAEL DEPINILLOS, HERMAN QUINONES and CHARLIE LOPEZ, Defendants.

Case No. 06-CR-845 (S-2) (FB)

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

536 F. Supp. 2d 267; 2008 U.S. Dist. LEXIS 13085

February 19, 2008, Decided

SUBSEQUENT HISTORY: Stay granted by United States v. Quinones, 2009 U.S. Dist. LEXIS 110175 (E.D.N.Y., Nov. 20, 2009)

CASE SUMMARY:

PROCEDURAL POSTURE: Five defendants were charged with (1) conspiracy to distribute, and to possess with intent to distribute, controlled substances, in violation of 21 U.S.C.S. § 846; (2) distributing, and possessing with intent to distribute, controlled substances, in violation of 21 U.S.C.S. § 841; and (3) money laundering conspiracy, in violation of 18 U.S.C.S. § 1956. Four defendants now moved to dismiss the indictment.

OVERVIEW: Defendants operated websites and in doing so, aided and abetted medical professionals to distribute controlled substances outside the usual course of practice. Defendants moved to dismiss the indictment on the grounds (1) that the acts they were alleged to have committed were not proscribed by federal drug laws; and, alternatively, (2) that those laws were unconstitutionally vague. The court found defendants' first argument without merit. Defendants were not being prosecuted simply for selling controlled substances over the Internet; rather, they were being prosecuted for conspiring with, and aiding and abetting, medical professionals to distribute controlled substances outside the usual course of professional practice. Such a prosecution was proper under existing federal laws. Moreover, 21 U.S.C.S. § 841 was not unconstitutionally vague. Section 841(a)(1) created a sweeping prohibition on distribution of controlled substances, subject to a relatively narrow exception for distribution within the usual scope of professional practice. Thus, § 841(a)(1) put a reasonable person on notice that distributing controlled substances was illegal unless it fit within the statute's exception.

OUTCOME: The court held that defendants' prosecution was proper.

CORE TERMS: controlled substances, professional practice, indictment, distribute, customer, doctor, prescription, drug laws, usual course, registrant, questionnaire, Telemedicine Act, prosecuted, authorize, pharmacy, website, patient, notice, on-line, telemedicine, prescribing,

dispensing, unconstitutionally vague, medical professionals, conspiracy, licensed, suicide, per se rule, medical practices, medical profession

LEXISNEXIS(R) HEADNOTES

Criminal Law & Procedure > Pretrial Motions & Procedures > General Overview

HN1 Fed. R. Crim. P. 12(2) precludes pretrial motions that would require a trial of the general issue.

Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Conspiracy > Elements
Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Elements

HN2 21 U.S.C.S. § 841(a)(1) provides that it shall be unlawful for any person knowingly or intentionally to distribute, or possess with intent to distribute, a controlled substance. 21 U.S.C.S. § 846 makes it a crime to conspire to violate 21 U.S.C.S. § 841.

Criminal Law & Procedure > Criminal Offenses > Inchoate Crimes > Conspiracy > General Overview
Criminal Law & Procedure > Criminal Offenses > Miscellaneous Offenses > Money Laundering > General Overview

HN3 18 U.S.C.S. § 1956 makes it unlawful to conspire to launder the proceeds of specified unlawful activity, which includes illegal distribution of controlled substances.

Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Elements

HN4 21 U.S.C.S. § 822(b) empowers the Attorney General to implement a registration process to authorize medical professionals, known as registrants, to dispense controlled substances: Persons registered by the Attorney General under this subchapter to distribute controlled substances are authorized to possess and distribute such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Elements

HN5 A controlled substance may be prescribed only for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 C.F.R. § 1306.04. The statutory and regulatory scheme amounts to a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons Thus, despite registration, physicians can be prosecuted under 21 U.S.C.S. § 841 when their activities fall outside the usual course of professional practice.

Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Elements

HN6 Non-registrants may be prosecuted under 21 U.S.C.S. § 841 for conspiring with a registrant, or aiding and abetting a registrant, to distribute controlled substances outside the

usual course of professional practice.

Criminal Law & Procedure > Criminal Offenses > Controlled Substances > Delivery, Distribution & Sale > Elements

HN7 The **Telemedicine** Act requires physicians to obtain the oral and written informed consent of the patient before performing **telemedicine** services. 20 L.P.R.A. § 6006.

Governments > Legislation > Interpretation

HN8 Statutes are construed by the courts with reference to the circumstances existing at the time of the passage. The interpretation placed upon an existing statute by a subsequent group of Congressmen who are promoting legislation and who are unsuccessful has no persuasive significance. Logically, several equally tenable inferences could be drawn from the failure of the Congress to adopt an amendment in the light of the interpretation placed upon the existing law by some of its members, including the inference that the existing legislation already incorporated the offered change.

Governments > Legislation > Vagueness

HN9 As a matter of due process, a criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute, or is so indefinite that it encourages arbitrary and erratic arrests and convictions, is void for vagueness.

Constitutional Law > Bill of Rights > Fundamental Rights > Procedural Due Process > Scope of Protection
Governments > Legislation > Vagueness

HN10 A statute or regulation is not required to specify every prohibited act. Similarly, it is immaterial that there is no litigated fact pattern precisely in point. All that due process requires is that a statute not lull the potential defendant into a false sense of security, giving him no reason even to suspect that his conduct might be within its scope.

COUNSEL: [**1] For the United States: BENTON J. CAMPBELL, ESQ., United States Attorney Eastern District of New York, By: JEFFREY RABKIN, ESQ., Assistant United States Attorney, Brooklyn, New York.

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For Defendant Michael Depinillos: EDWARD R. SHOHAT, ESQ., SHARON LEE KEGERREIS, ESQ., Miami, Florida.

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For Defendant Charlie Lopez: KEN T. LANGE, ESQ., North Miami, Florida.

JUDGES: FREDERIC BLOCK, Senior United States District Judge.

OPINION BY: FREDERIC BLOCK

OPINION

[*268] **MEMORANDUM**

BLOCK, Senior District Judge:

Defendants are charged in a Superseding Indictment with (1) conspiracy to distribute, and to possess with intent to distribute, controlled substances, in violation of 21 U.S.C. § 846; (2) distributing, and possessing with intent to distribute, controlled substances, in violation of 21 U.S.C. § 841; and (3) money laundering conspiracy, in violation of 18 U.S.C. § 1956. All defendants, except Alfred Valdivieso, have moved to dismiss the Superseding Indictment on the grounds (1) that the acts they are alleged [**2] to have committed are not proscribed by the federal drug laws; and, alternatively, (2) that those laws, as applied to them, are unconstitutionally vague.

Oral argument was held on January 18, 2008. At the conclusion of the argument, the Court denied the motions and stated that a full explanation would be forthcoming in a written decision.

I

This prosecution is, by no means, a typical drug case. The government does not allege that the defendants distributed and conspired to distribute controlled substances through clandestine deals in a dark alley; rather, it alleges that defendants Antonio Quinones, Herman Quinones, Michael Depinillos and Charlie Lopez ("the [*269] moving defendants") created and operated several websites, and in so doing, conspired with and aided and abetted medical professionals such as defendant Alfred Valdivieso, a physician licensed in Puerto Rico, to distribute controlled substances outside the usual course of professional practice. The Superseding Indictment describes the details of the operation as follows:

The websites "permitted customers to provide their credit card information and required them to complete brief on-line questionnaires before ordering specific drugs, [**3] including the Controlled Substances. Customers were not required to submit a valid form of identification or a valid prescription for the Controlled Substances they ordered." Superseding Indictment P 21.

The on-line questionnaires were sent to doctors such as Valdivieso. These doctors "purported to review the on-line questionnaires and then wrote and authorized a prescription for the Controlled Substances requested by the customers." *Id.* P 22. Although the on-line questionnaires included a brief medical history, "at no time during the questionnaire review process did defendant ALFRED VALDIVIESO physically examine and obtain a complete medical history from the customers. Nor did VALDIVIESO make an effort to confirm the accuracy of the information provided by the customers in the on-line questionnaires. Rather, after purportedly reviewing only the customers' on-line questionnaires, defendant ALFRED VALDIVIESO wrote and authorized

prescriptions for the Controlled Substances requested by the customers." *Id.* P 23.

Various pharmacies throughout the United States (including the Eastern District of New York) accessed the websites, filled the orders once prescriptions were issued, and shipped [**4] them to customers using Federal Express accounts held by Antonio Quinones, Herman Quinories and Michael Depinillos. See *id.* PP 24, 26.

Each completed order was charged to the credit card information the customer had provided. Proceeds from the sales were wire-transferred to bank accounts controlled by Antonio Quinones, Herman Quinones and Michael Depinillos. *See id.* P 25.

For each order, the website operators paid a fee to All Service Consultants, Inc. All Service Consultants, in turn, paid Valdivieso a fee for each order he reviewed. *See id.* P 27.

At this stage, these allegations must be taken as true because HN1 Federal Rule of Criminal Procedure 12(2) precludes pretrial motions that would require "a trial of the general issue." *See also United States v. Alfonso,* 143 F.3d 772, 777 (2d Cir. 1998) ("[T]he sufficiency of the evidence is not appropriately addressed on a pretrial motion to dismiss an indictment."); *United States v. Tomero,* 496 F. Supp. 2d 253, 2007 WL 1522615, at *1 (S.D.N.Y. 2007) ("There is no summary judgment in criminal cases.").

II

HN2 21 U.S.C. § 841(a)(1) provides that "it shall be unlawful for any person knowingly or intentionally [to] distribute, . . . or possess with intent to . . . distribute, [**5] … a controlled substance." 21 U.S.C. § 846 makes it a crime to conspire to violate § 841. HN3 18 U.S.C. § 1956 makes it unlawful to conspire to launder the proceeds of "specified unlawful activity," which includes illegal distribution of controlled substances.

The federal drug laws contain several exceptions to the broad prohibition on the [*270] distribution of controlled substances. The exception relevant here is found in HN4 21 U.S.C. § 822(b), which empowers the Attorney General to implement a registration process to authorize medical professionals, known as "registrants," to dispense controlled substances:
Persons registered by the Attorney General under this subchapter . . . to distribute . . . controlled substances . . . are authorized to possess [and] distribute . . . such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.
The Superseding Indictment does not allege which of the defendants, if any, are registrants; nevertheless, based on the parties' submissions, it is safe to assume that Valdivieso - a licensed physician - is, but that the moving defendants [**6] are not.

In 1971, the Attorney General promulgated a regulation providing that HN5 a controlled substance may be prescribed only "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. In *Moore v. United States,* 423 U.S. 122, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975), the Supreme Court held that the

statutory and regulatory scheme amounted to "a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons." *Id.* at 131. Thus, the Court held that, despite registration, "physicians can be prosecuted under § 841 *when their activities fall outside the usual course of professional practice.*" *Id.* at 124 (emphasis added). Presumably in recognition of *Moore*, Valdivieso does not move to dismiss the indictment.

The moving defendants argue (A) that their activities are not proscribed by § 841, and (B) even if they were, the phrase "usual course of professional practice" is unconstitutionally vague because, as applied to them, it does not put a reasonable person on notice of what conduct is proscribed. The Court addresses these arguments in turn. [1]

A. Legality of Defendants' Conduct

FOOTNOTES

[1] Defendants initially raised [**7] a third argument: that the original indictment was defective because it did not allege that the drug distribution was outside the usual scope of professional practice, which they characterized as an essential element of the crime defined by § 841. The Second Circuit has not spoken on that issue, and the other circuit courts are divided. *Compare, e.g., United States v. Steele*, 147 F.3d 1316, 1317 (11th Cir. 1998) ("[A]n indictment of a practitioner for unlawfully dispensing drugs need not aver that it was done outside the course of professional practice."), *with, e.g., United States v. King*, 587 F.2d 956, 963 (9th Cir. 1978) ("[L]ack of authorization to distribute or dispense controlled substances is an element of the crime."). The Court need not address the issue because it has become moot: the Superseding Indictment specifically alleges that the defendants acted "outside the scope of professional practice and not for a legitimate medical purpose." Superseding Indictment P 29.

Since *Moore*, the Second Circuit and other courts have consistently held that HN6 non-registrants may be prosecuted under § 841 for conspiring with a registrant, or aiding and abetting a registrant, to distribute controlled [**8] substances outside the usual course of professional practice. *See United States v. Vamos*, 797 F.2d 1146 (2d Cir. 1986) (upholding conviction of nurse/office manager under conspiracy and aiding-and-abetting theories); *United States v. Johnson*, 831 F.2d 124 (6th Cir. 1987) (upholding conviction of non-physician clinic operator under aiding-and-abetting theory); *United States v. Hicks*, 529 F.2d 841 [*271] (5th Cir. 1976) (upholding conviction of security guard on conspiracy theory). Sidestepping these cases, the moving defendants argue that the distribution of controlled substances through so-called Internet pharmacies is not currently illegal.

That the moving defendants allegedly carried out their activities through the Internet is of no consequence. Two circuit courts have approved the application of the federal drug laws to the operation of Internet pharmacies. *See United States v. Nelson,* 383 F.3d 1227 (10th Cir. 2004) (affirming conviction of physician issuing prescriptions for Internet pharmacy); *United States v. Fuchs,* 467 F.3d 889 (5th Cir. 2006) (affirming conviction of pharmacist who had set up Internet pharmacy). Although *Nelson* and *Fuchs* dealt with registrants (a physician and a pharmacist, [**9] respectively), the Court sees no reason why the logic of *Vamos, Johnson* and *Hicks* - that non-registrants can be prosecuted for conspiring with or aiding and abetting registrants - would not apply regardless of the means used to carry out the distribution: If the means are within the usual scope of professional practice, they are legal; if they are outside that scope, they are illegal.

The moving defendants argue that the prosecution is an attempt by the government to establish a *per se* rule that dispensing controlled substances without a face-to-face meeting between patient and doctor is outside the usual scope of professional practice; they argue that this attempt runs afoul of the Supreme Court's decision in *Gonzales v. Oregon,* 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006).

At issue in *Gonzales* was a 2001 interpretative rule promulgated by the Attorney General; the rule declared "that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act." 66 Fed. Reg. 56607, 56608. The State of Oregon, which had passed a law authorizing physician-assisted [**10] suicide, sought to enjoin enforcement of the rule. The Supreme Court held that the federal drug laws, as interpreted in *Moore,* do "not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct." *Id.* at 925.

The moving defendants take *Gonzales* to mean that the Attorney General does not have the authority to decide what medical practices constitute a violation of the federal drug laws. While that is certainly a fair reading of *Gonzales,* it is a gross mischaracterization of the present prosecution. The government is not trying to establish a *per se* rule that Internet prescriptions are invalid; rather, it is prosecuting the defendants under the rule established in *Moore* that prescribing drugs outside the usual scope of professional practice is illegal. The government is making no attempt, as in *Gonzales,* to unilaterally define which practices fall outside that scope; rather, it intends to leave that question where it has been for over 30 years - with the jury. [2]

FOOTNOTES

[2] In a related vein, in a supplement to their motions to dismiss, the moving defendants argue that the Superseding Indictment improperly [**11] attempts to define "usual scope of professional practice" by reference to the Professional Ethics Canons of the Medical Profession

of Puerto Rico, the New York State Department of Health's regulations governing the issuance of prescriptions, and the positions of the American Medical Association and Federation of State Medical Boards. That the government has set forth in detail how it intends to prove to a jury that the moving defendants conspired with and aided and abetted registrants to distribute controlled substances outside the usual scope of professional practice does not mean that it is attempting to unilaterally define the phrase. At worst, the challenged allegations amount to surplusage, which, as the Court explained at oral argument, will not be read to or given to the jury.

[*272] Drawing on *Gonzales*, and in particular, the Supreme Court's federalism-based observation that "[t]he structure and operation of the [federal drug laws] presume and rely upon a functioning medical profession regulated under the States' police powers," 126 S. Ct. at 923, the moving defendants argue that the law of Puerto Rico (where Valdivieso was licensed) authorizes "**telemedicine**." Specifically, they rely [**12] on Puerto Rico's **Telemedicine** Act, which authorizes physicians to provide medical services - including prescriptions - via "advanced technologic telecommunication means" to patients in "distant geographical areas." 20 L.P.R.A. § 6001.

At oral argument, the government cited *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 316, 2007 U.S. Dist. LEXIS 79104, 2007 WL 3125179 (D.P.R. Oct. 24, 2007), for the proposition that the **Telemedicine** Act does not authorize doctors in Puerto Rico to practice "**telemedicine**" nationwide. In *Valdivieso Rodriguez*, Magistrate Judge Camille L. Velez-Rive of the District of Puerto Rico addressed a motion to dismiss a prosecution against seven Puerto Rican doctors (including Valdivieso) for prescribing controlled substances over the Internet outside the usual scope of professional practice; as here, the defendants argued that the **Telemedicine** Act authorized their actions.

The magistrate judge concluded that the act authorized the practice of **telemedicine** only within Puerto Rico. *See* 2007 U.S. Dist. LEXIS 79104, [WL] at *7-*8 ("[D]efendants cannot conclude they are authorized to practice medicine *per se* or **telemedicine** for this purpose [i.e., prescribing controlled substances over the Internet] in multiple jurisdictions…. [I]f a patient [**13] is seen in another state, the physician should be licensed to practice medicine in that state."). The district court, however, neither adopted nor rejected the magistrate judge's conclusion, instead holding that, regardless of the **Telemedicine** Act, "the issue of whether a physician's conduct exceeds the bounds of professional medical practice … is one for determination by a jury," and, therefore, "not properly the subject of a motion to dismiss." 2007 U.S. Dist. LEXIS 79104 at *9, [WL] at *3.

The Court agrees that whether conduct is outside the bounds of professional practice is a jury question; however, it does not follow that the jury should decide that issue informed by an

erroneous interpretation of the relevant legal standards. Thus, unlike the district court in *Valdivieso Rodriguez,* the Court addresses whether the **Telemedicine** Act has any relevance to this prosecution.

The moving defendants contend that the act means that doctors in Puerto Rico may prescribe medication for anyone, anywhere; however, the more reasonable interpretation is that it was intended to afford medical services to those living in remote areas of Puerto Rico not well-served by traditional medical practices. The Court agrees with the magistrate [**14] judge in *Valdivieso Rodriguez, 532 F. Supp. 2d 316* that the act was not intended to authorize doctors in Puerto Rico to prescribe medication to anyone in the United States, thereby stripping every state in the union of its power to regulate the health and safety of its citizens. *Cf. Goya de Puerto Rico v. Rowland Coffee,* 206 F. Supp. 2d 211, 215 n.4 (D.P.R. 2002) ("It is well settled that Puerto Rico's laws cannot be interpreted to have an extraterritorial effect.").

[*273] Moreover, whatever its territorial reach, HN7 the **Telemedicine** Act requires physicians to obtain "the *oral* and written informed consent of the patient" before performing **telemedicine** services. 20 L.P.R.A. § 6006 (emphasis added). Even assuming that the information provided by customers of the moving defendants' websites constitutes "written informed consent," the government alleges that no doctor ever spoke to any customer.

Finally, the moving defendants point out that Congress has proposed - but not passed - legislation that would specifically criminalize dispensing prescriptions over the Internet where the prescriber has not conducted at least one face-to-face medical evaluation of the "patient." *See* S. 980, 110th Cong. § 2(d) (2007). That Congress [**15] has considered clearer legislation, however, does not mean that existing laws do not apply:

> HN8 [S]tatutes are construed by the courts with reference to the circumstances existing at the time of the passage. The interpretation placed upon an existing statute by a subsequent group of Congressmen who are promoting legislation and who are unsuccessful has no persuasive significance…. Logically, several equally tenable inferences could be drawn from the failure of the Congress to adopt an amendment in the light of the interpretation placed upon the existing law by some of its members, including the inference that the existing legislation already incorporated the offered change.

United States v. Wise, 370 U.S. 405, 411, 82 S. Ct. 1354, 8 L. Ed. 2d 590 (1962). Here, it may well be that Congress intended the proposed legislation to proscribe, by a clear-cut, *per se* rule, the distribution of controlled substances over the Internet without a face-to-face meeting between patient and doctor; it does not follow that the same conduct is not within the embrace of the current prohibition of distribution outside the usual scope of professional practice.

In sum, the moving defendants are not being prosecuted simply for selling controlled [**16] substances over the Internet; rather, they are being prosecuted for conspiring with, and aiding and abetting, medical professionals like Valdivieso to distribute controlled substances outside the usual course of professional practice. As *Moore* and its progeny make clear, such a prosecution is proper under existing federal drug laws.

B. Vagueness

HN9 "[A]s a matter of due process, a criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute, or is so indefinite that it encourages arbitrary and erratic arrests and convictions, is void for vagueness." *Colautti v. Franklin*, 439 U.S. 379, 390, 99 S. Ct. 675, 58 L. Ed. 2d 596 (1979) (citations and internal quotation marks omitted). The moving defendants argue that § 841 (a)(1) cannot constitutionally be applied to them because they are lay people who, unlike physicians, pharmacists and other medical professionals, cannot be charged with knowledge of what constitutes the "usual course of professional practice."

The government argues that the moving defendants were put on notice by Drug Enforcement Administration ("DEA") Guidelines, published in 2001, stating the agency's position that prescribing controlled [**17] substances over the Internet without a physical examination "can subject the operators of the Internet site and any pharmacies or doctors who participate in the activity to criminal, civil or administrative sanctions." 66 Fed. Reg. 21181, 21183 (Apr. 27, 2001). As Justice Scalia has [*274] observed, however, what the DEA believes the statute proscribes is immaterial: "The Justice Department, of course, has a very specific responsibility to determine for itself what [criminal statutes mean], in order to decide when to prosecute; but we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference." *Crandon v. United States*, 494 U.S. 152, 177, 110 S. Ct. 997, 108 L. Ed. 2d 132 (1990) (Scalia, J., concurring in the judgment).

Although the Court rejects the notion that DEA's official interpretation is sufficient to give the moving defendants fair notice that their conduct might be prosecuted, it concludes that the phrase "usual scope of professional practice" is not unconstitutionally vague. The moving defendants argue that § 841(a)(1) does not give fair notice that operating a website might result in criminal liability. But HN10 "a statute or regulation is not required to specify [**18] every prohibited act." *Perez v. Hoblock*, 368 F.3d 166, 175 (2d Cir. 2004). Similarly, "it is immaterial that there is no litigated fact pattern precisely in point." *United States v. Kinzler*, 55 F.3d 70, 74 (2d Cir. 1995) (citations and internal quotation marks omitted). All that due process requires is that a statute "not lull the potential defendant into a false sense of security, giving him no reason even to suspect that his conduct might be within its scope." *United States v. Herrera*, 584 F.2d 1137, 1149 (2d Cir. 1978).

By its terms, § 841(a)(1) creates a sweeping prohibition on distribution of controlled substances, subject to a relatively narrow exception for distribution within the usual scope of professional practice. That latter phrase has an objective meaning that prevents arbitrary prosecution and conviction: Neither the government nor the jury is free to impose its own subjective views about what is and is not appropriate; rather, the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the circumstances.

Morever, a reasonable person reading § 841(a)(1) is on notice that distributing controlled substances [**19] is illegal unless it fits within the exception; it is not too great a burden to require that person to investigate the extent of the exception before plunging ahead. Put another way, it is disingenuous that the moving defendants seek to invoke the exception as legalizing their actions, but then claim that they do not know what the exception means.

In sum, the conduct alleged in the Superseding Indictment falls within the embrace of the current federal drug laws. Those laws are not unconstitutionally vague.

Brooklyn, New York

February 19, 2008

FREDERIC BLOCK

Senior United States District Judge

UNITED STATES OF AMERICA, Plaintiff, v. ALFRED VALDIVIESO RODRIGUEZ, ET AL., Defendants.

CRIMINAL NO. 07-032 (JAG)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

532 F. Supp. 2d 316; 2007 U.S. Dist. LEXIS 95830

September 11, 2007, Decided
September 11, 2007, Filed

SUBSEQUENT HISTORY: Adopted by, Motion denied by United States v. Valdivieso Rodriguez, 532 F. Supp. 2d 316, 2007 U.S. Dist. LEXIS 79104 (D.P.R., Oct. 24, 2007)

PRIOR HISTORY: United States v. Valdivieso Rodriguez, 2007 U.S. Dist. LEXIS 95826 (D.P.R., Aug. 9, 2007)

CORE TERMS: telemedicine, controlled substances, co-defendant, indictment, internet, patient, medical practice, criminal investigations, practitioner's, prosecutorial misconduct, professional practice, license, prescription, state law, recommended, licensed, http, usual course, grand jury, medicine, practice of medicine, www, medical profession, practice medicine, drug abuse, good faith, unconstitutionality, criminalizing, prescribing, distribute

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JUDGES: CAMILLE L. VELEZ-RIVE, UNITED STATES MAGISTRATE JUDGE.

OPINION BY: CAMILLE L. VELEZ-RIVE

OPINION

[*323] **REPORT AND RECOMMENDATION**

INTRODUCTION

Defendant Alfred Valdivieso Rodriguez filed a Motion to Dismiss the Superseding Indictment which was referred by the [*324] Court (**Docket Nos. 202, 203**). Co-defendants Juan A. Tosado-Polanco, Maileen Lugo Torres and Norberto J. Seda Olmo have joined the Motion to Dismiss (**Docket No. 204**). On July 26, 2007, the government filed its response (**Docket Nos. 217, 221**). Co-defendants Valdivieso and Lugo Torres requested and were granted time to oppose the government's response as to their Motion to Dismiss (**Docket Nos. 226, 229**). On August 23, 2007, Valdivieso filed his reply to response (**Docket No. 246**).

Co-defendant Lugo Torres has, in addition to joining Valdivieso's [**2] prior motion, submitted a Motion to Dismiss on grounds of prosecutorial misconduct (**Docket No. 206**).

We are now in a position to discuss both Motions to Dismiss referred by the Court.

FACTUAL BACKGROUND

Above defendants were charged, in a forty one counts Superseding Indictment with violations of Title 21, United States Code, Sections 841(a)(1) and 846 (a conspiracy to distribute controlled substances and distribution of controlled substances; Title 18, United States Code, Section 1343 (wire fraud); Title 18, United States Code, Sections 1956(a)(1)(A)(l) and (h) (money laundering) and two forfeitures counts. The Superseding indictment charges a total of seven medical doctors, who were not licensed to practice medicine in any other jurisdiction but the Commonwealth of Puerto Rico, for having participated in a scheme to distribute drugs and dispense drugs through the internet to individuals with whom they lacked a doctor-patient relationship, in violation of federal regulations wherein prescriptions may only be issued for legitimate medical purposes.

Defendant Valdivieso has requested the dismissal of these federal charges claiming Section 841(a)(1), which sanctions distribution of controlled [**3] substances, conflicts with state law provisions allowing them as licensed physicians to offer **Telemedicine** [1]. Thus, said authorization from the state would not allow individuals in their position to ascertain their conduct being illegal. Defendant Valdivieso submits in his subsequent response to the government's reply he is not challenging Section 841 as unconstitutional, contrary to the government's discussion. [2] Rather, Valdivieso's contention is that state medical practice, as physicians were authorized to follow in the Commonwealth of Puerto Rico, deprived the federal government from criminalizing their conduct under the controlled substance act.

FOOTNOTES

[1] Puerto Rico **Telemedicine** Law, Law No. 227 of August 11, 1998, as amended by Law No. 415 of October 9, 2000.

[2] Still, co-defendant Torres Lugo's Motion to Dismiss includes as grounds the

unconstitutionality of this federal law provision.

Co-defendant Lugo Torres has additionally submitted in her Motion to Dismiss, the government has sought the Indictment in the present case after she had been subject to parallel civil and criminal investigations by the Drug Enforcement Administration. By said administrative process, co-defendant Lugo Torres [**4] claims the government attempted to obtain an unfair advantage against her in its prospective criminal prosecution, concealing from her at the time she was object of a criminal investigation and luring her to make incriminating statements. Due to said conduct, it is alleged the government obtained incriminating admissions and caused her to prematurely reveal the nature of any criminal defense. On account of such alleged prosecutorial misconduct, co-defendant Lugo Torres avers the Superseding Indictment should be dismissed (**Docket No. 206**).

[*325] **LEGAL DISCUSSION**

Defendant Valdivieso and co-defendants Tosado-Polanco, Lugo Torres and Seda Olmo aver they held the corresponding licenses from the Drug Enforcement Agency ("DEA") to prescribe controlled substances. Additionally, the practice of **Telemedicine** as regulated in the Commonwealth of Puerto Rico by Act No. 227 of 1998, includes any test, diagnosis, treatment, operation or prescription for any physical and/or mental illness, ailment, pain, lesion, deformity or condition performed on a patient by a physician, surgeon or osteologist who practices as such, through advanced technologic telecommunication means in order to exchange information and [**5] provide the health services mentioned above in distant geographical areas. *See* Title 20, Laws of P.R. Ann. §6001(b).

Thus, defendants argue that by said **Telemedicine** Act, the Puerto Rico State Board of Medical Examiners has authorized them to practice **telemedicine** and, therefore, allowed them to prescribe controlled substances to their internet customers.

A. Puerto Rico Telemedicine Law.

The federal Superseding Indictment charges defendants, while working with various internet facilitation centers, with providing prescription services of controlled substances to numerous individuals who reside in states across the continental United States, without having a patient-doctor relationship, no mental or physical examination or using appropriate diagnostic or laboratory testing to monitor medication response, solely after filling out an online questionnaire and providing payment. [3]

FOOTNOTES

[3] To convict a practitioner registered to distribute controlled substances of violating §841(a)(1), the government must show that he prescribed controlled substances outside "the

course of professional practice". *See* United States v. Moore, 423 U.S. 122, 141, 96 S.Ct. 335, 46 L. Ed. 2d 333 (1976); United States v. Bek, 493 F.3d 790 (7th Cir. 2007); [**6] United States v. Green, 511 F.2d 1062, 1067 (7th Cir. 1975); *see also* United States v. McIver, 470 F.3d 550, 564 (4th Cir. 2006).

Defendants submit the Puerto Rico **Telemedicine** Law authorizes their actions and would not have placed them on notice that acting in conformity thereof would knowingly infringe federal controlled substance laws.

A perusal of the Commonwealth of Puerto Rico Act which governs medicine services shows the Medical Examining Board licenses and authorizes the medical practice of physicians, surgeons and osteologist, among others, "in the Commonwealth of Puerto Rico." Title 20, L.P.R.A. Sec. 34. The state provisions regarding the practice of **telemedicine** reveals in its statement of motives as a primary function of the Commonwealth of Puerto Rico to monitor the rendering and offering to "residents of the island [Puerto Rico]" health services of outmost quality and without any type of barriers that would hinder access to such services. The law has the purpose to protect the best interest of the "patients in Puerto Rico" by establishing controls as to the form and manner **telemedicine** may be carried out "in the Commonwealth of Puerto Rico". Title 20, L.P.R.A., Sec. 6001.

As [**7] illustrative of the internet medical practices *vis a vis* regular face to face practice, when a Court instructs a jury as to conviction or acquittal of a medical practitioner for a federal controlled substance violation, [4] it will indicate that to convict the [*326] jury must determine whether the defendant's conduct was within the bounds of professional medical practice and consider also any testimony as to the norms of professional practice. Practices inconsistent with legitimate medical care may include uniform, superficial and careless medical examinations, exceedingly poor record-keeping, disregard of signs of drug abuse, prescribing multiple medications having the same effect or drugs that are dangerous when taken in combination, among others. These situations may be assessed from the existence or non-existence of appropriate patient's medical record and/or adequate record of prescribed medications. The prescribing of a controlled substance by a physician is "authorized only when the physicians" act with a legitimate medical purpose and in the usual course of professional practice." *See* United States v. Nelson, 383 F.3d 1227, 1233 (10th Cir. 2004) (*citing* 21 C.F.R. §1306.04(a); *see also* [**8] United States v. Moore, 423 U.S. 122, 96 S. Ct. 335, 46 L. Ed. 2d 333.

FOOTNOTES

[4] The Controlled Substance Act defines "practitioner" as a "physician … licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he practices … to

distribute, dispense, [or] administer … a controlled substance in the course of professional practice." *Id.* Section 802-(21).

By definition, **telemedicine** is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Closely associated with **telemedicine** is the term "**telehealth,**" which is often used to encompass a broader definition of remote healthcare which does not always involve clinical services. **Telemedicine** is not a separate medical specialty. [5] *See* American **Telemedicine** Association's webpage; http://www.atmeda.org/news/definition.html.

FOOTNOTES

[5] Even the amendment to the Puerto Rico **Telemedicine** Law was enacted to clarify there was no need for an additional medical license as construed as to Law No. 227 of August 11, 1998. See Law No. 413 of October 9, 2000.

When medically under served patients and physicians are located in separate states the issue of practitioner licensure arises. Licensure laws which [**9] regulate interstate **telemedicine** practice vary from state to state. States and in the present case, the Commonwealth of Puerto Rico, have restrictive licensure for **telemedicine**, while other jurisdictions may have reciprocal license for such practice. Reciprocity, as mutual exchange of privileges, permits one state to recognize a license in good standing that a practitioner holds in another jurisdiction. In the three states (Alabama, California and Oregon) which have adopted this model, the licensee is explicitly not permitted to practice medicine in-person-- only interstate **telemedicine** care is allowed. *See* **Telemedicine** Information Exchange; http://tie.telemed.org. The Commonwealth of Puerto Rico lacks reciprocity in this aspect, for which defendants cannot conclude they are authorized to practice medicine *per se* or **telemedicine** for this purpose in multiple jurisdictions.

It is well recognized that at this stage, for **telemedicine** and/or **telehealth** care to fully be implemented, licensure and credentialing issues must be resolved. [6] Currently, before practicing in any state, physicians are required to be licensed in that state (Charles, 2000). *See* Veronica Thurmond RN, MS, ***Telehealth*** *[**10] in the Year 2010;* veronica.thurmond@us.army.mi; [*327] http://www.hhdev.psu.edu/nurs/ojni/dm/52/article3.htm.

FOOTNOTES

[6] The best philosophy and approach to **telemedicine** is that the same standards of care and

protocols applicable to more traditional forms of medicine exist with **telemedicine**. The physician-patient relationship and interaction are the same. The process should be the same as if the patient were in the room with the doctor. You also hear terms like **telehealth** and e-health. *See* http://www.ttuhsc.edu/**telemedicine**/FAQS.html.

There are few laws specific to **telemedicine**. Laws and rules pertaining to the practice of medicine will also apply to **telemedicine**. The key is to not let the technology alter the manner in which physicians practice. The issue of licensing varies from state to state. Most states' policy is that the practice of medicine transpires where the patient is located. Therefore, if a patient is seen in another state, the physician should be licensed to practice medicine in that state. *See* http://www.ttuhsc.edu/**telemedicine**/FAQS.html.

Regardless of the **telemedicine** system under which the physician is operating, the principles of medical ethics which are globally binding upon the medical [**11] profession must never be compromised. Physicians practicing **telemedicine** must be authorized to practice medicine in the country or state in which they are located, and should be competent in the field of medicine they are practicing. When practicing **telemedicine** directly with a patient located in another country or state, the physician must be authorized to practice in that state or country, or it should be an internationally approved service. *See* policies of the World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of **Telemedicine**, Adopted by the 51st World Medical Assembly Tel Aviv, Israel, October 1999 and rescinded at the WMA General Assembly, Pilanesberg, South Africa, 2006; PREAMBLE http://www.wma.net/e/policy/a7.htm. [7]

FOOTNOTES

[7] The American **Telemedicine** Association is working in the development of ATA national and regional governors and state legislative associations regarding mutual recognition of medical licenses.

The above non-legal information is merely illustrative to show numerous and easily available internet resources that may assist practitioners, such as herein defendants, when they encounter good-faith questions and doubts [**12] as to the scope of their authority to practice **telemedicine**. Defendants herein have taken the easy road of requesting dismissal supported by a subjective interpretation of their authority under local state law to sustain their practice and further claiming their interpretation of state law supports lack of knowledge of any criminal intent when their actions collide with federal laws and regulations. [8]

FOOTNOTES

[8] Although medical professionals who are registered with the Attorney General are generally permitted to dispense controlled substances, they can be prosecuted under the Controlled Substances Act when their activities fall outside the usual course of professional practice. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 401, 21 U.S.C.A. § 841. United States v. Fuchs, 467 F.3d 889 (5th Cir. 2006).

Defendants' averment they could not have known their conduct to be illegal because of their interpretation of what the **Telemedicine** Law of Puerto Rico authorizes them to do, is an attempt to navigate blindfolded through their wanton ignorance of the law. [9]

FOOTNOTES

[9] Not discussed by defendant is that the "knowingly" act to be discussed applies to the dispensation or distribution of controlled [**13] substance not to their "knowingly" practice of the medical profession as not covering their actions. *See* United States v. Celio, 230 Fed. Appx. 818, 2007 WL 1241635 (10th Cir. 2007).

In view of the foregoing, it is recommended that defendants' request for dismissal on above discussed grounds be DENIED.

B. Prosecutorial Misconduct.

Co-defendant Lugo Torres further submits that as far back as September 2005, [*328] the DEA served her with an Order to Show Cause and Immediate Suspension of Registration in regard to investigation of another co-defendant who had been identified through wire transfers to have received monies from co-defendant Valdivieso. She was extensively interviewed by two DEA agents. The summary suspension of her registration license was predicated on alleged prescriptions authorized over the internet regarding patients located in several states in the United States. Finally, and while represented by counsel, Lugo Torres executed a Memorandum of Agreement by which a full and final settlement was reached by the parties without a hearing and need of further litigation. These administrative proceedings were terminated around September of 2006.

Lugo Torres now claims that by that time, she had already [**14] incriminated herself in interviews with DEA agents and had tacitly admitted to the DEA's allegations of illegal

practice of medicine based on the internet prescriptions. On account of these administrative proceedings, Lugo Torres states she surrendered to the government any possible defense she might have in future criminal proceedings, had disclosed her defenses and "might have" relied on the good faith of the government [10] in that consenting to the two-year suspension and complying with the rest of the terms of the Memorandum Agreement would put an end to the matter. *See* Motion to Dismiss, p. 7. (**Docket No. 206**). However, the government had already commenced criminal investigation of her and other co-defendants for which defendant Lugo Torres now claims the government was simply using the administrative proceeding as an additional discovery tool and abused the same. Lugo Torres now seeks dismissal of the indictment on account of said alleged prosecutorial misconduct.

FOOTNOTES

[10] The potential use of the verb in this case may be construed as a mood of probability, indicating that the action most likely, but not certainly, occurs. See also:

1. Used to indicate a possibility or probability that [**15] is weaker than *may: We might discover a pot of gold at the end of the rainbow.* [Middle English, from Old English meahte, mihte, first and third person sing. past tense of *magan*, to be able].

The government's response to co-defendants' Motion to Dismiss did not address Lugo Torres' contention of prosecutorial misconduct (**Docket No. 217**). Rather, the government filed a separate response with specific reference to the administrative process followed and the alleged misconduct claimed by defendant if true, to be considered harmless (**Docket No. 223**). The government admits the criminal investigation in this case began around December 30, 2003, resulting from an administrative inspection conducted by the DEA under the agency's regulatory power to inspect pharmacies periodically. The allegations were that physicians within Puerto Rico were illegally prescribing controlled substances over the internet to persons outside Puerto Rico, that is, the continental United States. The government submits at no time any information regarding the criminal investigation was provided to the Office of the Chief Counsel of the DEA nor that *vice versa*, the information from the DEA Chief Counsel Office as to [**16] the criminal investigation was received or used in regard to the suspension of Lugo Torres' DEA registration. The government further submits co- defendant Torres Lugo has not showed any evidence that information concerning the criminal investigation was shared with the administrative investigators.

The government also states as to defendant Lugo Torres' claims that the Memorandum [*329] of Agreement would indicate her First Amendment rights to due process were violated, this agreement does not show any clause therein prohibiting the prosecution of defendant on criminal charges but was entered into for the sole purpose of ensuring that Lugo Torres could reapply for her DEA license after a twenty-four (24) months period. [11]

FOOTNOTES

[11] Neither defendant Lugo Torres nor the government in fact included copy of the Memorandum of Agreement with the electronic filing of the motion to dismiss or the subsequent government's response (Docket Nos. 206, 223).

The government submits discovery provided to defendant and the government's designation of evidence would show the criminal investigation in this case was conducted separately employing investigative techniques commonly used in criminal investigations and defendant [**17] Lugo Torres has not shown that any evidence was obtained as a result of the administrative proceedings. Thus, the government's contention is that Lugo Torres has made no showing of actual prejudice.

A perusal of the record shows co-defendant Lugo Torres' motion for dismissal on grounds of prosecutorial misconduct does not impeach the Grand Jury proceedings but the administrative events that took place prior to the indictment. There is, thus, no parallel Kastigar claim made by this defendant. [12]

FOOTNOTES

[12] Defense which may be raised when agents and officers of the United States … obtained, directly and indirectly and as a result of immunized testimony, evidence which resulted in the indictment by the grand jury." *See* Kastigar v. United States, 406 U.S. 441, 92 S.Ct. 1653, 32 L. Ed. 2d 212; Murphy v. Waterfront Commission of New York Harbor, 378 U.S. 52, 84 S.Ct. 1594, 12 L. Ed. 2d 678 (1964).

In fact, the case law provided by defendant Lugo Torres as to United States v. Kordel, 397 U.S. 1, 90 S.Ct. 763, 25 L. Ed. 2d 1 (1970) fails to support the claim that a Fifth Amendment violation would require dismissal. In Kordel, the Supreme Court held that the answer to the government in civil proceedings where the defendant could have invoked his Fifth Amendment [**18] but failed to do so, could not assert being forced to give testimony against himself, even if information supplied in answers provided evidence or led useful to government in a criminal prosecution.

It has long been recognized that "[t]he Constitution does not forbid the asking of criminative questions". United States v. Monia, 317 U.S. 424, 433, 63 S.Ct., 409, 413, 87 L. Ed. 376 (1943). Neither does the incriminating nature of a question, by itself, excuses a timely assertion of the

privilege. *See e.g.*, United States v. Mandujano, 425 U.S. 564, 574-575, 96 S.Ct. 1768, 1775-1776, 48 L. Ed. 2d 212 (1976). If a witness--even one under a general compulsion to testify--answers a question that both he and the government should reasonably expect to incriminate him/her, the Court need ask only whether the particular disclosure was "compelled" within the meaning of the Fifth Amendment. Minnesota v. Murphy, 465 U.S. 420, 104 S. Ct. 1136, 79 L. Ed. 2d 409 (1984).

As the Court of Appeals for the First Circuit has affirmed, it is well established that "[a]n indictment returned by a legally constituted and unbiased grand jury, … if valid on its face, is enough to call for trial of the charge on the merits". Costello v. United States, 350 U.S. 359, 363, 76 S.Ct. 406, 409, 100 L. Ed. 397, 1956-1 C.B. 639 (1956). [**19] *See* Lawn v. United States, 355 U.S. 339, 78 S.Ct. 311, 2 L. Ed. 2d 321, 1958-1 C.B. 540 (1958). The Supreme Court has also held that an indictment returned by a legally constituted an unbiased grand jury "is not [*330] subject to challenge on the grounds that the grand jury acted on the basis of inadequate or incompetent evidence". United States v. Calandra, 414 U.S. 338, 363, 94 S.Ct. 613, 627, 38 L. Ed. 2d 561 (1974). *See* United States v. Rivera Santiago, 872 F.2d 1073 (1st Cir. 1989).

Defendant Lugo Torres also submits in her Motion to Dismiss case law to support her claim, including United States v. Smith [13] and United States v. Grunewald [14]. Thereunder, as well as in United States v. Tweel [15] the Courts discussed IRS regulations did not allow to proceed with a civil audit once agents reached during the audits the point when auditors develop a firm indication of fraud. Still, the burden is on the moving party to establish the agents resorted to deception during an administrative audit/investigation, since Courts give weight to the internal regulations and to the Internal Revenue System which being based on good faith of taxpayers is consonant with taxpayers' expectation of good faith from the government.

FOOTNOTES

[13] 924 F.2D 889, 897 (9th Cir. 1991) [**20] (dealing with the government using a civil investigation by SEC personnel to develop a criminal investigation).

[14] 987 F.2d 531, 534 (8th Cir. 1993). Grunewald dealt with an Internal Revenue investigation of defendant's tax practices.

[15] 550 F.2d 297 (5th Cir. 1977).

These cases cited by defendant provide the government's conduct to justify dismissal of the charges on prosecutorial misconduct and due process needs must be grossly shocking and outrageous as to violate a universal sense of fairness, making the agents' conduct evidently repugnant to the American system of dispensing justice. The above is hardly co-defendant Lugo

Torres' situation, who was represented by counsel during the administrative process at issue and who has not established she was deceived by the agents in signing the purported agreement.

Co-defendant Lugo Torres has thus failed to meet the burden of establishing prosecutorial misconduct and additionally also failed to establish she has suffered a harm as a result thereof.

Thus, it is recommended that co-defendant Lugo Torres' claims for dismissal of the Superseding Indictment for alleged government's misconduct be DENIED.

C. Constitutionality of Section 841.

Co-defendant [**21] Valdivieso in his response indicated he was not raising a constitutional claim. However, co-defendant Lugo Torres, when joining said motion, made reference to Gonzalez v. Oregon [16], wherein the interpretation of the Attorney General of the controlled substance act criminalizing defendants' conduct, one that was sanctioned by state regulation as within the proper practice of medicine, was held unconstitutional. [17]

FOOTNOTES

[16] 546 U.S. 243, 126 S.Ct. 904, 163 L. Ed. 2d 748 (2006).

[17] Attorney General's directive declaring that physician assisted suicide violated the Controlled Substances Act ("CSA") exercised control over an area of law traditionally reserved for state authority without unmistakably clear Congressional authorization, was found in violation of the "clear statement" rule. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 101 et seq., 21 U.S.C.A. § 801 *et seq.*

Defendant submits the government's position that seemly requires face-to-face contact with customers and their physicians when dispensing controlled substances through an internet business, although authorized by **telemedicine** state law to be otherwise, is but an attempt of the Attorney General to define the standards [*331] of medical practice [**22] and to regulate the practice of medicine by criminalizing defendants' actions as a controlled substance violation. By finding illegal the prescription of drugs over the internet, as being outside the scope of professional practice and not for a legitimate medical purposes, as contained in the overt acts of the instant Superseding Indictment, co-defendants herein consider the government is federally punishing actions state law allow within the practice of their medical profession.

Nowhere in the Commonwealth of Puerto Rico **Telemedicine** Act are herein defendants authorized to provide medical services outside Puerto Rico to patients/customers who are not residents of Puerto Rico since said state law is not a multi-district accreditation for physicians outside the boundaries of Puerto Rico on patients who are not residents herein and/or as to

whom, except for their internet communication, there is no prior physician-patient relationship. Thus, the government's response is appropriate in that defendants have never been licensed to practice medicine in the states where the internet customers were located nor where the pharmacy where the controlled substances were dispensed. Although we have [**23] discussed above the scope of the **Telemedicine** Act not impinging or modifying the accepted legitimate medical purposes, defendants' arguments now rest on the unconstitutionality.

Furthermore, federal law is not defining what the appropriate practice of medical profession is, but rather, reference to the particulars of applicable state definition, authorization and licensing, together with the recognized standards prevail. *See* United States v. Katz, 445 F.3d 1023, 1030 (8th Cir. 2006) (noting that "the material issue [was] whether defendant, a medical doctor, wrote … prescriptions outside the usual course of medical practice and without a legitimate medical purpose"). *See also* United States v. Hurwitz, 459 F.3d 463, 479 (4th Cir. 2006) ("We believe that the inquiry must be an objective one, a conclusion that has been reached by every court to specifically consider the question."); United States v. Feingold, 454 F.3d 1001, 1011-12 (9th Cir. 2006) ("[I]t is appropriate in cases such as this for the jury to consider the practitioner's behavior against the benchmark of acceptable and accepted medical practice. Just how that benchmark is expressed to the jury-here, the district court defined [**24] that benchmark in terms of the 'standard of medical practice generally recognized and accepted in the country'-is a matter within the district court's discretion.") (footnote and citation omitted); United States v. Vamos, 797 F.2d 1146, 1151 (2d Cir. 1986) ("The term 'professional practice' refers to generally accepted medical practice; a practitioner is not free deliberately to disregard prevailing standards of treatment. In short, the doctor must act in the good faith belief that his distribution of the controlled substance is for a legitimate medical purpose and in accordance with the usual course of generally accepted medical practice.") (*citing* United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986)). [18]

FOOTNOTES

[18] Only after assessing the standards to which medical professionals generally hold themselves is it possible to evaluate whether a practitioner's conduct in prescribing medication has deviated so far from the usual course of professional practice that his actions become criminal distribution of controlled substances. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 401(a). United States v. Feingold, 454 F.3d 1001 (9th Cir. 2006).

Defendants' submission the Controlled [**25] Substance Act should be deemed unconstitutional for criminalizing their authorized [*332] state action as medical practitioners is not supported by a mere rational reading of the statute nor by their subjective interpretation of what state provisions authorize them to do *vis a vis* their charged actions. At this juncture, it is recommended that defendants' request for dismissal because of unconstitutionality of the Controlled Substance Act under the rationale of Gonzalez v. Oregon be DENIED.

CONCLUSION

In view of the foregoing, it is recommended consonant with above, that the Motion to Dismiss the Superseding Indictment be **DENIED (Docket Nos. 202, 221, 204).** It is further recommended that the request for dismissal because of prosecutorial misconduct and unconstitutionality of Section 841 be **DENIED (Docket No. 206).**

IT IS SO RECOMMENDED.

The parties have ten (10) days to file any objections to this report and recommendation. Failure to file same within the specified time waives the right to appeal this order. Henley Drilling Co. v. McGee, 36 F.3d 143, 150-151 (1st Cir. 1994); United States v. Valencia, 792 F.2d 4 (1st Cir. 1986). *See* Paterson-Leitch Co. v. Mass. Mun. Wholesale Elec. Co., 840 F.2d 985, 991 (1st Cir. 1988) [**26] ("Systemic efficiencies would be frustrated and the magistrate's role reduced to that a mere dress rehearser if a party were allowed to feint and weave at the initial hearing, and save its knockout punch for the second round").

San Juan, Puerto Rico, this 11th day of September of 2007.

s/ CAMILLE L. VELEZ-RIVE

CAMILLE L. VELEZ-RIVE

UNITED STATES MAGISTRATE JUDGE