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ARTICLES

CYBERSURGERY: INNOVATION OR A MEANS TO CLOSE COMMUNITY HOSPITALS AND DISPLACE PHYSICIANS?

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I. INTRODUCTION

In late 2001, the world's first cybersurgical procedure was performed.[1] Cybersurgery is a surgical technique that allows a surgeon, using a telecommunication conduit connected to a robotic instrument, to operate on a remote patient.[2] Cybersurgery, because of its complex interactions between man and machine, clearly has the potential to cause significant human injury.[3] Thus, although cybersurgery has the potential to bring cutting edge surgical intervention to the rural United States, to the front line of a battle field, or even to rescue an astronaut with appendicitis;[4] the key issue that will determine cybersurgery's mar-

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1. *See* Angela Doland, *Fast Signal Across 4,000 Miles Made Operation Possible*, Chi. Trib. A1 (Sept. 20, 2001) (describing how on Sept. 7, 2001, Dr. Jacques Marescaux located in Manhattan, and connected by 4000 miles of transatlantic fiberoptic cable to *Zeus* robotic instrument, removed the gallbladder of a patient located in Strasbourg, France).

2. Thomas R. McLean, *Cybersurgery: An Argument for Entertainment Liability*, 23 J. Leg. Med. 167, 167-68 (2002) [hereinafter McLean, *Cybersurgery*].

3. *Id.* at 179-80 (discussing the three-ring circus hypothetical where the actions of a cybersurgeon, products manufacturer and a telecommunication conduit harm a patient in a manor that suggest indivisible injury).

4. *Id.* at 170-72.

ket value will be whether cybersurgery can be made safe.[5] Yet, this same market potential, and hence potential profits, will mean that providing safe cybersurgery will be irresistible to well-financed health care providers.[6]

One mechanism to make cybersurgery safe is to require its operators to have enterprise liability coverage.[7] As used here enterprise liability is a system under which a business organization that provides a medical service becomes the exclusive bearer of liability for all medical negligence, regardless of any actor's status, then enterprise liability is the superior method to assign liability for cybersurgery because a rational compensation scheme allows for injuries caused by cybersurgery to be accurately rewarded.[8]

However, using enterprise liability to provide health care providers with the proper financial incentives to operate the robotic instrument correctly is neither an exclusive nor a surefire mechanism to make cybersurgery safer. Technology, itself, offers another independent solution to make cybersurgery safer: the automatic surgeon. Just as the use of an automatic pilot makes flying an airplane safer by removing the human pilot from the operation of the plane; so too will an automatic surgeon make cybersurgery safer by removing the human surgeon from much of the cybersurgical procedure. Because automatic cybersurgery will eliminate human error and makes greater use of physician extenders, rather

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5. *Id.* at 208-09. "Arguably, the only two rational justifications for performing cybersurgery are to facilitate patient care in a remote areas; and second to have only the most qualified surgeons provide surgical services in order to avoid having to pay for the remedial care provided by marginal surgeons." *Id.* Thus, unless cybersurgery can be made as safe as traditional surgery, where the surgeon is at the patient's side, the added expense of cybersurgery is of questionable medical value. *Id.* However, as a marketing tool, to demonstrate that a hospital is on the cutting edge of technology, is another question. *Id.*

6. P. Greg Gulick, *The Development of a Global Hospital Is Closer Than We Think: An Examination of the International Implications of Telemedicine and the Developments, Uses and Problems Facing International Telemedicine Programs*, 11 Ind. Int'l & Comp. L. Rev. 183, 185 (2000) [hereinafter Gulick, *Global Hospital*] (citing H.R. Subcomm. on Veteran's Affairs, *VA Health Care and Technology*, 101st Cong. (1994)). Cybersurgery, because it is still in its infancy, has little in the way of hard-figure market analysis. However, if one looks to the telemedicine market, in general, it has been estimated to be forty to sixty billion dollars market. (Statement of Michael D. McDonald, Senior Advisor, Health and Telecomm., The C. Everett Koop Institute). This forty to sixty billion dollar market is predicated only on the domestic market; and ignores the interesting and yet untapped market for cybersurgery to be exported by U.S. surgeons to other countries. *Id.* at 183. However, the actual size of the telemedicine market remains in dispute. *See DeBakey Corp. v. Raytheon Serv.*, LEXIS 14947 (Del. Ch., Aug. 25, 2000).

7. Gulick, *Global Hospital, supra* n. 6, at 205-10.

8. *Id.* at 205; *see also* Thomas R. McLean, *Crossing the Quality Chasm: Autonomous Physician Extenders Will Necessitate a Shift to Enterprise Liability Coverage for Health Care Delivery*, 12 Health Matrix 227 (2002) [hereinafter McLean, *Crossing*] (discussing enterprise liability from another point of view).

than physicians, is certainly consistent with the recommendation of the Institute of Medicine for making our health care system safer and more cost effective.[9]

Because of the high cost to enter the market, cybersurgery will only be provided by centers of excellence and centers with deep pockets that provide high quality and high volumes of specialized services. Thus, cybersurgery is compatible with another paradigm shift in health care. Government and quasi-governmental agencies are reforming our health care system so that care is increasingly provided by centers of excellence rather than community hospitals.[10] Dr. Ken Kizer, the CEO of the National Quality Foundation ("NQF") has remarked that in the future, health care providers who work within the system, will be rewarded; while those who do not, will not be part of the system.[11] As market forces close surplus community hospitals, health care providers who are compliant with the NQF's clinical guidelines will be rewarded by being asked to join the staff of a center of excellence. Thus cybersurgery, as with any inchoate technologic innovation, is associated with a plethora of sociologic, and hence legal, questions. What happens to the community hospital and its physicians when they cannot afford the technology to enter the market? Is our capitalistic society going to allow centers of excellence to using far-reaching cybersurgical instruments, and more generally, telemedicine, to raid the markets of community hospitals? And if we do allow centers of excellence to wield cybersurgerical technology to usurp market share from community hospitals and physicians, do the community hospital and physicians have any legal recourse?

This article intends to further the discussion of the place of cybersurgery in the U.S. health care system of the twenty-first century. Part II reviews the field of cybersurgery and how the automatic surgeon will make off-line remote surgery possible. Because the off-line automatic surgeon will improve patient safety during remote surgery, surgeons, both in the United States and abroad, for the first time will be able to globally export their expertise. Part III examines the global economy. The need for the United States to compete in a global economy, means than an invisible hand must be used to control health care costs. To com-

9. Comm. on Quality of Health Care in Am., Inst. of Med., *Crossing the Quality Chasm: A New Heath Care System for the 21st Century* (2001) [hereinafter *Quality Chasm*]; Comm. of Quality of Health Care in Am., Inst. of Med., *To Err Is Human: Building a Safer Health System* 1 (Linda T. Kohn et al. eds., 2000) [hereinafter *To Err Is Human*]; *see also* Thomas R. McLean, *The Implications of Patient Safety Research & Risk Managed Care*, 26 S. Ill. U. Law L.J. 227 (2002) [hereinafter *Implications*] (discussing the implications of these two Institute of Medicine reports).

10. Thomas R. McLean, *Application of Administrative Law to Health Care Reform: The Real Politic of Crossing the Quality Chasm* 16 J. L. & Health 1 (2002).

11. Ken Kizer, Speech, The Cerner Millennium Health Imperative Conf. (Kan. City, Mo. Sept. 11, 2001).

pete effectively the United States needs to achieve economies of scale in the health care sector. This paradigm shift, which favors a center of excellence using cybersurgery, will unleash economic forces that will encourage the closure of community hospitals and the displacement of physicians into the general work force. Part IV examines the ability of the community hospitals and physicians to protect themselves with trade barriers and antitrust laws. This article concludes that, while trade barriers and antitrust laws may retard the implementation of newer medical technology, trade barriers and antitrust laws will not provide adequate protection because such legal devices are designed to protect competition and not the individual competitors like a community hospital and its surgeons.

II. THE AUTOMATIC CYBERSURGEON

A. THE APPLICATION AND LIMITATIONS OF CYBERSURGERY

1. *Background*

Because cybersurgery is impossible without robotic instrumentation, it seems reasonable to set the birth of cybersurgery to the year 2000 when Intuitive Surgical's[12] *da Vinci*[13] Surgical System "became the first surgical robot approved by the U.S. Food and Drug Administration."[14] Shortly thereafter, Intuitive Surgical's only other serious competitor in the market, Computer Motion,[15] obtained approval for its computer robotic instrument: *Zeus*. *da Vinci* and *Zeus* are clearly different robotic instrumenst. For example, consider the differences in the imaging systems and the robotic arm of the two surgical instruments. The *da Vinci* robotic instrument is capable of providing the surgeon with true stereoscopic vision while *Zeus'* imaging system only provides the surgeon with a two-dimensional video screen. On the other hand, the *da Vinci* robotic arms respond only to manual commands, while *Zeus'* unique robotic arms are capable of responding to voice commends, in addition to manual commands.

Still, the two robotic surgical instruments, *da Vinci* and *Zeus*, have much in common. The business end of both the *da Vinci* and *Zeus* instruments consist of two articulating robotic arms that are capable of fine

12. Located at 1340 W. Middlefield Rd, Mountain View, Ca., 94043.

13. All of the products named in article are trademarked. For readability I have eliminated ™ symbol.

14. Jeremy Manier, *Assisted by Robotics, Doctors Performing Surgeries from Afar*, Chi. Trib. A1 (Oct. 10, 2000); *see also Intuitive Surgical da Vinci* <http://www.intuitivesurgical.com> (accessed Nov. 11, 2002) (stating at present FDA approval of this medical device is limited to the performance of cholecystectomies, Nissen fundoplications and the harvesting of internal mammary arteries).

15. Located at 130-B Cremona Drive, Santa Barbara, Ca. 93117.

motor work. Regardless of the machine, these robotic arms are linked by a fiberoptic cable to a control panel. It is from the control panel, and not the patient's side, that the cybersurgeon controls the robotic instrument during a cybersurgical procedure. Thus unlike the traditional surgeon who, of necessity, is physically required to stand next to a patient to operate with traditional hand-held surgical instruments, the cybersurgeon is not required to be anywhere near the surgical patient. In fact, during the world's first cybersurgical procedure, the operating surgeon was in New York while the patient was in France.[16] The distance that can exist between cybersurgeon and patient is limited, not by the cost of the cable between the two, but rather by inherent delay associated with the transmission of the electromagnetic signal down the fiber optic cable that connects the control panel to the robotic arms.[17] The actual delay associated with fiberoptic cable transmission is determined by both the physical distance between the cybersurgeon and patient and the complexity of the telecommunication connection between the two and the complexity of the telecommunication conduit.[18] After cybersurgery evolves beyond the prototype stage, it is expected that the fiberoptic cable telecommunication circuit between the cybersurgeon and patient will be eliminated, as fiberoptic transmission is supplanted by broadband technology.[19]

Without question cybersurgery offers society potential benefits. An earth-bound surgeon could operate on a patient located on a space station or a patient trapped in a biologically contaminated battlefield.[20] Because time after an episode of urban violence or a motor vehicle accident is critical,[21] by bringing a cybersurgeon and a surgical theater to the pa-

16. *See* Doland, *supra* n. 1, at ¶¶ 1-3.

17. The delay associated with signal transmission determines whether coordinated purposeful movement can be achieved. To understand this it must be realizes that humans are not capable of coordinating movement when the time between a signal's initiation in the brain and the corresponding movement is delayed by more than 100 msec.

18. Lynda A. Cleveland, Interview, Telecomm. Atty. (Overland Park, Kan. Oct. 1, 2001). In fiberoptic systems, transmission of a telecommunication signal is most substantially delayed by "roators" or switches in the circuit. *Id.* That is in fiberoptic cable transmitters, roators are the rate-limiting step. *Id.* To illustrate the importance of roator in cybersurgery, consider the fact that a trans-oceanic phone line has been used in all of the prototype cybersurgical procedures. *Id.* While other consideration may have played a factor, at least one reason for using a trans-oceanic connection is that such a connection keeps the number of roators to a minimum. *Id.*

19. McLean, *Cybersurgery*, *supra* n. 2, at 172-73.

20. Susan E. Volkert, *Telemedicine: Rx for the Future of Health Care,* 6 Mich. Telecomm. & Tech. L. Rev. 147, 148-49 (2000). "A mobile telemedicine platform was employed by the U.S. military in Bosnia. Because there were radiologists, orthopedists and other specialists in the United States to immediately address soldiers' illnesses or injuries, soldiers did not need to evacuate to Germany." *Id.*

21. McLean, *Cybersurgery, supra* n. 2, at 171 n. 21. "A line of medical reports from the Ben Taub Hospital in Houston Tx. supports the conclusion that survival after major

tient, rather than bringing the patient to the surgeon via an ambulance, cybersurgery would be expected to improve patient outcome after major trauma.[22] Cybersurgery would facilitate the security requirement associated with providing medical attention for prisoners by eliminating the need to transport the prison for needed surgery intervention.[23] Even the cybersurgeon would benefit from operating remotely on a patient because the surgeon's hands are not actually exposed to a patient's blood; therefore the cybersurgeon would have less occupational exposure to blood born diseases.[24]

2. *The Limitations of Cybersurgery*

But there is more than the (roughly) one million dollar price tag associated with a *da Vinci* or *Zeus* instrument that will hinder broad based acceptance to cybersurgery. Because cybersurgery adds complexity to traditional surgical intervention, it is to be expected that cybersurgery will carry with it some unique risks. I have previously illustrated these unique risks with the following hypothetical:

> A surgical instrument manufacturer obtains 510(k) FDA approval for a cybersurgical control panel and remote robotic instrument based on the instrument being a substantial equivalent to laparoscopic surgical instrument already on the market. The manufacturer contracts with a national telephone company to provide the necessary connections to link the control panel located in a large urban area to a remote rural location in the same state. Later, during a routine cybersurgical cholecystectomy, the cybersurgeon sits at the control panel, views the screen, and gives a command to the remote robotic instrument to cut the cystic duct so that the gallbladder can be removed. As the surgeon presses the button to close the scissors, the surgeon observes that the operative field begin to shake and suddenly the computer screen goes momentarily blank. When the image returns to the computer screen, the field of view is entirely red. The telephone located next to the surgeon rings, and the surgeon is told that his patient has just expired. (At autopsy the patient's aorta was found to be lacerated which accounted for the patient's death by exsanguation and hence, the red field of view on the surgeon's computer screen.) The remote site surgical staff files an incident report per accreditation requirement protocol. The report commented that just prior to the patient's demise, a physician's assistant inadvertently bumped into the robotic instrument. In the evening paper, the telephone company acknowledged that (just prior to the patient's death) there had been a fire at one of the telephone company's

trauma is dependant on getting the trauma victim to surgeon as quickly as possible; or relevant to cybersurgery getting the surgeon to the trauma victim." *Id.*

22. *Id.* at 171.

23. *Id.*

24. *Id.* at 172.

switching stations, causing the telephone service to the surgical suite to be momentarily interrupted.[25]

All of the events described in this hypothetical are based on real occurances; I have only manufactured the sequence. While such a sequence of events may never actually happen, it is still important to recognize that the performance of cybersurgery, which is dependant on a real-time telecommunication connection, has associated risks that clearly are not present with the performance of traditional surgery. While the liability associated with traditional surgical intervention may involves at most two actors (the surgeon and the manufacturer of the surgical instrument); cybersurgery's unique dependence on the telecommunication conduit provider adds a third actor to the analysis of liability after a surgical misadventure. In the above hypothetical, the cybersurgeon, the robotic manufacturer and the telecommunication conduit all had some control over the instrumentality that caused the patient's injury. Thus, cybersurgerical misadventures that cause injuries raise an issue of whether the three actors indivisibly caused injury to a patient.[26]

In litigation associated with a traditional surgical misadventure, the surgeon and the product manufacturer are virtual adversaries, who are ready to point an accusatory finger at each other. In such cases the outcome is a settlement.[27] After a cybersurgical misadventure litigation will be more complex, not only because there will be three defendants: the cybersurgeon, the product manufacturer, and the telecommunication conduit provider; but also because a telecommunication conduit provider *is* a defendant. Under existing statutory and case law, the telecommunication conduit provider is not liable for any signal interruption.[28] This leads to the inescapable conclusion that, under current law, after a cybersurgical misadventure, the telecommunication conduit will not bare any liability. Thus, after a cybersurgical misadventure, both the surgeon and the product manufacturer will still point an accusatory finger at each other; but unlike traditional surgery litigation, in cybersurgery litigation both the surgeon and the robotic manufacturer may be truly innocent. The immunity of the conduit provider means that after a cybersurgical misadventure, the surgeon and the product manufacturer may be required to pay for an injury that was entirely caused by the negligent conduct of the telephone service provider. Consequently, using traditional medical malpractice calculus after a cybersurgical misadventure will provide awards that are entirely irrational.[29]

25. *Id.* at 179 (citations omitted).

26. *See generally Summers v. Tice*, 199 P.2d 1 (Ca. 1948).

27. McLean, *Cybersurgery, supra* n. 2, at 193.

28. *Id.* at 197-202.

29. *Id.* at 202-05.

Regardless of the liability associated with transmission interruption, if cybersurgery is to become a reality, then cybersurgery has to be made as safe as traditional surgery. One method to improve patient safety associated with cybersurgery is to provide financial incentives to the cybersurgical provider so that every effort is made to minimize risks. One such financial incentive would be to jettison traditional medical malpractice coverage and require that cybersurgical providers operate with enterprise liability coverage.[30] Specifically, if enterprise liability is

> defined as a system under which a business organization that provides a medical service becomes the exclusive bearer of liability for all medical negligence, regardless of any actor's status, then enterprise liability is the superior method to assign liability for cybersurgery because a rational compensation scheme allows for compensatory for cybersurgery negligence to be accurately rewarded.[31]

But, while enterprise liability provides incentives for safe surgery, it does not by itself provide for safer surgery.[32] One method to make cybersurgery safer is to perform more of the surgical intervention off-line. With a greater portion of surgery performed off-line, cybersurgery would be less vulnerable to transmission interruption.

B. The Automatic Surgeon; a Safety Devise for Cybersurgery

Cybersurgery could be made safer by two technological innovations. First, independent master surgeons located in a center of excellence, who are well-trained in cybersurgical technique, could supervise the surgical training of other surgeons; thereby minimizing the human injury associated with surgical learning curves. Second, the development of an automatic surgeon, analogous to an automatic pilot, would make cybersurgery safer by allowing for more of the surgical procedure to be performed off-line. These two techniques overlap and are not mutually exclusive.

1. *When Socrates Becomes Zeus Teacher*

A fundamental problem with technologic innovation in surgery, or in any field, is that the work force that receives the benefit of innovation is frequently insufficiently trained to properly handle innovation. This was well illustrated in the early 1990s when the laperscopic technique was introduced to the surgical world. Unlike traditional surgery that is performed through an open incision, laproscopic technique involves the per-

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30. *Id.* at 205-210; *see also* McLean, *Crossing, supra* n. 8, at 205.

31. McLean, *Cybersurgery, supra* n. 2, at 205.

32. *U.S. v. Carroll Towing,* 159 F.2d 169 (2d Cir. 1974) (stating risk benefit analysis contemplates new technology). Financial incentives to make cybersurgery safer should contemplate technological innovations. *Id.*

formance of a traditional surgical procedure through key-hole incisions with the aid of fiberoptic instruments. Because surgical anatomy is only 2-D when viewed through a fiberoptic scope, rather than the 3-D as viewed through an open incision, laparoscopic surgery was associated with a learning curve. That is, a surgeon's first 50-100 laperoscopic procedures were associated with excessive, often serious, complications when compared with the surgical results obtained with the traditional open technique. The reason these injuries occurred was that while "classical training in surgery produces technicians that have truly masterful hand-eye coordination, the hand-eye coordination requirements of laparoscopic surgeon are altogether different."[33]

Laperoscopic surgery illustrates, as did the introduction of the coronary artery bypass ("CABG") procedure did a generation earlier, that unleashing a new technology into the surgical world will result in excessive morbidly and mortality as surgeons learn what they are actually capable of performing. Turning loose a sophisticated surgical instrument on a technologically challenged market, as occurred with laparoscopic surgery and the CABG, is clearly foreseeable misuse.[34] Accordingly, an instrument manufacturer, whether it be a laparoscopic or robotic manufacturer, will face products liability unless the manufacturer can demonstrate that the surgeon is a learned intermediary.[35]

Enter *Socrates*. No, not the famous Greek teacher and philosopher; but rather the latest technological innovation from Computer Motion.[36] *Socrates* is the "first, and only, FDA-approved robotic telementoring system [that provides] a remote surgeon direct access to an operative environment."[37] While this is an accurate and concise description of *Socrates,* a little more detail is appropriate for those not familiar with the term "telementoring." Recall, Computer Motion refers to its cybersurgical system (i.e. the remote control panel connected two robotic arms) as *Zeus*. *Socrates* is, in essence, merely the addition of a second control panel to the cybersurgery system. However, the key feature of the *Socrates* control panel is that the surgeon using it has robotic arm priority over the surgeon at *Zeus* control panel. Because the surgeon at the Socrates control panel can override direction given by the surgeon at the *Zeus* control panel, the *Socrates* surgeon is functionally supervising or mentoring the

33. McLean, *Cybersurgery, supra* n. 2, at 175.

34. *Id.* at 193-96. A detailed discussion of products liability is beyond the scope of this article.

35. *Id.*

36. *See supra* n. 15.

37. Andy Lajoie, Letter, Sr. Dir., Prod. Mgt., Computer Motion (Feb. 14, 2002) (on file with author).

Zeus surgeon.[38]

Comments from Mr. Bill Day, a Computer Motion vice president,[39] indicated that Computer Motion developed *Socrates* precisely to insure that a learned intermediary exist to accept liability in the event of a products liability suit. Computer Motion has even gone so far as to develop a "four-step *Evolve Surgical Continuum*, which is designed for surgeons to safely and sensibly learn new robotic and endoscopic surgical techniques."[40] In the *Evolve Surgical Continuum* (which is in addition to training course that the company provides with purchase of their *Zeus* system) Computer Motion arranges for a company recognized "master" surgeon to mentor the new purchasers.

Without question *Socrates,* and instruments like it, are going to change the field of surgery. Because of the real risk of harm, when I teach surgery to residents I cannot always grab the scalpel out of a resident's hand to prevent a misadventure. Thus *Socrates'* ability to freeze or lock the robotic arms of *Zeus*, has unequivocal appeal to those who teach surgery.[41] Moreover, *Socrates* clearly raises the bar for the quality of continuing medical education ("CME").[42] When laparoscopic technique was introduced into the market place ten years ago, I, like all of my board certified surgical colleagues, took a weekend training course in laparoscopic technique that was put on by the makers of the laparoscopic instruments. (These weekend courses are analogous to the short courses currently provided by the surgical robotic manufactures incident to the sale of a robotic system.) Having completed the animal-model based course, I was now "certified" to perform laparoscopic surgery. Given the

38. Bill Day, Interview, Area Vice-Pres., Computer Motion at the Socy. of Thoracic Surgeon's Meeting (Ft. Lauderdale, Fla. Jan. 29, 2002). In Computer Motion's opinion the *Socrates* surgeon functions as teacher of *Zeus* surgeon in a manor entirely analogous an attending surgeon teaching a surgical resident how to operate. Having had the opportunity to use *Socrates* and being in the business of training surgical residents, I find this to be a very true analogy.

39. *Id.*

40. Lajoie, *supra* n. 37. Manufactures of high tech surgical devises and equipment in all fields of surgery are presently providing specialized mentoring to surgeons. Dr. Kirk Hance, Personal Communication, Asst. Prof. of Surgery, U. of Kan. Sch. of Med. (Oct. 2, 2002). For example, endovascular surgery is developing so fast that the graft manufactures are paying trained surgeons to supervise surgeons who are doing there first endovascular cases. The obvious problems with such mentoring are that is that it is labor intensive and the product manufacturer must pay for the mentoring surgeons travel expenses.

41. Closely related to training in cybersurgery, but beyond the scope of this article, is surgical training by computer simulation. *See Simulation Making Major Inroads Into Medical Training*, 31 Cardiology 1,1 (2002); Andis Robezneieks, *Controlling Chaos: Training with Surgical Simulators*, AM News <http://www.ama-assn.org/sci-pubs/amnews/pick_02/prsa0225.htm> (Feb. 25, 2002).

42. Continuing medical education is entirely analogous to continuing legal education (CLE).

minimal level of training to achieve certification in laparoscopy, it was no surprise that transition from the 3-D world of traditional surgery to the 2-D world of laparoscopic surgery was littered with the morbidity and mortality of human suffering.[43] Thus, from a pedagogic perspective Computer Motion's *Evolve* mentoring process represents a superior method for providing surgical CME. Moreover, while telementoring is being developed for the surgical field, it clearly has value for other fields of medicine. I would postulate, that in the future the establishment of a learned intermediate in medicine will turn, not on a demonstration of certification by a weekend course, but rather by the demonstration that a physician was telementored for an appropriate period of time.

But *Socrates* will also raise three legal issues for the surgeons involved. First, because the *Socrates* surgeon is invisible, in essence a stranger, to the *Zeus*-surgeon patient relationship, the telementoring by the *Socrates*-surgeon raises the issue of itinerant surgery.[44] In a telementoring relationship, it is the *Socrates*-surgeon and not the *Zeus*-surgeon who controls the operation. Closely related to the concept of itinerant surgery is whether there is a false claim involved. The lesson of the Physician at Teaching Hospitals audit program is that when an attending physician who acts as a teacher, bills for medical services actually provided by a resident in training, then there is false claims liability.[45] Thus, if the *Zeus*-surgeon bills for the surgical procedure how is the *Socrates* surgeon, the more experience master, to be compensated for time spent supervising the procedure? The perceived need by Computer Motion to have a learned intermediate to provide protection in a product liability action is so strong that Mr. Day has indicated that Computer Motion is contemplating directly paying the *Socrates* surgeon for his or her time to be mentor.[46] The final legal issue concerns liability of the *Zeus*-surgeon for surgical misadventures. In a training program, the

43. As examples of significant iatrogenic injuries occurring during elective cholecystectomy. *See Pearson v. Bridges*, 2001 WL 261944; *Dingle v. Belin*, 749 A.2d 157 (Md. 2000); *Fusilier v. Dauterive*, 764 So. 2d at 74 (La. 2000); *Kippers v. Corcoran*, 707 So. 2d 463 (La. App. 1998); *Dicks v. U.S. Health Corp. of Southern Ohio*, 1996 Ohio App. LEXIS 1987; *Roberts v. Hobohm*, 1997 Ohio App. LEXIS 5770.

44. A detailed discussion of itinerant surgery is beyond the scope of this article. *But see Koefoot v. Am. College of Surgeons*, 610 F. Supp. 1298, 1300 (N.D. Ill. 1985) (stating that itinerant surgery is the "performance of surgical operations . . . under circumstances in which the responsibility for diagnosis or care of the patient is delegated to another who is not fully qualified to undertake it"); Carl T. Dechsler, *Physicians, Surgeons, and Other Healers*, 61 Am. Jur. 2d 66 (1981) (citing *Kirk v. State*, 150 S.W. 83 (Tenn. 1911) (explaining the extent to which surgery is performed in an itinerant fashion is controversial).

45. Gordon E. Rountree, Jr., *Health Care Providers and Fraud Investigations: What Can You Do When the Government Changes the Rules in the Middle of the Game?*, 8 Ann. Health L. 97, 104 (1999).

46. Day, *supra* n. 38.

supervising surgeon is liable for the results of a resident-in-training's outcome. By analogy, it would seem reasonable to hold the *Zeus* surgeon to the same standard of liability.

Socrates also raises an important business question with legal implications: leverage. Nothing prevents the *Socrates*-surgeon from simultaneously supervising multiple *Zeus*-surgeons. While the concept that a senior surgeon could leverage his or her expertise and simultaneously supervise multiple surgical procedures is presently out of vogue, is not a new concept. In the early 1970s, Dr. DeBakey simultaneously supervised as many as ten residents-in-training performing CABGs.[47] Similarly, there is nothing about the cyberspace that prevents the *Socrates*-surgeon from telementoring ten *Zeus*-surgeons simultaneously.[48] To the contrary, because leveraging the expertise of the *Socrates*-surgeon creates an economy of scale, it is more cost-efficient. Therefore, it appears likely that telementoring will ultimately involve the simultaneous supervision of multiple surgeons-in-training. To illustrate, consider the viewpoint of the robotic manufacturer who wants to put on an *Evolve*-type mentoring process. If the company has to reimburse the *Socrates*-surgeon at flat per hour rate that cost could be distributed over multiple cases thereby decreasing the telementoring cost per case. Because the cost of telementoring is likely to be hidden in the price of the robotic instrument, holding the cost of telementoring to a minimum would have appeal to robotic manufacturer. In fact obtaining economies of scale to control price is an important principle in global economics.[49]

2. *Improving Surgical Safety by Using the Automatic Surgeon*

Because *Socrates* will facilitate diffusion of surgical expertise into the market place, it will lessen the human suffering by minimizing the learning curve that is associated with cybersurgery. But *Socrates* is not the only technology that will make the performance of cybersurgery safer. In fact, if you really believe that technology is the salvation of mankind, then the techies' ultimate solution to patient safety is to remove the human from the process.[50] After all, why leave a human to trip, stumble, and fall into some form of human error; when it is better to fully automate a process and eliminate human error. Moreover, in cyber-

47. Thomas Thompson, *Hearts of Surgeons and Transplants, Miracles and Disasters Along the Cardiac Frontier*, McCall Pub. Co., N.Y. (1971).

48. Leveraging of a physician expertise is in line with the Institute of Medicine's recommendation to liberalize the use of physician extenders. *See Quality Chasm*, *supra* n. 9; McLean, *Crossing*, *supra* n. 8.

49. *See infra* next section of the accompanying text: *Improving Surgical Safety by Using Automatic Surgeon.*

50. Laura Landro, *Medical Studies Link Mistakes and the Lack of IT Solutions*, Wall St. J. (Sept. 3, 2002).

surgery, full automation would not only eliminate human error, but would minimize the impact of telephone interruption.

Cybersurgery could be automated in a manor entirely analogues to that used in the aviation field. If industry can create an automatic pilot to fly a 747 airplane, then there is no reason, given enough money, that an automatic surgeon could not be developed to perform surgical procedures.[51] This is not to say that surgeons are about to become obsolete. Prior to placing a plane on automatic pilot, a human pilot must get the airplane off the ground and assess the atmospheric conditions. The pilot then inputs the meteorological data and the flight plan into a computer, a.k.a. the automatic pilot, and the automatic pilot does the rest. The pilot's function after turning on the automatic pilot is to be available in the event that some unanticipated event occurs. An automatic surgeon would function in a corresponding manner. The surgeon would still need to get the procedure started and assess the patient's individual anatomy for any unexpected variations. The surgeon would then input the particulars of the patient's anatomy and the operative plan into a computer, a.k.a. the automatic surgeon, and the automatic surgeon would do the rest. The surgeon's function after turning on the automatic surgeon would be to be available in the event that some unanticipated event occurs.

An automatic surgeon clearly would make cybersurgery safer by severing the dependency of cybersurgery on the telecommunication conduit. The telecommunication link would be less important because much of the surgical procedure would be preformed off-line by the automatic surgeon. With an available automatic surgeon, the only time cybersurgery would be critically dependent on a telecommunication connection between the cybersurgeon and remote patient would be during the first few minutes of the procedure where the surgeon has to assess the patient's individual anatomy. After the particulars of a patient's individual anatomy are identified and stored in automatic surgeon, the automatic surgeon could be switched on, and the procedure could then continue off-line.

Once the automatic surgeon was switched on, the cybersurgeon, like the a pilot of an airplane would only need to supervise the conduct of the procedure and be ready to go online to take control of the case if there where an unforeseen event that constituted foreshadow for a surgical misadventure. One can now see that in the world of cybersurgery, *Socrates* complements, rather than competes with, the automatic surgeon. *Socrates* ability to supervise multiple surgeons is not limited to the supervision of human surgeons. To the contrary, nothing prevents a *Socra-*

51. Computer Motions' Zeus is capable of creating a running linear suture line, as might be used to close an abdominal incision, without human assistance.

tes-surgeon from telementoring or supervising multiple off-line automatic robotically performed surgical procedures. That is the technology for telementoring can be used to set up a commercial enterprise where a cybersurgeon in a center of excellence supervises multiple simultaneous remote cybersurgical procedures. The remote facilities could be staffed by either surgical residents or physician extenders. (Thirty years ago, it was with the assistance of a closed-circuit television monitoring system to keep tabs on the surgical residents that Dr. DeBakey supervised multiple GABG operations.)[52] In short, by leveraging the talent of a *Socrates* surgeon with several automatic surgeons, a center of excellence could obtain an economy of scale that could make providing cybersurgery lucrative.

The ability to leverage the cybersurgeon's expertise is the feature that distinguishes the automatic surgeon from the automatic pilot. When a cybersurgeon, who is monitoring multiple surgical procedures being performed by an automatic surgeon detects a problem in any one procedure, the cybersurgeon merely need to take control of the case exhibiting peril, freeze the robotic arms instruments that are under the control of the other automatic surgeons, and call for supervisory backup. In contrast, while a pilot conceivably could fly several planes on automatic pilot simultaneously, the pilot cannot simply shut-off the automatic pilot on the planes not in trouble and call for back up assistance.

3. *Science Fiction or Societal Goal*

Without question many of my surgical colleagues, will think that I should be spending more of my time in the operating room and less time with my nose in law books. In their mind, the concept of an automatic surgeon ever working, let alone working safely is an impossibility. But, I am sure that was the same response that IBM's management gave to queries about *Apple's* new personal computer in the early 1980's. Moreover, computerized surgery has already gone well beyond the flirtation or brainstorming stage.[53] Rather the biggest impediment to the automatic surgery is whether society is ready to embrace the technology.[54] Hence,

52. Thompson, *supra* n. 47.

53. *See* Luis H. Diodato et al., *Robotically Assisted Versus Conventional Freehand Technique During Beating Heart Anastomoses of the Left Internal Thoracic Artery to the Left Anterior Descending Artery*, 73 Ann. Thor. Surg. 825, 826 (2002). Computers are already facilitating surgeon's hand eye coordination. *Id.*

54. *See* William J. Broad, *U.S. to Vaccinate 500,000 Workers Against Smallpox*, N.Y. Times A1 (July 8, 2002) <http://www.nytimes.com/2002/07/07/national/07SMAL.html> (accessed Nov. 11, 2002). For example, genetically engineered smallpox vaccine could have been developed years ago but because we assumed that the disease had been irradiated, a vaccine was not manufactured. Now that we know that the Russian have smallpox as biologic weapon, America is ready to use genetic engineering to mass produce smallpox vaccine.

the question is not whether the technology exists, but rather whether the market place is ready to embrace the technology; for if a market exists in a capitalistic society, someone will exploit it for profit.

The evolution of our health care system over the last ten years suggests that society is ready to embrace an automatic surgeon.[55] The Institute of Medicine's *Crossing the Quality Chasm: A New Heath Care System for the 21st Century* begins with a clear manifesto: the "American health care delivery system is in need of a fundamental change."[56] The reason our health care system is in need of remedial care is because if America is going to effectively compete in a global market place it must control its health care costs.[57] Politicians and pundits have come to a realization that the quality of health care delivery is inexorably linked to the method of payment.[58] Accordingly, the key to making health care more cost effective is to minimize the number of adverse clinical events and thereby save the cost of providing remedial health care.[59] To eliminate adverse events, the Institute of Medicine has advocated that the United States embrace physician extenders and technology to control health care costs.[60] Automatic cybersurgery is certainly consistent with the Institute of Medicine's vision of the future.

The Institute of Medicine's brave new world of health care however has a dark side: fewer community hospitals and physicians will be needed. The economies of scale associated with performance of multiple simultaneous automatic cybersurgerical procedures from a center of excellence implicitly contemplates the elimination of redundant overhead in favor of a uniform and centralized distribution system. Ten commu-

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55. This is especially true in e-health. *See* Gulick, *Global Hospital, supra* n. 6, at 194-200.

56. *Quality Chasm, supra* n. 9, at 1. With respect to technology, the entire world is ready to embrace the benefits of telemedicine and cybersurgery.

57. *See* McLean, *Implications, supra* n. 9, at 243-44.

> But to compete in the global economy, American businesses suffered because their products were more expensive, not only because of direct labor cost, but also because of the cost of health insurance. Thus, by the early 1980s General Motors Corporation was paying Blue Cross as much for medical insurance as it was paying to US Steel for sheet metal. Ideally, the American business industry would like to be on the same playing field as the rest of the Western world. Congress attempted to do this with the Health Security Act of 1993, which would have created a single payor system for medical benefits. Unfortunately, attempts to separate health care benefits from the ability to work are a hard sell to the public because, as the failure to enact the Health Security Act illustrates, if the government were to take on the burden of administration and funding of a universal health care system, then personal income taxes would have to be raised.

Id. (citations omitted).

58. McLean, *Implications, supra* n. 9, at 227; *see also* Anthony R. Kovner & Steven Jonas, *Health Care Delivery In the United States*, at 372-74 (6th ed. 1999).

59. *See generally* McLean, *Implications, supra* n. 9.

60. *See generally Quality Chasm, supra* n. 9, at 2-3.

nity hospitals could be replaced by one center of excellence and nine outpatient or limited care facilities. Because the center of excellence will probably be developed from existing academic tertiary care centers, it is not hard to imagine that an urban tertiary care institution, a future center of excellence, would want to compete with suburban community hospitals for market share.[61] Fewer community hospitals will mean that fewer surgeons and physicians will be needed because they will be replaced by technology and physician extenders. In the view of Institute of Medicine, elimination of physicians is paramount because the autonomous physician is the greatest threat to health care cost containment.[62]

III. "GO GLOBAL!"

When skilled workers, whether they are craftsmen or physicians, are threaten with replacement or displacement by technology, they resist innovation. Even before the Industrial Revolution, in 1661, when Charles II issued Orders in Counsel that prohibited coinage from being manufactured in hand-made individual pieces and proclaimed that henceforth all coinage was to be mass-produced by machine, the mint workers reacted negatively.[63] Using various means, the mint works resisted the implementation of automation for thirty years; and only acquiesced to technology when it was necessitated by economic forces.[64] Similarly, since telemedicine technology, like cybersurgery, leverages a physician's expertise, the United States will not require as many physicians to deliver health care.[65] So, just as the seventeenth century mint works created impediments to the automation, it should be expected that physicians threatened with displacement by telemedicine will create impediments to telemedicine including automatic cybersurgery.[66] Imposi-

61. *See* Anita Slomski, *Could You Compete With an Academic Medical Center?,* 16 Med. Econ. 52 (1999). Considering the financial stress academic tertiary care centers have been under in recent years, such tertiary care centers would undoubtedly need little motivation to want to compete with community hospitals of patient. *Id.*

62. *Quality Chasm*, *supra* n. 9.

63. Peter L. Bernstein, *The Power of Gold*, Disc 3, track 5, Random House Audio Books (2000).

64. *Id.*

65. Because the need for physicians varies with specialty and region of the country, the medical profession places a positive spin on the excessive number of physicians in America by deeming the problem to be a "misdistribution," rather than a "surplus" of physicians. However, "[c]oastal cities—preferred by many job seekers—are saturated with doctors, as are most cosmopolitan areas." Robert Lowes, *Where the Jobs Are*, 18 Med. Econ. 18, 18 (2001).

66. 66. Ind. Code Ann. § 25-22.5-1-1.1(a)(4) (1998); Okla. Stat. Ann. tit. 59 § 492(c)(3)(b) (1998); Tex. Health & Safety Code Ann. § 151.056(a) (1996). The most glaring of trade barrier in the health care arena are the state medical licensure statutes that prohibit the practice of telemedicine within the forum state by anyone not fully licensed.

tion of trade barriers[67] and antitrust laws[68] will be the principle mechanisms used by physicians to impede the implementation of innovations in telemedicine. Like the mint workers, the length of time the physicians will be able to resist technologic innovation will depend on economic forces. Because "Go Global!" the mantra of the business communities for almost two decades, represents the most important economic force in the United States,[69] the place of the community hospital and physicians in a global economy needs to be examined to determine if sufficient economic pressure exists to force the innovation on telemedicine, and more specifically the automatic cybersurgery, on the medical community.

A. WHY GM MAKES CARS IN CANADA

General Motors Corporation has many reasons for making cars in Canada. But an important reason is the cost of health insurance. By the early 1980s, General Motors was paying Blue Cross as much for medical insurance coverage for its employee as it was paying to U.S. Steel for the raw material to make its product.[70] These seemingly incongruous facts can be rectified when it is realized that the United States uniquely ties health care benefits to the ability to work.[71] Moreover, while

> some European countries, like Germany, tax employers to provide specific benefits, only in America is access to health care benefits dependent on working, and working for an employer who chooses the benefits. In a global economy, the added cost of health benefits to products and services means that America's labor-intensives businesses that offer health insurance are less competitive when compared to similar U.S. companies that do not offer benefits and foreign companies.[72]

Simply put, health care benefits, which cost over one trillion dollars per year,[73] act like a tax on U.S. products and services thereby making these products and services less desirable in the global market place.

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67. *Infra* this section of the accompanying text.

68. *Infra* Section IV of the accompanying text.

69. Edmund L. Andrews, *A Civil War Within a Trade Dispute*, N.Y. Times 1 (Sept. 20, 2002) (describing a $100 billion dollar a year tax brake, that turns on international trade has gridlocked Congress as large multinational corporations fight over whether the tax break should be scarped).

70. George D. Lundberg & James Stacy, *Severed Trust: Why American Medicine Hasn't Been Fixed*, 102 (2002).

71. William Neikirk, *Global Economy Changing the Ways of Doing Business*, Chi. Trib. C2 (Apr. 30, 1989).

72. Thomas R. McLean, *Health v. Stealth: Tort Reform Is a Complex Subject*, Bull. Am. Coll. Surg. (in press).

73. David Leonhardt, *Health Care As Main Engine: Is That So Bad?*, N.Y. Times § 3, 1 (Nov. 11, 2001).

Going global is therefore as much about markets as manufacturing. Ideally, the U.S. business would like to level the playing field with the rest of the Western world.[74] In 1993, health care reformers attempted to level the field with the *Health Security Act*,[75] which would have created a Canadian-style single-payor system for medical benefits. Unfortunately, attempts to separate health care benefits from the ability to work proved to be too difficult a sell to the public; because, as the *Health Security Act* illustrates, if the government were to take on the burden of administrating and funding a universal health care system, personal income taxes would have to be raised.[76] Having failed to eliminate health care benefits from corporate balance sheets, reformers move to the next best strategy: controlling cost by limiting health care to only those services which were medically appropriate according to medical guidelines. Using patient safety as pretext, health care reformers are currently gathering scientific data that will allow for the development of cost-conscious clinical guidelines that will define appropriate medical care.[77] In other words, to control health care cost, we are moving to a system to ration medical care; without calling it rationing.[78]

From a global prospective, the development of medical guidelines is just another step in our evolution from a society based on traditional free trade to a society based on international trade. Traditional free trade theory

> assumes that factor endowments in natural resources, labor, geography, and climate confer a comparative advantage upon states rich in such endowments. States exporting goods in which they are the most efficient producers and importing goods most efficiently produced abroad would derive significant benefits.[79]

In contrast, "international trade itself operates differently, with economies of scale and technological potential beginning to eclipse factor endowments in importance."[80] This paradigm shift, from free trade to international trade, applies to medicine as well as the business world and is not going to be insignificant. Cybersurgery, and more generally telemedicine, as the most technologically advanced field of medicine will

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74. Lundberg and Stacy, *supra* n. 70, at 21-24.

75. *Health Service Act Sen. 223*, 103d Cong. (1993).

76. McLean, *Implications, supra* n. 9, at 244.

77. McLean, *Implications, supra* n. 9.

78. P. Greg Gulick, *E-Health and The Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 Alb. L.J. Sci. & Tech. 351, 352 (2002) (stating the "healthcare industry is facing a paradigm shift in the way in which health services are provided").

79. Marc S. Ehrlich, *Towards a New Dialogue Between International Relations Theory and International Trade Theory*, 2 UCLA J. Int'l L. & For. Aff. 259, 264 (1998) (citations omitted).

80. *Id.* at 265.

undoubtedly be the proving grounds where medicine learns about international trade and economies of scale.

B. ECONOMIES OF SCALE

1. *International Concerns*

"Economies of scale" is a concept born in the industrial age that remains a viable concept in the age of global information. An economy of scale refers to the idea that profit margins can be improved by acquiring certain efficiencies associated with mass production of a good or service.[81] In a global economy, where profit margins are razor thin;[82] economies of scale are a necessity.[83] The industrial age paradigm of keeping physical outputs high and prices low is gone;[84] and replaced with "just in time" production of products and services that allows a supplier to hold cost and profit to minimum.[85]

To operate an economy of scale, one must necessarily manage waste and labor efficiently. GM learned long ago that it could not afford to produce defective and undesirable cars.[86] Presently, corporate America has adopted as the pillar of its management philosophy the Six Sigma concept of the elimination of mistakes that waste time or money improves the profit margins.[87] The key to understanding Six Sigma is that the size of business operations has become so large, that even reduction of even a fraction of a percent results in a significant cost savings. U.S. business' pre-occupation with controlling cost by elimination of errors has created a powerful mindset that is being used by corporate America to judge the quality of medicine it purchases as a benefit to for its employees. Corporate America, has calculated that the elimination of fifty percent of medical errors could reduce health care cost by as much as $30 billion dollars.[88] Because health care providers, pass medical costs on to employers, who with the federal government pay virtually all of the cost of

81. *Arippa v. PUC*, 792 A.2d 636, 686 (2001).

82. Thomas L. Friedmen, *The Lexus and the Olive Tree: Understanding Globalization* (Audio Division of Simon and Schuster Inc. 1999).

83. Peter J. Hammer and William M. Sage, *Antitrust, Health Care Quality, and the Courts,* 102 Colum. L. Rev. 545, 546 (2002) [hereinafter *Hammer and Sage*].

84. *Id.* at 546.

85. John M. Broder, *Port Operators on West Coast Cancel Threat of a Lockout*, N.Y. Times A (Sept. 20, 2002). Just-in-Time (JIT) manufacturing is predicated on the use of telecommunication to coordinate manufactory of a completed product, available for immediate shipping; i.e. just as the buyer signs the contract. *Id.* JIT improves the profit margin by the elimination of the need to have inventory. *Id.* However, JIT is not without risk, because anything which disrupts the coordination of product assembly and distribution has the potential of creating customer dissatisfaction. *Id.*

86. John DeLaurean, *On a Clear Day You Can See General Motors* (1976).

87. Jack Welch, *Straight from the Gut* (Time Warner Audio Books, N.Y., 2001).

88. *To Err Is Human, supra* n. 9.

health care,[89] both business and government have a strong incentive to reduce the cost of remedial medical care.

Accordingly, the Institute of Medicine, in to *Err is Human* and *Crossing the Quality Chasm*, has proposed an outline of a comprehensive and intergraded program to substantially reduce the incidence of medical errors. Briefly, this plan involves defining what is medically appropriate in clinical guidelines[90] and the elimination of providers who are non-compliant with the guidelines.[91] In short, to understand the changes in the United State's health care policy requires an understanding of the impact of health care cost on international trade. To compete in the global economy, corporate health care costs must be minimized. Moreover, telemedicine and cybersurgery add another dimension to the force of international commerce on health care, and one that potentially threatens the United State's hegemony in medical science: foreign medical doctors. To illustrate this threat, consider the following hypothetical.

You have just learned that you are in need of a specialized operation, but you do not want to leave your family and friends to travel the long distance to receive expert care. Fortunately, a new cybersurgical franchise facility has open in your town. Using telemedical technology, you are interviewed by Dr. Marcus Welbe, who is the director of the cybersurgery center at the Baylor College of Medicine or the Mayo Clinic. He is a board certified surgeon and states that he will personally supervise your cybersurgical operation; remotely of course. After having the risk and benefits of cybersurgery explained by Dr. Welbe, you successfully undergo the needed operation and return home. All is as it should be. Now imagine that program director, and your surgeon, is not Dr. Welbe, but a person of color.[92] Although future cybersurgical franchise maybe operated by a prestigious U.S. university, there is no reason why it could not have been operated by an equally prestigious Beijing World Wide Surgical Consultants, Beijing, China.[93]

In the age of information, where there are no physical boundaries and any monopoly on technology is ephemeral, very little prevents a group of foreign physicians from operating a telemedical or cybersurgical

89. The federal government in providing health benefits for its employees has the same desire to eliminate medical waste as corporate America.

90. Performance of unnecessary medical treatment is a form of waste in the medical industry that corporate payors and the federal government would like to control. A more detail discussion on the cost of health care is provided *infra* next section of the accompanying text: *National Concerns*.

91. Ken Kizer, Prepared Remarks, CEO National Quality Forum at the Cemer Millennium Health Imperative Conference (Kan. City, Mo. Sept. 9, 2001).

92. John Grisham, *A Time to Kill* (Bantam Books, N.Y., 1992).

93. An imaginary organization.

franchise within the United States.[94] Presumably, the foreign physicians would have a competitive advantage over U.S. physicians, because the foreign physicians could eliminate the cost of their own health insurance and under bid their U.S. counterparts. Moreover, given that other countries have a lower standard of living compared to the United States, it is likely that foreign medical physicians would be willing to work for substantially less than U.S. physicians.[95] And, if a foreign cybersurgical provider employed the automatic surgeon, so that the foreign provider were operating on several patients simultaneously, worldwide, the foreign cybersurgery provider would have an economy of scale. Because the foreign cybersurgical operation would carry less salary and insurance overhead, and use technology to leverage cybersurgical expertise, the foreign cybersurgical provided would be a formidable economic competitor to a U.S. surgeon using the traditional one-patient-one-surgeon technique.[96] Sound far fetched? If so, consider the opinion of Dr. Eric Tangalos of the Mayo Clinic who has opined that if the United States exports its telemedical expertise, the United States could earn enough "money to fund our domestic health care system."[97] In a global economy, it seems naïve to think that the Chinese are not contemplating setting up a telemedicine/cybersurgical system that help them pay for health care for their citizens.[98]

2. *National Concerns*

Even if foreign medical doctors do not establish a market presence in

94. A detailed discussion of licensure is beyond the scope of this article. *But see* Volkert, *supra* n. 20.

95. *See* Brian J. Caveney, *Going, Going, Gone . . . The Opportunities and Legal Pitfalls of Online Surgical Auctions*, 103 W. Va L. Rev. 591 (2001). A closely related topic is the surgical auction. *Id.* In a surgical auction a patient place a bid, consisting of the requested surgical procedure and their past medical history on an internet web site. *Id.* Surgeons then compete for the patient's business by price concessions. *Id.* In the future, nothing will prevent a surgeon trained in the technique of automatic cybersurgery from offering his or her services to a worldwide audience through surgical auctions.

96. I recognize significant costs will be associated with market entry into the cybersurgical field. I assume that an integrated healthcare provider would incorporate such costs into their strategic plan to spread the cost over the first several years of operation. After investment is returned however, it is "estimated forty to sixty billion dollars a year could be saved with the implementation of an interactive telemedicine system." Gulick, *Global Hospital, supra* n. 6, at 186.

97. Gulick, *Global Hospital, supra* n. 6, at 186.

98. A. Thomas Pezzella, *Progress in International Cardiac Surgery: Emerging Strategies*, 71 Ann. Thor. Surg. 407, 407 (2001) (observing while historically cardiac surgery had been performed in "economically advanced countries;" cardiac surgery is increasing being performed in "underdeveloped or politically and economically hampered countries").

the United States to compete directly with U.S. physicians for patients,[99] the federal government still will need to control health care costs. The federal government, which directly or indirectly pays for half of the nation's health care,[100] has ample reason to want to control health care costs by obtaining economies of scale. As a demonstration project, to show the benefits of utilizing economies of scale, the Centers for Medicare and Medicaid Services ("CMS") is in the process of launching the *Medicare Partnerships for Quality Cardiovascular Services and Quality Total Joint Replacement Services* ("Quality Service Program").[101] The *Quality Service Program*, which is to be up and running in Illinois, Michigan and Ohio in early 2003, is designed to show that the concentration of "certain high volume, high cost procedures will improve the coordination and quality of care provided to beneficiaries as well as achieve savings for the Medicare program."[102] That is, this project is intended to demonstrate that mass-production of medical services is not only cost effective, but improves patient safety.[103]

a. A Proposal to Regionalize Medical Services

While the detail of the *Quality Service Program* have yet to be published, the operating principles are clear. In exchange for the voluntary cooperation of an institutional provider's efforts to create economies of scale in cardiovascular services,[104] CMS will relax some of its regulation.[105] CMS will give the selected institutions "flexibility to allocate re-

99. Perhaps the best illustration of America's preoccupation with the global economy and foreign competition can be observed in the rapidity in which the *Corporate Fraud Act* (H.R. 3763) was overwhelmingly passed. *See* Sandra Sobieraj, *Bush Enacts Corporate Fraud Law*, Chi. Trib. (July 30, 2002) (available in LEXIS, News library). In the wake of the collapse of Enron and Worldcom, Congress' enactment of the Corporate Fraud Law indicates that America will not tolerate the use of creative accounting practice that ultimately result in money being moved out of the American stock market to other countries. *Id.*

100. Anthony R. Kovner & Steve Jonas, *Health Care Delivery in the United States*, 372 (1999).

101. *Center for Medicaid and Medicare Services* <http://www.hcfa.gov/research/qpfsdem.htm> (accessed Nov. 11, 2002).

102. *Id.*

103. The government will undoubtedly demonstrate that economies of scale for complex surgical procedures are cost effective because the government has indicated its bias toward such a conclusion. *See* Rules and Regulations, Dept. of Health and Human Serv., Health Care Financing Admin., 64 FR 36071 (July 2, 1999) (explaining as part of the condition of participation in Medicare, hospitals are mandated to disclose the "volume of certain procedures performed" and "clinical quality performance measurements" to "customers" of "health care facilities").

104. Orthopedic services are also covered, but to avoid redundancy I will only discuss the issues as they relate to cardiovascular services.

105. Jodi Blatt, Telephone Interview, Project Officer for Partnerships for Quality Cardiovascular Services and Quality Total Joint Replacement Services (July, 29, 2002).

sources as they determine most appropriate, thus having an incentive to work together to provide coordinated, cost effective care."[106] This offer is not open to every institutional provider of cardiovascular services however; because the institutional provider must already be providing a wide range of cardiovascular services at fairly high volumes.[107] Specifically, the institution must already be performing over 900 cardiac catheterizations, over 400 percutanous coronary revascularizations and over 500 open heart surgical procedures.[108] These criteria for selecting an institutional provider for the *Quality Service Program* suggest that CMS has a preconceived idea of what is the optimal volume of cardiovascular services an institution must be providing to be both safe and cost effective.

CMS's program on its face appears to be rational. While what constitute safe and effective medical care can be debated,[109] there is mounting clinical evidence to support the conclusion that high volume medical institutional providers are safer than low volume institutional providers. This is true not only for health care delivery in general,[110] but applies to a wide variety of specialty treatments including coronary artery disease,[111] general surgery,[112] and solid organ transplantation.[113] While the data analysis in clinical volume to outcome studies is flawed,[114] in

106. Center for Medicare and Medicaid, *Medicare Partnerships For Quality Cardiovascular Services And Quality Total Joint Replacement Services* <http://www.hcfa.gov/research/qpfsdem. htm> (accessed Nov. 11, 2002).

107. *Id.*

108. *Id.*

109. Compare Lucian L. Leape et al., *What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety*, 288 J.A.M.A. 501 (2002) (stating safe practices are not always those with scientific evidence); Kavel G. Shojania et al., *Safe But Sound Patient Safety Meets Evidence-Based Medicine*, 288 J.A.M.A. 508 (2002) (stating evidence does exist for safe practices).

110. Bradford Kirkman-Liff, *Health Systems*, 284 J.A.M.A. 3062 (2000); R. Adams Dudley et al., *Selective Referral to High-Volume Hospitals: Estimating Potentially Avoidable Deaths*, 283 J.A.M.A. 1159 (2000).

111. Paul McGraft et al., *Relation Between Operator and Hospital Volume and Outcomes Following Percutaneous Coronary Interventions in the Era of the Coronary Stent.*, 284 J.A.M.A. 3137 (2000); David J. Migid, *Relation Between Hospital Primary Angioplasty Volume and Mortality for Patients With Acute MI Treated With Primary Angioplasty vs Thrombolytic Therapy*, 284 J.A.M.A. 3131 (2000).

112. Deborah Schrag et. al., *Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer,* 284 J.A.M.A. 3028 (2000); F. Kee et al., *Influence of Hospital And Clinician Workload on Survival from Colorectal Cancer: Cohort Study,* 318 BJM 1381 (1999).

113. Lin Hung-Mo et al., *Center-Specific Graft and Patient Survival Rates*, 280 J.A.M.A. 1153 (1998).

114. *See* Martin McKee and Judith Healy, *The Role of the Hospital in a Changing Environment*, 78 Bulletin of the WHO, 803 (2000) (citing York, Natl. Health Serv. Center for Rev. and Dissemination, U. of York, 1996). The general problem with volume to outcome investigations is that they lack statistical power to demonstrate scientific causation between volume and outcome. *Id.*

Washington it is becoming an accepted "fact" that at the hospital level, the hospital's volume is inversely related to the number of medical errors that occur.[115] Congressional testimony supports the regulation of low volume providers.[116] In short, high volume hospitals are viewed not only more cost effective, but also safer.

But other evidence suggest that what CMS's real interest in launching the *Quality Service Program* is not necessarily quality care,[117] but simply obtaining economies of scale for cardiovascular services, so that cardiovascular services become more affordable.[118] True, modern principles of management suggest that because economies of scale operate to eliminate variability of a product or service, initiatives like the *Quality Service Program* would be expected to improve quality and be cost effective.[119] However, it is well known that because economies of scale have an optimal function range; and for patients care the optimal relationship

115. Hospital volume and health care outcomes, costs and patient access. *Id.* While this relationship has been widely accepted at the institutional level it not been demonstrated at the individual health care provider level. *See* EL Hannan et al., *Investigation of the Relationship Between Volume and Mortality for Surgical Procedures Performed in New York State Hospitals,* 262 J.A.M.A. 503 (1989); JV Kelly and FJ Hellinger, *Heart Disease and Hospital Deaths: An Empirical Study,* 22 Health Services Research 369 (1987); JV Kelly and FJ Hellinger, *Physician and Hospital Factors Associated with Mortality of Surgical Patients,* 24 Med. Care 785 (1986); AB Flood et al., *Does Practice Make Perfect? Part I: The Relation Between Hospital Volume and Outcomes for Selected Diagnostic Categories,* 22 Med. Care 98 (1984). Even at the institutional level however for some services a correlation between provider volume and mortality has not been demonstrated. *See* Barry J. Saver, *The Rising Tide of Hospitalism: Evidence-Based or Anecdote-Based Medicine?,* 46 J. Fam. Pract. 465 (1998); ML LeFevre. *Physician Volume and Obstetric Outcome,* 30 Med. Care 866 (1992).

116. John G. Martinez, *H. of Rep. Ways and Means Testimony* (Aug. 9, 1994) (1994 WL 413451 (FDCH)).

117. McClean, *Implications, supra* n. 9, at 227 (explaining while the current mantra in health care is "patient safety," the subtext is of the two Institution of Medicine reports is cost control).

118. *See* Hans G. Brost, *The Hammer, the Sickle and the Scalpel: A Cardiac Surgeon's View of Eastern Europe,* 69 Ann. Thor. Surg. 1655 (2000) (observing that America surgeons perform significantly more cardiac surgical procedures per 100,000 population then surgeons in any other industrial country). In addition to cost-effectiveness a collateral benefit of achieve economies of scale is control of the number of providers. *Id.* The reason this is important is because America appears to be providing more health care than is necessary. *Id.* Thus, if health care was provided by fewer high volume institutional providers, it is more likely that unnecessary treatments will be detected and eliminated. *Id.*

119. Mark R. Chassin, *Is Health Care Ready for Six Sigma Quality?,* 76 Milbank Q. 565 (1998).

> Solving overuse and misuse problems reduces health care costs and improves quality at the same time. Available evidence suggests that problems in these two areas are so extensive that solving them might allow us to save enough that we could afford to correct our underuse problems, including providing health insurance to those who currently lack it.

Id.

between patient volume and patient outcome is not linear.[120] Outcome studies are influenced not only by the number of patients seen by an institution, but also by the subspecialty provider mix.[121] Moreover, because institutional providers of theoretic optimum size and composition of specialty services are rarities,[122] little hard data exists for policymakers to identify the composition of the optimal high volume hospital.[123] In short, while CMS's preconceived selection criteria for institutional providers in the *Quality Service Program* will undoubtedly result in a cost saving associated with the program, whether the *Quality Service Program* is designed to scientifically demonstrate better quality of care is a harder question.

b. Centers of Excellence

CMS's *Quality Service Program* exemplifies the "Center of Excellent" model for health care delivery.[124] The establishment of a Center of Excellence is as much of a threat to the economic well-being of community hospital and its physician staff as would be the establishment of a cybersurgical franchise facility operated Beijing World Wide Surgical Consultants. Both the Center of Excellence model and the cybersurgical franchise model mean that community hospitals will face an unprecedented form of competition. To illustrate, consider what will happen to community hospitals that provide cardiac surgery, if the *Quality Service Program* proves successful.

Currently, the best data on cardiac surgery volumes and outcomes is maintained by the Society of Thoracic Surgeons ("STS"). In 2001, the STS's data reveals that, 367 institutional providers performed 15,264 open heart surgical procedures;[125] for an average of 423 open heart pro-

120. Martin McKee and Judith Healy, *The Role of the Hospital in a Changing Environment*, 78 Bulletin of the WHO, 803, 805 (2000) (estimating that the optimal bed capacity of a hospital is 200-400).

121. *Id.*

122. *Id.*

123. *See* Rules and Regulations, Dept. of Health and Human Services, Health Care Financing Adm., 42 CFR §§ 409, 413, 419, 424, 489, 498, 1003 (Apr. 7, 2000).

124. *See* Mark F. Miller, Dep. Dir., Dept. of Health and Human Services, Letter to "Hospital Chief Executive Officers" (Nov. 20, 2001). "Center of Excellence" is used herein because it is a familiar term that denotes an institution that has superior outcomes. *Id.* In fact, CMS had originally wanted to refer to its "Partnerships for Quality Cardiovascular Services and Quality Total Joint Replacement Services" as a "Centers of Excellence" demonstration. *Id.* However, many institutions not involved in the demonstration projected objected to the use of "Center of Excellence" because of the fear that a negative inference would become associated with hospitals that were non-participating institutions. Blatt, *supra* n. 105. Because I do not intend that any pejorative value be associated with "Center of Excellence," I will continue to use this term.

125. *STS Natl. Database 2002 Exec. Summary Contents* <http://www.ctsnet.org/file/2002ExecutiveReport_Rev.pdf> (accessed Nov. 11, 2002). Because CMS is only concerned

cedures being performed per year at reporting institutions.[126] Although, it is not possible to translate the average number into a percentile score, it is still clear that a large number of hospitals that currently are performing cardiac surgery are not eligible to become providers in the *Quality Service Program*. Adoption of a Center of Excellence model therefore would mean that many community hospital cardiac surgery programs would have to close.[127]

Similarly, only a minority of cardiac surgeons perform more than 125 cases per year.[128] Surgeons not performing the requisite number of cases will not be allowed to relocate their practices to a Center of Excellence for two reasons. First, to control health cost, it is reasonable to expect that CMS and private medical insurers will not be willing to pay for "unnecessary" cardiac surgery. Evidence already exist that the United States is performing more cardiac surgery per capita than any other industrialized nation.[129] Under guideline driven medical care,[130] the United States will be performing less cardiac surgery; therefore the U.S. will need fewer cardiac surgeons per capita.[131] Second low-volume cardiac surgeons will not be allowed to join a Center of Excellence because to do so would be self-defeating. The more cardiac surgeons on staff at a Center of Excellence, the fewer cases would be performed per surgeon. To that the clinical material endure is not diluted, Centers of Excellence would reasonable want to operate with as few surgeons as possible.

In short, even without the cybersurgery and an increased foreign competition for patients, competition for patients in the United States is going to increase as the United States shift to a Center of Excellence

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with the number of coronary artery bypass procedures and valve procedures performed at an institution, only the number of these procedures were abstracted from the STS's data bank. *Id.*

126. Contribution to the STS's data bank is voluntary. Many of the lower-volume institutional providers do not contribute to data bank; therefore 423 open hearts/ provider/ years is probably a "best case scenario" snap shot of the volume of heart surgery perform at a single location.

127. Rather than having patients travel for miles to obtain a needed need coronary intervention, cybersurgery will bring medical expertise to the patient.

128. *See e.g.* N.Y. State Dept. of Pub. Health, *Coronary Artery Bypass Surgery in New York State* <http://www.health.state.ny.us/nysdoh/consumer/heart/1996-98cabg.pdf> (accessed Nov. 11. 2002).

129. Brost, *supra* n. 118, at 1656 (observing that America surgeons perform significantly more cardiac surgical procedures per 100,000 population then surgeons in any other industrial country); *see also* Tom R. DeMeester, 12 Surg Endosc 261 (1998) (observing that surgeons can increase their practice volume, even in a market saturated with surgeons, through advertisement).

130. *See generally* McLean, *Implications, supra* n. 9.

131. Independent of guidelines, better medical care in general will diminish the need for cardiac surgery.

model for health care delivery. Because human nature has not changed since the time of Charles II, like the mint works, when community hospitals are threaten with closure and physicians are threaten with displacment into the general economy, both are going to resist attempts to implement advanced technology and the creation of Centers of Excellence. The next section will examine the potential for health care provides to proactively resist change by implementing trade barriers and applying antitrust law. As we will see, trade barriers may delay, but do not derail innovation. Moreover, because antitrust laws protect competition, not competitors, antitrust law will also be an ineffective method to resist the paradigm shift in the practice of medicine.

IV. PROTECTING MARKETS: TRADER BARRIERS AND ANTITRUST LAWS

A. TRADE BARRIERS

Trade barriers are perhaps the oldest method of protecting a market. A trade barrier is any device used to impede the establishment of a new industry.[132] In the field of heath care, the pre-eminent trade barrier is the need to have a license.[133] A review of "state licensure and the scope of practice acts demonstrate that the place of health care delivery regulation is firmly in the hands of the state governments."[134] The Institute of Medicine, in *Crossing the Quality Chasm,* referred to state licensure laws as the most significant barrier to "provide for a predictable cost-efficient quality medical care;" i.e. state licensure laws are the most significant barrier to the creations of economies of scale in health care.[135]

State licensure laws acting as trade barriers are illustrated by the modification of the law in several state to prevent foreign telemedicine franchise operators from entering the market. Some states have made telemedical consultations by foreign physicians "impractical if not impossible."[136] Indiana "considers consultations transmitted through 'elec-

132. *N.Y. v. U.S.*, 331 U.S. 284, 308 (1947).

133. Lauretta Higgins Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DePaul J. Health Care L. 261 (2001). (explaining that a Certificate of Need (CON) is another example of a trade barrier and that although CONs are less important than a decade ago, as America moves toward a Center of Excellence model for health care delivery, CONs may become an important trade barrier again); *see also* American College of Cardiology *CABG Death Rates Higher in States Without CON Regulation's* Advocacy Weekly, Oct. 21, 2002 a study stated that of over 900,000 patients, Medicare found the mortality rate of Coronary Artery Bypass Grafting (CABG) "was 22 percent higher in states without a CON regulation." *Id.*

134. *See generally*, McLean, *Crossing, supra* n. 8.

135. *Id.* (citing *Quality Chasm, supra* n. 9, at 207-20).

136. Volkert, *supra* n. 20, at 169 (citing Ala. Code 34-24-72).

tronic communications' on a 'regular, routine, and non-episodic basis' to constitute the practice of medicine."[137] Accordingly, for a physician "located outside of Indiana to engage in a telemedical consultation with a patient located in Indiana, the physician has to be licensed to practice medicine in Indiana."[138] Texas has a similarly worded statute.[139] In California for a "telemedical consultation to be legal, the patient has to be under the care of a physician who is licensed in California."[140] A second California statute

> specifically authorizes telemedical consultations from physicians located in another state so long as the consulting physician does not 'open an office, appoint a place to meet patients, receive calls from patients within the limits of the state, give orders, or have ultimate authority over the care or primary diagnosis of a patient who is located within [California].[141]

In short, telemedical licensure statutes function as classic trade barriers to protect in-state physicians from economic competition by out-of-states physicians.

Trade barriers however are only a temporizing maneuver to control a market. Even in the industrial and pre-industrial age, economic competition found either a way around the trade barrier[142] or away to tear down the barrier.[143] In the global economy era, the only modification of this principle is that the speed in which the competition learns how to neutralize trade barrier has been accelerated.[144] In the global economy, it is free trade, and not trade barriers, which has proven to "provide the richest benefits and highest efficiency in a self-regulating global marketplace."[145] Because globalization is no longer an option if a nation wants to prosper, trade barriers are increasingly becoming historical footnotes in the structure of the global economy.[146] Worse, trade barriers re-

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137. Gulick, *Global Hospital, supra* n. 78, at 366 (citing Ind. Code Ann. 25-22.5-1-1.1(a)(4)(A) & (B) (Michie 1999).

138. *Id.*

139. Tex. Occ. Code Ann. § 151.056(a) (2002).

140. Gulick, *supra* n. 78 at 366 (citing Cal. Bus. & Prof. Code art. 2290.5(a)(1) & (b) (West 1990 & Supp. 2002)).

141. Cal. Bus. & Prof. Code art. 2060 (West 1999 & Supp. 2002).

142. *Id.* (noting that for example, although Genoa and Venice controlled the Mediterranean trade routes for hundreds of year, Spain and Portugal eventual found trade route that avoided Italian middlemen).

143. *Id.* (explaining that after China enacted law to control opium traffic, the English in essence went to war with China during the Boxer Rebellion to remove the trade impediment).

144. Thomas L. Friedman, *The Lexus and the Olive Tree: Understanding Globalization* (Audio Division of Simon and Schuster Inc. 1999) (cassette tape recording).

145. Marc S. Ehrlich, *Towards A New Dialogue Between International Relations Theory And International Trade Theory*, 2 UCLA J. Int'l L. & For. Aff. 259, 265 (1998).

146. *Id.*

present an antiquated notion that encourages "gamesmanship in the international trading arena."[147] Such game playing is disruptive to achieving an integrated economy that is essential to the creation of the economies of scales so essential for a nation's prosperity in global environment.[148] Thus, if rulers of a third world country want to remain in power, more and more of their effort must be directed towards the democratization of capital, information, and communication.[149] And this means removal of any and all trade barriers.

The need to recognize that trade barriers are an ineffective means to control a market, is nowhere more true than in the field of medicine. Third world countries are no longer going to tolerate third-rate medical care.[150] Telecommunications, whether it is the Internet or CNN, has opened the world to what is available.[151] Thirty years ago, the world came to Dr. DeBakey and Cooley, not the other way around. The reason for this behavior was that at the time Dr. DeBakey and Cooley had a monopoly of scientific knowledge (and hand-eye coordination) that functioned as a trade barrier. Only those surgeons, who were admitted to the guild of cardiac surgeons, either in Houston or elsewhere were allowed to practice cardiac surgery. In a global economy however excellent surgeons are not confined to Houston and a few cities in the United States. Eastern Europe for example, after the introduction of capitalism in the 1990s, has seen a raise in the number of centers performing state of the art surgery.[152] Eastern Europeans are well aware of what is available in the United States, and they want the same standard of living for themselves.[153]

Increasing awareness in third world countries will create political pressure on the leaders of such countries to improve their health care systems. But because the non-industrial world is aware of what is in the United States, any improvement will unlikely be based on "the theory that patient care should be hospital based and involve face-to-face interaction between physicians and patients located in the same room, and towards the theory that e-health" is the way of the future.[154] Rather than build elaborate hospitals to warehouse patients, improvement of health care in the non-industrial world will involve investments in

147. Julian Epstein, *The Other Side of Harmony: Can Trade and Competition Laws Work Together in the International Marketplace?,* 17 Am. U. Int'l L. Rev. 343, 343 (2002).

148. *See generally* Friedman, *supra* n. 144.

149. *Id.*

150. *Id.*

151. Gulick, *Global Hospital, supra* n. 6, at 94 n. 79. (quoting "the World Health Organization (WHO) actively promotes telemedicine as a tool for improving world health").

152. *See generally* Brost, *supra* n. 118.

153. *See generally* Friedman, *supra* n. 144.

154. Gulick, *Global Hospital, supra* n. 78, at 352.

telemedicine and cybersurgery. Because licensure laws act as trade barriers are antagonistic to the implementation of telemedicine and cybersurgery, non-industrialized countries will increasing jettison these barriers to improve their standard of health care. As expertise in telemedicine and cybersurgery is gained it will further threaten the United State's hegemony in telemedicine and cybersurgery.[155] Therefore, just as United States is enacting laws to control health care costs so that United States businesses will not be taxed when they provided health care benefits, to preserve the United States' hegemony in telemedicine and cybersurgery it is reasonable to expect legislation that will facilitate these industries. That is, repeal of state licensure laws to facilitate the practice of telemedicine and cybersurgery is to be expected.[156]

Trade barriers however are not the only method that is available to health care providers to resist the introduction of technology in the marketplace. Because the "free market system cannot survive in the face of cartels"[157] and antitrust law "represents the principal legal tool the U.S. employs to police private markets"[158] its reasonable to expect health care providers will challenge the establishment of cybersurgical franchises under the antitrust laws.

B. The Interface between Cybersurgery and Antitrust Law

1. *The Franchise Model*

The franchise or brand-name model of health care delivery, which is in reality a method for capturing market share, is well established. On the national level, probably the best example of a franchise health care delivery system is the Mayo Clinic with its remote locations in Scottsdale, Arizona and Jacksonville, Florida.[159] A less well-known national franchise is Michael E. DeBakey, MD regional cardiac centers, which are

155. *See generally* Friedman, *supra* n. 144 (stating that in the global economy, the key feature of a superior company is their integration with the market place). Moreover, in a global environment it is impossible to retain a monopoly on technology for any substantial length of time. *Id.* These principles are important to American health care because while the French, German, and Japanese telephone companies have been involved in prototype cybersurgical demonstrations projects, none of the American telephone companies have shown any interest. *Id.* That is, America is falling behind the rest of the world in telemedical expertise. *Id.*

156. *Id.* (noting that if the Mayo Clinic were to offer telemedical services in rural North Dakota for example, a location that tradition has been underserved by physicians, it seems unlikely that North Dakota's state legislature will enact a law that limits the ability of its citizens to obtain convenient medical care).

157. *U.S. v. Topco Assoc.*, 405 U.S. 596, 610 (1972).

158. *Hammer and Sage*, *supra* n. 84, at 546.

159. *General Information about Mayo Clinic* ¶ 12 <http://www.mayoclinic.org/about/> (accessed Nov. 11, 2002) (noting that in addition the Mayo Health System operates primary

headquartered in Houston and has remote locations in Kenosha, Wisconsin and Hays, Kansas. On a regional level, there are many operators of franchise health care systems. Examples of regional health franchise system include the Barnes-Jewish Hospital system in St. Louis, and the Rush-Presbyterian system in Chicago. Regional health care franchise systems have several characteristics in common. First, the franchise system is anchored by an eponymous hospital that is a well established venerated institution; and it operates as a Center of Excellence. Second, the eponymous hospital is frequently located in an urban area that has seen its referral base eroded in the last fifteen to twenty years due to both suburban migration of patients and increasing competition from other urban and suburban hospitals. Third, to survive reductions in reimbursement during the past ten to fifteen years, the eponymous hospital's strategic plan has called for increasing its volume of patients. These strategic plans have generally involved opening of franchise or satellite facilities to capture patients who are at some distance from the hospitals in the suburbs; and the patients were unable or unwilling to commute into the urban anchor Center of Excellence for routine care. The franchise facilities, in turn, not only provided the hospital franchise system with a greater volume of patients overall, but also served as referral source for the Center of Excellence. That is, when patients with complex medical problems were identified, such patients were transferred to the anchor hospital for treatment.[160]

More formally, a franchise is defined as:

> a contract or agreement by which (a) a franchisee is granted the right to engage in the business of offering, selling or distributing goods or services under a marketing plan or system prescribed in substantial part by a franchisor; (b) the operation of the franchisee's business pursuant to that plan or system is substantially associated with the franchisor's trademark and (c) the franchisee is required to pay, directly or indirectly a franchise fee.[161]

Although this definition accurately represents the business structure of the McDonald Corporation,[162] as applied to health care, it is not a perfect fit, because it contemplates that the franchisee and franchisor are two distinct persons, rather than a single entity operating branch

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care facilities in "62 communities in southern Minnesota, northern Iowa, and western Wisconsin").

160. R. Kuttner, *Columbia/HCA and the Resurgence of the For-Profit Hospital Business*, 335 New Eng. J. Med. 362-368 (Part 1) (1996); 335 New Eng. J. Med. 446-453 (Part 2) (1996) (stating that the hospital franchise model is intentionally simplified; for without question more complex and rapacious franchise models, like Columbia HCA have been developed).

161. *Gingiss Intl. v. Ludwig*, 2002 U.S. Dist. LEXIS 12792, at *18 (citing California Franchise Relations Act § 20001; California Franchise Investment Law § 31005(a)).

162. *See generally* John F. Love, *McDonalds: Behind the Golden Arches*

facility.[163] But viewing a hospital system as being analogous to a branch banking system does not seem appropriate because of the extensive regulation of the banking industry.[164] Rather, because the key characteristic of the modern franchise relationships is the "pervasive" control that franchisor exerts of the franchisee,[165] a franchise system is a reasonable term to apply to a central hospital operating satellite facilities. After all, once the satellite facility is acquired by the central hospital, the satellite facility is pervasively controlled, and trademarked, by central hospital.

The franchise health care system is designed to increase patient volume within the system. However, patient volume alone is insufficient to make a system profitable; the system must operate efficiently. Hence, what makes franchise hospital systems more profitable is their ability to create economies of scale. The primary strategy to create economies of scale within a franchise hospital system is to minimize the time that overhead, both personal and equipment, is under utilized.[166] One method to maximize the utilization of overhead is to eliminate any duplicate services. Thus, whereas a single free-standing hospital will of necessity require a dedicated clinical laboratory and radiology department; a franchised hospital system conceptually only requires one clinical laboratory and one radiology department for the entire system. Elimination of laboratory and radiology departments will, in turn, decrease the need for hospital-based physicians. Moreover, because a franchise hospital system only purchases one piece of expensive equipment for the entire system, other than routine downtime for maintenance, the expensive equipment is always in use.[167]

Cost-effective hospital franchise systems, armed with technology

163. *See generally* Modern Dictionary for the Legal Profession (Gerry W. Beyer & Kenneth R. Redden, 3rd Ed., William S. Hein & Co., Inc. 2001) (stating that if the distinct persons are in competition for a market a cartel situation may exist; as a cartel is composed of "organizations that makes decisions regarding prices, production, and various policies for an entire group").

164. *U.S.* v. *Citizens & Southern National Bank*, 422 U.S. 86 (1975) (stating that in many ways, the hospital that operates satellite or branch locations is analogous to a central bank with its branch offices and quoting *U.S.* v. *Marine Bancorporation*, 418 U.S. 602, 606 (1874)). However, because "applying the antitrust laws to banking, careful account must be taken of the pervasive federal and state regulation characteristic of the industry, 'particularly the legal restraints on entry unique to this line of commerce." *Id.*

165. *Principe v. McDonald's Corp.*, 631 F.2d 303, 304 (4th Cir. 1980).

166. Reed Abelson, *Merged Hospitals Gain Both Power and Critics*, N.Y. Times (Sept. 26, 2002) (internet edition).

167. *Id.* (stating the return on investment time on an expensive piece of equipment, like a *de Vinci* or *Zeus* robotic instrument, will be the shortest where the equipment can be used for more hours or the day). To ensure that the expensive equipment is in use for most of the day in turn requires a sufficient volume of patients in the system to create a backlog. *Id.* As the waiting time increase with the limited number of available CT scanners in the early 1980s, patients were willing to come for diagnostic testing in the middle of the night. *Id.*

and economies of scale are formidable competitors.[168] Falling reimbursements for medical services[169] aids the franchised hospital system in asserting hegemony in the market place. After the franchised hospital system is created by the mergers and consolidation of community hospital; the system then moves to improve its bottom line by eliminating any duplication of services to create economies of scale.[170] Thus, while the business financial strategy behind franchised hospital system is clear, it is less clear how to sell the newly created hospital system.[171] Just how does one communicate to a community that "they'll no longer have their own community hospital?" or the services of their most revered physicians are no longer needed?[172] More importantly, if the rural or suburban community objects to the introduction of a new franchise hospital system in their community can an existing rural or suburban hospital and its physician staff resist the franchise's expansion with antitrust laws?[173] The answer, in a word is no.[174]

168. *Id.* (noting that this article also observes that in addition to economies of scale, franchised hospital systems, because of increased market power, can become more profitable by demanding greater price concession from insurers).

169. *Dateline Washington*, 87 Am. Coll. Surg. Bull. 6, Newsletter of Division of Advocacy and Health Policy (Aug. 2, 2002) (discussing the negotiation to recalculate Medicare's Economic Index which will reduce physician reimbursement by 5 percent in each of the next four years).

170. *California: Big Hospital Chains Facing Backlash Over Closings*, American Health Line (Aug. 22, 2002) (discussing Tenet Healthcare's problems that arose after closing several hospital in California); Ken Terry, *Hospital Hardball: Maine Physicians Are Being Pressured to Pick Sides In a Nasty Fight Over Economic Credentialing*, *79* Medical Economics 72 (2002) (discussing how the creation of a hospital system lead to the elimination of need of a group of cardiologist). Examples for hospital closures and displacement of physicians are legion. *Id.*

171. *See generally* Abelson, *supra* n. 166.

172. Tom DeSanto, *Think You've Got Marketing Woes?,* Marketing Health Services 44 (Fall 2002).

173. *Id.* (stating other methods of resistance, for example a state's attorney general to challenge the conversion of a non-for-profit hospital into member of for-profit franchise hospital system, are beyond the scope of this article).

174. *Id.* (noting the answer is clearly no when a franchise health care provider opens a brand new facility). The answer is a little more complicated if franchise health care provider obtains it facility through market consolidation; i.e. buys out a competitor. *Id.* Although, market consolidation triggers antitrust laws, the short answer still appears to be "no" because such market consolidation is general not challenged by FTC; and when the hospital consolidations are challenged the FTC does not prevail in court. *Hammer and Sage*, *supra* n. 84, at 617. Also, "[h]ospital merger cases may give some local judges the pleasure of telling a bunch of Washington based lawyers and bureaucrats spouting general theories of consumer protection how little they know about the institutions they are attacking." *Id.* However, the FTC posture may change during the Bush administration. *See* Henry Allen, American Health Line, Aug. 9, 2002 (noting that "[m]ost of us would find striking out seven consecutive times demoralizing, but the FTC appears to have the courage to step back into the batter's box"); *see generally* Abelson, *supra* n. 166.

Interesting, while it is human nature to resist technology innovation that threatens your livelihood; in the field of medicine, where the most significant technologic innovation in a generation is telemedicine and cybersurgery, there is a paucity of comments analyzing physician resistance to this technology.[175] But physician resistance is inevitable: just as Charles II's mint workers resisted the introduction of the automated coinage machines; it is to expect that community hospitals and surgeons will attempt to use antitrust law to resist the introduction of remote automated cybersurgery into their market place.

2. *Overview: Medical Antitrust Law*

The specter of antitrust regulation of the medical profession was first raised in the *America Medical Association v United States*.[176] The case alleged that AMA had engaged in the unlawful restraint of trade in the District of Columbia. The AMA's position was that, within the meaning of the *Sherman Act*, the practice of medicine was not a trade.[177] The *Sherman Act* prohibits "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States or with foreign nations."[178] To prevail in a *Sherman* antitrust action the plaintiff must demonstrate: 1) a contract, combination or conspiracy; 2) affecting interstate commerce; 3) which imposes an 'unreasonable' restraint on trade.[179] In *AMA,* the trial court's conviction of the AMA was upheld by the Supreme Court because the *Sherman Act* applied to any "person;" the Court therefore evaded the issue of whether the practice of medicine constituted a trade.[180] In J. Roberts' view, the prosecution successfully demonstrated that the AMA, a person, had engaged in the essential elements of unlawful restraint of trade.

Thirty years later, the Supreme Court took a more decisive look at the nature of professional commerce. In *Goldfarb v. Virginia State Bar*,[181] a case involving the ability of a state bar to control the minimum

175. John D. Blum's *The Role Of Law In Global E-Health: A Tool For Development And Equity In A Digitally Divided World*, 46 St. Louis L.J. 85 (2002) (noting this is especial true of law review article that survey the laws that will be impacted by telemedicine and the coming age of cybersurgery). The word "antitrust" appear in a single sentence. *See generally* Volkert, *supra* n. 20; *see also* Gulick, *Global Hospital, supra* n. 78 (showing the word antitrust does not appear); *see also* Brian J. Caveney, *Going, Going, Gone . . . The Opportunities And Legal Pitfalls Of Online Surgical Auctions*, 103 W. Va L. Rev. 591, 614 (2001) (observing that few governmental agencies had the foresight to plan for the difficult questions that arise in the e-health space).

176. 317 U.S. 519 (1943).

177. *Id.* at 527.

178. 15 U.S.C. at § 1 (2002).

179. *White and White, Inc. v. Am. Hosp. Supply Corp.*, 723 F.2d 495, 504 (6th Cir. 1983).

180. 317 U.S. 519 at 535-36.

181. 421 U.S. 773, 774 (1975).

price an attorney could charge, the Supreme Court announced that the antitrust laws applied to the learned professions. Three years later, in *National Soc. of Professional Engineers v. United States*,[182] the Court, while allowing that "professional services may differ significantly from other business services," held that a professional ban on competitive bidding violated antitrust law.[183] Then in 1982, in *Arizona v. Maricopa County Medical Society*,[184] the Court held that it was a *per se* violation of the *Sherman Act* for competing physicians to fix prices for medical services.[185]

Per se violations of the *Sherman Act* occur when a person's restraint on trade is so unreasonable that it is plainly anticompetitive by nature.[186] Thus, concerted refusal to deal, i.e. engaging in a boycott, has been held to be illegal.[187] Similarly, "certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."[188] For plaintiffs proceeding under a *per se* analysis is beneficial because the plaintiff will not be required to provide a detailed analysis of the market.[189]

The *per se* analysis is to be contrasted with the rule of reason analysis.[190] *Per se* analysis worked well with horizontal monopolies; but proved to be less effective against vertical monopolies which did not in-

182. 435 U.S. 679, 692 (1978).

183. *Id.* at 696.

184. 457 U.S. 332 (1982).

185. *Id.* at 335-37, 357.

186. *Nat'l. Socy. of Prof. Engineers*, 435 U.S. 679 , 692.

187. Ind. Federation of Dentists, 476 U.S. 447, 458 (stating that under a per se analysis a boycott is construed narrowly). "It is not an antitrust 'boycott' when one supplier enters into an exclusive supply agreement with one customer, even though the supplier's competitors are 'foreclosed' from that customer for the life of the contract." *Minn. Assoc. of Nurse Anesthetists v. Unity Hospital*, 208 F.3d 655, 660 (2000).

188. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *see also Retina Assoc., v. Southern Baptist Hospital of Fla.*, 105 F.3d 1376 (11th Cir. 1997) (holding an exclusive referral agreement was held not to constitute a horizontal concerted refusal-to-deal or group boycott); *Kartell v. Blue Shield*, 749 F.2d 922, 923-26 (1st Cir.1984) (holding that an insurer's setting a ceiling on the price to be paid for medical services is not a per se violation).

189. *Jefferson Parish Hospital Dist. No. 2 v. Hyde*, 466 U.S. 2, 15-16 (1984).

190. *California Dental Association v. FTC*, 526 U.S. 756, 769 (1999) (stating that between the per se rule and the rule of reason there exists the so called "quick look" analysis). Under the quick look analysis, a detailed analysis of the relevant market can be omitted if "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* To simplify my discussion, I have omitted discussion of the hybrid quick look analysis which is discussed in more detail in *National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla.*, 468 U.S. 85 (1984); *see also Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 594 (1st Cir.1993).

volve the concerted actions of competitors.[191] Thus, in *Standard Oil Co. v. United States,*[192] a case involving a vertical monopoly that was specifically designed to evade the reach of the *Sherman Act*, the Supreme Court announced the rule of reason analysis, wherein any unreasonable restraint on trade would constitute a violation of the *Sherman Act.*[193] Unreasonable restraints on commerce occur where a business' conduct has no procompetitive rationale in a given market.[194] That is, the courts are not interest in prohibiting conduct that in the long run is beneficial for society, even if in the short run some trade is restrained.

Rule of reason analysis, unlike the bright line *per se* analysis, necessitates a fact specific inquiry into the purpose behind a contract *and* the contract's effect on the market.[195] The critical element of this fact specific inquiry is the determination of market power.[196] The ability to raise prices above a competitive level in a relevant market by reducing production is market power.[197] The relevant market, in turn consists of two components, the "product market," and the "geographic market."[198] Product market refers to the ability of consumer to switch from one product or service to another product or service in the same line of commerce.[199] Geographic market refers to the geographic area where the

191. *Standard Oil Co. v U.S.*, 221 U.S. 1 (1911) (stating that not all federal antitrust law flows from the *Sherman Act*). In the wake of complex litigation associated with in 1914, Cong. passed the *Clayton Act* 15 U.S.C.A. § 18 (West 1997), which prohibited "persons engaged in, or affecting, interstate commerce from acquiring "stock or other share capital" of another." *Id.* Thus, *Clayton Act* more directly addressed issues associated with vertical monopolies. *Id.* The *Clayton Act* was amended to increase consumer protection by the *Celler-Kefauver Act*, 64 Stat. 1125 (1950) (codified in 15 U.S.C.A. 18, 21 (West 1997). Finally, the *Robinson-Patman Act*, 15 U.S.C.S. § 13, which concerns discriminatory pricing, overlaps with the *Sherman Act*. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 113 S. Ct. 2578, 2587 (1993) (noting that reference to all for of these acts collectively as antitrust laws).

192. 221 U.S. 1 (1911).

193. *Id.* at 58-64 (stating that Standard Oil was the prototypic vertical monopoly). In creating the business structure for Standard Oil, John D Rockefeller had his attorneys design a structure that would avoid *Sherman Act* liability. Daniel Yergin, *The Prize* (Touchstone Book, N.Y., 1991). In part the prolong litigation and need to create a rule of reason analysis flows directly from Rockefeller's attempts to avoid *Sherman Act* liability. *Id.*

194. Levine v. C. Fla. Med. Affiliates, 72 F.3d 1538, 1551 (11th Cir.1996).

195. *Broad. Music v. Columbia Broad. Sys.*, 441 U.S. 1, 24-25 (1979).

196. *Schachar v. Am. Acad. of Ophthalmology*, 870 F.2d 397, 398 (7th Cir. 1989); *see also Valley Liquors v. Renfield Importers*, 822 F.2d 656, 666 (7th Cir. 1987).

197. *National Collegiate Athletic Assn*, 468 U.S. 85, 109 n. 38.

198. *U. S. v. Marine Bancorporation*, 418 U.S. 602, 618 (1974).

199. *Thurman Indus. v. Pay 'N Pak Stores*, 875 F.2d 1369, 1374 (9th Cir. 1989); *see also Brown Shoe v. U. S.*, 370 U.S. 294, (1962); *see also U.S. v. E.I. du Pont de Nemours*, 351 U.S. 377, 395 (1956).

product or service is available.[200] Perhaps because the calculations of product market and geographic market are inherently soft, being based on a number of assumptions, courts have generally declined to find antitrust effect when a defendant has market power of less than fifty percent.[201]

In health care, rule of reason analysis' allowance that conduct that has a procompetive, or beneficial, effect on society does not violate antitrust law, has lead to the development of the patient care defense: the government is not interest edin prosecuting health care providers if they are "getting together and improving quality, not fixing prices."[202] The patient care defense was raised, unsuccessfully, in the high profile case of *Wilks v. AMA*.[203] The AMA had for years, through the use of its ethical cannons, prevented physicians from associating, collaborating, and referring patients to chiropractors. Wilks, on behalf of chiropractors in general alleged that the AMA's ethical cannons where not about ethics but were designed to

> prevent chiropractors from obtaining access to hospital diagnostic services and membership on hospital medical staffs, to prevent medical physicians from teaching at chiropractic colleges or engaging in any joint research, and to prevent any cooperation between the two groups in the delivery of health care services.[204]

In its defense, the AMA asserted that its ethical cannons were created in the best interest of patients. However, the AMA was unable to demonstrate "concern for scientific methods in patient care had been objectively reasonable."[205] Accordingly, the Supreme Court, applying rule of reason analysis concluded that the AMA was not entitled to have its antitrust effect negated by the patient care defense. *Wilks* suggest that patient care is an affirmative defense, requiring that health care providers have more than rhetoric to support concern for the well-being of the public at large to prevail.

Regardless of whether a *per se* or rule of reason analysis is applied in a particular case, the goal of the inquiry remains the same: to determine the "competitive significance" of the activity on trade.[206] The choice of applying a *per se* or rule of reason analysis is a question of law.[207]

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200. *Fed. Trade Comm'n v. Staples*, 970 F. Supp. 1066, 1072 (D.D.C. 1997); *see also Freeman Hosp.*, 69 F.3d at 268. Geographic market is frequent calculated based on the Elzinga-Hogarty test. *Mercy Health*, 902 F. Supp. at 978.

201. *Beville v. Curry*, 39 P.3d 754 (Okla. 2001).

202. Reed Abelson, *U.S. to Step Up Antitrust Effort On Health Care*, N.Y. Times A1 (Aug. 9, 2002) (quoting FTC Chairman Timothy J. Muris).

203. 895 F.2d 352, 356 (1990).

204. *Id.* at 355.

205. *Id.* at 356.

206. *Wilks*, 895 F.2d at 358.

207. *In re Am. Honda Motor*, 941 F. Supp. 528, 562 (D. Md. 1996).

Courts, wishing to extend deference to the medical profession, have been reluctant to apply *per se* analysis in cases involving rules adopted by professional association.[208] Even the Supreme Court was "reluctant to extend the per se rule to restraints imposed in the context of business relationships where a practice's economic impact is not immediately apparent."[209] Consequently, in medical antitrust cases there is a presumption that a rule of reason analysis will be applied.[210]

Litigation under rule of reason is expensive because it requires a fact specific inquiry. The expenses are primarily due to the need for expert testimony.[211] Two implications of high costs litigation for medical antitrust cases are: 1) few published cases exist and 2) Federal Trade Commission ("FTC") has become the *de facto* medical antitrust watch dog. In a review of over 500 published medical antitrust cases collected over a fifteen year period, Hammer and Sage found that only ten percent of published cases concern barriers to market entry.[212] (Most of the litigated cases pitted a solo physician against a hospital, after the latter had denied the physician admitting privileges.)[213] Of these 500 cases, *Retina Associates, P.A. v. Southern Baptist Hospital of Florida, Inc.*,[214] and *Beville v. Curry*[215] are illustrative of the application of the rule of reason; and more generally of medical antitrust litigation.

In *Retina Associates*, Baptist Eye Institute ("BEI") had wanted to improve the facilities for patient care and to create a "one-stop shop" for opthmologic services and entered into an exclusive referral arrangement with the local community hospital and retina specialists.[216] Consequently, Retina Associates, a competitor of BEI, observed a drop in their patient volume.[217] Retina Associates filed suit asserting that BEI and hospital had enter into a "horizontal concerted refusal to deal or group boycott."[218] The court ruled that the plaintiff had to proceed under a rule of reason analysis, because a *per se* analysis was inappropriate for two reasons: "1) the boycott alleged here is not of the type that has been historically shown to always or almost always adversely affect competition; and 2) the market power possessed by defendants in terms of patient

208. *Ind. Fedn. of Dentists*, 476 U.S. at 458.

209. *Hammer and Sage, supra* n. 84, at 559 (stating that even giving deference to the medical community, courts still occasionally are willing to apply the per se analysis); *see also In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (2000).

210. *Cal. Dental Assoc.*, 526 U.S. at 756.

211. *Hammer and Sage, supra* n. 84, at 563.

212. *Id.* at 581.

213. *Id.* at 556.

214. *Retina Assoc. v. S. Baptist Hosp. of Fla.* . 105 F.3d 1376 (11th Cir. 1997).

215. *Beveille v. Curry*, 39 P.3d 754 (Okla. 2001).

216. *Retina Assoc.*, 105 F.3d at 1378.

217. *Id.* at 1379.

218. *Id.* at 1380.

referrals is insufficient as a matter of law to justify *per se* treatment."[219] In a similar case, *Levine v. Cent. Florida Medical Affiliates*, the Eleventh Circuit had upheld summary judgment for the defendant because the plaintiff had failed to define the market and demonstrate antitrust intent.[220] In remanding *Retina Associates*, the Eleventh Circuit observed that "BEI's guiding goal is the provision of a "one-stop shop" for eye care and the cost-containment and convenience that it represents."[221] Thus, the court directed that for Retina Associates to prevail, they would not only have to define the relevant market, but also address the patient care defense.

Beville[222] illustrates just how important public interest, i.e. the patient care defense, is under the rule of reason analysis. Dr. Beville and Comanche County Memorial Hospital each sought to set up a teleradiology franchise in rural Oklahoma.[223] When Dr. Beville's plans failed to come to fruition, and Comanche set up a teleradiology franchise system without Dr. Beville, he sought redress against Comanche under 79 O.S. 1991 § 25, which is similar to the *Sherman Act*.[224] Dr. Beville asserted that Comanche had organized a boycott against him. In affirming summary judgment for the defendant, the court noted that the Dr. Beville had demonstrated neither that the defendant had sufficient market power nor was their any injury-in-fact.[225] But taking up where *Retina Associates* left off, the court observed that even if Comanche has sufficient market power and had harmed the doctor, Comanche's franchise radiology network may still "yield a procompetetive benefit."[226] Because antitrust law is to protect competition and not competitors,[227] the fundamental test for "restrains trade, is its effect on the public."[228] In short Dr. Beville, who has expended substantial sums of money on expert witnesses, appears to be headed for failure if he further pursuits his antitrust action.

Dr. Beville is not alone; Hammer and Sage's review of medical antitrust litigation found that the plaintiff prevails only infrequently.[229]

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219. *Id.* at 1381.

220. 72 F.3d 1538 (11th Cir. 1996).

221. *Id.* at 1550.

222. 39 P.3d 754 (Okla. 2001).

223. *Id.* at 757.

224. *Id.* at 759 (stating "the provisions of this state's antitrust statutes are similar to federal legislation, and interpretation of federal antitrust legislation provides assistance in interpreting the provisions of the Oklahoma statutes"); *see also Teleco v. Ford Industries*, 587 P.2d 1360, 1362 (Okla. 2001).

225. *Beville*, 39 P.3d at 761.

226. *Id.* at 762.

227. *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 344 (1962).

228. *Beville*, 39 P.3d at 764.

229. *Hammer and Sage, supra* n. 84, at 575.

Hammer and Sage opined that a reason behind the paucity of published medical antitrust case is because medical antitrust litigation is not cost effective. Medical plaintiffs spend substantial sums of money on litigation only to lose.[230] Moreover, if antitrust law is the "principal legal tool the U.S. employs to police private markets,"[231] the scarcity of private antitrust litigation implies that the FTC plays an important role in policing the medical market place.

Under the *Clayton Act*, the FTC has "jurisdiction over corporate acquisitions where the parties are engaged in commerce or in any activity affecting commerce."[232] The FTC, moreover, appears to be ready, able and willing to enter the medical antitrust arena; having recently increased it spending on medical antitrust cases by fifty percent.[233] But, the FTC has become a *de facto* watch dog of the medical trade, not because of a large number of litigated cases,[234] but rather because of the disproportionate effect an adverse FTC judgment has in deterring anticompetitive conduct.[235]

As in private medical antitrust litigation, the FTC is most successful when the defendant has committed a *per se* antitrust violation. *Per se* cases are the easy cases. As in the private antitrust litigation, when a health care provider has engaged *per se* prohibited conduct, to prevail all the FTC has to demonstrate is that the provider engage in the prohibited conduct.[236] For example, the FTC was able to step into the limelight in 2002 when it settled antitrust actions against two physicians groups: one in the Dallas-Ft. Worth area and one in the Denver area.[237] The antitrust violation in each of these cases was price-fixing; and the FTC has at least ten more cases like these two in the pipeline.[238]

The harder cases, like *FTC v. Tenet Healthcare,*[239] require the government to develop its case under a rule of reason analysis. In *Tenet Health Care,* Tenet who owned Lucy Lee Hospital in Popular Bluff, Mo.,

230. *Id.*

231. *Id.* at 547.

232. *Id.*

233. Abelson, *supra* n. 202, at ¶ 2.

234. *Hammer and Sage, supra* n. 84, at 605. Published antitrust actions in Hammer and Sage's review only accounted for 6% of published cases. *Id.*

235. *Id.*

236. 15 U.S.C §§ 1, 18 (noting that both the *Sherman Act* and the *Clayton Act* are strict liability statutes; meaning that intent does not have to be demonstrated to trigger liability).

237. Mark Taylor, *Another Round Resolved; FTC Settles Price-Fixing Cases With IPAs, Doc Groups*, Modern Healthcare 12 (Aug. 26, 2002).

238. *Id.*

239. 186 F.3d 1045, 1052-1055 (8th Cir. 1999); *see also State of Cali. v. Sutter Health System*, 84 F. Supp. 2d 1057, 1066-1086 (N.D. Cal. 2000) (showing a similar analysis and conclusion to *FTC v. Tenet Healthcare*, 186 F.3d 1049 (9th Cir. 2002)).

sought to merge the hospital with Popular Bluff's only other hospital: Doctors' Regional Medical Center. Pursuant to FTC procedure, Tenet filed for premerger certification.[240] Such certification requires the FTC to gather data concerning market participants and geographic area[241] to determine market power. Additionally, expert witnesses provide testimony concerning the economic consequences, and hence competitive effects of the planned merger or acquisition.[242] After gathering the data, the FTC denied Tenet certification to merge the two hospitals, and this decision was upheld by the trial court.[243] The trial court noted that the government had only defined the geographic market by using a common sense approach rather than a statistical analysis.[244] Tenet appealed arguing that the trial court had improperly shifted the burden of proof away from the government.[245]

The appellate court began its analysis by observing that the FTC may enjoin a merger or acquisition if after "weighing the equities [such an] action would be in the public interest."[246] The weighing of equities begins with a determination of a relevant market; because without a "well-defined relevant market, a merger's effect on competition cannot be evaluated."[247] A relevant market, in turn "consists of two components: a product market and a geographic market."[248] Therefore the validity of a monopolistic claim "often succeeds or fails strictly on the definition of the product or geographic market,"[249] for which the government has the burden of proof[250] to demonstrate a geographic market by "a factual inquiry into the commercial realities faced by consumers."[251] Here, because the government had used antidotal data to define the geographic market, the appellate court had no trouble concluding that the government had erred in defining the geographic market affect by the merger of the two hospitals too narrowly.[252] Accordingly, the court overruled the trial court and allowed the merger of the hospitals to go forward.

240. 15 U.S.C. § 18(a).

241. *Tenet*, 186 F.3d at 1049-51.

242. *Id.*

243. *Id.* at 1051.

244. *Id.*

245. *Id.*

246. 15 U.S.C. § 53(b) (2002).

247. *Tenet*, 186 F.3d at 1051 (citing Freeman Hosp., 69 F.3d at 268).

248. *Id.*

249. *Id.* at 1052 (citing *Morgenstern v. Wilson*, 29 F.3d 1291, 1296 (8th Cir. 1994)).

250. *U.S. v. Conn. Nat'l Bank*, 418 U.S. 656, 669 (1974) (stating that in developing a case against a health care provider, the FTC follows various guidelines, which are summarized in Department of Justices and F.T.C. Statement of Antitrust Enforcement Policy in Health Care) <http://www.ftc.gov/reports/hlth3s.htm> (accessed Nov. 11, 2002).

251. *Tenet*, 186 F.3d at 1052 (citing *Flegel*, 4 F.3d at 690).

252. *Id.* at 1053.

Tenet demonstrates that to successfully block a health care merger or acquisition, the FTC must develop a case against the merger or acquisition that will satisfy a rule of reason analyze. Accordingly, the government must collect and analysis complex statistical data. However, unlike private antitrust litigation the FTC does not have to endure the expense of retaining expert witness because courts will defer to the expertise of agency.[253] Still, complex merger and acquisition data analysis requires that the FTC commit substantial resources to challenge a hospital consolidation proposal. Not surprisingly, when the FTC challenges a merger or acquisition under a rule of reason analysis, the FTC has lost its last seven cases.[254] Moreover, the cost and track record of FTC medical antitrust litigation, in situations where the rule of reason applies, helps to explain why Richard Feinstein, the former head of the FTC's Bureau of Competition, observation that there are no hospitals consolidation proposals on FTC's litigation radar screen.[255] The FTC would rather concentrate its litigation arm on the low cost, more high successful and headline grabbing litigation associated *per se* violation committed by physicians.[256]

In medical antitrust litigation, the FTC has more than pecuniary limitations. As the *Tenet* case illustrate, in addition to spending money, the FTC must be willing to spend political capital. When the FTC elects to challenge a merger, it provides some of the local judges with the opportunity to tell a "bunch of Washington based lawyers and bureaucrats spouting general theories of consumer protection how little they know about the institutions they are attacking."[257] That is, in challenging a proposed market consolidation in the health care industry, the FTC must be prepared to wrestle with the pillars of the community who are members of a hospital board and already have cast their votes for or against consolidation. The bottom line is that, under rule of reason analysis, it not any easier for the FTC to prevail in medical antitrust litigation, than it is for private parties.

253. *See generally Vt. Yankee Nuclear Power v. Natural Def. Council*, 435 US 519 (1978).

254. Abelson, *supra* n. 202, at ¶ 11.

255. Mark Taylor, *Another Round Resolved; FTC Settles Price-Fixing Cases With IPAs, Doc Groups,* Modern Healthcare 12 (Aug. 26, 2002). However, as popular sentiment changes, so may the FTC's litigation strategy. *California: Big Hospital Chains Facing Backlash over Closings,* American Health Line (Aug. 22, 2002) (discussing the public backlash experienced by Tenet Health Care when it attempted to close a Los Angles community hospital).

256. Taylor, *supra* n. 255, at ¶ 3.

257. *Hammer and Sage, supra* n. 84, at 617.

3. *Antitrust Law v. Franchised Health Care*

So what does this discussion on medical antitrust law mean if in tomorrow's paper there is an announcement that the Mayo Clinic, Rush Presbyterian Hospital or Barnes-Jewish Hospital system elected to open a cybersurgery center in your community? Because antitrust law protects competition and not competitors, antitrust law is not a particularly inviting strategy to protect the local hospital or community physicians from the establishment of a cybersurgery outposts.

a. No Merger or Acquisition; No Problem

This discussion of antitrust law leads to the inexorable conclusion that without a merger or acquisition; or without some form of market consolidation, there cannot be an antitrust injury. Thus, if a well financed medical institution, like the Mayo Clinic, elects to open a franchise cybersurgery facility outside of its geographic market then there is little that antitrust law can do to stop such expansion. Opening a franchise cybersurgery facility, without more, is not a *per se* violation.[258] And, if the franchise facility, were opened outside of the parent institution's geographic area, then under a rule of reason analysis there could not be a antitrust injury because an isolated franchise cybersurgical facility would lack market power.[259] Consequently, antitrust commentators and the FTC were silent when the Mayo Clinic expanded into the Arizona and Florida markets. In short, the opening of a remote cybersurgical facility[260] would not raise any antitrust issues.

b. The Invisible Hand, Competitors and Competition

But using cybersurgery to expand within the geographic market of the parent institution is a little more problematic. In contrast to the Mayo Clinic's model of out-of-state expansion, consider the franchise expansion of Rush Presbyterian Hospital or Barnes-Jewish Hospital. In both cases, Rush and Barnes-Jewish have elected to open franchise facilities through the purchase of not-too-remote urban and suburban medical centers. Such expansion is a form of market consolidation which triggers antitrust concerns. However, any antitrust injury that may be present would have to be analyzed with respect to a relevant market;

258. To conclude otherwise would have a disastrous implication for the McDonald's Corporation. *See generally* John F. Love, *McDonalds: Behind the Golden Arches* (Bantom Books, New York 1986).

259. McLean, *Cybersurgery*, *supra* n. 2, at 172 (stating that because the opening of a new facility does not trigger antitrust concerns, an interesting question will be whether mobile platform automatic cybersurgery facilities will even trigger an antitrust injury).

260. *Id.* (stating that conceptually the remote franchise facility could be permanent, within a building; or alternatively the expansion could be by a mobile platform).

which means that cybersurgery franchise expansion within a metropolitan area would have to be analyzed under a rule of reason.

Accordingly, even if market consolidation is used to create a cybersurgical facility that threatens a community hospital and its physicians, it is unlikely that the hospital and its physicians would be able to entice the FTC to enter into the litigation arena. Because even fifty percent market power has been held to be insufficient to trigger an antitrust liability, it is unlikely that franchisor-parent institution will have sufficient market power. For example, consider the potential markets analysis that might be associated with Rush Presbyterian's proposal to build a cybersurgery facility on the near west side of Chicago. Within blocks of Rush's main campus are Cook County Hospital, University of Illinois Hospital and Clinics, the Veterans Administration West Side Hospital and the Illinois State Psychiatric Hospital. True, these institution do not attract the same patient populations, for the most part they are providing the same services. Because these hospitals are in a common geographic market and a common product market, they would very likely be found to be in the same relevant market for rule of reason analysis. However, with so many existing competitions in the market it is unlikely that any one hospital would have sufficient market power to cause an antitrust injury. Alternatively, if Rush elected to open a cybersurgical franchise in a more remote suburban location, the geographic market analysis would have to consider a much larger geographic area. The greater geographic area of such a calculation would mean that even more hospitals would have to be included in the calculation of market power. Because inclusion of other hospitals would serve to dilute Rush's share of the market, suburban expansion would still not give Rush sufficient market power to trigger antitrust liability.

But even if we allow that the calculation of market power is sufficiently high, franchise expansion of urban cybersurgical facility into the suburban communities is still not barred. Assuming that sufficient market power exist, an antitrust injury will not occur unless an unreasonable restraint, characterized by a contemplated lack of a procompetitive rationale, exists.[261] On a local level, if an urban cybersurgery provider would buy a remote, failing or failed hospital facility, the community would benefit by the retention of jobs. On a national level if automatic cybersurgery can be demonstrated to be more cost effective because of the economy of scale that the urban hospital obtains in providing surgery, then cybersurgery would have a procompetitive effect for American industry in the global economy. Finally, the Chairman of the FTC, Timothy Muris has indicated that the FTC is not going to get involved in situation where health care providers are legitimately trying to improve

261. *Levine*, 72 F.3d at 1551.

services. If automatic cybersurgery can be demonstrated to be either safer or more cost effective than traditional surgical intervention it is unlikely a provider of automatic cybersurgery will be found liable for antitrust injury.

The bottom line is that antitrust laws protect competition not competitors. Market forces, rather than antitrust laws will determine the success of the franchise health care system. When the Mayo Clinic Foundation franchised its medical operation no one blinked an eye. But, when the Mayo Clinic Foundation franchised its HMO operation, it was market forces that checked the franchise expansion.[262] The truth is that while antitrust law is the principle legal tool to police the market,[263] our capitalistic markets are policed by an invisible hand. Rather than prospectively checking the market expansion of corporations with antitrust law, our capitalistic society is more comfortable waiting for the economic bubble associated with such expansion to burst.[264] In an analogous fashion, it is unlikely that America will check the expansion of a well-funded health care institution's expansion into the world of cybersurgery. Rather, we will ultimately let the market determine whether cybersurgery is a better technique than more traditional surgical technique.

V. CONCLUSION

Cybersurgery, which today exist only at the prototype stage, will soon be improved by the use of automated off-line technology. As the automatic surgeon, analogues to an automatic pilot, becomes more commonplace, the cybersurgery like any other mature technology will threaten the market participants. In medicine the market participants are hospitals and physicians. Telemedicine technology, and cybersurgery in particular, is going to be a powerful economic force on hospitals and physicians. As it is human nature to resist change that threats one's livelihood, community hospitals and physicians look to use trade barriers and antitrust laws to regulate cybersurgery. Unfortunately, because these laws are designed to protect competition and not competitors, the community hospitals and physicians will be left without a defense against the coming technologic innovations. Whether the community hospitals close and physicians become under-employed as a result of automated cybersurgery will ultimately turn on patient demand, and hence satisfaction with, cybersurgery; and not on the medical profession's erection of trade barriers or the deployment of antitrust law.

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262. *General Information about Mayo Clinic* ¶ 12 <http://www.mayoclinic.org/about/> (accessed Nov. 11, 2002) (stating that Mayo exiting the market).

263. *Hammer and Sage*, *supra* n. 84, at 547.

264. John Kenneth Galbraith, *A Short History of Financial Euphoria* (Viking Books, N.Y. 1993).