

Frontiers of Medical Technology: Reflections on the Intersection of Innovation and the Health Care System

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In Professor Chen's provocative introductory essay to this issue, he notes that C.P. Snow's observations in his famous lecture, *The Two Cultures*, still resonate in our society.¹ Snow condemned the dominant literary culture's failure to embrace science and the consequences to the "underfed . . . [who] die before their time."² Snow yearned for a bridge over the divide, "something like a third culture," comprising a community of social scientists "concerned with how human beings are living or have lived."³

Recognizing the need for social science to build bridges, University of Minnesota's conference⁴ sought to address the intersection between the "life sciences and the political demands and social aspirations of the law."⁵ My specific challenge was to explore the interface between innovation in medical technology and the political and social demands of the health care delivery system. This interface is constantly evolving in response to technological innovation.

C.P. Snow and his generation would be surprised by the

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1. Jim Chen, *The Midas Touch*, 7 MINN. J.L. SCI. & TECH., at i (2005) (citing C.P. SNOW, *THE TWO CULTURES: AND A SECOND LOOK* 22 (2d ed. 1964)).

2. SNOW, *supra* note 1, at 6-7.

3. *Id.* at 70.

4. "Where are Law, Ethics and the Life Sciences Headed? Frontier Issues," cosponsored by the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences and Joint Degree Program in Law, Health and the Life Sciences and the *Minnesota Journal of Law, Science & Technology* (May 20, 2005).

5. Chen, *supra* note 1, at iii.

rapid acceleration of advances in medical technology and its enthusiastic embrace by Americans. From the perspective of the 1950s, when Snow penned his controversial lecture,⁶ we have taken an audacious leap. Medical technology harnesses scientific and engineering advances, born out of the industrial revolution and transformed in the late twentieth century, to alter, replace, and repair a dizzying array of human functions.⁷ The success of technology in extending life and improving the quality of life is reflected in the importance that Americans place on access to health care. After all, we spent \$1.7 trillion or \$5,670 per capita (15.3% of GDP), in 2003 on health.⁸ Indeed, just as science held the potential to ameliorate “the underfed” of Snow’s day, so now does access to medical care, in all of its technological splendor, distinguish between those who have and those who have not.

It is essential to note that medical technology does not enter American society unencumbered. Our embrace is not unconditional; it is, in fact, quite fickle. Law conditions medical technology’s arrival by imposing high social standards of safety. Once a technology is approved for marketing, the health care delivery system imposes further constraints.

Before embarking on an exploration of the intersection between medical technology and law, we must clarify both terms of the equation. What do we mean by medical technology? The Office of Technology Assessment once broadly defined medical technology to include “drugs, devices, medical surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided.”⁹ It is not surprising that innovation across such a wide range of activities varies significantly.

Examples of medical technology innovation abound. There have been a plethora of new drugs introduced in the last few decades, and the advent of biotechnology presents promise for conventional pharmaceuticals and combinations of drugs and

6. See SNOW, *supra* note 1, at 1.

7. For a history of the evolution of medical technology, see generally SUSAN BARTLETT FOOTE, *MANAGING THE MEDICAL ARMS RACE: PUBLIC POLICY AND MEDICAL DEVICE INNOVATION* (1992).

8. See Cynthia Smith et al., *Health Spending Growth Slows in 2003*, 24 HEALTH AFF. 185-86 (2005).

9. OFFICE OF TECH. ASSESSMENT, *MEDICAL TECHNOLOGY UNDER PROPOSALS TO INCREASE COMPETITION IN HEALTH CARE*, at ix (1982), available at http://www.blackvault.com/documents/ota/Ota_4/DATA/1982/8218.PDF.

biologics.¹⁰ Recent advances in molecular biology, proteomic technologies, cellular and tissue engineering, and genomic applications are just a few of the cutting-edge advances.¹¹

Once an insignificant part of the medical arsenal, medical devices are now used in thousands of interventions.¹² Devices include implanted artificial hips and knees, a wide range of cardiac interventions, such as stents, pacemakers, and defibrillators, medical lasers, and diagnostic tools, such as magnetic resonance imaging, computerized tomography, and positron emission tomography.¹³ There is significant innovation on the horizon, including computer-assisted telemanipulators that merge robotics, 3-D visualization systems, and computer technology,¹⁴ and nanotechnology applications,¹⁵ to name just a few. Medical device innovation embraces the frontiers of science and engineering, adapting computer technology, nanotechnology, and biotechnology to medical applications.¹⁶ Many of these technologies are delivered by physicians in in-patient and out-patient settings and are embedded in the service delivery system.¹⁷ Physicians' needs and experiences in clinical settings often trigger innovation and incremental improvements; physicians also require ongoing training to effectively use innovative therapies.¹⁸

A few areas of medical technology, such as reproductive techniques, cloning, and genetic manipulation, raise unique controversial ethical issues. However, the focus here is on

10. See, e.g., John Miller, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 COLUM. SCI. & TECH. L. REV. 1 (2003).

11. See generally Phil B. Fontanarosa & Catherine D. DeAngelis, *Medical Applications of Biotechnology*, 293 J. AM. MED. ASS'N 866, 866-67 (2005).

12. See, e.g., HEALTH INDUS. MFRS. ASS'N, OUTLOOK FOR MEDICAL TECHNOLOGY INNOVATION: WILL PATIENTS GET THE CARE THEY NEED? REPORT 1: THE STATE OF THE INDUSTRY (2000).

13. See generally *id.* (discussing medical devices and the industry as a whole).

14. See generally Mark A. Talamini & Eric J. Hanly, *Technology in the Operating Suite*, 293 J. AM. MED. ASS'N 863, 863-66 (2005).

15. See Miller, *supra* note 10, at 5 (defining nanomedicine as "the monitoring, repair, construction and control of human biological systems at the molecular level, using engineered nanodevices and nanostructures").

16. See HEALTH INDUS. MFRS. ASS'N, *supra* note 12, at 7-9.

17. See, e.g., *id.* at 12.

18. See, e.g., Cinda Becker, *Shock Treatment*, MODERN HEALTHCARE, May 9, 2005, at 34, 36 (discussing advances in electrophysiology and the concurrent need for physician training).

“workaday” medical products and procedures, many in widespread use, that have become expected therapies for patients and account for billions of dollars in health care spending.¹⁹

Turning to the other term in the equation, references to “law” in the context of health care are necessarily broad-gauged. The American health care system is enormously complex, with a mix of federal and state legislation and regulation by a myriad of agencies.²⁰ It is beyond the scope of this paper to labor through a primer on the U.S. health care system. What is important to note, however, is that medical device technology can be directly and indirectly affected by a wide range of laws and regulations and change in response to innovation is a frequent occurrence.²¹

Each component of medical technology faces different regulatory and legal hurdles. For example, the Food and Drug Administration’s (FDA) authority has evolved to tailor regulations to the specific characteristics of drugs, devices, and biologics.²² The FDA does not have authority to directly regulate physicians or the procedures that they perform; its scope only extends to the products that physicians use.²³ Often change is triggered by a regulatory reaction to innovation.²⁴

19. There are controversies surrounding how the costs of medical devices specifically or medical technology generally are calculated to determine what contribution they make to health care spending. One way is to look at the costs of the devices themselves, scaled to market size. See HEALTH INDUS. MFRS. ASS’N, *supra* note 12, at 13.

20. See FOOTE, *supra* note 7, at 26-52.

21. See *id.*

22. Indeed, the statutory definition of medical devices describes a series of product types that are specifically “non-drugs,” meaning that they are not metabolized by the human body:

The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and *which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*”

21 U.S.C. § 321(h) (2000) (emphasis added).

23. See FOOTE, *supra* note 7, at 44-45.

24. See Susan Bartlett Foote & Robert J. Berlin, *Can Regulation Be as*

Change can also be triggered by product failures. Recent product safety scandals involving antidepressants, painkillers, and defibrillators have generated calls for FDA reforms.²⁵ Payment, coverage, insurance, and liability issues also vary for the components of medical technology.²⁶ Because access to drugs is considered an essential part of a complete health regimen, increasingly there is a demand for insurance coverage. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003²⁷ designed a drug benefit for beneficiaries that will be implemented in 2006.²⁸

The common theme is constant change. Technological change has dramatically affected all aspects of health care, and the health care system affects how that technology is evaluated, accepted, diffused, and reimbursed. If “jurisdynamics” captures the concept of growth and change in law,²⁹ medical technology exemplifies growth and change in health care.

At this intersection, then, between medical technology and the health care system, are three “frontier policy issues”—access to care, costs of care, and value of care. It is to these that we now turn.

ACCESS TO CARE

The American approach to health care access is ambivalent. Our government does not provide universal access to care, unlike nations such as Japan or Canada where all citizens are entitled to participate in the government-supported health care system.³⁰ Access to care in America is not so

Innovative as Science and Technology? The FDA's Regulation of Combination Products, 6 MINN. J.L. SCI. & TECH. 619, 619-39 (2005) (discussing this phenomenon at length).

25. See Gardiner Harris, *F.D.A. Responds to Criticism with New Caution*, N.Y. TIMES, Aug. 6, 2005, at A1.

26. See HEALTH INDUS. MFRS. ASS'N, *supra* note 12, at 52-62.

27. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

28. For a discussion of the new prescription drug program, see Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, 24 HEALTH AFF. (WEB EXCLUSIVES) W5-152, W5-152 to W5-166 (Supp. 1 2005), available at <http://content.healthaffairs.org/webexclusives/index.dtl?year=2005>.

29. See generally Jim Chen, *The Pragmatic Ecologist: Environmental Protection as a Jurisdynamic Experience*, 87 MINN. L. REV. 847 (2003).

30. See Strategic Pol'y & Research: Intergovernmental Affairs, *Health Care Systems: An International Comparison* 4 (2001),

simple. Some Americans do receive health care as an entitlement. For example, over forty million Americans qualify for Medicare based on age, disability, and contribution to the system.³¹ Others qualify for the Medicaid entitlement based on state-based criteria of low income and other welfare-related status indicators.³² Because the Medicaid entitlement is based on status, changes due to income increases, for example, can cause the loss of entitlement.³³

Most other Americans must ensure access, if they can, through private insurance.³⁴ They purchase access either with employer assistance or on the open market.³⁵ Because employers are not required to offer or subsidize insurance, many working Americans do not have employment-based coverage.³⁶ Moreover, rising costs have led some employers to drop insurance subsidies.³⁷ The ranks of those without any health insurance for at least some part of a year have swelled during the past ten years.³⁸ In 2003, the number of uninsured Americans was forty-five million, and the uninsured population is predicted to grow another twenty-five percent, to fifty-six million Americans, by 2013.³⁹

These individuals are not completely without access. Medical technology and medical procedures are not perceived as run-of-the-mill consumer goods, such as computers or automobiles, which are available only to those with the resources to purchase them. At some level, medical services

<http://www.pnrec.org/2001papers/DaigneaultLajoie.pdf>.

31. See <http://www.medicare.gov> (last visited Oct. 8, 2005).

32. See <http://www.cms.hhs.gov> (last visited Oct. 8, 2005).

33. See *id.*; see also <http://www.ihs.gov> (last visited Oct. 8, 2005) (describing access to the Indian Health Service for certain Native Americans); <http://www.tricare.osd.mil> (last visited Oct. 8, 2005) (describing access for active duty service personnel, through the Department of Defense program called Tricare); <http://www.vba.va.gov> (last visited Oct. 8, 2005) (describing access for certain veterans through the Veterans Benefits Administration).

34. See GARY CLAXTON, KAISER FAMILY FOUND., *HOW PRIVATE INSURANCE WORKS: A PRIMER* 1 (2002).

35. See *id.*

36. See KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUC. TRUST, *EMPLOYER HEALTH BENEFITS: 2005 SUMMARY OF FINDINGS* 4 (2005).

37. See *id.* at 11.

38. See Todd Gilmer & Richard Kronick, *It's the Premiums, Stupid: Projections of the Uninsured Through 2013*, 24 HEALTH AFF. (WEB EXCLUSIVES) W5-143, W5-145 ex.1 (Supp. 1 2005), available at <http://content.healthaffairs.org/webexclusives/index.dtl?year=2005>.

39. *Id.* at W5-148 to W5-149. For an extensive discussion of the estimates, see generally *id.*

are treated as “merit goods” that have greater social value and should be more widely available.⁴⁰ Therefore, hospitals are required by law to treat any emergencies that arrive at their doors, regardless of the insurance status of the patient.⁴¹ However, these patients lack access to nonemergency needs, including elective, preventive, and life-saving technologies that are not “emergencies.”

A recent *New York Times* article focused on access differences based not on insurance status, but based on social class.⁴² In the second in a series of articles titled *Class Matters*, the reporter traced the effect of social class, defined as “that elusive combination of income, education, occupation and wealth,” on three patients who had heart attacks in New York City.⁴³ As Ichiro Kawachi, a professor of social epidemiology at the Harvard School of Public Health, noted in the article: “It’s like diffusion of innovation: whenever innovation comes along, the well-to-do are much quicker at adopting it. . . . Mortality rates even among the poor are coming down, but the rate is not anywhere near as fast as for the well-to-do.”⁴⁴ Bruce G. Link, a professor at Columbia University, observed: “We’re creating disparities. It’s almost as if it’s transforming health, which used to be like fate, into a commodity. Like the distribution of BMW’s or goat cheese.”⁴⁵ Law and policy do not ensure equitable access to health care, especially the high-tech care associated with expensive drugs, devices, and life-enhancing procedures.

Despite inequitable access to care, America spends more on health care than any other nation.⁴⁶ The rising costs of health care threaten access for those who do not have sufficient resources to pay. Technological change has played a role in

40. Merit goods are defined as “those goods and services to which people are entitled as a birthright, simply by virtue of being members of society, regardless of ability to pay.” *Economic Brief No. 16: Merit Goods: A Policy Dilemma*, COMMUNITY LEADER’S LETTER (Clemson Univ. Cmty. & Econ. Dev. Program, Clemson, S.C.), Summer 1994, at 2, available at <http://www.strom.clemson.edu/teams/ced/cll/5-2Summer94.pdf>.

41. See 42 U.S.C. § 1395dd (2000).

42. See Janny Scott, *Life at the Top in America Isn’t Just Better, It’s Longer: Three Heart Attacks, and What Came Next*, N.Y. TIMES, May 16, 2005, at A1, A14-15.

43. *Id.* at A1.

44. *Id.* at A14.

45. *Id.*

46. See WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2004: CHANGING HISTORY 136–43 (2004).

raising the cost of care. As the noted economists David Cutler and Mark McClellan have found: "It is widely accepted that technological change has accounted for the bulk of medical care cost increases over time."⁴⁷ Thus, changing technology exacerbates access problems.

COSTS OF CARE

Determining how technology in medicine affects costs is a challenge. When a new technology substitutes for an older version, the costs can either rise or fall. At the same time, new technologies often lead to the expansion of the patient population to be treated, resulting in higher overall costs. For example, when cataract surgery was improved, the number of surgical procedures grew.⁴⁸ In 2003, the American College of Cardiology reported that 70,785 heart patients were eligible for expensive implantable cardiac defibrillators (ICDs).⁴⁹ With expanded coverage policies for patients not quite as sick as traditional ICD patients, the estimate has grown to 240,000 eligible Medicare patients in 2005.⁵⁰

Many reports praising the value of new medical technologies are accompanied by lamentations about their costs. At the end of an article on the future of surgical robotics, the authors warn:

As surgery has rushed into the world of innovation, a few cautionary flags are in order. Innovative technology is very expensive. Who is going to pay for these advances? Which innovations are truly better for patients and which are simply enticing? Who will pay for the studies to distinguish between these? Are those technology-based procedures that appear to be better truly cost-effective? Are there sufficient safeguards in place? Should the free market be allowed to decide which technologies will become entrenched, or should the government take a bigger role?⁵¹

At the end of an article on ICDs, a consultant notes: "It's exciting, [but] it's just that somebody has to pay for all of this."⁵²

47. David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?*, 20 HEALTH AFF. 11, 11 (2001).

48. See IRVING SHAPIRO, MATTHEW D. SHAPIRO & DAVID W. WILCOX, MEASURING THE VALUE OF CATARACT SURGERY 9 (1998), available at <http://www-personal.umich.edu/~shapiro/crhw-rv2.pdf>.

49. See Becker, *supra* note 18, at 34.

50. See *id.*

51. Talamini & Hanly, *supra* note 14, at 865-66.

52. Becker, *supra* note 18, at 36.

VALUE OF CARE

Rising costs coupled with the rising number of uninsured individuals have led to calls for change. A few have argued that we need to ration access to costly technologies, similar to efforts by Oregon to define limits for its Medicaid population.⁵³ Many others have called for the rationalization of utilization of technologies by subjecting innovations to greater scrutiny and by seeking to eliminate services that do not produce net improvements in health outcomes.

The Medicare program has undertaken significant changes in its process for evaluating new technologies before making coverage decisions.⁵⁴ Research by John Wennberg and his colleagues has shown significant variations in how medicine is practiced across the country,⁵⁵ concluding that hospital and physician capacity is directly related to higher spending, often without improved quality or length of life.⁵⁶ The Commonwealth Fund has also recently issued data documenting variation in quality of care in the Medicare program.⁵⁷ Medicare is experimenting with pay-for-performance demonstration projects,⁵⁸ and physician groups are working to impose practice standards on their members.⁵⁹

53. See, e.g., Daniel M. Fox & Howard M. Leichter, *Rationing Care in Oregon: The New Accountability*, 10 HEALTH AFF. 7 (1991) (discussing Oregon's rationing of its medical care resources).

54. For a discussion of the evolution of Medicare's coverage process, see Susan Bartlett Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis*, 27 J. HEALTH POL. POL'Y & L. 707 (2002).

55. See John E. Wennberg, *Practice Variations and Health Care Reform: Connecting the Dots*, 24 HEALTH AFF. (VARIATIONS REVISITED) VAR-140, VAR-140 to VAR-144 (2004).

56. See John E. Wennberg, Elliot S. Fisher & Jonathan S. Skinner, *Geography and the Debate over Medicare Reform*, 21 HEALTH AFF. (WEB EXCLUSIVES) W96, W98 to W102 (2002), <http://content.healthaffairs.org/webexclusives/index.dtl?year=2002>.

57. See SHEILA LEATHERMAN & DOUGLAS MCCARTHY, COMMONWEALTH FUND, *QUALITY OF HEALTH CARE FOR MEDICARE BENEFICIARIES: A CHARTBOOK* 11 (2005), available at http://www.cmf.org/usr_doc/MedicareChartbk.pdf (concluding that despite signs of progress, there is a wide variety of quality across the country).

58. Press Release, Center for Medicare & Medicaid Services, Medicare "Pay for Performance (P4P)" Initiatives (Jan. 31, 2005), <http://www.cms.hhs.gov/media/press/release.asp?Counter=1343>.

59. See Warren A. Jones et al., *Task Force Report 3: Report of the Task Force on Continuous Personal, Professional, and Practice Development in Family Medicine*, 2 ANNALS FAM. MED. S65, S65-S74 (Supp. 2004); *Doctor Involvement Grows in Practice-Improvement Efforts*, 59 MED. & HEALTH, Apr. 25, 2005, at 1-2.

These efforts in the public and private sectors are aimed at eliminating waste and reducing use of costly treatments whose marginal value is low. That is an important goal. However, it has been argued that these goals will “directly or indirectly retard technological progress.”⁶⁰ In addition, the fragmentation of the American system makes comprehensive and effective evaluation of new technology very difficult.

Americans have embraced the frontiers of medical technology. They support investments in research and are avid consumers of technology. Many of the fruits of that technology have resulted in longer and better lives for many Americans. These outcomes satisfy the call of C.P. Snow to harness science and technology, to alleviate need, and to show concern for “how human beings are living or have lived.”⁶¹ The challenge, however, is formidable. Valuable medical technology must navigate between the Scylla of rising costs and the Charybdis of ensuring access to care.⁶² To date, our quest has been elusive at best as we struggle to balance social and legal values with science and technology in the service of improved health for all Americans.

60. Cutler & McClellan, *supra* note 47, at 25.

61. SNOW, *supra* note 1, at 70.

62. See THOMAS BULFINCH, BULFINCH'S MYTHOLOGY: ILLUSTRATED EDITION 243-45 (1979) (recounting the story of Scylla and Charybdis, who have become “proverbial, to denote opposite dangers which beset one's course”).