NOTE

Allowing FDA Regulation of Communications Software Used in Telemedicine: A Potentially Fatal Misdiagnosis?

Ann K. Schooley*

* B.B.A., University of Cincinnati, 1993; candidate for J.D., Indiana University School of Law—Bloomington, 1998.

I. INTRODUCTION

The way in which medicine is practiced changes almost daily thanks to emerging technologies. Today, "telemedicine" allows a physician to treat a patient who is halfway across the country—or even halfway around the world. Within the broad category of telemedicine, a host of subfields are emerging. Many medical specialties and services are now developing and offering services via video conferencing and the use of communications technology. Teleradiology, teleimaging, telerobotics, teleoperation, telepsychiatry, telepresence, teleorthopedics, teledermatology, and telehealth[1] are just some of the specialties using advanced telecommunications technology to provide medical care. Entire health care systems and providers are now using telemedicine. For example, Iowa has a virtual hospital and Singapore created a cyberspace hospital.[2]

Telemedicine promises to benefit everyone involved in the provision of medical care: doctors, patients, health care providers, hospitals, and insurers.[3] For example, it benefits doctors by lowering the risk of malpractice since telemedicine allows quick and easy consultation with other doctors. Great potential exists for the use of telemedicine in training and educational contexts.[4] In addition, doctors can greatly expand their potential patient base once they are no longer limited by geography. With health care professionals on both ends of a telemedicine transaction, telemedicine will improve treatment and provide better overall care, benefiting the patients.[5] Patients in rural areas gain access to specialists and treatments that currently are only readily available in metropolitan areas.[6] Telemedicine

---

1. Claire B. Mailhot, *Telepresence: What Is It?*, 27 NURSING MGMT. 32I (1996); *Treatment in the Video Age: Televised Visits May Help Patients Who Can't Get There in Person*, BEHAVIORAL HEALTH TREATMENT, Aug. 1996, at 1.

2. Liam J. Donaldson, *From Black Bag to Black Box: Will Computers Improve the NHS?*, 312 BRIT. MED. J. 1371 (1996).

3. *Senate Approves Bill Designed to Remove Barriers to Telemedicine*, 5 Health L. Rep. (BNA) 910 (June 13, 1996).

4. Chappell Brown, *Experts' Prognosis: Technology Has Potential as Teaching, Decision-Making Aid*, ELEC. ENG'G TIMES, Aug. 12, 1996, at 34; Regan Solmo, *A High-Tech Rx*, SUCCESSFUL MEETINGS, Sept. 1996, at 103.

5. Robert F. Pendrak & Peter R. Ericson, *Telemedicine May Spawn Long-Distance Lawsuits*, NAT'L UNDERWRITER LIFE & HEALTH-FIN. SERVS., Sept. 30, 1996, at 17, 17.

6. *NIIT Update: Denver Health and Hospitals Link Rural Areas*, HEALTH MGMT. TECH., May 1996, at 38, 38.

can also save time in delivering patient care,[7] particularly in emergency situations.[8]

Organizations that reimburse for health care expenses are perhaps the largest potential beneficiaries of telemedicine. The cost savings, especially long-term, are phenomenal. Some commentators estimate the cost of health care can be reduced by 36 billion dollars a year through the use of telemedicine.[9] Telemedicine removes commuting and transportation costs of both doctor and patient, reduces duplication of tests and records, makes claim processing more efficient and cost effective, and reduces other administrative costs and delays.

While telemedicine promises great benefits, it also creates many societal, technological, and legal obstacles. Patients will have to be reeducated and given a chance to adjust to a new type of treatment. Many people may not feel comfortable being diagnosed by a doctor who is hundreds of miles away.[10] The initial investment in equipment can also be substantial, with quoted start-up costs averaging $134,378 to $287,503,[11] depending on how advanced the equipment is and its applications. Start-up costs can be reduced somewhat by using "off the shelf" systems rather than custom-made systems.[12] After the initial investment there are also fees for transmission and maintenance, which average anywhere from $18,573 to $80,068 annually.[13] Equipment compatibility is a basic requirement, often difficult and expensive to achieve.

The legal issues involved in developing, operating, and maintaining a telemedicine system are endless. Maintaining the security of these systems, as well as protecting the patient's privacy, are major concerns that now are being addressed. Patients are unlikely to embrace telemedicine

---

7. Anthony Birritteri, *Technology: A Prescription for Speedy Recovery*, N.J. BUS., Oct. 1996, at 48.

8. Terese Hudson, *When Every Second Counts*, HOSP. & HEALTH NETWORKS, Sept. 5, 1996, at 61; Leslie Sandberg, *Northern California Rates a 'TENN'*, HEALTH MGMT. TECH., June 1996, at 17.

9. *Use of Medical Technology Blocked by State Regulations*, 3 Health L. Rep. (BNA) 1354 (Sept. 29, 1994); Douglas D. Bradham et al., *The Information Superhighway and Telemedicine: Applications, Status and Issues*, 30 WAKE FOREST L. REV. 145, 147 (1995).

10. Mailhot, *supra* note 1, at 32K.

11. JOINT WORKING GROUP ON TELEMEDICINE, REPORT TO CONGRESS pt. II.G. (Jan. 31, 1997) <http://www.ntia.doc.gov/reports/telemed/index.htm> [hereinafter TELEMEDICINE REPORT].

12. Telemedicine systems can be custom-made by manufacturers and tailored to suit a specific medical practice or need, or they can be created "off the shelf" by literally going to vendors and purchasing separate components intended for use in a variety of applications and then building the system from the various components.

13. TELEMEDICINE REPORT, *supra* note 11, pt. II.G.

without assurances of confidentiality.[14] Reimbursement by insurers is a major barrier to widespread use of telemedicine. Many insurers, including Medicare and Medicaid, will only reimburse for services provided with a face-to-face encounter between the doctor and patient.[15] Because a large percentage of medical expenses are paid by insurers rather than the patients themselves, insurers' refusal to pay for telemedicine will sharply curtail its use. Doctors will be hesitant to use the new technology for fear of nonpayment.

Physician licensing and malpractice liability are also barriers to telemedicine.[16] Because telemedicine does not recognize state boundaries, it creates the problem of a physician practicing in a state where she is not licensed[17] or covered by malpractice insurance. Issues of jurisdiction and liability for mistransmission of data are also concerns that must be resolved prior to the widespread use of telemedicine. Governments are taking steps to address a number of these issues, mainly through legislation, and often on the state level.[18]

The complex problems and vast benefits created by telemedicine make it likely that the federal government will step in to regulate the field. If the federal government attempts to regulate telemedicine, the question will become: who will be in charge of creating the rules? The Federal Communications Commission (FCC or Commission), and the Food and Drug Administration (FDA) under the authority of the Food, Drug and Cosmetics Act (FDCA) are likely to be the key agencies involved since telemedicine involves both communications technology and medical technology. Of course numerous other agencies could assert jurisdiction, including, but not limited to: the Consumer Product Safety Commission, the Occupational Health and Safety Administration, and the Department of Health and Human Services.[19]

This Note discusses the potential jurisdiction of and attempts by one

---

14. Bradham, *supra* note 9, at 161; *see also Use of Medical Technology Blocked by State Regulations*, *supra* note 9.

15. John Bennett, *Weighing the Costs and Benefits of Telepsychiatry*, BEHAV. HEALTH TREATMENT, Aug. 1996, at 5; *Use of Medical Technology Blocked by State Regulations*, *supra* note 9.

16. Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 ANN. HEALTH L. 61, 66 (1996).

17. *Id.*

18. *Senate Approves Bill Designed to Remove Barriers to Telemedicine*, *supra* note 3; Jeanne Schulte Scott, *State Responses to Telemedicine Licensing Issues*, HEALTHCARE FIN. MGMT., Dec. 1996, at 48, 48.

19. Gary E. Gamerman, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 826-29 (1993).

of these agencies, the FDA, to regulate telemedicine as a medical device.[20] Part II looks at current definitions of telemedicine and the types of applications included in telemedicine. Part III discusses the definition of a medical device, the FDA's regulatory scheme for medical devices, and the FDA's current stance on regulation of telemedicine systems. Part IV examines issues raised by FDA regulation of telemedicine and the impact such regulation will have on telemedicine and related industries, particularly the communications industry.

II. WHAT IS TELEMEDICINE?

Half the battle in dealing with this new genre of patient care is defining telemedicine and determining what telemedicine encompasses. Many definitions are used, but most of the definitions tend to be rather broad. In formulating a general definition of telemedicine and in understanding the range of services telemedicine encompasses, it is helpful to look at some of the applications and their common factors.

A. *Applications of Telemedicine*

The potential applications of telemedicine are limitless. Everything from 911 emergency service[21] to surgery performed by a doctor miles away[22] to Web sites containing information on disease prevention[23] has been labeled "telemedicine." Some current applications include: sharing of patient information and records to save time and administrative costs;[24] kiosks set up in urban areas allowing people access to basic healthcare;[25] use in prisons to insure physician safety when treating inmates;[26] use by the military to treat personnel at sea and in distant locations;[27] home monitoring of the elderly and disabled;[28] education and training;[29] and providing

20. 21 U.S.C. § 321(h) (1994).

21. Robert Bellinger, *Report Proposes Rx for Telemedicine*, ELEC. ENG'G TIMES, Nov. 11, 1996, at 117, 117.

22. Mailhot, *supra* note 1, at 321.

23. John Morrisey, *Med Center, School Finalists for Award*, MODERN HEALTHCARE, Dec. 2, 1996, at 62, 62.

24. Denise Pappalardo, *Networked Medicine, Sprint Helps Hospitals Redefine Healthcare*, TELEPHONY, Oct. 7, 1996, at 92.

25. Joshua Dean, *In New Jersey, the Doctor Is In-teractive*, GOVERNING MAG., Jan. 1997, at 43, 43.

26. *Most Active Videoconferencing*, ELEC. DESIGN, Dec. 16, 1996, at 64FF.

27. *Treatment in the Video Age: Televised Visits May Help Patients Who Can't Get There in Person*, *supra* note 1.

28. Bellinger, *supra* note 21.

29. Brown, *supra* note 4.

health care to residents of rural areas.[30] Another application is computer diagnostic systems, often called medical expert systems (MES), which use one central computer to provide diagnostic information, calculations, and assessments to other remote users. However, all the potential uses have one common element: the use, in one way or another, of communications services and technology to transmit information from one place to another.[31]

B. General Definitions of Telemedicine

Creating a definition that would include all potential applications, or alternatively, determining which applications should be excluded is not easy. Overly broad definitions include any medical application that uses communications technology in any way, regardless of the small part such technology plays. For example, a phone conversation with a doctor is not what many people envision when thinking of telemedicine; yet, communications technology is used to help provide medical care. On the other hand, almost everyone would agree that a physical examination of a patient by a doctor miles away, using video conferencing and advanced technology is telemedicine. Yet determining where the line should be drawn—which applications should be considered telemedicine—is a difficult task.

The California Senate defined telemedicine as "the use of information technology to deliver medical services and information from one location to another."[32] Telemedicine has also been defined as "the use of information and communications technologies to provide and support health care where distance separates the participants,"[33] "medical diagnosis and treatment via telecommunications,"[34] and the European Commission defines it as "rapid access to shared and remote medical expertise by means of telecommunications and information technologies, no matter where the patient or relevant information is located."[35]

The Joint Working Group on Telemedicine (Working Group), an interagency group headed by the Department of Health and Human Services, has created "working definitions" for telemedicine and telehealth.[36] Tele-

30. Sandberg, *supra* note 8.

31. Mailhot, *supra* note 1.

32. Telemedicine Development Act, 1996 Cal. Legis. Serv. Ch. 864, § 1 (West) (S.B. 1665).

33. Bellinger, *supra* note 21, at 117.

34. Vyborny, *supra* note 16, at 61.

35. Patrick Hook, *Skyhigh Healthcare: Airlines Are Finally Considering Fitting Telemedicine Equipment*, FLIGHT INT'L, Aug. 21-27, 1996, at 29, 29.

36. *Telemedicine Related Activities* (July 11, 1996) <http://www.fda.gov/cdrh/telemed.html>.

medicine refers to health care services for individuals, while telehealth deals with general health care services. The Working Group's definition of telemedicine is:

> The delivery and provision of health care and consultative services to individual patients and the transmission of information related to care, over distance, using telecommunications technologies, and incorporating the following activities:
>
> I. Direct clinical, preventive, diagnostic, and therapeutic services and treatment, including procedures where a provider may be present with the patient, and clinical training and consultative clinical Grand Rounds, if used for decision making regarding the clinical care of a specific patient.
>
> II. Consultative and follow-up services.
>
> III. Remote monitoring, including the remote reading and interpretation of results of patient's procedures.
>
> IV. Rehabilitative services.
>
> V. Patient education provided in context of delivering health care to individuals.[37]

The above definition includes a wide range of applications. It includes the type of services that many people think of as telemedicine, particularly video conferencing. But it also includes phone consultation between a doctor and patient as they discuss test results.

The Working Group's definition excludes certain significant applications such as numerous Web sites geared toward providing information to individuals; currently, these are numerous.[38] In spite of the exclusion of applications such as Web sites, the Working Group's definition of telemedicine is one of the most specific and complete definitions and is the one used for purposes of this Note.

C. Components Involved in Telemedicine

It is important to consider what elements are included in telemedicine systems when trying to regulate them. By its nature, telemedicine involves multiple components and multiple parties. A minimum of three parties will be involved in any telemedicine transaction: the initiator of the transmission, the receiver of the transmission, and the communication service provider. Quite often more parties will be involved. The information may be transmitted to more than one doctor in more than one location. Additionally, because of the way in which phone service is currently provided, un-

37. *Id.*

38. Brief descriptions of several of these Web sites can be found at <http://www.gii-awards.com/finalists/FinHealth.html>.

less the transmission is within a small geographic area, several service providers are needed to complete the transmission of the data via modem. Each party to a telemedicine transaction will have its own equipment, both hardware and software, all of which could be a device for purposes of FDA regulation.

The number of components used in telemedicine, which could potentially be regulated by the FDA as medical devices, is tremendous. These include the hardware used by both the initiator and receiver: the monitors, video cameras, computers, wires and cables, keyboards, modems, printers, facsimile machines, and any other equipment used at their locations. In addition, the communications service provider uses hardware: the phone lines, cables, telephone poles, fiber optic cable, satellite equipment, switches, and other equipment which could face regulation as medical devices.

The software used by all the parties is another component in telemedicine systems and could potentially be regulated. The end users (both the initiator and receiver) of the transmission will have several types of software on their system. At a minimum, users must have some communications software in order to convert the data or images to digital form and then transmit them. The companies providing the communications service will also have their own software to direct the transmissions and deal with other routine and advanced functions. As part of a telemedicine system, all of these components are potentially subject to regulation as medical devices by the FDA.[39]

III. FDA REGULATION OF MEDICAL DEVICES

Prior to 1976, the FDCA allowed the FDA to regulate drugs, but it was not able to regulate medical devices directly.[40] If the FDA wanted to regulate a medical device it had to first classify it as a drug, and then the device could be regulated according to the regulations applicable to drugs.[41] This burdensome method of regulating medical devices ended in 1976 with the passage of the Medical Device Amendments of 1976,[42] which gave the FDA authority to regulate medical devices directly. The Safe Medical Devices Act of 1990[43] supplemented the 1976 Amendments and attempted to create improved, comprehensive regulation of medical

39. 21 U.S.C. § 321 (h)(1994).

40. Gamerman, *supra* note 19, at 817-18.

41. *Id.*

42. Medical Device Amendments of 1976, 21 U.S.C. §§ 360c-360k.

43. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 1(a), 104 Stat. 4511, 4511 (1990) (codified in scattered sections of 21 U.S.C. & 42 U.S.C. (1994)).

devices designed to promote public health and safety.

A. *Medical Device Regulation under the 1976 and 1990 Amendments*[44]

The 1976 and 1990 Amendments to the FDCA were intended to allow FDA jurisdiction over medical devices to ensure that the device itself and its use did not pose a risk to the safety or health of the public. The FDA asserted its jurisdiction and created extensive regulations applicable to medical devices. Unfortunately, the regulatory scheme proved to be overly burdensome. In addition to preventing the distribution and use of unsafe medical devices, the delays in reviewing the required application documentation prevented the use and distribution of many safe and helpful medical devices.

1. Defining a Medical Device

> The FDCA defines a device at 21 U.S.C. § 321(h) as:
> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is
> (1) recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and
> which is not dependent upon being metabolized for the achievement of its primary intended purposes.[45]

Only one of the three elements listed above must be present to classify an object as a medical device. This definition is extremely broad and can be interpreted to cover a vast array of products.[46] In fact, this definition gives the FDA jurisdiction over almost any device or product used in the medical field.

The FDA has found many products that are not widely regarded as

---

44. The following is a very basic, simplified overview of FDA regulation of medical devices. It is not meant to be comprehensive, but merely to give a quick glance at some of the main provisions.

45. 21 U.S.C. § 321(h).

46. Committee of Dental Amalgam Mfrs. and Distribs. v. Stratton, 92 F.3d 807, 810 (9th Cir. 1996).

devices intended for medical purposes to be medical devices under § 321(h). Such products include an E-meter (a polygraph-like device used by the Church of Scientology allegedly to cure disease),[47] a vinyl-covered bed with speakers mounted on the sides,[48] and phonograph records.[49] The FDA has also regulated devices that never have any direct contact with patients, such as laboratory specimen collection containers[50] and surgical instrument sterilizers.[51]

The courts found that in determining whether a device qualifies as a medical device for regulatory purposes, first the court "must give broad deference to the FDA's reasonable interpretation of the statutory scheme that it is entrusted to administer."[52] Additionally, no direct contact with patients was necessary for an item to be a device. "Indeed, even device 'accessories' and 'components' intended for use in devices standing alone, constitute devices."[53] The court stated:

> [T]he Supreme Court noted that Congress intended products "such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches" to be devices. The inclusiveness of such items as devices reflects Congress' clear intent to characterize "basic aids used in the routine operation of a hospital . . ." as devices.[54]

One Senator lamented "[t]he language [of the bill] is broad enough to cover any device of which the Food and Drug Bureau of the Agricultural Department chooses to take jurisdiction."[55] The courts have generally given broad discretion to decisions of the FDA as to the devices subject to regulation under § 321(h).

Most medical devices fall under § 321(h)(2) as "intended for use in the diagnosis . . . cure, mitigation, treatment, or prevention of disease . . . ."[56] Almost any of the components of a telemedicine system could fall under this provision. After all, the purpose of telemedicine is to allow

---

47. United States v. Article or Device, "Hubbard Electrometer", 333 F. Supp. 357 (D.D.C. 1971).

48. United States v. One Labeled Unit, 885 F. Supp. 1025 (N.D. Ohio 1995).

49. United States v. 23, More or Less, Articles, 192 F.2d 308 (2d Cir. 1951).

50. Clinical Reference Lab., Inc. v. Sullivan, 791 F. Supp. 1499 (D. Kan. 1992).

51. United States v. 22 Rectangular or Cylindrical Finished Devices, 714 F. Supp. 1159 (D. Utah 1989).

52. *Clinical Reference Lab.*, 791 F. Supp. at 1509.

53. *22 Rectangular or Cylindrical Finished Devices*, 714 F. Supp. at 1164.

54. *Id.* at 1164 n.12 (quoting United States v. Article of Drug, Bacto-Unidisk, 394 U.S. 784, 800 (1969)).

55. United States v. 25 Cases, More or Less, of an Article or Device, 942 F.2d 1179, 1182 (7th Cir. 1991) (alterations in original).

56. 21 U.S.C. § 321(h)(2) (1994).

for the treatment, diagnosis, or prevention of disease using communications services to connect the doctor and patient. It is not much of a jump for the FDA to attempt to regulate telemedicine systems either as a whole or to regulate parts of such systems. The broad definition of a medical device in § 321(h) would allow regulation of virtually any part of a telemedicine system, including communications equipment and services.

2. Classifying Medical Devices

Once an item is found to be a device under § 321(h), it must be classified. The FDA places devices into one of three categories based upon the level of risk they create to the health and safety of both the patients and health care providers.[57] Class I is the classification applicable to devices creating the lowest risk,[58] therefore subject to the least regulation.[59] The general controls for Class I devices are applicable to all devices regardless of their classification.[60] Devices placed in Class II create more risk than those in Class I and are subject to additional controls to ensure their safety.[61] Most medical devices are placed in Class II.[62] Class III devices pose the greatest risk, requiring the most scrutiny, including premarket approval by the FDA.[63] All new devices that are not substantially equivalent to a device existing prior to the 1976 amendments are automatically placed into Class III.[64]

a. Class I Devices

The Class I general controls are applicable to all medical devices. They include requirements placed on adulterated devices;[65] requirements for misbranded devices;[66] registration;[67] inspection of premises require-

57. Frank D. Nguyen, *Regulation of Medical Expert Systems: A Necessary Evil?*, 34 SANTA CLARA L. REV. 1187, 1205 (1994); 21 U.S.C. § 360c(c).

58. Nguyen, *supra* note 57, at 1206. Devices placed in Class I include "tongue depressors, elastic bandages, ice bags, and bedpans." *Id.*

59. 21 U.S.C. § 360c(a)(1)(A) (1994).

60. Nguyen, *supra* note 57, at 1206.

61. 21 U.S.C. § 360c(a)(1)(B).

62. Nguyen, *supra* note 57, at 1206. "Class II devices include syringes, bone plates, hearing aids, resuscitators, and electrocardiograph electrodes." *Id.*

63. 21 U.S.C. § 360c(a)(1)(C); Nguyen, *supra* note 57, at 1206. Examples of Class III devices are "pacemakers, intra-uterine contraceptive devices (IUDs), artificial hearts, and artificial joints." *Id.*

64. 21 U.S.C. § 360c(f)(1).

65. *Id.* § 351.

66. *Id.* § 352.

67. *Id.* § 360(b).

ments;[68] listing of devices manufactured;[69] premarketing notification;[70] notification of risk to purchasers and users of the device;[71] reporting of adverse effects of the device;[72] and good manufacturing practice requirements.[73]

While this is a very simplified glance at the Class I requirements, the effect of the above requirements on manufacturers of telemedicine devices or systems can still be seen. Particularly, the requirement that notice be given to the FDA prior to marketing of such systems or certain components of the system intended for use in telemedicine will deter companies from developing and marketing such devices. Additionally, compliance with the good manufacturing requirements and premises inspection requirements may call for such a change in the way businesses manufacture that it will not be economically feasible for them to comply. Rather, businesses will simply not market their components and systems for use in a telemedicine context.

b. Class II Devices

Class II devices are subject to additional regulations beyond the general controls for Class I devices. The special controls or performance standards for Class II devices can include "promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, . . . recommendations, and other appropriate actions as the Secretary deems necessary to provide [reasonable] assurance [of the safety and effectiveness of the device]."[74] Rather than being generally applicable to all Class II devices, these special controls are often imposed on a device-by-device basis.[75] Due to the large number of devices in Class II,[76] the process of issuing standards for all Class II devices is daunting. Administrative regulations for classifying devices further hinder the process.[77] Consequently, few performance standards for Class II devices have been issued.[78] This in practice eliminates the distinction be-

68. *Id.* § 360(h).
69. *Id.* § 360(j).
70. *Id.* § 360(k).
71. *Id.* § 360i.
72. *Id.* § 360h.
73. *Id.* § 360j.
74. *Id.* §§ 360c(a)(1)(B), 360d(a)(1).
75. Nguyen, *supra* note 57, at 1207.
76. David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 361 (1987).
77. *Id.*
78. *Id.*

tween Class I and Class II devices because until Class II standards are created, compliance with the general Class I standards is all that is required.[79]

c. *Class III Devices*

Premarket approval (PMA) is required for all Class III devices. Premarket approval requires the manufacturer to file an application showing that the device is safe and effective;[80] describing the components and properties of the device;[81] the methods used in manufacturing and packaging the device;[82] and the proposed labeling for the device.[83] Additionally, PMA allows only that particular applicant to market the device.[84] If another manufacturer desires to market its own version of the same device, it must go through the PMA process anew for its version of the device.[85] The FDA is required to act on applications for PMA within 180 days of receipt.[86] However, in practice the process takes approximately one year.[87]

The long delay in obtaining PMA for telemedicine systems and/or their components will severely hinder the development and application of telemedicine. As rapidly as communications technology changes, a one-year delay in receiving PMA is equivalent to an eternity. Manufacturers cannot sell any Class III device or system until the device has received PMA. If forced to wait a year or longer for approval, the technology that the approved system was based on may become obsolete and uneconomical to produce. Without an economic incentive to produce these systems and components, manufacturers will withdraw from the market, to the detriment of telemedicine.

B. *Current FDA Attempts at Regulation of Telemedicine Systems and Components*

The FDA has provided no clear guidance regarding the role it will take in the regulation of telemedicine systems. Thus far the FDA has made no attempts to regulate telemedicine systems as a whole, and has done relatively little to regulate the individual components of such systems, be-

---

79. *Id.*
80. 21 U.S.C. § 360e(c)(A) (1994).
81. *Id.* § 360e(c)(1)(B).
82. *Id.* § 360e(c)(1)(C).
83. *Id.* § 360e(c)(1)(F).
84. Kessler, *supra* note 76, at 359.
85. *Id.* There are limited exceptions to this rule; most significantly, manufacturers are allowed to use data from other PMA applications once it has been accepted by the medical community.
86. 21 U.S.C. § 360e(d)(1)(A).
87. Kessler, *supra* note 76, at 359.

yond regulating "traditional" medical devices used in telemedicine.[88] The lack of guidance from the FDA poses a huge problem for those developing such systems, for those manufacturing components of the systems, and for those health care providers purchasing a system—only to later find out it does not comply with newly created FDA regulations. The problem of compliance with FDA regulations may also arise because many of the systems used today are "adaptations of existing teleconferencing or desk top computer systems which were originally designed for purposes other than health care delivery."[89] It is unlikely that a computer manufacturer will be willing to change its manufacturing process and procedures to comply with FDA regulation of a manufacturer's system when the system was not intended for medical use and can be marketed for numerous other profitable applications.

Despite the problems of regulating telemedicine, it is unlikely that the FDA will simply decline to assert jurisdiction over telemedicine. The Telemedicine Report to Congress states "[w]ith respect to telemedicine, the FDA is responsible for ensuring the safety and effectiveness of telemedicine devices marketed in the United States."[90] The FDA is beginning to take steps to regulate telemedicine. It has already started to regulate hardware, specifically teleradiology systems and medical imaging systems.[91] What, if any, regulation other hardware will be subject to remains unclear.[92]

A key component or area that the FDA is beginning to regulate is software used in telemedicine systems. However, exactly what is regulated and to what extent is unclear. Several draft policies have been issued, but they do not have the force of regulations.[93] The policies have recognized some software as medical devices.[94] Other software is currently regulated on an ad hoc basis.[95]

---

88. These "traditional" medical devices include those devices which are merely hooked into the telemedicine system or used during the telemedicine consult, but would also be used in a regular face-to-face consultation. Some such devices are: stethoscopes, an EKG machines, heart monitors, and x-ray machines.

89. TELEMEDICINE REPORT, *supra* note 11, pt. V.A.

90. *Id.*

91. COUNCIL ON COMPETITIVENESS, HIGHWAY TO HEALTH: TRANSFORMING U.S. HEALTHCARE IN THE INFORMATION AGE (Mar. 1996) <http://nii.nist.gov/pubs/coc_hghwy_to_hlth/hii.txt> [hereinafter HIGHWAY TO HEALTH].

92. *Id.*

93. *Id.*

94. Center for Devices and Radiological Health, FDA, Software Policy Workshop: FDA Regulation of Medical Device Software (Sept. 3-4, 1996) (points prepared for discussion available at <http://www.fda.gov/cdrh/ost/points.html>).

95. Center for Devices and Radiological Health, FDA, Software Policy Workshop:

If the FDA uses the traditional approach to medical device regulation, it has the option of simply labeling the software as a general purpose device; as such the software is not subject to regulation.[96] In an FDA software policy workshop, several examples falling into this category of general purpose devices included programs controlling computer hardware that were not specifically designed for medical applications, as well as "off-the-shelf" software such as word processing programs and database programs.[97] The communications software used in most telemedicine systems was not designed for a medical application and would seem to fall into the category of general-purpose devices.

Alternatively, it has been suggested that if the software is an accessory, used in conjunction with another device regulated by the FDA as a medical device, the software could be subject to the same level of regulation as the associated device.[98] This seems to indicate that communications software used as part of a telemedicine system could be subject to FDA regulation if it is found to be an accessory to another regulated device. For example, communications software could be viewed as an accessory to traditionally regulated devices, such as radiology equipment. The software could enhance the equipment by allowing the images to be transmitted via wire lines to a remote physician. Thus, the software becomes an accessory to the radiology equipment, and the FDA can regulate the communications software.

In its *Guidance for the Content and Review of 510(K) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices* (*Guidance for PACS*), the FDA, through the Center for Devices and Radiological Health, seems to include communications software as a medical device subject to regulation. The document begins by stating "[t]his guidance is applicable to picture archiving and communications systems (PACS). PACS are systems which are intended to provide transmission, storage and viewing facilities for medical diagnostic images at distributed locations."[99] In essence, PACS are the "linchpin" of many telemedicine systems,[100] and the *Guidance for PACS* seems to indicate that

---

Classification and Risk-Based Criteria (Sept. 3-4, 1996) (points prepared for discussion available at <http://www.fda.gov/cdrh/ost/classif.html>).

96. *Id.*

97. *Id.*

98. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA, GUIDANCE FOR THE CONTENT AND REVIEW OF 510(K) NOTIFICATIONS FOR PICTURE ARCHIVING AND COMMUNICATIONS SYSTEMS (PACS) AND RELATED DEVICES (visited Jan. 30, 1998) <http://www.fda.gov/cdrh/ode/odeot416.html> [hereinafter GUIDANCE FOR PACS].

99. *Id.*

100. TELEMEDICINE REPORT, *supra* note 11, pt. V.

PACS systems can and will be regulated as medical devices.

The *Guidance for PACS* then states that it is also applicable to related devices that perform functions provided by PACS, including image communications equipment, both networks and interfaces.[101] This would give the FDA jurisdiction to regulate not only communications software but communications networks as well. This is a frightening proposition for those developing and maintaining networks and providing communications services. Confusing the issue further, the document goes on to state:

> The guidance does not apply to general purpose devices if they are not specifically indicated or promoted for use in conjunction with medical images. These products are not considered to be medical devices and premarket notifications are not required. Examples of such devices include general purpose communications systems, data storage media and software. However, if general purpose devices are indicated or promoted for medical use, a 510 (k) must be submitted. Also, if they are sold as a PACS component, they must be described in the 510 (k) for the system.[102]

The applicable level of FDA regulation seems to depend on whether manufacturers indicate or promote the device for medical use. If they promote it for medical use, then they are subject to the entire gambit of FDA regulation. If they simply allow their device to be used as a component but do not promote it for medical use, then the device only needs to be described in the required documentation for the PACS system, rather than being subject to its own separate review. To subject two different manufacturers making an essentially identical product, ultimately used in the same manner in a telemedicine system, to different levels of regulation based on how they promote their product makes little sense.

Other approaches have been suggested for the regulation of devices containing software, such as establishing levels of concern and regulating based upon the level of concern or risk the device creates, rather than the traditional class system. The FDA drafted such a proposal, and the proposal indicated that some level of scrutiny would be applied to software regardless of whether it was general purpose software or software designed for medical uses.[103]

So far, the FDA has issued no consistent, clearly articulated regulations or policies regarding communications software used in telemedicine systems. The documents currently available provide little assistance to those manufacturing or developing telemedicine systems or the software for such systems. Despite the lack of specific guidance from the FDA, it

101. GUIDANCE FOR PACS, *supra* note 98.

102. *Id.*

103. *See* HIGHWAY TO HEALTH, *supra* note 91, ch. 5.

appears that the FDA has adopted an approach of regulating the individual telemedicine system components rather than regulating the systems as single units or single medical devices. This has important implications for those involved in creating and developing both the components of such systems and the systems themselves.

IV. APPROACHES TO FDA REGULATIONS OF TELEMEDICINE AND THEIR IMPLICATIONS

When evaluating approaches to the regulation of communications hardware and software used in telemedicine and their implications, it is important to remember exactly what parts or components are involved in a telemedicine system. The actual computer hardware and software used to run the systems at the health care provider's office; the communications software used by the health care provider; the modems; the video cameras; the monitors; the specialized medical equipment that is connected to the system; the communications software used by the communications service provider (such as AT&T, MCI, and Ameritech); the hardware (copper lines, fiber-optic cable, satellites, etc.) used by the service provider to transmit the data; and the method in which the information is sent are each potentially subject to regulation under the current, broad definition of a medical device.

The FDA has several options in attempting to regulate telemedicine systems and components. One is to regulate the systems as a whole or as a single medical device. But to set out one regulatory scheme or approach applicable to all the different components within a system is a complex, virtually impossible task. Some components of a system pose a greater risk to the safety and health of patients and users than others. Different systems pose varying levels of risk depending on their applications. Regulations appropriate for medical software used for telemedicine may not be appropriate for the cables transmitting the information to its destination.

Regulating systems as a whole would require the FDA to regulate not only the communications software and hardware, but also the equipment used to transmit the data and the manner in which the data is transmitted. Any regulation would cover the communications service provider's hardware and software as well as the individual communications software used by the health care provider. It is questionable whether it is desirable for the FDA to become involved in regulating communications in any aspect, and the communications companies are unlikely to agree to stricter standards in their hardware, software, and procedures—especially if it increases their costs. Rather than incur additional costs related to FDA compliance, manufacturers will simply market their communications software and hardware for other more profitable applications, and withdraw from the telemedicine

market.

Further, any change in the system could require new approval for the entire system.[104] Each time a device is changed, no matter how minor the change, FDA approval is required.[105] The use of new cable or wire could place the system behind all of the other devices awaiting FDA approval. An already backlogged FDA is unlikely to provide quick approval, even for minor changes.[106] All of these factors lead to the conclusion that FDA regulation of telemedicine systems as a whole is not desirable or feasible. Wisely, the FDA does not appear to be aggressively pursuing this approach.

A second approach, similar to the current stance taken by the FDA, is to individually regulate each component of telemedicine systems. This approach addresses many of the concerns about regulating the systems as single medical devices. Regulation on a component-by-component basis allows consideration of the different levels of risk created by the different components, and allows for varying levels of regulation based on the level of risk.

This also avoids new FDA approval for the entire system each time one component is changed. Approval can be sought only for the component that is changed. The effect of the change on the entire system can be documented and submitted, but there is no need to redocument the entire system for new FDA approval.

The biggest advantage of regulating the components of the system individually is the possibility of the FDA exempting certain portions of the systems from FDA regulation. As discussed previously, FDA regulation of the communications industry is troublesome. This will allow exemption of communications hardware and software, particularly PACS. The FDA can continue to regulate those components that are truly medical devices and are used directly in the diagnostic process. For example, x-ray systems, CAT Scan systems, and heart monitors would still be regulated by the FDA. However, those components dealing with other functions, such as communications, data processing, and management, could be excluded from FDA regulation. Freeing communications software providers and developers from potential FDA regulation would encourage their active participation in telemedicine projects and would be a huge boost to the development of telemedicine. Communications service providers are much

104. *See Software CBER Short on Experts, Long on Blood Software 510(k)s*, MED. DEVICE APPROVAL LETTER, July 1, 1996, *available in* 1996 WL 8642124.

105. HIGHWAY TO HEALTH, *supra* note 91, ch. 5.

106. *See 510(k)s Submitted for Blood Bank Software*, MED. DEVICE APPROVAL LETTER, April 1, 1996, *available in* 1996 WL 8642107.

more likely to support telemedicine if their involvement does not impose additional regulations and costs.

Communications providers will continue to be subject to the regulations imposed by other regulatory agencies, but will not have the additional burden of FDA regulation. Due to the crucial nature of the data being transmitted, higher standards may be desirable. However, if such standards cause the service providers to withdraw from the market, then the benefits of telemedicine are lost. Any risk of mistransmission or a total loss of data can be distributed between the parties involved through individual contracts allocating the risk. By allocating the risk via contract, each party will know what their potential liability is and will be able to act accordingly.

Although regulation on a component-by-component basis is more desirable than regulation of entire telemedicine systems, a component-by-component approach will work only if the FDA acts reasonably with regard to the components of telemedicine systems over which it attempts to assert jurisdiction. While initially regulating only "traditional" medical devices, the FDA is increasingly moving toward broader assertions of jurisdiction. As it attempts to regulate more and more aspects of telemedicine systems and computer software, more problems will arise.

Software manufacturers or developers are in an especially problematic position to deal with FDA regulation. With each new version of the software, new FDA approval would be necessary. Every change to eliminate a bug in the program could potentially require additional FDA approval. Requiring essentially continual FDA approval for every change in the software "'will have a chilling effect on the evolution of software technology.'"[107] Even if approval is granted in a mere six to seven months, [108] well within the current time frame of one year, the software will be out of date upon its approval. Consequently, telemedicine systems will be forced to use outdated software, often with known and correctable errors, due to lack of FDA approval of the updated version.

This dilemma and its results can be seen in the context of blood bank software. Once the FDA asserted jurisdiction over blood bank software and promulgated regulations, the number of developers and manufacturers immediately began to decrease. "'Some software developers have already with drawn [sic] from the blood bank market. They feel it's not that large of a market for them, and feel that software changes are sort of an evolutionary thing, and that any software upgrade would require a resubmis-

107. *Id.* (quoting Edward Allera of Akin, Gump, Strauss, Hauer & Feld).
108. *Id.*

sion.'"[109]

A similar result is likely to occur in the communications software industry. As the FDA begins to assert jurisdiction over communications software used in telemedicine, developers of such software will leave the market rather than incur the additional costs of compliance with FDA regulation. This is especially true since communications software has a multitude of nonmedical applications that do not require compliance with burdensome regulations.

While it is not apparent that the FDA needs to regulate communications software to ensure the safety and effectiveness of telemedicine systems, if it is unwilling to decline jurisdiction, it must take a different approach to the regulation of communications software. New guidelines specifically for software must be created. Rather than regulate software through the traditional scheme now in place for medical devices, software could be dealt with separately on an expedited basis. Thus the rapid changes and limited life of software could be taken into account, allowing telemedicine systems to use updated and current software without awaiting slow, traditional FDA approval.

V. CONCLUSION

Telemedicine systems and their components fall under the broad definition of medical devices set out in 21 U.S.C. § 321(h). Technically, there is nothing to prohibit the FDA from asserting its jurisdiction over telemedicine systems or components. Already the FDA has begun to regulate some components of telemedicine systems and is beginning to regulate PACS and other related communications software.

The current lack of clear guidance on the regulation of communications software and PACS will hinder the development and use of telemedicine. Clearer policies and guidance on the FDA's approach to telemedicine systems are essential. Without them, systems manufacturers and developers will be wary of entering the market, not knowing whether they are in compliance, and whether they will be subject to penalties for noncompliance.

As the FDA attempts to regulate telemedicine, a decision has to be made whether to regulate the systems as a whole or as individual components. Although the FDA appears to have adopted a reasonable, component-by-component approach, it remains to be seen how it will implement that approach. The FDA's actions on this point will dramatically affect the future of telemedicine.

---

109. *Id.* (quoting Carolyn Jones, HIMA Director of Technology and Regulatory Affairs).

If the FDA asserts jurisdiction over all components in telemedicine systems, including communications hardware and software, the results will be disastrous. As communications services are finally becoming deregulated, the last thing the providers want is to comply with additional FDA regulations, especially since telemedicine is likely to be a small part of their overall market. Without communications services, telemedicine is at a standstill. Maintaining an appropriate balance between regulation to ensure safety of telemedicine systems and deregulation of the communications industry is essential to the future success of telemedicine.