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United States v. Valdivieso Rodriguez: The Trend of Telemedicine

*Meera Shenoy**

I. INTRODUCTION

This case addresses the relatively new practice of telemedicine in the critical area of physician licensure. The issue is whether the Telemedicine Act of the Commonwealth of Puerto Rico authorized the defendants to prescribe controlled substances to internet customers within the United States without violating United States federal regulations, which state that “prescriptions may only be issued for legitimate medical purposes.”¹ The District Court of Puerto Rico denied the motion to dismiss and found for the United States. The court held that when practicing telemedicine with a patient located in another state or country, a physician must be licensed to practice within that state or country.² The court reasoned that the motive behind Puerto Rico’s telemedicine law is to protect Puerto Rican patients from unlicensed medical practitioners, not to license Puerto Rican practitioners to practice telemedicine outside Puerto Rico.³ Furthermore, the court stated that even though the physician defendants were registered with the Drug Enforcement Agency (hereinafter “DEA”), “they can be prosecuted under the Controlled Substances Act when their activities fall outside the usual course of professional practice.”⁴ This case clarifies some of the uncertainty present in the area of telemedicine with regard to licensure and professional standards of care.

II. FACTUAL BACKGROUND

Seven physicians, who were only licensed to practice medicine in the Commonwealth of Puerto Rico, were charged with participating in an internet scheme to prescribe prescription medications to individuals within the United States.⁵ The formal charges included conspiracy to distribute controlled substances, distribution of controlled substances, wire fraud, money laundering, and two counts of forfeiture.⁶ The primary defendant, Alfred

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1. *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 316, 324 (D.P.R. 2007).
2. *Id.* at 332.
3. *Id.* at 325.
4. *Id.* at 327 n.8.
5. *Id.* at 324.
6. *Id.*

Valdivieso Rodriguez, claims that his conduct was legal if the criminal statute was read in light of the provisions of Puerto Rican law, which allows the practice of telemedicine.⁷ The defendants contend that medical practice in Puerto Rico authorized physicians to practice telemedicine, thereby “depriv[ing] the federal government from criminalizing their conduct under the Controlled Substance Act.”⁸

III. DESCRIPTION OF PLAINTIFF’S CLAIM

The case was filed in the United States District Court for the District of Puerto Rico, charging seven defendants in a single, forty-one-count, Superseding Indictment.⁹ The charges included the following violations: 21 U.S.C. § 841(a)(1) (conspiracy to distribute controlled substances); 21 U.S.C. § 846 (distribution of controlled substances); 18 U.S.C. § 1343 (wire fraud); 18 U.S.C. §§ 1956(a)(1)(A)(i) and (h) (money laundering); and two counts of forfeiture.¹⁰ The defendants’ motion to suppress evidence was denied.¹¹ Thereafter, the defendants argued that Puerto Rican state law permitted them to prescribe controlled substances through the use of the internet and were not in violation of United States federal law.¹² The United States claimed that the seven physicians were only licensed to practice medicine within the Commonwealth of Puerto Rico, yet they prescribed and dispensed prescription drugs via the internet to individuals within the United States.¹³ Further, the prosecution alleged that a physician-patient relationship had not been established, and the physicians were not licensed to practice medicine within any state of the United States. Thus, the doctors violated federal regulations prohibiting the distribution of controlled substances for anything less than legitimate medical purposes.¹⁴

IV. PROCEDURAL AND SUBSTANTIVE HISTORY

The matters of this case were heard by the same court in a prior hearing on a motion to suppress evidence.¹⁵ After the defendants had been formally

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7. *Id.*; see 21 U.S.C. § 841(a)(1) (conspiracy to distribute controlled substances) (2009).
 8. *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 332, 334 (D.P.R. 2007).
 9. *Id.* at 337.
 10. *Id.*; 18 U.S.C. §§ 1343, 1956(a)(1)(A)(i),(h) (2009); 21 U.S.C. §§ 841(a)(1), 846 (2009).
 11. *Valdivieso Rodriguez*, 532 F. Supp. 2d 332, 337.
 12. *Valdivieso Rodriguez*, 532 F. Supp. 2d 316, 325.
 13. *See id.* at 324.
 14. *Id.*
 15. *See Valdivieso Rodriguez*, 532 F. Supp. 2d 332, 338.

charged, the defendants filed a motion to suppress evidence and requested the dismissal of the federal charges, stating that they were “unconstitutional as applied to [their] conduct.”¹⁶ In addition, the defendants contend that (1) there was no reference made in the written affidavits in support of the search warrants to the fact that the defendants were physicians licensed to issue controlled substances, and (2) no reference was made to the telemedicine law in Puerto Rico.¹⁷ The defendants take their argument a step further to allege that the lack of references improperly influenced the judge to issue the search warrants, and therefore, because there was an omission of evidence, the court should allow for an evidentiary hearing.¹⁸ The government responded by stating that an evidentiary hearing was not required; only legal arguments are raised in regards to the motion to suppress and no testimony is needed.¹⁹ The District Court of Puerto Rico denied the motion to suppress evidence; however, the magistrate judge gave the defendants the opportunity to have their arguments heard about Puerto Rican telemedicine law permitting them to prescribe controlled substances over the internet.²⁰ The decision that followed from the same court is the focus of this case note.

V. DISTRICT COURT HOLDING AND OVERVIEW OF RATIONALE

The United States District Court of Puerto Rico denied the motion to suppress evidence.²¹ The defendants sought to suppress evidence from email accounts and the search of defendant’s real estate, alleging the evidence was the tainted product of a Fourth Amendment probable-cause violation.²² The court responded by stating that “probable cause to search exists so long as the underlying affidavit contains information showing a fair probability that evidence of a crime would be found there.”²³ Further, citing a good faith exemption, when an officer reasonably believes a warrant is necessary, suppression of evidence is inappropriate.²⁴ The defendants, in addressing the Puerto Rico Telemedicine Law and the Controlled Substance Act, state that:

since the practice of Telemedicine in the Commonwealth of Puerto Rico does not seem to require a face to face communication or physical examination . . . regardless if it is a sound practice of

16. *Valdivieso Rodriguez*, 532 F. Supp. 2d 332, 337.

17. *Id.* at 338.

18. *Id.*

19. *Id.*

20. *Id.* at 345.

21. *Id.*

22. *Id.* at 338.

23. *Id.* at 340.

24. *Id.* at 342.

medicine or not, it is one encouraged by state law and cannot be criminalized by the federal government.²⁵

The magistrate judge reserved judgment, in order to permit Valdivieso to develop this issue and to allow for an in-depth determination into the case at hand.²⁶

VI. COURT'S RATIONALE

Under 21 U.S.C. § 841(a)(1), it is "unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance."²⁷ Therefore, in order for the United States to prevail in an action against the seven physician defendants, the United States must prove three elements: (1) that the defendants acted knowingly or intentionally; (2) that the defendants distributed a controlled substance; and (3) that the defendants acted "without a legitimate medical purpose or outside the usual course of professional practice."²⁸ The court focuses on the third element and denies the motion to dismiss, since it disagreed with the defendants' contentions that they were acting within the scope of professional practice and that their conduct constituted a legitimate medical purpose.²⁹ As with the regular practice of medicine, to convict physicians of a federal controlled substance violation through internet-provided medical practice, the jury must: (1) "determine whether the defendants' conduct was within the bounds of professional medical practice" and (2) "consider any testimony as to the norms of professional practice."³⁰ The third element must be proven by the government to the jury and cannot be subject of a motion to dismiss.³¹

The defendants argue that the Puerto Rico Telemedicine Law authorizes physicians registered with the DEA to distribute controlled substances "through advanced technologic telecommunication means," and that they did not "knowingly infringe federal controlled substance laws."³² The court disagrees and specifically focuses on the problem of licensure, especially how it relates to the supposed good faith behavior by the Puerto Rican physicians.³³ Licensure laws differ from state-to-state and country-to-country.³⁴ The doc-

25. *Id.* at 344.

26. *Id.* at 345.

27. 21 U.S.C. § 841(a)(1) (2009).

28. *Id.*; *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 316, at 322 (quoting *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004)).

29. *See Valdivieso Rodriguez*, 532 F. Supp. 2d at 327.

30. *Id.* at 326.

31. *See id.* at 325 n.3.

32. *Id.* at 325.

33. *Id.* at 327.

34. *Id.* at 326.

trine of reciprocity “permits one state to recognize a license in good standing that a practitioner holds in another jurisdiction.”³⁵ However, the reciprocity doctrine for practitioner licenses has only been adopted in Alabama, California, and Oregon.³⁶ Puerto Rico does not grant reciprocity.³⁷ Thus, the defendants are unable to claim that they are authorized to practice telemedicine in many locations.³⁸

Further discounting the defendants’ arguments, the District Court noted that the motive behind Puerto Rico’s telemedicine law is 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’” and did not give permission for Puerto Rican physicians to practice telemedicine outside Puerto Rico.³⁹ Licensure laws related to medicine also apply to telemedicine.⁴⁰ If a patient is seen in another state, “the physician should be licensed to practice medicine in that state.”⁴¹ The court emphasized that there are many internet and other sources available to physicians around the world when they come across good faith questions and doubts about their authority to practice telemedicine.⁴² The court adamantly stated that the physician defendants’ argument regarding the interpretation of Puerto Rican and United States federal law was “an attempt to navigate blindfolded through their wanton ignorance of the law.”⁴³

The physician defendants maintained throughout the entire case that they were acting in conformity with Puerto Rican Telemedicine law. However, the arguments made were not premised upon elements establishing their conformity with a law, rather upon a theory that the physicians acted without a legitimate medical purpose or outside the usual course of professional practice.⁴⁴ The court “neither adopted nor rejected the magistrate judge’s conclusion” that the Telemedicine Act authorized the practice of telemedicine only in Puerto Rico.⁴⁵ Accordingly, the court denied the motion to dismiss, because the third element regarding conduct falling outside the usual course of

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.* at 325; P.R. Laws Ann. tit. 20, § 6001 (2006).

40. *Valdivieso Rodriguez*, 532 F. Supp. 2d at 327.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.* at 326 (quoting *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004)).

45. *United States v. Quinones*, 536 F. Supp. 2d 267, 272 (E.D.N.Y. 2008).

professional practice or without a legitimate purpose needed to be proved by the United States to a jury.⁴⁶

VII. CRITIQUE OF COURT'S APPROACH

Since there is a lack of legal precedent in the area of telemedicine, most courts are aware that they are creating law and are therefore cautious in their approach. This district court did not diverge from the manner in which other courts have previously decided such issues. For example, in *Holzhauser v. State Med. Bd. of Ohio*, the defendant worked for Medsnationwide.com, an internet company that prescribes medication.⁴⁷ The defendant electronically signed prescriptions for patients whom she never personally physically examined nor diagnosed.⁴⁸ A significant majority of the medication the defendant prescribed was for the controlled substance hydrocodone.⁴⁹ The board notified her that it was determining whether to sanction her medical license; in particular, it alleged that the defendant prescribed controlled substances to patients without administering a personal examination and acting in this manner was in direct violation of an Ohio statute and an Ohio administrative rule.⁵⁰ The defendant claimed that her actions were not intentional violations because the internet company quelled any fears she had about improprieties that could be associated with her conduct.⁵¹ To avoid criminal liability, the defendant argued that the statute conflicts with the administrative rule, and therefore the existing statute is invalid.⁵² The Ohio Administrative Code 4731-11-09 ("the rule") "prohibits a physician from prescribing, dispensing, or otherwise providing any controlled substance to a person the physician has never personally physically examined and diagnosed."⁵³ The defendant claims that this rule conflicts with R.C. 4731.296, ("the statute") which "allows physicians to practice telemedicine, the practice of medicine through any communication, be it oral, written or electronic, by a physician located outside the state."⁵⁴ The defendant argued that the statute allows physicians outside the state of Ohio to prescribe prescriptions for controlled substances to Ohio residents without personally physically examining them, which di-

46. *Valdivieso Rodriguez*, 532 F. Supp. 2d at 327.

47. *Holzhauser v. State Med. Bd. of Ohio*, 2007-Ohio-5003, 2007 WL 2773472, at *1 (Ohio Ct. App. 2007).

48. *Id.*

49. *Id.*

50. *Id.* at *2.

51. *Id.*

52. *Id.* at *3.

53. *Id.*; OHIO ADMIN. CODE § 4731-11-09 (2009); OHIO REV. CODE ANN. § 4731.296 (West 2009).

54. *Holzhauser*, 2007 WL 2773472 at *3; OHIO ADMIN. CODE § 4731-11-09 (2009); OHIO REV. CODE ANN. § 4731.296 (West 2009).

rectly conflicts with the prohibitions stated in the rule.⁵⁵ The court disagreed with the defendant and reasoned that the statute provides that “a physician with a telemedicine certificate may be disciplined for any violation of [the statute] or a violation of the board’s rule.”⁵⁶ Further, physicians carrying a telemedicine certificate “must comply with the board’s rules, including the rule violated herein, which prohibits physicians from prescribing medications to a patient they have not personally examined and diagnosed; thus the two provisions do not conflict.”⁵⁷

The conflict of the interpretation of the Ohio administrative law against the Ohio statute is similar to the conflict between the Puerto Rican Telemedicine Law and the federal Controlled Substance Act. The physician defendants stated a similar defense—that they were following one law—but they were actually violating the theory behind the other law.⁵⁸ Likewise, both cases addressed the prescribing of medications over the internet and this court had the same holding as in *Valdivieso*.⁵⁹ A distinction between the two cases is the fact that the defendant in *Holzhauser* asked legal experts in the field of medicine whether online prescribing was permitted, while the Puerto Rican physicians did not consult the websites available to them.⁶⁰ Therefore, neither court treated a good-faith effort as a dispositive factor in determining the result of the cases.

Another example of where the *Valdivieso* Court held similarly to other courts was in *Low Cost Pharmacy, Inc. v. Ariz. State Bd. of Pharmacy*, where a licensed physician defendant prescribed medications over the phone and the internet, which constituted unprofessional conduct pursuant to Arizona Revised Statutes.⁶¹ The court held that the online pharmacy filled prescriptions in violation of the state statute.⁶² Thus far, most courts have found that prescriptions made over the internet to patients who are not physically examined nor diagnosed are in violation of state or federal law.⁶³ As a policy consideration, having overmedicated or improperly medicated individuals in society is a problem that can be avoided, and physicians should not be fueling addictions due to poorly done diagnoses.

55. *Holzhauser*, 2007 WL 2773472 at *3.

56. *Id.*

57. *Id.*

58. *See Valdivieso Rodriguez*, 532 F. Supp. 2d 316, at 327; *see also Holzhauser*, 2007 WL 2773472 at *3.

59. *Id.*

60. *Id.*

61. *Low Cost Pharmacy, Inc. v. Ariz. State Bd. of Pharmacy*, 2008 WL 2154793, at *2 (Ariz. Ct. App. 2008).

62. *Id.*

63. *See id.*

Following the two cases adjudicated by the District Court of Puerto Rico, another matter regarding the defendants in *Valdivieso* was brought before the District Court for the Eastern District of New York.⁶⁴ In that case, the government advances the argument that pharmacist defendants not only illegally sold controlled substances over the internet, but they also “created and operated several websites. And in so doing, the defendants conspired with, aided, and abetted defendant Alfred Valdivieso, a physician licensed in Puerto Rico, to distribute controlled substances outside the usual course of professional practice.”⁶⁵ The pharmacist defendants argued that the phrase “usual course of professional practice” was unconstitutionally vague—yet they relied on this phrase to prove that their actions were within the legal boundaries.⁶⁶ The court disagreed with the defendants and noted that the pharmacists were put on notice by DEA guidelines which highlighted internet pharmacies as subject to criminal violations.⁶⁷ Moreover, the court states that Section 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.”⁶⁸ Unrelentingly, the court stated that “it is disingenuous that the moving defendants seek to invoke the exception as legalizing their actions, but then claim they do not know what the exception means.”⁶⁹

Because there is not much case law on telemedicine, it will be difficult to find a case so early into the use of the technology that states a physician or a pharmacy was not in violation of state or federal law. Licensing of health-care professionals is one of the basic ways the state has the ability to promote quality healthcare. Moreover, healthcare is an area of the law where legislatures want consistency. Courts are reluctant to reverse medical boards, because courts lack expertise in the area of patient safety. In essence, judges are making discretionary calls, because they often lack the proper knowledge of medical services. Further, if the court “gets it wrong,” their decision would be a direct threat to the health and safety of patients in the community.

As the area of telemedicine law develops, courts will have to decide on complicated issues relating to telemedicine: licensing, credentialing, professional standards of care, and assessments of telemedical technology. Because of uncertainty in this area of law, telemedicine cases are problematic for all parties involved. The case at hand is even more complicated due to the merging of the laws of the Commonwealth of Puerto Rico and the federal laws of the United States.

64. *Quinones*, 536 F. Supp. 2d at 268.

65. *Id.* at 268-69.

66. *Id.* at 270.

67. *Id.* at 274.

68. *Id.*

69. *Id.*

The purpose of telemedicine is to connect patient to physician for remote clinical diagnosis and treatment. Courts do not tolerate direct threats to this process.⁷⁰ When dealing with the specifics of licensure, courts will have to distinguish between remote consultations and direct patient diagnosis and treatment in order to determine whether multiple licenses may be required.⁷¹ The policy behind holding physicians liable for malpractice becomes difficult to enforce because of the inability to allocate liability in an internet practice. Health care systems owe a duty to patients who enter their facilities—the duty to prevent harm negligently caused by them, their employees, and agents. But it is increasingly difficult for courts to determine the bounds of the physicians' facilities.⁷²

VIII. CONCLUSION

The holding of the District Court of Puerto Rico and the issues presented in this case generally present two problems. First, international law is merging with United States federal law. Second, there is not much law on the topic of telemedicine in general. The lack of legal precedents makes the outcome of telemedicine cases difficult to determine. This case is a guideline for shaping the law regarding the practice of telemedicine. Further, it will impact the merging of United States federal law with the Commonwealth of Puerto Rico's state law. Moreover, while this case did not directly address malpractice, it will impact how courts determine the issue of malpractice liability for the medical profession and the healthcare industry. Over time there will be more certainty about the impact of telemedicine and technology.

70. Sharon Klein & William Manning, *Telemedicine and the Law*, <http://www.netreach.net/~wmanning/telemedar.htm>.

71. *Id.*

72. *Id.* (emphasis added).

