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SCIENCE, TECHNOLOGY AND THE LAW

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Editor's Note

The *Annals of Health Law* editorial staff is proud to present, *Advance Directive*, our new online health law journal. We chose the theme of Science, Technology and the Law for our inaugural issue of *Advance Directive* to complement our Fall 2008 Symposium entitled, "Patents versus Patients: Can They Co-Exist?". With vast technological and scientific advances in medicine and the healthcare industry, the law is continually evolving and increasingly complex. Our member contributors have attacked these legal issues head-on, writing about timely topics ranging from pharmaceutical and genetic patents to electronic medical records and the emerging field of telemedicine.

Our goal is to present a wide range of student perspectives that address the intersection of health law, science and technology. This issue first looks at the controversies surrounding gene patents and their potential to impede research on disease genes and diagnostics. The first article proposes solutions such as responsive licensing policies, which could promote innovation and ensure access to genetic tests and therapies. The next article explores an important breakthrough in stem cell research: the advent of human induced pluripotent stem cells (iPSCs). The author examines how the ability to patent iPSCs could spur innovation and research that is free of the ethical controversies surrounding human embryonic stem cells. We then address the strengths and weaknesses of the Bayh-Dole Act in facilitating technology transfer.

Our authors tackle the issue of FDA approval and regulation of investigational medical devices; and the controversy surrounding insurance coverage of untested treatments involving new, high-priced medical technologies. We then look at the use of internet health information resources to promote more informed patient

health care decisions and, as a result, better public health outcomes. Next, our authors weigh the benefits and drawbacks of electronic file storage of medical records, as well as the implications to electronic medical records that may arise from the new tort for medical privacy and confidentiality. Finally, our first issue reviews promises and challenges within the emerging field of telemedicine, from the perspectives of physicians, hospitals and academics.

I would like to thank Claire St. Aubin, our Technical Production Editor, and Tiffany Gehrke and Alexis Shrawder, our Website Senior Editors, for their invaluable contributions to *Advance Directive*, from conception to publication. Additionally, much appreciation goes to the *Annals* Executive Board--Adam Larson, Angela Epolito and Tamara Forys--for their editorial support; and to all of our member contributors for their creativity, hard work and perseverance in putting together this first issue. Finally, our faculty advisors, Professors Lawrence Singer and John Blum, deserve a special acknowledgment for their continued support of *Annals* and for their encouragement to launch this online journal.

We hope you enjoy this first issue of *Advance Directive*.

Sincerely,

Ann Weilbaecher
Editor-in-Chief
Annals of Health Law
Loyola University Chicago School of Law

ANNALS OF HEALTH LAW
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Gene Patents: Promoting Discovery or Hindering Research?

Amy Fuetterer[*]

Granting patent rights for new genetic discoveries is a topic of heated debate in patent law due to the ethical, legal, and economic concerns involved.[1] Since the United States Patent and Trademark Office (USPTO) issued the first gene patent in 1982,[2] the number of gene patents in the United States has skyrocketed.[3] At the start of the biotechnology revolution in the early 1980s, gene patents were widely recognized as the driving motivation behind the willingness of biotechnology companies to invest in extremely expensive and unpredictable development of biotechnology products.[4] Today, it is less clear

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[1] Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006), *available at* http://www.wulaw.wustl.edu/faculty/documents/kieff/Articles/CaulfieldCookDeeganKieffWalschAnalysisofHumanGenePatents.pdf.

[2] *Gene Patent and Global Competition Issues: Protection of Biotechnology Under Patent Law*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 1, 2006, http://www.genengnews.com/articles/chitem_print.aspx?aid=1163&chid=0 (issued to the Regents of the University of California for "work carried out on the construction of a plasmid contained in a bacterium and expression of genes for chorionic somatomammotropin").

[3] Christopher M. Holman, *Recent Legislative Proposals Aimed at the Perceived Problem of Gene Patents*, BIOTECH BRIEFING (ABA Section of Sci. & Tech. Law, Chicago, I.L.), Fall 2008, http://www.abanet.org/scitech/genepatents.html; *see* Caulfield et al., *supra* note 1 at 1091 ("The mid-1990s was also a period of rapid (roughly 50% per annum) growth in DNA-related patents in the United States"); *see also* Mike Stott & Jill Valentine, *Patenting and Medical Research: A View From a Pharmaceutical Company*, 3 NATURE 364, 367 (2004), *available at* http://www.brown.edu/Courses/BI8/2004/group04/PDFSandReviews/BI%208/Ethics%20in%20Biotechnology/Article%202/Gene%20Patenting.pdf ("In 2001 alone, 1500 patents were issue claiming human genetic material.").

[4] Holman, *supra* note 3.

whether the proliferation of gene patents advance biotechnology by providing an incentive for researchers to create new and useful gene sequences or hinder research by making it too costly and cumbersome for researchers to license or design around the patents of others.[5] It is clear that "*both* patents and freedom to undertake research are crucial to the successful delivery of medicines to society."[6]

I. WHAT IS A GENE PATENT?

Traditionally, a "gene patent" is a patent claiming a protein encoding DNA sequence.[7] However, the term is often used loosely to describe patents for gene-fragments, expressed sequence tags (ESTs), or single nucleotide polymorphisms (SNPs).[8] For the purposes of this Article, "gene patent" refers to the traditional definition of a DNA sequence that encodes for a protein. This Article will also address patents claiming "disease genes," gene sequences utilized in diagnostic testing for disease gene markers.[9]

II. PATENTABLE SUBJECT MATTER?

The general rule is that "raw products of nature" are not patentable subject matter.[10] Why then is patent protection extended to DNA when DNA is a product of nature? In *Diamond v. Chakrabarty*, the Supreme Court set forth the broad standard that "anything under the sun made by man" is patentable subject matter.[11] Thus, gene sequences are only patentable when isolated, purified, genetically altered, or genetically engineered by man to produce a unique form

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[5] *See* Caulfield et al., *supra* note 1, at 1091-92.
[6] Stott & Valentine, *supra* note 3, at 364.
[7] *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the H. Judiciary Subcomm. on Courts, the Internet, and Intellectual Property* 2 (Oct. 30, 2007) (statement of Lawrence M. Sung, Partner, Dewey & LeBoeuf LLP), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1005&context=cong_test.
[8] *Id.*
[9] JON F. MERZ, PRESENTATION TO THE SECRETARY'S ADVISORY COMMITTEE ON GENETIC TESTING, ON THE EXCLUSIVE LICENSING OF DISEASE GENE PATENTS 4 (June 7, 2000), http://www.bioethics.upenn.edu/prog/ethicsgenes/pdf/SACGT_20000507.pdf.
[10] Genetics and Patenting, Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml (last visited Nov. 6, 2008) [hereinafter Human Genome Project].
[11] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

not found in nature.[12] Currently, United States patent policy allows for gene patents when an inventor can (1) "identify novel genetic sequences," (2) "specify the sequence's product" and "its use," and (3) "enable one skilled in the field to use the sequence for its stated purpose."[13]

III. GENE PATENT HOLDERS AND LICENSING PRACTICES

The majority of genomic information is either patented or in the public domain.[14] Current holders of gene patents in the United States include academic institutions, the Government, and biotechnology and pharmaceutical companies.[15] Both academic institutions and the Government typically license gene patents non-exclusively to downstream developers who make the genes available to the public.[16] Similarly, many biotechnology and pharmaceutical companies out-license their gene patents on a non-exclusive basis.[17] Some big industry players, however, have stirred up controversy by using important diagnostic disease gene patents exclusively for internal development.[18]

IV. THE OPPOSITION TO GENE PATENTS

Many public institution researchers and medical practitioners strongly oppose gene patents, arguing that patents are not a necessary incentive for biotechnology research[19] and that the costs associated with licensing patented research data impedes the development of diagnostics and therapeutics. [20] For

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[12] Human Genome Project, *supra* note 10.
[13] *Id.*
[14] Lin Sun-Hoffman, How Does Private Sector Handle Licensing of Genetic Discoveries?, Presentation at the National Institute of Health Secretary's Advisory Committee on Genetics, Health, and Society 12th Meeting 8 (March 27, 2007), (slides available at http://www4.od.nih.gov/oba/sacghs/meetings/Mar2007/Tues%20am%20-%20Sun-Hoffman.pdf).
[15] *Id.* at 6.
[16] *Id.* at 9.
[17] *Id.* at 10.
[18] *Id.* (such as the BRCA1 and BRCA2 breast cancer genes).
[19] Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 405-06 (2005) (arguing that there are many other incentives for the discovery of genetic sequences other that patents, such as "medical interests and the potential for academic advancement and status").
[20] Human Genome Project, *supra* note 10.

example, a laboratory wishing to run a diagnostic test that involves a plethora of patented gene sequences must pay royalties to patent owners for every gene involved.[21]

An even greater problem arises when a patent owner is unwilling to license disease gene patents necessary for genetic testing to other researchers.[22] Such practices arguably diminish the quality of genetic tests and interfere with access to health care by limiting research and development to the patent owner.[23] If a patented gene sequence needed for research is not being licensed, the only options for researchers are (1) to move offshore to use the gene outside of the United States (this is too costly for smaller startup companies); (2) design around the patented gene (usually difficult in the case of a DNA sequence); or (3) use the patented gene without a license (this is an unstable policy).[24] Therefore, there is currently no satisfactory solution to the problem that arises when patentees engage in exclusive licensing practices.

V. IS THERE REALLY A PROBLEM WITH GENE PATENTS?

A. Gene Patents are Generally Regarded as Positive

Many industry biotechnology and pharmaceutical companies claim that they are unwilling to make a substantial investment in research without the ability to prevent competitors from making or using the invention without a license.[25] Additionally, patents allow private-sector researchers to make new gene sequences public without losing exclusive rights, thus avoiding secrecy and promoting the dissemination of knowledge regarding genetic discoveries.[26]

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[21] *See* Roger D. Klein, *Gene Patents and Personalized Medicine*, 4 PERSONALIZED MED. 237, 239-40 (2007), http://www.futuremedicine.com/doi/pdf/10.2217/17410541.4.3.237?cookieSet=1.
[22] Caulfield et al., *supra* note 1, at 1092.
[23] Andrews & Paradise, *supra* note 19, at 412.
[24] Stott & Valentine, *supra* note 3, at 366; Caulfield et al., *supra* note 1, at 1093.
[25] Human Genome Project, *supra* note 10.
[26] *Id.*

B. There is No Empirical Evidence that Gene Patents Hinder Research

Despite the arguments that gene patents hinder research, empirical data shows that this argument is more anecdotal than factual.[27] The data indicates that many researchers do have access to patented technology, suggesting that licensing is non-exclusive.[28] In fact, the "vast majority" of gene patents are available for licensing.[29] Furthermore, only one percent of biomedical researchers in the United States reported having to delay a project, and none reported having to abandon a project, as a result of gene patents, suggesting that licensing costs are not seriously limiting academic research.[30]

C. Real Concern Exists in the Area of Disease Gene Patents

The asserted problems of exclusive licensing may legitimately hinder diagnostic testing in the area of disease gene patents.[31] In this case, there are more instances of researchers and firms abandoning the development of genetic tests as a result of disease gene patents.[32] Furthermore, medical practitioners who diagnose diseases based on genetic information agree that gene patents have limited their medical practice.[33]

VI. RECENT JUDICIAL DECISIONS COUNTERACTING ALLEGED PROBLEMS WITH GENE PATENTS

In light of recent Supreme Court decisions, it is increasingly difficult for applicants to obtain and enforce gene patents.[34] In *KSR Int'l Co. v. Teleflex Inc.*,

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[27] Caulfield et al., *supra* note 1, at 1092.
[28] *Id.*
[29] Stott & Valentine, *supra* note 3, at 366.
[30] Caulfield et al., *supra* note 1, at 1092.
[31] *Id.*
[32] *Id.* ("For example, 30% of clinical labs report not developing or abandoning testing for the HFE gene" and "25% of labs had abandoned one or more genetic tests as a result of patents, with [the BRCA1 and BRCA2 breast cancer gene patents] among the most frequently mentioned").
[33] *See, e.g.*, DEBRA LEONARD, COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS, EFFECTS OF GENE PATENTS ON GENETIC TESTING AND RESEARCH 2 (Oct. 1, 2004), www7.nationalacademies.org/step/Leonard_presentation_October_proteomics.ppt.
[34] *See* Sung, *supra* note 7, at 7.

the Supreme Court held that an invention may be too obvious to be patentable if the invention would "occur in the ordinary course without real innovation," or if "a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem."[35] As a result of the human genome project and the availability of genetic sequences in online databases, gene sequences are readily available prior art to biotechnology researchers.[36] Furthermore, the extremely high market demand for genetic testing renders the development of new gene sequences an attractive and potentially obvious investment for researchers.[37] Therefore, *KSR* will most likely reduce the number of gene patents granted due to obvious rejections by the USPTO.

In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court imposed an injunctive relief restraint based on public interest factors.[38] In this case, the denial of injunctive relief for the patentee, although not compulsory licensing *per se*, amounted to the equivalent because the infringer could continue to use the patented invention in exchange for paying a reasonable royalty.[39] Thus, *eBay* may solve the problem of exclusive licensing by providing a strong incentive for patent holders to grant non-exclusive licenses for reasonable royalties to avoid litigation that might not result in injunctive relief.

Lastly, the Supreme Court Decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, expanded 35 U.S.C. § 271(e)(1), a statutory research exemption from infringement liability for research related to the preparation and submission of applications for Food and Drug Administration (FDA) approval. [40] *Merck* held that the exemption includes all uses where there is a reasonable basis

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[35] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 398 (2007).
[36] *See, e.g.*, Gene Gateway – Exploring Disease and Genetic Disorders, http://genomics.energy.gov/genegateway (last visited Nov. 6, 2008) (web site sponsored by the U.S. Department of Energy Biological and Environmental Research containing a "chromosome viewer" and links to comprehensive gene sequence databases such as GenBank).
[37] *See* Research and Markets, U.S. Genetic Testing Markets, http://www.researchandmarkets.com/reports/364798/u_s_genetic_testing_markets.htm (last visited Nov. 6, 2008) (reporting that "genetic testing is the highest growth segment of the diagnostics industry" and "the frontier of tremendous potential for companies").
[38] *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390-91 (2006).
[39] Sung, *supra* note 7, at 7.
[40] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

to believe that the compound tested could be the subject of an FDA submission, including preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process.[41] Therefore, *Merck* potentially reduces the problem caused by exclusive licensing of disease gene patents if the use of disease genes qualifies for the FDA exemption.

VII. SOLUTIONS OUTSIDE OF THE JUDICIARY

Outside of the judiciary, existing and proposed legislation aims to counter the alleged negative impacts of exclusive licensing, unreasonable royalties, and the costs associated with licensing multiple genes for complex genetic tests. First, the Bayh-Dohl Act (P.L. 96-517) already exists to allow a federal agency, such as the National Institutes of Health (NIH), to compel a patent owner to non-exclusively license patented technology when necessary for public health and safety.[42] Although the NIH has never done so, the Bayh-Dohl Act is a potential means for the government to compel non-exclusive licensing of disease gene patents.[43]

Instead of relying on the Bayh-Dole Act or *eBay* to ensure non-exclusive licensing, Congress could alternatively adopt laws to ensure that physicians and non-profit research institutions can access non-exclusive licenses at a reasonable cost.[44] Or, instead of compulsory licensing laws, Congress could create statutory infringement exemptions for these groups.[45] Either proposal accomplishes the

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[41] *Id.*
[42] Holman, *supra* note 3.
[43] *Id.*
[44] MERZ, *supra* note 9, at 20.
[45] *See* Sung, *supra* note 7, at 13 (proposing draft legislation that would preclude claims against public non-profit researchers and institutions on the condition the use is for basic research that becomes dedicated to the public, and that the patent owner is provided with actual notice of "open and notorious" use); Genome.gov, Roundtable Summary on Genetic Patenting, http://www.genome.gov/11007377 (last visited Nov. 6, 2008) (finding that the NIH should explore a "Bayh-Dole – like" research exemption for Federal grant recipients giving royalty free research use licenses to federally funded inventions).

goal of preserving "freedom to undertake research"[46] while maintaining the integrity of the patent system.

One last, particularly valuable proposal is the creation of "patent pools," wherein gene patent owners who collectively wish to pursue a certain research endeavor or genetic test involving multiple patents come together and create a so called "clearing house" of patented gene sequences.[47] Such a system would allow technologies utilizing related patents to collaborate to prevent such patents from "blocking" one another, thus, minimizing transaction costs for all collaborators using the technology.[48] The patent pool proposal gained interest in recent years,[49] and is an excellent addition to non-exclusive licensing or research and/or physician exemption laws.

VIII. CONCLUSION

While gene patents have been hotly opposed, there is little factual evidence to show that gene patents are hindering research, except in the context of disease genes and diagnostic testing.[50] These problems may be alleviated by the new obviousness standard in *KSR*, the broad interpretation of the statutory FDA exemption in *eBay*, and the refusal to grant injunctions for infringement in *Merck*.[51] Furthermore, the Bayh-Dole Act provides the NIH with the opportunity to compel gene patent licensing if it is necessary for public health and safety. Additionally, Congress should consider new laws creating statutory infringement exemptions or compelling non-exclusive licenses at reasonable royalty rates for non-profit research institutions and doctors engaged in genetic testing. Lastly, gene pools are a progressive way for industry and academia to work together in

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[46] Stott & Valentine, *supra* note 3, at 364.
[47] HUGO INTELLECTUAL PROPERTY COMMITTEE, STATEMENT ON THE SCOPE OF GENE PATENTS RESEARCH EXEMPTION, AND LICENSING OF PATENTED GENE SEQUENCES FOR DIAGNOSTICS 3 (Dec. 2003), http://www.hugo-international.org/img/ip_gene_2003.pdf [hereinafter HUGO]; Sung, *supra* note 7, at 8-10.
[48] Sung, *supra* note 7, at 9.
[49] *Id.* at 9-10.
[50] Caulfield et al., *supra* note 1, at 1091-92
[51] *See* Sung, *supra* note 7, at 5-7, 10-11.

furtherance of similar research goals, thus encouraging and enabling research to go forward at a reasonable cost.[52] Notwithstanding promising policy proposals, gene patent holders must adopt responsible licensing policies to ensure that gene patents continue to serve their purpose of advancing the progress of science.

[52] *See* HUGO, *supra* note 47, at 3.

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Reprogramming the Future of Stem Cell Patents

Jana E. Harris, Ph.D.[*]

Stem cells have the potential to be extremely powerful tools in the medical field. There are two main types of stem cells: somatic stem cells and embryonic stem cells.[1] Somatic stem cells are found in mature organs and tissues and give rise to the cell types of that particular organ or tissue.[2] For example, hematopoietic stem cells give rise to all the blood cell types in the body.[3] Human embryonic stem cells (hESCs) are derived from the inner cell masses of a human embryo.[4] hESCs are pluripotent, which means that they have the ability "to give rise to all of the various cell types that make up the [human] body."[5] This significant characteristic indicates that hESCs have the capability to treat diseases, such as cancer, neurodegenerative disorders, and diabetes, and replace diseased tissues and organs. Further, scientists can use hESCs to study various developmental and biological processes.[6]

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[1] NIH Stem Cell Information, Stem Cell Basics: Introduction, http://stemcells.nih.gov/info/basics/basics1.asp (last visited Oct. 28, 2008).

[2] NIH Stem Cell Information, Stem Cell Basics: What are adult stem cells?, http://stemcells.nih.gov/info/basics/basics4.asp (last visited Oct. 28, 2008).

[3] *Id.*

[4] SCOTT F. GILBERT, DEVELOPMENTAL BIOLOGY 708 (8th ed. 2006); NIH Stem Cell Information, Glossary, http://stemcells.nih.gov/ (follow "Info Center" hyperlink; then follow "Glossary" hyperlink) (last visited Oct. 10, 2008).

[5] NIH Stem Cell Information, Frequently Asked Questions, http://stemcells.nih.gov/research/registry/pluripotent_faq.asp (last visited Oct. 6, 2008).

[6] *See* GILBERT *supra* note 4; NIH Stem Cell Information, Stem Cells and Diseases, http://stemcells.nih.gov/info/health.asp (last visited Oct. 28, 2008); Julia vom Wege Dovi,

Despite the possible benefits of hESCs, President George W. Bush has implemented regulations that restrict the use of these cells in research due to their highly controversial origin. On August 9, 2001, President Bush banned the creation of new hESC lines.[7] His policy also restricted federal funding for hESC research by limiting grants to those researchers who only utilize hESC lines previously derived from embryos obtained with informed consent for reproductive purposes.[8] These moral concerns and changes in policy have motivated scientists to explore alternatives to hESCs.[9]

In November 2007, a major breakthrough in stem cell research was made with the creation of human induced pluripotent stem cells (iPSCs).[10] These stem cells are adult cells reprogrammed to be like an embryonic stem cell by being forced to express certain genetic factors.[11] Compared to hESCs, iPSCs promise similar and additional benefits. Since iPSCs are derived from adult cells, they have the same genetic makeup as the individual from which they were derived.[12] Therefore, medical treatment resulting from the use of the iPSCs can be tailored specifically to that individual's genetic makeup.[13] For instance, the recipient of a donated organ bears the risk of his or her body rejecting the transplant.[14] This

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Speaking Words of Wisdom: Let it be the Reexamination of the Human Embryonic Stem Cell Patents, 12 MARQ. INTELL. PROP. L. REV. 107, 109 (2008); ScienceDaily.com, Module Map Links Embryonic Stem Cells and Cancer Stem Cells, Apr. 9, 2008, http://www.sciencedaily.com/releases/2008/04/080409130711.htm (last visited Nov. 7, 2008).

[7] *See The President's Decision; Bush's Address on Federal Financing for Research With Embryonic Stem Cells*, N.Y. TIMES, Aug. 10, 2001, http://nytimes.com (search "Bush's Address on Federal Financing"; then follow "The President's Decision" hyperlink) [hereinafter *President's Decision*]; NIH Stem Cell Information, Federal Policy, http://stemcells.nih.gov/policy/ (last visited Oct. 10, 2008).

[8] *See President's Decision supra* note 7; NIH *supra* note 7.

[9] Christopher Thomas Scott & Renee A. Reijo Pera, *The Road to Pluripotence: The Research Response to the Empbryonic Stem Cell Debate*, 17 HUMAN MOLECULAR GENETICS R3, R3-R7 (2008); *see* President George W. Bush, *Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways*, THE WHITE HOUSE, June 20, 2007, http://www.whitehouse.gov/news/releases/2007/06/20070620-6.html.

[10] *See* Yu, et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCI. MAG. 1917, 1917-20 (2007); *See* Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 861-72 (Nov. 30, 2007).

[11] *See generally* Yu, et al, *supra* note 10; Takahashi et al., *supra* note 10.

[12] Yu, et al., *supra* note 10, at 1920

[13] *Id*.

[14] *Id*.

complication could be eliminated by creating organs or tissues developed from patient-specific iPSC lines.[15] Also, disease-specific iPSC lines could be derived for drug development and research.[16] Moreover, since iPSCs are not derived from embryos, the ethical concerns that accompany hESCs are not currently at issue.[17] Research using pluripotent stem cells derived from non-embryonic sources has been, and continues to be, eligible for federal funds.[18]

Despite the potential of iPSCs to serve as a replacement for hESCs, the molecular similarities between the two types of stems cells is not yet clear. If iPSCs and hESCs are molecularly similar, then inventors may face the same resistance towards patenting iPSCs that they faced in patenting hESCs. However, if iPSCs and hESCs are not molecularly similar, then inventors may not face as much resistance in patenting iPSCs. Moreover, if obtaining and maintaining iPSC patent rights mirrors what has occurred with hESC patent rights,[19] then researchers may be less inclined to pursue scientific advancements related to iPSCs because their advancements may not be patentable.

Recently, the United States Patent and Trademark Office (USPTO) reexamined several hESC patents[20] developed by James A. Thomson of the University of Wisconsin.[21] The challengers had criticized the patents as being overly broad for claiming the rights to all hESC lines and to the particular method of making them.[22] Despite a preliminary ruling finding that the hESC patents

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[15] *Id.*
[16] *Id.*
[17] *See* Scott & Pera *supra* note 9, at R6.
[18] NIH, *supra* note 5.
[19] Currently, hESCs are patentable subject matter. The USPTO has not deemed hESCs to be the equivalent of a human being, which is precluded from patentability, *see* MANUAL OF PATENTING EXAMINING PROCEDURE §2105 (8th ed., 6th rev. 2007); *see also* Todd N. Spalding & Michele M. Simkin, *How Will Patents Impact the Commercialization of Stem Cell Therapeutics?*, 19 No. 1 INTELL. PROP. & TECH. L.J. 7, 7 (Jan. 2007).
[20] U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (June 26, 1998); U.S. Patent 7,029,913 (filed Oct. 18, 2001).
[21] U.S. Patent No. 5,843,780RE (filed July 17, 2006); U.S. Patent No. 6,200,806RE (filed July 17, 2006); U.S. Patent 7,029,913RE (filed July 17, 2006).
[22] *See* '780RE Patent, '806RE Patent, '913RE Patent, *supra* note 21; *see* also Katja Triller Vrtovec & Christopher Thomas Scott, *Patenting Pluripotence: The Next Battle for Stem Cell Intellectual Property*, 26 NATURE BIOTECHNOLOGY 393, 393 (Apr. 2008).

were invalid for being obvious in light of prior art,[23] the USPTO eventually affirmed the validity of the patents.[24]

In addition, the USPTO ultimately rejected a continuation application of one of Thomson's hESC patents for being too broad because it encompassed all human pluripotent stem cells (PSCs), not just hESCs.[25] In its rejection, the USPTO recognized a critical difference between other types of PSCs and hESCs: hESCs produced from the inner cell mass of embryos do not express a specific type of cell-surface marker found on other types of PSCs.[26] Since hESCs do not have this distinguishing cell-surface marker, the USPTO refused to extend the hESC patent claims to include all PSCs because PSCs with the cell-surface marker potentially could be separately patentable.[27]

Conversely, iPSCs might not be patentable separate from hESC patents, because hESC patents might encompass iPSCs. Research shows that human iPSCs and hESCs are similar; however, theorists predict that whether they are so similar that both are encompassed in the hESC patents will depend upon the characteristics of PSCs.[28] Like hESCs, iPSCs do not possess the specific cell-surface marker that other types of PSCs have.[29] Therefore, if the characterization of a hESC depends on the presence or absence of the cell-surface marker, iPSC patents already would be covered by the hESC patents.[30] However, if hESCs are characterized by their origin, then iPSCs may be patentable over hESCs because they are derived from adult cells, not embryos.[31] Other theorists are certain that if the hESC patents were narrowed in scope, then iPSCs would not be covered

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[23] Aurora Plomer et al., *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 14 (Jan. 2008); Joe Vanden Plas, *Patent Office Upholds Key WARF Stem Cell Patent; Appeal is Likely*, WIS. TECH. NETWORK NEWS, Feb. 29, 2008, http://wistechnology.com/articles/4571.
[24] Vrtovec & Scott, *supra* note 22, at 393.
[25] *Id.* at 393.
[26] *Id.* at 394.
[27] *See Id.*
[28] *Id.*
[29] Vrtovec & Scott, *supra* note 22, at 394.
[30] *Id.*
[31] *Id.*

within the scope of hESC patents.[32] Therefore, iPSCs could be separately patentable, provided they meet all other patentability requirements. [33]

At the end of 2007, both James A. Thomson from the University of Wisconsin and Shinya Yamanaka from Kyoto University in Japan published articles that described the generation of iPSCs from humans.[34] Yamanaka had already obtained a Japanese patent on iPSCs and filed an application for iPSCs with the USPTO in December 2006.[35] In March 2008, Thomson also filed a U.S. patent application for iPSCs.[36] However, it is unclear who will be awarded patent protection in the U.S., because if two different inventors file a patent application in the U.S. for the same invention, then the inventor who proves to be the first to invent will be entitled to the patent.[37] In this case, both applications are currently pending, therefore the USPTO has not resolved the dispute over which party was first to invent, and thus which party is entitled to patent rights, should the patent be granted. Additionally, the iPSCs still need to meet other statutory requirements, such as nonobviousness in light of previous publications by Yamanaka, in order to be patented.[38]

Therefore, if Yamanaka is granted a U.S. patent, then Thomson may face additional patentability issues depending on the breadth of Yamanaka's claims. Yamanaka's Japanese patent is narrow and has claims directed towards reprogramming a cell with four genetic factors.[39] Thomson's published U.S. patent application claims the method of adult cell reprogramming and the reprogrammed cells themselves, but the factors he utilizes do not include two of

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[32] Plas, *supra* note 23.
[33] *Id*.
[34] *See* Yu et al., *supra* note 10 at 1; Takahashi et al., *supra* note 10, at 1.
[35] David Cyranoski, *Japan Fast-Tracks Stem-Cell Patent*, 455 NATURE 269, 269 (Sept. 2008) (the international application is PCT/JP2006/324881); Vrtovec & Scott, *supra* note 22, at 394-95 (Yamanaka filed an international application under the World Intellectual Property Organization (WIPO) Patent Cooperation Treaty (PCT) and lists the U.S. as one of the designated countries).
[36] U.S. Patent Application No. 12/053,440 (filed Mar. 21, 2008).
[37] About.com: Inventors, Information Concerning Patents Interferences, http://inventors.about.com/library/bl/toc/blusptointerference.htm (last visited Oct. 29, 2008).
[38] *Id*.
[39] Cyranoski, *supra* note 35.

Yamanaka's factors.[40] Currently, the claims in Yamanaka's international application are written broadly,[41] however the USPTO might not require the claims to be narrowed in order to obtain a U.S. patent.[42] Therefore, if the USPTO grants Yamanaka a patent in which the claims are broad enough to cover iPSCs from any non-embryonic cell of any species, Thomson's - and future - iPSC patent applications could be affected.[43] A broad patent could preclude the patenting of all iPSCs regardless of whether novel combinations of genetic factors were used to create the cells.[44] However, if Yamanaka's application is restricted to his four factors, Thomson's use of a different set of factors could be separately patentable.[45] Therefore, a narrow interpretation of Yamanaka's application could open the door to future patents on iPSCs.

The potential health benefits conferred from iPSCs is exciting. Since iPSCs are not restricted by federal funding regulations, the ability to patent this technology would greatly spur innovation and research in this area. While there still is a critical need for hESC research, iPSCs offer a very promising alternative without the ethical barrier. Even though stem cell intellectual property is complex due to moral, technical, and legal factors, the future path for iPSCs hopefully will be smoother than that of its predecessor hESCs to allow for the growth and development of this promising scientific discovery. [46]

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[40] *See* '440 Patent, *supra* note 36; *see generally* Takahashi et. al., *supra* note 10.
[41] *See* '440 Patent, *supra* note 36.
[42] *Id.*
[43] Cyranoski, *supra* note 35.
[44] *Id.*
[45] '440 Patent, *supra* note 36.
[46] Plomer, *supra* note 23.

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Innovation versus Access: The Great Debate between Pharmaceutical Patent Holders and Generic Manufacturers

Themistocles Frangos[*]

I. INTRODUCTION

Pharmaceutical patent holders (brand name drug) and generic drug manufactures (generic drug) continually debate the optimal balance between innovation and access. Policymakers must confront brand name companies that argue, "research and development is a 'costly and risky activity,'" as well as social groups that contend, "the right of every individual [is] to enjoy the benefits of scientific progress and its applications."[1] In response to these challenges, the United States government is taking legislative steps to lower the cost of pharmaceuticals by promoting generic drugs while still permitting brand name drug manufactures to maintain exclusivity of their patents.[2] With that in mind,

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[1] Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188, 2191 (2002) (quoting Joseph A. Dimasi, Henry G. Grabowski & John Vernon, *R&D Costs, Innovative Output and Firm Size in the Pharmaceutical Industry*, 2 INT'L J. ECON. BUS. 201-19 (1995)); Sheja Ehtesham and Niranjan Mansingh, *Conflicting Interests in Drug Pricing: Innovation vs Social Needs*, 94 CURRENT SCI. 168, 168 (2008) *available at* http://www.ias.ac.in/currsci/jan252008/168.pdf (referencing International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), ¶ 15, U.N. Doc 14531 (Dec. 16, 1966) *available at* http://www.unhchr.ch/html/menu3/b/a_cescr.htm).

[2] Press Release, The White House, President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs (Oct. 21, 2002), http://www.whitehouse.gov/news/releases/2002/10/print/20021021-4.html [hereinafter *President*]; *cf.* ROBIN J. STRONGIN, NAT'L. HEALTH POL'Y FORUM., HATCH-WAXMAN, GENERICS, AND PATENTS: BALANCING PRESCRIPTION DRUG INNOVATION, COMPETITION AND AFFORDABILITY 15 (2002) *available at*

policymakers need to balance intellectual property rights with public health that is "consistent with [the] broadly defined social objectives."[3]

II. THE APPROVAL PROCESS FOR DRUG PATENTS BY THE FDA AND USPTO

A brand name patent holder is granted the maximum patent term of twenty years.[4] However, the Federal Drug and Administration (FDA) must approve a drug before the drug can be marketed and sold to consumers.[5] The patent term begins to run from the time that the United States Patent and Trademark Office (USPTO) grants the patent, and not from the time of FDA approval.[6] Therefore, while a drug is pending FDA approval, the term of the patent is encroached upon, thus reducing the effective patent term to below twenty years.[7] Between the years of 1966 and 1979, a patent holder was granted a maximum patent term of seventeen years, and the average market exclusivity of a brand name drug patent declined from 13.6 years to 9.5 years.[8] This decline primarily resulted from the increase in the time that brand name drug companies awaited FDA regulatory approval.[9] Thus, brand name drug companies sought legislation that would allow term extensions on pharmaceutical patents to compensate for market time lost while the pharmaceutical awaited approval.[10]

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http://www.nhpf.org/pdfs_bp/BP_HatchWaxman_6-02.pdf (explaining how exclusivity is maintained).

[3] *See* Ehtesham, *supra* note 1, at 169 (explaining the conflicting interests between providing incentives for innovation and availability of drugs based on social welfare); Internal Centre for Trade and Sustainable Development, *Fostering R&D and Promoting Access to Medicines*, http://ictsd.net/i/events/dialogues/11554/ (last visited Oct. 9, 2008) (explaining how the World Trade Organization has tried to promote innovation and creativity while increasing the public's access to medicines).

[4] Consumer Project on Technology, The Hatch-Waxman Act and New Legislation to Close Its Loopholes, http://www.cptech.org/ip/health/generic/hw.html (last visited Oct. 9, 2008).

[5] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Frequently Asked Questions on the Patent Term Restoration Program, http://www.fda.gov/CDER/about/smallbiz/patent_term.htm (last visited Oct. 24, 2008) [hereinafter *CDER*].

[6] *Id.*

[7] *Id.*

[8] Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 WHITTIER L. REV. 775, 778 (2003); *see also* CDER *supra* note 5.

[9] Tong, *supra* note 8, at 778.

[10] *Id.*

Further, the FDA treated generic drug manufacturers seeking regulatory approval as new drug applicants.[11] Generic drug manufactures, often relatively small in size, had problems meeting the additional demands and documentation required for a new drug application because they had access to fewer resources than big brand name drug companies.[12] As a result, there was a large disparity in the number of drugs being produced between brand name drug companies and generic manufacturers.[13]

III. THE HATCH-WAXMAN ACT: A SOLUTION BETWEEN INNOVATION AND ACCESS

Legislation could be used to strike a balance between the marketing exclusivity afforded to brand name drug patent holders and the need of generic drug manufacturers to have access to those patented drugs for timely FDA approval. Senator Orrin Hatch and Representative Henry Waxman introduced legislation to solve the problems of patent term extension and generic drugs approval. [14] The purpose of the legislation was (1) "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval" and (2) "to make available more low cost generic drugs by establishing a generic approval procedure." [15]

Congress codified the Hatch-Waxman Act under 35 U.S.C. § 156 and § 271(e).[16] The first provision under the Hatch-Waxman Act, section 156, provides the patent holder with a term extension for the time lost during the premarket approval process.[17] Under section 156:

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[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] Tong, *supra* note 8, at 777.
[15] Alison Ladd, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 316 (2005) (quoting H.R. Rep. No. 98-857(I), at 14-15 (1985)).
[16] Hatch-Waxman Act, 35 U.S.C. §156 (2006); Hatch-Waxman Act, 35 U.S.C. §271 (2006). *See generally Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008) (providing an example where the patent infringement involved related to an aerosol spray commonly used in various drug delivery devices, such as nasal spray pumps and inhalers).
[17] *Proveris*, 536 F.3d at 1260-61.

> The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended . . . from the original expiration date of the patent . . . [if] the product has been subject to a regulatory review period before its commercial marketing or use . . .[18]

Additionally, Congress capped the term extension on a patent at a maximum of five years.[19]

Brand name drug companies claim that if market exclusivity on drug patents issued is not "adhered to, then investment in research and development will dwindle" and that "[n]ew drugs will cease to be created," causing everyone to suffer consequences.[20] Further, selling drugs at a price far above the cost of manufacturing is "the only way to recoup the enormous costs of years of research and development, and continue to fund research."[21] Brand name drug companies spend years developing and researching drugs that include "extremely expensive clinical trials" and the abandonment of many drugs that never produce positive results.[22] Extensions on drug patents will allow brand name drug manufacturers to recover the costs of new drug research and development.[23] Therefore, by providing brand name drug companies with extensions on drug patents, pharmaceutical companies will be able to recoup the portion of time lost while the patent was going through the FDA approval process.[24]

The second provision under the Hatch-Waxman Act, section 271(e), eliminates the infringement cause of action against generic drug manufacturers during the FDA approval process by "providing a safe harbor that immunize[s] competitors from infringement."[25] Prior to the passage of section 271(e), a generic drug manufacturer could be found to infringe upon a brand name drug

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[18] Hatch-Waxman Act, 35 U.S.C. §156(a) (2006).
[19] Consumer Project on Technology, *supra* note 4.
[20] *Innovation vs. Access: Two Epidemics Transform the Pharmaceutical Patent Law Debate into an International Controversy*, 19 J. YOUNG INVESTIGATORS 1, 1 (2008) *available at* http://www.jyi.org/features/ft.php?id=467 [hereinafter *Innovation*].
[21] *Id.*
[22] Ehtesham, *supra* note 1, at 168.
[23] Ladd, *supra* note 15, at 348.
[24] *Id.* at 318.
[25] *Proveris*, 536 F.3d at 1261.

patent because "a generic manufacturer could not begin the testing necessary for FDA approval of the generic drug product prior to the expiration of the innovative drug's patent."[26] Further, brand name drug companies prevent generic drug manufactures from bringing generic drugs to market by using "extra market exclusivity" extensions to "keep generics off the market by protecting their drugs." [27] Under section 271(e),

> [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.[28]

As a result, section 271 allows "competitors to begin the regulatory approval process while the patent [is] still in force, followed by market entry immediately upon patent expiration."[29] Thus, the combination of sections 156 and 271(e) allows for the promotion of generic drugs and permits continued incentives for research and development.[30]

The Hatch-Waxman Act restricted the regulation of term extensions to brand name drug patents. However, the safe harbor provision in section 271(e) did not clearly define the breadth of the term "drugs" and the specific type of drug patents that are covered by the provision.[31] In *Proveris Scientific Corp. v. Innovasystems, Inc.*, the Federal Circuit held that Congress created the safe harbor provision under section 271(e) to provide "generic drug developers with the means to compete commercially immediately upon the expiration of a drug's patent."[32]

While section 156 "adversely affected patentees," section 271(e) "adversely affected those seeking FDA approval in order to enter the market to

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[26] Ladd, *supra* note 15, at 319.
[27] Consumer Project on Technology, *supra* note 4.
[28] Hatch-Waxman Act, 35 U.S.C. §271 (2006).
[29] *Proveris*, 536 F.3d at 1261.
[30] Consumer Project on Technology, *supra* note 4.
[31] Ladd, *supra* note 15, at 316.
[32] *Proveris*, 536 F.3d at 1264.

complete with patentees."[33] The court concluded that to be eligible for the safe harbor provision under section 271(e), the drug patent had to be defined under section 156(f) resulting in a "nearly perfect product correlation" between the two sections.[34] Therefore, the decision by the court narrowly determines the protection for generic drug companies under the safe harbor provision for section 271(e).

As a result, the safe harbor provision will help "promote drug discovery and development, with an objective to make affordable novel drugs to major infectious diseases."[35] In addition, the UK-based pharmaceutical group GlaxoSmithKline claims that lowering prices on pharmaceuticals will help "free[] up governments' scarce health resources."[36] Therefore, the increase in accessibility to generic drugs could result in savings of three-billion dollars per year in drug savings for Americans.[37]

IV. CONCLUSION

Throughout the decades, Congress has tried to find an optimal balance between innovation by brand name drug companies and access to brand name drug patents by generic drug manufactures. In an attempt to achieve this balance, Congress passed the Hatch-Waxman Act, codified under section 156 and section 271(e). The Act provides benefits to pharmaceutical companies by extending the market exclusivity of patents for the time the patent was under review by the FDA and precludes generic drug manufactures from being held liable of certain types of infringement of brand name drug patents towards the end of a patent's life. Although legislation has been passed, problems remain. As Congress moves

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[33] *Id.* at 1265.
[34] *Id.*
[35] Ehtesham, *supra* note 1, at 168.
[36] Andrew Jack, *GSK Varies Prices to Raise Sales*, Financial Times, (2008) http://www.ft.com/cms/s/0/4dc2b3bc-f380-11dc-b6bc-0000779fd2ac.htm (last visited Nov. 5, 2008).
[37] President, *supra* note 2.

forward, it needs to balance the interests of both innovation and access to develop legislation that will benefit everyone.

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Biotechnical Transfer: The Weaknesses and Strengths of Bayh-Dole

Heidi Schroeder[*]

In 1980, Congress enacted the Patent and Trademark Law Amendments Act, which is generally referred to as the Bayh-Dole Act.[1] Even though Bayh-Dole was enacted almost three decades ago, its ramifications still persist today.[2] This statute instructed universities to patent and commercialize publicly-funded scientific research.[3] The rationale behind Bayh-Dole was to allow "universities and small businesses…to become directly involved in the commercialization process."[4] In short, Bayh-Dole facilitates the transfer of research results from universities to the commercial marketplace for the public benefit; a practice known as technology transfer.[5] Since its passage in 1980, Bayh-Dole has turned universities into centers for breakthroughs in technology and medicine.[6]

Congress enacted this legislation after a series of congressional debates

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[1] The Patent and Trademark Law Amendments Act (Bayh-Dole) of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980); COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1 (1999), *available at* http://www.cogr.edu/docs/Bayh_Dole.pdf [hereinafter COGR].

[2] Brett T. Roseman, *Advice from the Top: University Research Helps USA Compete*, USA TODAY, June 5, 2008, *available at* http://www.usatoday.com/money/companies/management/2008-05-18-texas-instruments-rich-templeton_N.htm.

[3] THE INT'L EXPERT GROUP ON BIOTECHNOLOGY, INNOVATION, AND INTELL. PROPERTY, TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION (EXECUTIVE SUMMARY) 5 (2008), *available at* http://www.theinnovationpartnership.org/ieg/documents/report/TIP_Executive_Summary_E.pdf [hereinafter NEW ERA].

[4] COGR, *supra* note 1, at 2.

[5] *Id.* at 1.

[6] Roseman, *supra* note 2.

and deliberations throughout the 1960s and 1970s.[7] Prior to 1980, the private sector utilized less than five percent of government-owned patents, despite the fact that there was potential for further commercialization.[8] At the time, government-owned patents offered little protection because they were made available through non-exclusive licenses and were offered to anyone who wanted to utilize them.[9] Industry investment in technology development was curtailed because exclusive licenses were not widely available for government-funded inventions.[10] Congress thought the economy would be stimulated if the inventions of publicly funded universities could be easily licensed to businesses that would manufacture resulting products.[11] The legislation reflects this belief, stating:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research or development; ...to promote collaboration between commercial concerns and nonprofit organizations, including universities; ...to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions....[12]

To accomplish its objective, Bayh-Dole provides that universities may retain title to any invention made with federal funds, except in limited circumstances where the government determines that restriction or elimination of the right to retain title is necessary.[13] If the university chooses to retain title, the

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[7] WENDY H. SCHACHT, CONG. RES. SERV., THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 1 (2008) *available at* http://italy.usembassy.gov/pdf/other/RL32076.pdf.
[8] COGR, *supra* note 1, at 2.
[9] *Id.*
[10] SCHACHT, *supra* note 7, at 2.
[11] COGR, *supra* note 1, at 2.
[12] The Patent and Trademark Law Amendments (Bayh-Dole) Act of 1980, Pub. L. No. 96-517, § 200, 94 Stat. 3015 (1980).
[13] SCHACHT, *supra* note 7, at 7.

government retains a non-exclusive, non-transferable, irrevocable right to practice or have practiced the invention on behalf of the United States.[14] The university "must commit to commercialization within a predetermined, agreed upon, time frame."[15] If the university does not meet this requirement, the government may exercise "march-in rights," which enable the government to require a contractor to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants."[16] The university is also obligated to obtain written agreements with its technical staff and faculty requiring assignment and disclosure of inventions.[17] Moreover, the university must disclose each new invention to the federal agency that provided federal funding within two months of the inventor disclosing the discovery to the university.[18]

Many Bayh-Dole supporters contend that it is a catalyst for economic growth and is vital for the transfer of technology from university to industry.[19] That assertion, however, is countered by the argument that a fixation on patents and privately-controlled research often impedes innovation.[20] For example, one study examined stem cell researchers and suggested that the least collaborative researchers are those who patent the most.[21] Still, the United States granted 8,000 patents to institutions between 1993 and 1997, with more than 1,000 products based on university-licensed inventions currently on the market.[22] A Government Accountability Office study found that nine out of ten business executives identified Bayh-Dole as an "important factor" in their decisions to fund research

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[14] COGR, *supra* note 1, at 5.
[15] SCHACHT, *supra* note 7, at 7.
[16] *Id.* at 7-8.
[17] COGR, *supra* note 1, at 4.
[18] *Id.*
[19] Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320, 320 (2006), *available at* http://www.bios.net/daisy/cambia/2012/version/default/part/AttachmentData/data/Bayh-Dole-_if_we_knew_then_what_we_know_now.pdf.
[20] NEW ERA, *supra* note 3, at 5.
[21] Maureen Martino, *Landmark Study Reports Breakdown in Biotech Patent System*, FIERCEBIOTECH, Sept. 10, 2008, http://www.fiercebiotech.com/press-releases/landmark-study-reports-breakdown-biotech-patent-system.
[22] COGR, *supra* note 1, at 9.

and development in academia.[23]

A growing area of concern with regard to Bayh-Dole is the increasing number of patents being issued for research tools. A research tool is technology that is used by researchers to refine, design, or identify new innovations.[24] A study of U.S. academic scientists has shown that research tool patents have posed such a hurdle to innovation that scientists routinely ignore patent rights in conducting their research.[25] In response, research institutions funded by the National Institutes of Health voluntarily adopted a guideline that research tools be nonexclusively licensed.[26] The International Expert Group on Biotechnology, Innovation and Intellectual Property suggested that universities implement clear values relating to the use and spread of intellectual property to promote broad licensing and greater access to research tools.[27] Some have suggested that research tools should be protected by implementing a federal research tool policy which would encompass Bayh-Dole.[28] In contrast, a Yale scholar posited that although research tools ought to be kept in the public domain, Bayh-Dole is not responsible for their privatization.[29] Instead, research tool privatization lies with patent law enacted by Congress and developed by the courts.[30]

For a long time, researchers operated under Bayh-Dole thinking that they were exempted from patents, so long as they were only using the technology for further research.[31] However, in the wake of *Madey v. Duke University*, it appears that any university research may be considered to advance the business interests of the institution, making such pursuits commercial, not philosophical (or exempt

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[23] SCHACHT, *supra* note 7, at 9.
[24] ANN MILLS & PATTI TERESKERZ, BIOTECHNOLOGY INDUSTRY ORGANIZATION, PROPOSED PATENT REFORM LEGISLATION: LIMITATIONS OF EMPIRICAL DATA USED TO INFORM THE PUBLIC POLICY DEBATE 7 (2008), *available at* http://bio.org/ip/domestic/UVA_Limitations_of_Empirical_Data.pdf.
[25] NEW ERA, *supra* note 3, at 5.
[26] Boettiger & Bennett, *supra* note 19, at 321.
[27] Martino, *supra* note 21.
[28] Boettiger & Bennett, *supra* note 19, at 321.
[29] SCHACHT, *supra* note 7, at 25.
[30] *Id.*
[31] Boettiger & Bennett, *supra* note 19, at 321.

from IP restrictions).[32] If an invention is exclusively licensed, it may be unavailable for future research, even by the very scientist who created it.[33] The University of California has been progressive in its licensing and patenting practices, so that other institutions may use University of California technology to further research.[34] However, this practice has not been widely adopted.[35]

Despite its difficulties, the current patenting procedure does not appear to be impeding research. A 2006 study identified the top five reasons for project abandonment, in order of frequency: "'lack of funding' (62%), 'conflict with other priorities' (60%), 'a judgment that the project was not feasible' (46%), 'not scientifically important (40%),' and 'not that interesting' (35%)."[36] Only three percent of survey respondents named "too many patents covering needed research inputs" as a reason for project abandonment.[37] However, no comment was made as to how much funding is needed to finance licenses on research inputs covered by patents. If this number is high, patents may be a greater impediment to research than these numbers suggest.

Despite concerns, Bayh-Dole is widely considered a success, causing one commentator to note that Bayh-Dole is "probably the most inspired piece of legislation to be enacted in America over the past half-century."[38] Bayh-Dole has elicited innovations such as artificial lung surfactant for use with newborn infants from the University of California; Citracal®, a calcium supplement from the University of Texas Southwestern Medical Center; and recombinant DNA technology from Stanford University and the University of California.[39]

Bayh-Dole and its subsequent amendments performed just as intended: the law provided incentives for industry, universities, and the government to

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[32] 307 F.3d 1351 (Fed. Cir. 2002); Boettiger & Bennett, *supra* note 19, at 321.
[33] Boettiger & Bennett, *supra* note 19, at 321.
[34] *Id.*
[35] *Id.*
[36] MILLS & TERESKERZ, *supra* note 24, at 17.
[37] *Id.* at 17-18.
[38] SCHACHT, *supra* note 7, at 10.
[39] COGR, *supra* note 1, at 8.

cooperate in the development of new technologies for the public benefit.[40] Bayh-Dole has allowed universities to generate funds for additional research. For example, in 2004, university licensees generated $1.4 billion in royalties.[41] Certainty of title and implementation of uniform patenting and licensing procedures for inventions made under federal funding are identified as the most important incentives for commercialization.[42] By actualizing these factors, at little cost to taxpayers, Bayh-Dole has proven to be a leader in the promotion of innovation.

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[40] *Id.* at 9.
[41] SCHACHT, *supra* note 7, at 11.
[42] COGR, *supra* note 1, at 9.

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Regulation of Investigational Medical Devices: Benefits and Obstacles

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I. INTRODUCTION

Statutory provisions are in place to regulate the performance standards of investigational medical devices.[1] An investigational medical device is "a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/ or safety of the device."[2] Medical devices are split into three categories: Class I, Class II, and Class III.[3] Examples of devices that fall into these three classifications include stethoscopes, computer tomography scanners, and pacemakers, respectively.[4] Depending on the classification, the device is subject to varying levels of regulatory scrutiny before being marketed to the public.[5]

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[1] *See generally* 21 U.S.C. § 360(d) (2006).

[2] OFFICE OF COMM'R, FDA, GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS 1998 UPDATE (1998), http://www.fda.gov/oc/ohrt/irbs/devices.html [hereinafter FDA, IRB GUIDANCE]; *see generally* Richard A. Merrill, *Regulation of Drugs and Devices: An Evolution*, 13 HEALTH AFFAIRS 47, 55-58 (1994) (providing background information about investigational medical devices and discussing the history device regulation).

[3] 21 U.S.C. § 360(c)(a)(1) (2006).

[4] William H. Maisel, *Medical Device Regulation: An Introduction for the Practicing Physician*, 140 ANNALS INTERNAL MED. 296, 296-297 (2004) (describing different classifications of medical devices).

[5] 21 U.S.C. § 360(c)(a)(1).

Class I devices pose no potential for unreasonable risk of illness or injury, whereas Class II devices present the potential for such a risk, although the potential risk is generally not life-threatening.[6] Class III devices have the highest likelihood that harm will occur and are subject to a process of scientific and regulatory review, known as premarket approval, because the Food and Drug Administration (FDA) has determined that the regulations for Class I and Class II devices are inadequate to ensure the safety of these Class III devices.[7] Therefore, Class III devices are subject to more stringent FDA regulations and safeguards before they are approved for public use. These provisions are set up to ensure that medical devices are safe and effective.[8]

Nonetheless, some groups criticize these regulations because the approval process for Class III devices raises public health concerns.[9] Some commentators are concerned that loopholes in the current regulations for medical devices, specifically regulations (or loopholes) that create a public health risk are flawed and increase a patient's risk for injury or death.[10]

This article discusses research protocol, regulatory procedure, and situations which warrant exceptions to the use of investigational medical devices before formal approval, along with justification for these exceptions. This article also discusses safeguards to minimize public exposure to harmful devices and obstacles to insurance coverage.

II. STANDARD RESEARCH AND APPROVAL PROCEDURES FOR HIGH RISK INVESTIGATIONAL DEVICES

Investigational devices that are considered high risk are not exempted from the pre-market approval process.[11] Before a high risk investigational device

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[6] *See* Maisel, *supra* note 4, at 296-297.
[7] Michael VanBuren, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 446-447 (2007) (discussing approval standards based on device classification).
[8] 21 U.S.C. § 360(d)(a)(1) (2006).
[9] *See generally* VanBuren, *supra* note 7, at 441-446.
[10] *Id.* at 441.
[11] FDA, IRB GUIDANCE, *supra* note 2.

is made available to the public, it must undergo rigorous testing to comply with FDA standards.[12] One part of the approval process is clinical investigation for testing on human participants.[13] If clinical investigators chose to conduct a clinical investigation, they must obtain an investigational device exemption (IDE) from the FDA before starting the investigation.[14] Typically, in the case of an IDE, the device is under clinical investigation "for a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative device or other therapy is available."[15] Because these are medical studies, the principal clinical investigators are usually physicians. An IDE allows the investigators to conduct the clinical trials necessary to gather data on the safety and effectiveness of the device to support market approval.[16] An unapproved device can not be used on human subjects until it is cleared for use in clinical trials with an IDE.[17] Once an IDE is granted, the investigators need to obtain approval from their respective institutional review board (IRB) whose purpose is to "protect the rights and welfare of human subjects involved in such investigations."[18] The IRB governs research studies at institutions to ensure compliance with research protocols, and is designed to minimize the risk of harm to research participants. If the study involves a "significant risk device," both the IRB and the FDA must approve the IDE.[19]

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[12] *See* CTR. FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH), FDA, DEVICE ADVICE 1 (2003), *available at* http://www.fda.gov/cdrh/devadvice/ide/print/ideall.pdf [hereinafter CDRH DEVICE ADVICE].
[13] 21 C.F.R. § 812.36(a) (2008).
[14] *Id.* § 812.1(a).
[15] *Id.* § 812.36(a)
[16] CDRH DEVICE ADVICE, *supra* note 12, at 1.
[17] GOOD CLINICAL PRACTICE PROGRAM, FDA, INFORMATION SHEET GUIDANCE FOR IRB'S, CLINICAL INVESTIGATORS, AND SPONSORS: FREQUENTLY ASKED QUESTIONS ABOUT MEDICAL DEVICES 9 (2006), http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf [hereinafter IRB MEDICAL DEVICES].
[18] 21 C.F.R. § 56.101(a) (2008); *see also* 21 C.F.R. § 56.102(f)(g) (defines IRB as "any board committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodical review of, biomedical research involving human subjects" and defines institutions as any public or private entity where the research is being conducted).
[19] CDRH DEVICE ADVICE, *supra* note 12, at 1.

III. EXCEPTIONS AND DEVIATIONS FROM STANDARD PROTOCOL

In certain situations, investigational devices may be used on a patient who is not a subject in the clinical trial. One exception includes emergency situations where the device is necessary to "save the life of a patient…suffering from a serious disease or condition for which there exists no other alternative therapy."[20] The FDA allows the use of investigational devices for such emergencies without prior approval.[21] However, the investigator must report and justify the emergency use to the FDA within five working days from the time the principal clinical investigator learns of it.[22] The investigator must also notify the IRB within five working days.[23]

Another exception to the formal approval process, in which investigational devices may be used on subjects not in a clinical trial, is termed "compassionate use."[24] Typically, compassionate-use patients are similar to emergency-use patients in that they have a serious disease or condition and there is no alternative treatment.[25] However, the compassionate-use patients do not meet preset inclusionary criteria for the clinical trials,[26] but the treating physician believes the patient will benefit from the device's use in the treatment of his or her disease or condition.[27] Unlike emergency use, compassionate use requires prior FDA approval.[28] Under the compassionate use exception, the FDA utilizes its regulatory discretion to grant a protocol deviation to treat the patient.[29] Overall, both compassionate and emergency uses allow patients the benefit of innovative

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[20] CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, FDA, GUIDANCE ON IDE POLICIES AND PROCEDURES 17 (1998) *available at* http://www.fda.gov/cdrh/ode/idepolcy.pdf [hereinafter CDRH IDE GUIDANCE]; *see also* 21 C.F.R. § 812.35(a)(2) (2008) (discussing studies involving Class III medical devices).
[21] 21 C.F.R. § 812.35(a)(2); *see* IRB MEDICAL DEVICES, *supra* note 17, at 9.
[22] 21 C.F.R. § 812.35(a)(2) (2008).
[23] *Id.* § 56.104(c).
[24] Robert J. Klepinski, *Access to Clinical Devices Through Nontraditional Routes*, 62 FOOD & DRUG L.J. 849, 851 (2007).
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] CDRH IDE GUIDANCE, *supra* note 20, at 19.
[29] Klepinski, *supra* note 24, at 851; *see* 21 C.F.R. § 812.35(a) (2008).

care while concurrently providing quality data on the effectiveness of investigational medical devices.[30]

Although the use of investigational devices in such situations can create unforeseen risks to patients, and are deviations from investigational protocols, the FDA exercises their aforementioned regulatory authority to minimize the potential of harm to patients. Furthermore, the FDA offers guidance to investigators, as well as to IRBs, to avoid confusion and maximize compliance.[31] One strategy the FDA employs to monitor the risks associated with investigational devices used in clinical studies is to require investigators to report adverse events.[32]

IV. MANDATORY REPORTING

An investigator, who has reason to believe that an investigational device caused or contributed to a serious injury or death, must report the incident to the FDA.[33] The Medical Device Reporting (MDR) provisions require investigators to report deaths and serious injuries within ten working days from the time the investigator becomes aware of the incident.[34] Investigators are only required to investigate and report adverse events that are "reasonably known" to them.[35] Investigators must also provide to the FDA an annual report of deaths and serious injuries.[36] Device manufacturers report a majority of the 80,000 to 120,000 adverse events received each year by the FDA.[37] In some cases, these devices may cause *an* injury, but investigators are only required to report device

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[30] *See* Klepinski, *supra* note 24, at 853.
[31] *See* IRB MEDICAL DEVICES, *supra* note 17, at 1.
[32] 21 C.F.R. § 803(1)(a) (2005).
[33] *Id.*
[34] Gay Parks Rainville, *When a Biomedical Device Fails: Navigating the Regulatory and Legal Landscape*, INTELL. PROP. & TECH. L.J., Feb. 2007, at 10 (discussing required procedure when devices cause serious injury or harm).
[35] *Id.*
[36] *Id.*
[37] Maisel, *supra* note 4, at 299.

malfunctions that actually cause *serious* injury or death.[38] Therefore, adverse events may be underreported.[39]

Unfortunately, there is an additional factor which leads to underreporting of injuries caused by malfunctioning devices. Conflicts of interest create barriers to disclosure in investigational research, especially when financial incentives are involved.[40] Manufacturers are concerned that disclosures may undermine their competitive advantage.[41] Consequently, concerns have been raised about the veracity of sponsor-related research data.[42] However, health care professionals and patients can also report to the FDA suspected injuries that result from malfunctioning medical devices.[43] Thus, the FDA is reliant upon physicians and consumers to report adverse events.[44] The FDA also takes an active role in the process by sending trained investigators to conduct routine field inspections, and to evaluate device malfunctions and irregularities.[45]

As an additional safeguard to maximize reporting of adverse events, the FDA has implemented penalties for failure to comply with reporting requirements.[46] Generally, the FDA will initially issue a warning letter.[47] Subsequent noncompliance could result in civil (and possibly criminal) penalties.[48] Although reports filed in accordance with MDR requirements are generally inadmissible in civil actions against private parties, the entities' officials and clinical investigators can be subject to substantial fines and prison sentences for failure to comply with reporting requirements.[49]

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[38] Rainville, *supra* note 34, at 10.
[39] Maisel, *supra* note 4, at 299.
[40] *See generally* Deborah A. Zarin & Tony Tse, *Moving Towards Transparency of Clinical Trials*, 319 SCI. 1340,1342 (2008) (discussing intellectual-property issues and data accuracy).
[41] *See Id.*
[42] *Id.*
[43] Maisel, *supra* note 4, at 299.
[44] *Id.* at 298.
[45] *Id.* at 299.
[46] Rainville, *supra* note 34, at 10-11.
[47] *Id.* at 11.
[48] *Id.*
[49] *Id.* at 10-11.

V. CLINICAL TRIALS: A SOLUTION OR A PROBLEM?

There is little disagreement regarding the need for rigorous clinical trials prior to public use of medical devices.[50] However, due to the lengthy and costly time frames of clinical trials, there are delays in delivering these products to patients who need them.[51] Consequently, the problems inherent in the design of some clinical trials increase patient mortality.[52] The current standards of clinical trials typically focus on factors, such as design safety and mortality, are quite costly because they can be lengthy and require patient tracking.[53] Some researchers and practitioners propose that there should be less emphasis on mortality data and greater focus on clinical efficacy.[54] These researchers argue that clinical efficacy focuses more specifically on the effectiveness of the device in the treatments of the specific disease, as opposed to the current standards that focus on death and mortality factors.[55] Establishing rigorous and efficient clinical trials that are consistent with FDA standards for safety and effectiveness will continue to be an ongoing challenge for research investigators.[56]

VI. REIMBURSEMENT OBSTACLES

In addition to the delays in the clinical trial process, insurance coverage is another obstacle that prevents the use of investigational or experimental treatment. Even when the FDA authorizes investigators to use experimental treatments, programs like Medicare and Medicaid exclude such treatments from

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[50] *See* Jennifer A. Henderson & John J. Smith, *Realizing the Potential for Biomarkers in Imaging: Background and Legal Basis*, 60 FOOD & DRUG L.J. 511, 515 (2005) (arguing for new clinical trial measuring methods in investigational research).
[51] *Id.* at 515-16.
[52] *Id.* at 516.
[53] Michael J. Schneck, *Critical Appraisal of Medical Devices in the Management of Cerebrovascular Disease*, 4 THERAPEUTICS & CLINICAL RISK MGMT. 19, 19 (2008); Henderson & Smith, *supra* note 50, at 516.
[54] *See* Henderson & Smith, *supra* note 50, at 517.
[55] *See Id.*
[56] *Id.*

reimbursement unless it has been proven efficacious.[57] Reimbursement obstacles can keep patients from receiving life-saving medical device treatment even after the device has been cleared for public use.[58] Device companies do not want payment rule-issuing agencies, such as the Centers for Medicare and Medicaid Services (CMS), to "create barriers that discourage Medicare beneficiaries from accessing new treatments being studied in clinical trials or that are commercially available."[59] Requirements for additional evidence of device efficacy before allowing reimbursement may leave patients paying expensive medical bills for a treatment necessary to save their lives.[60] However, some practitioners advocate that insurance companies should not provide full reimbursement until the device demonstrates unequivocal clinical efficacy.[61]

VII. CONCLUSION

Despite the limitations in regulating investigational medical devices, there seems to be consensus regarding their benefit to the public good. Unfortunately, this seems to be where the agreement ends. Some commentators urge that stricter FDA regulations would better serve the public by minimizing the use of unapproved, and potentially harmful, devices.[62] Others believe that more stringent clinical trials are the best solution.[63] As discussed, there are drawbacks to both potential solutions. The emergency and compassionate use exceptions exist to maintain a balance between providing patients with life-saving treatment and ensuring patient safety prior to formal approval of investigational devices.[64] Even after the product is finally approved and delivered to public consumers, the

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[57] Mark Barnes & Jerald Korn, *Medicare Reimbursement for Clinical Trial Services: Understanding Medicare Coverage in Establishing a Clinical Trial Budget*, 38 J. HEALTH L. 609, 610 (2005) (discussing exclusion of "experimental" treatment from insurance coverage).
[58] Thomas Novelli, *US Market: 2008 Priorities*, MED. DEVICE TECH., May/June 2008, at 58, 58, *available at* http://www.devicelink.com/mdt/archive/08/05/010.html.
[59] *Id.*
[60] *See Id.*
[61] Anthony J. Furlan & Marc Fisher, *Devices, Drugs, and the Food and Drug Administration: Increasing Implications for Ischemic Stroke*, 36 STROKE 398, 399 (2005).
[62] VanBuren, *supra* note 7, at 441.
[63] *See* Schneck, *supra* note 53, at 19; *see also* Henderson & Smith, *supra* note 50, at 517.
[64] *See* Klepinski, *supra* note 24, at 853 (discussing the compassionate use provision).

next question becomes: who pays for it? Insurance companies may not want to pay unless they are convinced of the efficacy, and some practitioners believe this is a proper standard.[65] In response, other practitioners argue that these medical treatments may be expensive, and thus requiring a higher standard of clinical efficacy before insurance companies will reimburse could prevent some patients from receiving beneficial medical treatment.[66] Finding a uniform solution does not appear likely in the near future, despite efforts toward such progress. Whatever the final solution becomes, it should be driven by the best interest of the patients and public health, not private interests or financial incentives.

[65] Barnes & Korn, *supra* note 57, at 610; *see also* Furlan & Fisher, *supra* note 61, at 399.
[66] Novelli, *supra* note 58, at 58.

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The Comparative Effectiveness Research Act of 2008: Reducing the Uncertainty of the Effectiveness of New Medical Technologies

Ana Maria Echiburu[*]

In recent years, the United States has spent an exorbitant amount of money on health care;[1] in 2006, alone, Americans spent over two trillion dollars.[2] Those expenditures accounted for sixteen percent of the U.S. economy, which means that "for every $100 in goods and services produced and consumed in American in 2006, $16 were for health care."[3] These high costs are due in part to technological advancements in medical treatments, and these costs have greatly affected the way the U.S. healthcare system functions.[4] Presently, the U.S. healthcare system has become a battleground between patients who want health insurance coverage for new technologies and health insurance companies who do not want to cover untested, experimental, and expensive treatments.[5] To address this tension, Senate Finance Committee Chairman Max Baucus (D - Mont). and Budget Committee Chairman Kent Conrad (D - N.D.) have introduced the Comparative Effectiveness Research Act of 2008 (S. 3408) in the United States

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[1] 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[2] *Id.*
[3] *Id.*
[4] Joseph B. Clamon, *Does My Health Insurance Cover It? Using Evidence-Based Medicine and Binding Arbitration Techniques to Determine What Therapies Fall Under Experimental Exclusion Clause in Health Insurance Contracts*, 54 DRAKE L.REV. 473, 474 (2006).
[5] *See* Gina Kolata, *When Doctors Say Yes and Insurers No*, N.Y. TIMES, Aug. 16, 1992, *available at* http://query.nytimes.com/gst/fullpage.html?sec=health&res=9E0CE7D9133CF935A2575BC0A964958260.

Senate, which has the potential to remedy one of the main issues associated with the cost of new technologies in healthcare: the determination of whether a new technology would be effective in treating a patient.[6]

Insurance companies struggle with the cost of medical technology, which "account[s] for [forty] percent of annual increases in health insurance premiums."[7] To combat these high prices, insurance companies have implemented numerous programs and guidelines to address emerging medical technologies.[8] For example, most health insurance companies exclude coverage of "experimental therapy."[9] This exclusion is triggered whenever evidence regarding a new therapy is inconclusive or if a procedure or technology is still being developed.[10] Thus, an insurance company will first determine whether researchers have reviewed the effectiveness of the technology, and, if so, the insurer will only cover the cost of that technology if the research establishes that it is a proven course of therapy.[11] Although this exclusion may benefit the insurance companies, it has significantly affected patients who are forced into a struggle with their insurer to obtain coverage for unproven treatments for their diseases.[12]

To provide better healthcare for these patients, many within the medical industry have called for increased research assessing the effectiveness of new and promising technologies and for government funding of these studies.[13] On July 31, 2008, that call may have finally been answered by Senators Max Baucus and Kent Conrad who introduced the Comparative Effectiveness Research Act of

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[6] *See* 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[7] Kolata, *supra* note 5.
[8] *See* Sandra J. Carnahan, *Medicare's Coverage With Study Participation Policy: Clinical Trials or Tribulations?*, 7 YALE J. HEALTH POL'Y, L. & ETHICS 229, 251-56 (2007); *Improving Health Care Quality: Hearing Before Senate Comm. on Finance*, 110th Cong. (2008) (statement of Sen. Baucus, Chairman, Senate Comm. on Finance) *available at* 2008 WLNR 17235017 (Westlaw).
[9] Clamon, *supra* note 4, at 476.
[10] *Id.* at 482.
[11] *Id.*
[12] *Id.* at 481.
[13] Kolata, *supra* note 5; BLUECROSS BLUESHIELD ASSOCIATION, THE PATHWAY TO COVERING AMERICA: ENSURING QUALITY, VALUE AND ACCESS 9 (2008), *available at* http://www.bcbs.com/issues/uninsured/pathway-to-covering-america/pathway-to-covering-america.pdf.

2008.[14] The bill proposes improving the quality of health care in the United States by establishing an organization to collect and distribute information regarding the effectiveness of various healthcare treatments, including new technologies.[15] Operating as the Health Care Comparative Effectiveness Research Institute ("Institute"), this private, nonprofit corporation will research the treatment of various health conditions to determine which treatments are most beneficial to individuals afflicted with specific conditions.[16]

To achieve this goal, the Institute would evaluate all forms of treatments, including medical devices, medical procedures, medical services, and other therapies.[17] The Institute would be overseen by a Board of Governors comprised of the Secretary of Health and Human Services, the Director of Agency for Healthcare Research Quality, the Director of the National Institutes of Health, and eighteen individuals appointed by the Comptroller General of the United States with backgrounds in various areas within the public and private sector.[18] Federal agencies and private entities approved by the Board of Governors would be enlisted to conduct the research.[19] All of the research findings would then be peer-reviewed, and a simplified version would be distributed to the public.[20]

Funding for the Institute would initially derive from general revenues with five million dollars of general funds coming from the Treasury in 2009, twenty-five million dollars in 2010, seventy-five million in 2011, and seventy-five million for each year from 2012 through 2018.[21] Beginning in 2012, funding would also come from revenues generated in the Medicare Trust Fund from fees

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[14] COMMITTEE ON FINANCE, BAUCUS-CONRAD PROPOSAL CAN IMPROVE QUALITY, LOWER COSTS THROUGHOUT AMERICAN HEALTH CARE SYSTEM (2008), http://finance.senate.gov/press/Bpress/2008press/prb080108.pdf.
[15] *Id.;* 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[16] COMMITTEE ON FINANCE, *supra* note 14.
[17] 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[18] COMMITTEE ON FINANCE, *supra* note 14.
[19] *Id.*
[20] *Id.*
[21] COMPARATIVE EFFECTIVENESS RESEARCH ACT OF 2008 SECTION-BY-SECTION OVERVIEW 9, Aug 1. 2008, http://finance.senate.gov/sitepages/leg/LEG%202008/080108%20CE%20Section-by-Section.pdf.

on private health insurance policies.[22] The private insurance fee would total one dollar per person each year, and the funding from Medicare would equal one dollar per beneficiary annually.[23]

Initial reactions to the bill generally have been positive.[24] Blue Cross Blue Shield Association noted that it has supported the creation of this type of institute for years and commended the Senators for taking the "first step towards creating a knowledge-based health care system where treatment decisions are based on sound clinical data."[25] The president and chief executive officer of the Advanced Medical Technology Association expressed qualified approval of the bill stating that "[i]t is also essential that research recognize the unique iterative nature of device innovation when establishing research priorities and conducting studies."[26] Other reactions, however, were not so positive. David Merritt from the Center for Healthcare Transformation found the amount of funding proposed for the Institute inadequate, especially when compared to the National Institutes of Health's thirty billion dollar budget.[27] He noted that the amount of funding the bill proposed was "not even a drop in the bucket compared to what's needed."[28] Further, several professionals in the medical device and pharmaceutical industries fear that the

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[22] *Baucus Comparative Effectiveness Bill Funded With Private/Public Partnership*, INSIDE CMS, Aug. 7, 2008, *available at* 2008 WLNR 14748807 (Westlaw).
[23] *Id.*
[24] Bureau of Nat'l Affairs, Inc., *Quality Assurance: Senators Propose Nonprofit Institute for Study of Comparative Effectiveness*, BNA MED. RES. L. & POL. REP. NEWS, Aug. 6, 2008, *available at* 7 BNA MRLP No. 15 d13 (Westlaw).
[25] U.S. Insurance News, BCBSA Throws Support Behind Proposed Comparative Effectiveness Research Institute, Aug. 11, 2008, http://www.digitalinsurancenews.com/000000008896/issues/bcbsa-throws-support-behind-proposed-comparative-effectiveness-research-institute.html.
[26] Bureau of Nat'l Affairs, Inc., *supra* note 24.
[27] Mark McCarty, *Washington Roundup: Comparative Effectiveness Bill Appears Aimed at Next Congress*, MED. DEVICE DAILY, Aug. 5, 2008, at 4, *available at* http://faculty.swosu.edu/jerrie.robinson/share/Health%20Care%20Administration/CMS%20declines%20more%20coverage%20for%20CAS.pdf.
[28] *Id.*

research could ultimately be manipulated to deny patients treatment and save government money if it is not properly managed.[29]

The proposed legislation has the potential to decrease tensions between health insurance companies and the insured by providing the evidence required to determine the effectiveness of new technologies.[30] The research conducted by the Institute will not only benefit patients[31] who want the benefits of new medical technology. The research also will assist insurers that are often unwilling to pay for an expensive, new technology due to the uncertainty of its effectiveness[32] when they make coverage decisions. With passage of the bill, not only will patients have better knowledge about the effectiveness of emerging treatments, but insurance companies will have the ability to eliminate coverage for ineffective treatments. These improvements may result in extra funds that both patients and insurance companies could use to pay for expensive but successful treatments and could decrease the healthcare community's hesitancy to embrace new medical technology.

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[29] *Baucus Comparative Effectiveness Bill Funded With Private/Public Partnership*, *supra* note 22; Peter Pitts, *America Shouldn't Repeat Britain's Health-Care Atrocities*, THE VALLEY NEWS, Sept. 13, 2008, *available at* http://www.valleynewsonline.com/viewnews.php?newsid=83411&id=2.
[30] *See* 154 CONG. REC. S7805, 7961 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[31] *Id.* at 7960.
[32] Clamon, *supra* note 4, at 482.

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Consumer Use of Internet Health Information Resources

Marisa Franchini[*]

Patients seeking care rarely think of themselves as consumers. The reasons for this are two-fold. First, patients pay flat fees for services and therefore are insulated from the true cost of treatments. Second, those who need medical care have been socialized to defer to the doctor's judgment rather than their own. When a person is ill, the only thing he or she thinks about is getting better; this can cloud practical reasoning about clinical and financial matters.

This is changing. With the rise and expansion of consumer health information resources, patients, families, caregivers, and consumers have been empowered by new sources of information to make medical treatment and care decisions based on both medical and financial considerations.[1] Internet-based consumer health information resources ("E-health communication") have the potential to improve value-based decisions and ultimately foster better public health outcomes.[2]

I. TRENDS IN E-HEALTH COMMUNICATION HAVE THE POTENTIAL TO TURN PATIENTS INTO INFORMED CONSUMERS

Many Americans are selecting their own health care coverage components from a complex array of various insurance companies, personal savings accounts,

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[1] Allan Keselman et al, *Developing Informatics Tools and Strategies for Consumer-centered Health Communication*, 15 J. AM. MED. INFORMATICS ASS'N 473, 473 (2008).

[2] *Id.*

and managed care options.[3] Consumer directed health care ("CDHC") is defined by interwoven components that together enable a consumer to exercise the right to choose health coverage within their own framework of personal priorities.[4] The first element is a high-deductable health insurance product that protects the individual against the risk of catastrophic health care costs.[5] This is coupled with an individually managed, tax-exempt, interest-bearing health savings account ("HSA") which is used to pay for routine and preventative health services that fall below the deductible amount of the insurance plan.[6] The plan requires an increased level of information to enable the consumer to exercise choice intelligently.[7] Generally, this information is offered through the internet from various sources.[8] Without accessible information about health care, patients will not benefit from CDHC. Ill-informed decision-making is not only risky for the consumer, but could also negate the increased efficiency and effectiveness promised by CDHC.[9]

Many health care consumers are already using the internet to access health care information. According to a study by PEW Internet and American Life study, between 75-80% of internet users have looked online for health information.[10] Internet users with a chronic disease or disability were found to be even more engaged in e-health with 75% of them saying that their last health search affected a decision about how to treat a condition compared with 55% of other users.[11]

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[3] Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice,* 2 J. HEALTH & BIOMED. L. 91, 92 (2006).
[4] *Id.* at 106-07.
[5] *Id*. at 107-08.
[6] *Id*. at 108.
[7] Arnold J. Rosoff, *Consumer Driven Health Care; Questions, Cautions, and an Inconvenient Truth*, 28 J. LEGAL MED. 11, 13 (2007).
[8] *Id.*
[9] Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U. C. DAVIS L. REV. 1577, 1579 (2007).
[10] Susannah Fox, *The Engaged E-patient Population*, PEW INTERNET AND AMERICAN LIFE PROJECT, (August 26, 2008), http://www.pewinternet.org/pdfs/PIP_Health_Aug08.pdf.
[11] *Id.*

"Consumer engagement in decisions about coverage, provider and treatment choices, and purchasing is central" to lowering healthcare costs.[12] State governments, the federal government, and insurance companies have all developed websites that let consumers compare hospitals on cost, quality and ratings by patients.[13] Proponents of CDHC say that it is crucial for consumers to have convenient access to "an adequate amount of relevant, accurate and comprehensible information."[14] In recent years there has been a "veritable explosion of health care information," with more sources coming online everyday.[15]

PatientsLikeMe is an online community built to support information exchange between patients."[16] "The site provides customized, disease-specific outcome and visualization tools to help patients understand and share information about their condition."[17] Members of the community locate others with similar experiences to answer specific health-related questions, to share personally acquired disease-management knowledge, and to foster relationships based on shared concerns. [18] A 2008 report on the PatientsLikeMe website, found that people with rare life-changing diseases benefit most from sites like this because it allows those afflicted to build communities despite geographic distances and mobility constraints.[19]

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[12] Ted von Glahn, *Evaluation of Consumer Decision Support Tools: Helping People Make Health Care Decisions*, Pacific Business Group on Health 1 (June, 2007), http://www.pbgh.org/documents/ConsumerToolsReport2007.pdf.
[13] *See generally* Florida Health Finder, http://www.floridahealthfinder.gov/CompareCare/SelectChoice.aspx (last visited Nov. 16, 2008) (providing an example of a state health services website); *see generally* US Department of Health and Human Services "Hospital Compare", http://www.hospitalcompare.hhs.gov (last visited Nov. 16, 2008) (providing an example of a federal health services website); s*ee generally* Heather Won Tesoriero, *Uniform Doctor Ratings Sought*, WALL ST. J., Apr. 2, 2008, at D7 (explaining doctor-rating programs).
[14] Rosoff, *supra* note 7, at 23.
[15] *Id.*
[16] Jeana H. Frost & Michael P. Massagli, *Social Uses of Personal Health Information Within PatientsLikeMe, an Online Patient Community: What Can Happen When Patients Have Access to One Another's Data*, 10 J. MED. INTERNET RES. 1, 1 (2008).
[17] *Id.*
[18] *Id*.
[19] *Id.* at 2.

In another online community, multiple sclerosis patients assist each other online during painful self-injections.[20] Multiple sclerosis patients from around the world coordinate weekly injections and meet in a chat room to self inject at the same time.[21] Patients find spiritual and practical support during this painful procedure by sharing the experience.[22] While much of the information shared in these communities is unregulated, an analysis of a breast cancer support group found that only a small percentage of posts were inaccurate and the inaccuracies were quickly corrected by another community member.[23] Some of these non-traditional e-health information sources may be more useful to patients because official sites for specific diseases may be more difficult to decipher.

II. DIGITAL HEALTH INFORMATION CHALLENGES

The rise of patients-as-consumers is evident in the recent investment in E-health informatics. As a society (or as policy) we have decided that adults are capable and willing to exercise health care related autonomy. However, both direct and indirect barriers hinder access to internet-based information. For example, those who most need health information often lack the means, knowledge, and skills necessary to benefit from internet health resources.[24] Although the percentage of adult Americans with home broadband internet connections has risen from 47% in 2007 to 55% in 2008, lower income Americans saw no growth in home internet access in the past year.[25] According to one December 2007 study, 23% of the population have no access to the Internet while 13% of the population have only dial-up access.[26] This low-access

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[20] Keselman et al, *supra* note 1, at 475.
[21] Johnson & Ambrose, *Neo-tribes: The Power and Potential of Online Communities in Health Care*, 49 COMMUNICATIONS OF THE ACM 107, 110 (2006).
[22] *Id.*
[23] Keselman et al, *supra* note 1, at 475.
[24] *Id*.
[25] John B. Horrigan, *Home Broadbnd Adoption 2008*, PEW Internet & American Life Project 1 (July 2008), http://www.pewinternet.org/pdfs/PIP_Broadband_2008.pdf (last visited Nov. 16, 2008).
[26] *Id*.

population was found to be lower income, older, and less educated than those with broadband access at home or at work.[27]

Another barrier to providing health resources to the medically underserved is health literacy.[28] Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health decisions."[29] Health literacy involves the "core competencies which are required to retrieve and process information online."[30] Skills include general literacy, numeracy skills, conceptual knowledge, health vocabulary, technological fluency, and rhetorical skills.[31] About 50% of U.S. adults do not possess adequate health literacy skills.[32] Studies suggest that individuals of all education levels have trouble interpreting probabilities, understanding the equivalence between percentages and proportions, and taking risks into account.[33] Evidence suggests that inadequate health literacy can have negative effects on clinical outcomes.[34] A patient who gets a doctor's advice might disagree with his advice and search for alternative treatments online. A health consumer struggling with health literacy might not always be capable of understanding their condition and the available treatment options in order to independently make decisions in their best interest. Also, when patients make decisions based on cost, there is a danger that consumers cannot always tell where desirable economy ends and dangerous thriftiness begins.[35] While the availability of health information can reduce consumer confusion, the question remains: is an individual better off being informed and treated by a physician or by the internet? Ill-informed decision-making can minimize efficiency benefits and subject patients to higher risks of injury.[36] Patients become vulnerable consumers when they find themselves trapped in a

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[27] Keselman et al, *supra* note 1, at 476.
[28] *Id*.
[29] *Id*. at 475.
[30] *Id.*
[31] *Id.*
[32] Keselman et al, *supra* note 1, at 476.
[33] *Id.*
[34] *Id.*
[35] Rosoff, *supra* note 7, at 27.
[36] Madison, *supra* note 9, at 1579.

market without access to accessible information, unable to make a prudent choice.[37] Access to information may or may not lead to increased quality of care. For example, one study reported that "only 34% of a [Consumer Driven Health Plan's] participants at the University of Minnesota visited the plan's informational web site in the year under study."[38] Thus, even if consumers have access to information it is not clear that they can or will use it effectively. [39]

Proponents of CDHC suggest that through the doctrine of informed consent, patients exercise autonomy when making clinical decisions and should therefore also be entrusted with decisions relating to insurance coverage and treatment options.[40] However, some argue that autonomy may be better served in some instances by giving the patient a more passive role rather than expecting proactive "shopping behavior" at every stage of the care process.[41] A more passive role may entail relying on the judgment of professionals but still retaining veto power in ultimate decision making. [42]

III. CONCLUSION

If CDHC is to have real potential to empower consumers and let them apply their available resources in a way that most suits their needs, than real, accessible, personalized information is critical.[43] Being a health care consumer is "harder than it looks, especially when buying unfamiliar things in unfamiliar situations."[44] Consumers often fail to inform themselves fully in order to understand and choose wisely.[45] Ill informed consumers do not understand

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[37] Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 646 (2008).
[38] Rosoff, *supra* note 7, at 25.
[39] *Id.*
[40] Kapp, *supra* note 3, at 117.
[41] Rossoff, *supra* note 7, at 26.
[42] *Id.*
[43] *Id.* at 20.
[44] Hall & Schneider, *supra* note 37, at 650.
[45] *Id.*

enough about their options.[46] With better information about health care, consumers will be able to take greater responsibility for their choices.

[46] *Id.*

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The Benefits and Limitations of Electronic Medical Files

Robert Ybarra[*]

Over the last several decades technology has taken an increasingly prominent role in most aspects of daily life. From how we shop to how we learn, technology has fundamentally altered the ways in which individuals interact with the world. The healthcare industry is no exception; entire new branches of medicine have been created, treatments devised, and services offered. Despite technology's omnipresence, in one area of health care, technological adoption remains sluggish. Considering all of the technological innovations in treatment and research, the transition to electronic methods of storing and using medical records has been slow.

A recent national study published by the *New England Journal of Medicine* (NEJM) examines the prevalence of Electronic Medical Records (EMR) among different groups of physicians.[1] As of early 2008, the study found that approximately seventeen percent of physicians in the United States use EMR systems.[2] Of this seventeen percent, most have only basic systems; a mere four percent have fully-integrated EMR systems in their practices.[3] The difference

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[1] Catherine M. DesRoches et al., *Electronic Health Records in Ambulatory Care – A National Survey of Physicians*, 359 NEW ENG. J. MED. 50, 50 (2008).
[2] *Id.* at 56.
[3] *Id.*

between basic and fully-integrated systems is the lack of certain order-management functions and automatic clinical-decision feedback.[4]

This article provides an overview of the benefits and limitations of EMR systems.

I. BENEFITS

EMR systems have the potential to significantly improve the healthcare system. As the proportion of physicians using EMR increases, the occurrence of preventable medical errors will decrease, the quality of patient care will improve, and costs to both physicians and patients will decline.[5]

A. Reduction of Medical Errors

Evidence suggests that the adoption of EMR systems helps prevent medical errors. Each year approximately 98,000 deaths result from medical errors; of these, approximately 7,000 are caused by preventable medication errors.[6] The NEJM study offers evidence that the risk of two common types of medication-related errors, the agitation of known drug allergies and accidental drug interactions, are reduced by EMR.[7]

A physician with access to a patient's EMR would be able to look at the entirety of the patient's medical history, including whether the patient has suffered an adverse reaction to a drug in the past, and what medications the patient is currently taking.[8] Also, even when the physician does not immediately recognize a potential drug interaction, EMR systems are often capable of issuing warnings regarding suspected interactions.[9] In the NEJM study, physicians

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[4] *Id.* at 52.
[5] Steve Lohr, *Health Industry Under Pressure to Computerize*, N.Y. TIMES, Feb. 19, 2005, at C1 [hereinafter Lohr, *Pressure to Computerize*].
[6] John P. Burke, *Preventing Medication Errors: Medication Errors*, 357 NEW ENG. J. MED. 624, 624 (2007).
[7] DesRoches, *supra* note 1, at 54.
[8] Cara B. Litvin, *In the Dark – The Case for Electronic Health Records*, 356 NEW ENG. J. MED. 2454, 2455 (2007).
[9] Steve Lohr, *Most Doctors Aren't Using Electronic Health Records*, N.Y. TIMES, June 19, 2008, at C3 [hereinafter Lohr, *Electronic Health Records*].

overwhelmingly reported that EMR systems helped to avert potential medication errors; of those physicians with fully-integrated systems, eighty percent averted a known drug allergy, while seventy-one percent prevented a potentially dangerous drug interaction.[10] With physicians able to access complete patient histories and automatic system feedback on potential risks, they will make significantly less medical errors.[11]

B. Improved Patient Care

Access to information is essential to providing quality patient care.[12] Recognizing this, the Department of Veterans Affairs (VA) became early adopters of EMR systems.[13] EMR created by VA physicians include information such as a patient's prescriptions, lab tests, studies, consultations, reports, and progress notes.[14] Access to this information improves patient care in that it allows for more accurate diagnoses.[15] Also, access to an accurate history allows a physician to work efficiently, concentrating on the patient's well-being instead of wasting time and resources performing tests that have already been conducted.[16]

A complete and accurate patient history can provide a physician with insight into the significance of particular symptoms. In one reported instance, a patient's EMR showed that he had suffered from a persistent symptom for a considerable amount of time and had recently undergone tests which ruled out certain diagnosis. As a result of this information, his treating physician was able to better tailor the patient's treatment around the recurring symptom.[17]

Further, physicians with access to comprehensive patient histories are able to avoid waste and increase efficiency. If a doctor knows that a patient has recently undergone a test, there is no need to repeat it, saving time and money for both

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[10] DesRoches, *supra* note 1, at 54.
[11] Lohr, *Pressure to Computerize*, *supra* note 5.
[12] Litvin, *supra* note 8, at 2455.
[13] *Id.*
[14] *Id.*
[15] *See Id.*
[16] *See Id.* at 2454.
[17] *Id.* at 2455.

parties.[18] In one example, a patient was admitted to an emergency room after being discharged from a different hospital.[19] Despite having received ten days of critical care, the only record of treatment provided was his discharge form, which consisted of "three sentence fragments and a one set of lab results."[20] Unable to contact the discharging physician, the emergency physician had no alternative but to perform several tests that were already recently conducted.[21]

C. Cost Reductions

Over time, the transition to EMR could reduce the cost of healthcare.[22] Although there is no conclusive evidence, studies suggest that switching to EMR systems could potentially reduce healthcare spending by five to ten percent or more, resulting in an estimated savings of eighty-one to one-hundred-seventy billion dollars each year.[23] These savings would result from increased efficiency and safety, a reduction in administrative costs, and the elimination of duplicative testing.[24] In a letter to the editor of the *New York Times*, one physician estimates that his recent switch to EMR will save his practice approximately $30,000 a year, while also improving patient safety.[25]

II. LIMITATIONS

Several factors limit the potential benefits of EMR; in particular, the initial costs of implementation and concerns over patient privacy.

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[18] Lohr, *Pressure to Computerize*, *supra* note 5.
[19] Litvin, *supra* note 8.
[20] *Id.*
[21] *Id.*
[22] Lohr, *Electronic Health Records*, *supra* note 9.
[23] Lohr, *Pressure to Computerize*, *supra* note 5; Jennifer Fisher Wilson, *Lessons for Health Care Could be Found Abroad*, 146 ANN. INTERNAL MED. 473, 474 (2007).
[24] Lohr, *Electronic Health Records*, *supra* note 9.
[25] Christopher A. Toth, Letter to the Editor, *Efficient Medical Records*, N.Y. TIMES, July 28, 2005, at A24.

A. High Initial Cost

The initial cost required to implement an electronic record system poses the greatest limitation to widespread EMR adoption.[26] In the NEJM study, sixty-six percent of physicians that did not use EMR claimed that the cost of adoption was a serious impediment.[27] By most estimates, the cost to purchase and implement an EMR system can range from $15,000 to more than $90,000 per system, depending upon the difficulty of the integration.[28] Support for the transition, however, is widely regarded as necessary, and in 2005 Medicare announced that it would give away the EMR software used by the VA.[29] With the free availability of software, the total cost of installation fell considerably to approximately $10,000 to $12,000 for an entire medical practice.[30]

B. Privacy Concerns

In addition, privacy concerns limit the potential benefits presented by EMR systems.[31] The optimal implementation of EMR involves the collection of patient information in a single, large database so the potential for abuse is great.[32] One common concern is that private health information may be used to disqualify individuals from certain benefits.[33] Also the security measures designed to safeguard the sensitive information of patients may prove inadequate.[34]

A common fear is that medical information will be used against the patient in some way. For example, many people believe that they could lose their health

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[26] DesRoches, *supra* note 1, at 54-56.
[27] *Id.*
[28] Rainu Kaushal et al., *The Costs of a National Health Information Network*, 143 ANN. INTERNAL MED. 165, 168 (2005).
[29] Gina Kolata, *In Unexpected Medicare Benefit, U.S. Will Offer Doctors Free Electronic Records System*, N.Y. TIMES, July 21, 2005, at A14.
[30] *Id.*
[31] Milt Freudenheim & Robert Pear, *Health Hazard: Computers Spilling Your History*, N.Y. TIMES, Dec. 3, 2006, at 31.
[32] *Id.*
[33] *Id.*
[34] *Id.*

insurance as a result of disclosure of information contained in their EMR.[35] Others fear that their employers may limit job possibilities or find excuses to terminate the employment of employees suffering from expensive ailments.[36] Although the *Health Insurance Portability and Accountability Act* (HIPAA) makes such improper uses of medical information a federal crime, such regulations are rarely enforced.[37] As of December 2006, approximately 22,000 complaints had been filed alleging violations of the HIPAA; of these, only three criminal cases were tried, and no civil fines were imposed.[38]

The sufficiency of the security measures in EMR to protect patient information has been reasonably questioned. In 2006, a laptop containing the unencrypted medical records of 28 million patients was stolen from a VA official.[39] The lack of encryption could have allowed an interested party to access the sensitive information, such as social security numbers and detailed health information. This danger compounds when medical records are available online. For example, an officer of VeriSign, an online security provider, researched the security of her own online medical files.[40] She was disappointed to discover that it would be relatively easy to hack into the account.[41] The officer's experience highlights the need for reliable methods of authenticating the identity of users.[42]

III. CONCLUSION

Healthcare professionals generally agree that the implementation of EMR systems will benefit the healthcare industry.[43] However, the potential for safer, more efficient care must be balanced against both the cost to the physician and the

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[35] *Id.*
[36] *Id.*
[37] Freudenheim & Pear, *supra* note 31.
[38] *Id.*
[39] *Id.*
[40] Posting of Jen Gilburg to http://blogs.verisign.com/identity/2008/02/security_of_online_medical_rec.php (Feb. 26, 2008, 15:14 CST).
[41] *Id.*
[42] *Id.*
[43] Lohr, *Pressure to Computerize*, *supra* note 5.

privacy concerns of individual patients.[44] Finding a balancing point on this critical issue is no small task; however, in this time of technological permeation, it is a crucial one.

[44] Freudenheim & Pear, *supra* note 31.

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A New Tort: The Unauthorized Disclosure of Medical Information and Implications for Electronic Medical Records

Robert T. Pickrell[*]

Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.
-The Hippocratic Oath, circa 400 B.C.

I. HISTORICAL PROGRESS OF TECHNOLOGY AND CONFIDENTIALITY LAW

Tort actions against those who breach confidentiality are nothing new; indeed, remedies for improperly divulging confidential information began to emerge as early as the eighteenth century.[1] Historically, many developments in breach of confidence law have followed the technological progress that made such breaches more common.[2] For example, by 1890, postal confidentiality and literary property laws began protecting the confidentiality of letters in response to the difficulty of properly sealing letters and the lack of mailboxes (requiring delivery to public places, such as bars and coffee houses).[3]

The invention of the telegraph in 1844 presented new issues as every telegraphic dispatch was viewable not only to the sender and the receiver, but to

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[1] Neil M. Richards & Daniel J. Solove, *Privacy's Other Path: Recovering the Law of Confidentiality*, 96 GEO. L.J. 123 at 136 (2007).
[2] *Id.* at 140-141.
[3] *Id.*

the telegraph company as well.[4] As a result, telegraphic communications became increasingly protected by law.[5] By 1879, two-thirds of the states had passed laws imposing a nondisclosure obligation on telegraph company employees in order to protect the "inviolability" of telegrams.[6] As these developments show, "by 1890 both public opinion and significant statutory law gave substantial protection to telegraphic confidentiality."[7]

The tort of medical breach of confidentiality began to emerge by the early twentieth century.[8] In 1920, the Nebraska Supreme Court held that because doctors were "bound" by "professional honor and the ethics of [their] high profession" to maintain patient confidentiality, a "wrongful breach of such confidence, and a betrayal of such trust, would give rise to a civil action for damages naturally flowing from such wrong."[9]

II. TECHNOLOGY AND MODERN BREACH OF CONFIDENTIALITY TORTS

In 1985, the Supreme Court of Massachusetts held that a physician owes a patient a duty not to disclose confidential information gained through their physician-patient relationship, and "a violation of that duty gives rise to a cause of action sounding in tort."[10] The recognition of similar torts throughout the country has since grown common.[11]

As with modern mail and the telegraph, breach of medical privacy and confidentiality law has evolved to meet some of the newer issues presented by e-mail and the internet. Recently, Georgetown University Hospital suspended a trial program with an electronic prescription-writing firm after a computer

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[4] *Id.* at 144.
[5] *Id.*
[6] MORRIS GRAY, A TREATISE ON COMMUNICATION BY TELEGRAPH 212-13 (1885).
[7] Richards & Solove, *supra* note 1, at 145.
[8] *Id.* at 151-52.
[9] Simonsen v. Swenson, 177 N.W. 831, 832 (Neb. 1920).
[10] Alberts v. Devine, 479 N.E.2d 113, 124 (Mass. 1985).
[11] Richards, *supra* note 1, at 158.

consultant stumbled across confidential data belonging to thousands of patients.[12] Generally, e-prescribing allows doctors to write and renew drug prescriptions electronically and transmit them to participating pharmacists for fulfillment. In this case, the private medical information of many as 23,000 patients was left viewable to the public.[13] While such examples remain relatively rare, accidental dissemination of electronically maintained medical files has the potential to create massive breaches of patients' privacy and confidentiality. In response to this threat, HMOs, clinics, hospitals, and doctors have implemented strict policies about what information can be stored electronically and where the information can be stored.[14]

Despite numerous attempts to regulate the dissemination of electronically maintained medical information, by both state and federal government, the Government Accountability Office (GAO) reported that approximately 570 data breaches have been reported by the media from January 2005 through December 2006.[15] These breaches have affected medical facilities and other institutions, though the precise number of patients' records that have been breached improperly remains unknown.[16]

Without precise records, it is difficult to quantify the extent to which private and confidential medical records have been breached or how many potential causes of action there may be against doctors and medical institutions. Clearly though, these sorts of breaches are becoming more common with the emergence of electronic prescriptions and maintenance of medical records.[17] Also, evidence shows that the emerging market for private companies to maintain

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[12] Kevin Poulsen, *E-Health Gaffe Exposes Hospital*, WIRED, July 25, 2006, *available at* http://www.wired.com/science/discoveries/news/2006/07/71453.
[13] *Id.*
[14] Don Hughes, *Data Breach Prevention*, ADVANCE FOR HEALTH INFORMATION PROFESSIONALS, May, 2007, *available at* http://health-information.advanceweb.com/article/data-breach-prevention.aspx.
[15] GAO, PERSONAL INFORMATION (2007), *available at* http://www.gao.gov/new.items/d07737.pdf.
[16] *Id.*
[17] *Id.* at 5-6.

these records increases the danger of a breach.[18] While any entity that bills for health care services, such as doctors, hospitals, or insurers, are bound by the federal Health Insurance Portability and Accountability Act (HIPAA), companies that only maintain health records are not covered by that law, which means people must rely on corporate privacy policies and a company's good faith.[19]

III. OHIO'S RECENT SUPREME COURT DECISIONS

The Supreme Court of Ohio recently held that an attorney's unauthorized disclosure of medical information learned during litigation could be the basis of a tort.[20] This Supreme Court of Ohio decision follows the growing country-wide trend to recognize a separate tort for breach of privacy and confidentiality related to medical records. As HIPAA and federal privacy laws generally contain no private right of action, this decision helps open the door for more suits based upon breaches of confidentiality.[21] The court held:

> With these considerations in mind, we hold that when the cloak of confidentiality that applies to medical records is waived for the purposes of litigation, the waiver is limited to that case. An attorney can certainly use medical records obtained lawfully through the discovery process for the purposes of the case at hand . . . However, an attorney may be liable to an opposing party for the unauthorized disclosure of that party's medical information that was obtained through litigation.[22]

In 1999, the same court also recognized a tort for breach of privacy and confidentiality related to medical records.[23] The court explicitly recognized that an "independent tort exists for the unauthorized, unprivileged disclosure to a third party of nonpublic medical information that a physician or hospital has learned

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[18] Deborah Gage, *Health Data Storage Sites Might Not Be Secure*, S.F. CHRONICLE, February 20, 2008, *available at* http://www.sfgate.com/cgibin/article.cgi?f=/c/a/2008/02/20/BU9UV5405.DTL.
[19] *Id.*
[20] Hageman v. Sw. Gen. Health Ctr., 893 N.E.2d 153, 158 (Ohio 2008).
[21] Biddle v. Warren Gen. Hosp., 715 N.E.2d 518, 519 (Ohio 1999); Janet Leach Richards et al. *Medical Confidentiality and Disclosure of Paternity*, 48 S.D. L. Rev. 409, 413-414 (2003).
[22] *Hageman*, 893 N.E.2d at 157.
[23] *Biddle*, 715 N.E.2d at 519.

through a physician-patient relationship."[24] While the court reinforced the existence of a common law tort for breach of confidentiality, it preserved the traditional statutory and common law exceptions to physician-patient confidentiality.[25] The court found that a physician or hospital may disclose confidential medical information to comply with a statutory mandate or common-law duty, or to protect a countervailing interest that outweighs the patient's interest in confidentiality.[26]

The court also extended liability under this new tort beyond physicians. Now, in fact, a third party can be held liable under this tort for inducing the unauthorized, unprivileged disclosure of confidential medical information when that information was learned by a physician or hospital through a physician-patient relationship. To prove this cause of action against a third party, the plaintiff must prove:

> "(1) the third party knew or reasonably should have known of the existence of physician-patient relationship; (2) the third party intended to induce physician to disclose information about the patient or the third party reasonably should have anticipated his actions would induce the physician to disclose such information; and (3) the third party did not reasonably believe the physician could disclose that information to the third party without violating duty of confidentiality that the physician owed the patient."[27]

The Supreme Court of Ohio's creation of a breach of medical privacy and confidentiality tort appears to be a part of a recent effort, focused primarily on physicians and other occupations where a duty of confidentiality exists, to deter such breaches.[28] It is likely that the trend towards electronic maintenance of medical records, and other advances in technology, will spur further adjustments in the law to meet these new challenges.

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[24] *Id.*
[25] *Id.*
[26] *Id.* at 402.
[27] *Id.* at 408.
[28] Richards & Solove, *supra* note 1, at 157.

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Licensure, Reimbursement and Liability in Telemedicine: An Academic Perspective

Anika D. Clifton[*]

Telemedicine is gaining ground throughout the United States healthcare system.[1] Its application and uses are so broad and far-reaching that, as a consequence, experts have had a difficult time restricting the concept to a narrow definition. For example, according to the American Telemedicine Association (ATA), telemedicine is defined as "the use of medical information exchanged from one site to another via electronic communications to improve patients' health status."[2] Alternatively, telemedicine.com defines telemedicine as "the ability to provide interactive healthcare utilizing modern technology and telecommunications."[3] While both definitions are accurate and both underscore the general idea, Professor John D. Blum, of Loyola University Chicago School of Law's Beazley Institute for Health Law and Policy, believes that the definition of telemedicine emanates from the subject of licensure. Professor Blum is a leading authority on the practice of telemedicine and serves on the board of the Center for Telehealth and E-Health Law (CTeL). Professor Blum believes that the state licensing authorities are the best initial source for the definition of

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[1] Alan Joch, *Telemedicine's Growing Pains: The Risks to Patients and Providers are Growing as Telemedicine Scales to Larger and Larger Populations*, GOVERNMENT HEALTH IT, Aug. 27, 2008, http://www.govhealthit.com/print/4_20/features/350521-1.html.

[2] American Telemedicine Association, ATA Defining Telemedicine, http://www.atmeda.org/news/definition.html (last visited November 2, 2008).

[3] Telemedicine.com, What is Telemedicine?, http://www.telemedicine.com/whatis.html (last visited Nov. 2, 2008).

telemedicine. He states, "the most appropriate definition for telemedicine starts with the licensing authorities in the respective jurisdiction in which the provider is based. It involves a patient who is receiving services from some type of electronic medium other than the telephone, primarily through a web-based system."[4] Professor Blum emphasizes that as with traditional medicine, telemedicine involves a one-on-one, doctor and patient relationship.[5]

One of the biggest topics of discussion surrounding telemedicine is the issue of liability. As Professor Blum reiterates, "[w]ith any delivery of service, liability is always going to be a big problem."[6] He believes the reason telemedicine is particularly fraught with liability stems from "the nature of the interface" and the technological applications involved.[7] Just like the conventional practice of medicine, telemedicine is confronted with the same variety of liabilities ranging from malpractice to privacy concerns. More accurately stated, exposure to liability is significantly enhanced in a telemedicine practice due to the technological modalities employed. Professor Blum underlines this point saying, "[w]hen you take the traditional environment of medicine and extend it and apply it to a new medium, you open yourself up to new liabilities."[8] While he acknowledges that consumers and providers alike are justified in worrying about the legal issues involved, Professor Blum does not see liability as a tremendous or insurmountable barrier.[9]

Nonetheless, the Center for Telehealth and E-Health Law asserts that there are several obstacles that telemedicine must confront and effectively address. Chief of these public policy concerns is that of licensure and reimbursement.[10] In addressing the importance of licensure, the Federation of State Licensing Boards

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[4] Interview with John D. Blum, J.D., John J. Waldron Research Professor, Loyola Univ. Chicago School of Law, in Chicago, Ill. (Oct. 9, 2008).
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] Center for Telehealth and E-Health Law (CTeL), Telehealth and Emerging Technologies, http://www.ctel.org/Barriers.html (last visited Nov. 2, 2008).

contends: "Increasing public demand for protection, coupled with the growth in the number and sophistication of fraudulent practitioners over the past two decades, has resulted in stronger and more complex licensing boards and licensing statutes throughout the country."[11] Providers of telemedicine are no less subject to the restrictions of licensure as those who practice medicine in the traditional setting. When asked whether a physician who practices telemedicine in one state can provide services to a patient in a different state, Professor Blum responds, "the simple answer is probably not."[12] However, he explains further that it is not uncommon for a treating physician to consult with another out-of-state physician regarding a particular patient's health. Professor Blum comments, "the way the state licensing laws are constructed does allow for occasional consultations to occur."[13] He warns, however, that this should not be an on-going or frequent occurrence.[14] The agency with the greatest amount of influence in the licensing arena is the Federation of State Medical Boards (FSMB).[15] The FSMB is a national organization responsible for representing the seventy different medical boards in the United States.[16] Currently, the FSMB is in the process of revising its position on medical licensure and discipline, according to Professor Blum.[17]

Along with licensure, the issue of reimbursement is another hurdle that must be cleared in order for telemedicine to gain more ground. Professor Blum states, "[y]ou can do all kinds of things to provide coverage using telemedicine technology as the vehicle, but the problem is how you get the services paid for and whether it will be reimbursed."[18] Professor Blum sees this issue as "the biggest practical challenge" facing the industry.[19] In addition to licensure and

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[11] Federation of State Medical Boards, Getting a License: The Basics, http://www.ama-assn.org/ama/pub/category/2644.html (last visited Nov. 2, 2008).
[12] Interview with John D. Blum, *supra* note 4.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] Federation of State Medical Boards, http://www.fsmb.org/ (last visited Nov. 2, 2008).
[17] Interview with John D. Blum, *supra* note 4.
[18] *Id.*
[19] *Id.*

reimbursement, it is important to note that telemedicine raises several other liability concerns including privacy, security and confidentiality.[20]

Despite all the issues and challenges facing telemedicine, "[t]he addition of telemedicine technology to healthcare delivery has had positive effects on the practice of medicine…"[21] Perhaps most significantly, telemedicine has increased access to health care to geographically or otherwise isolated patients.[22] Professor Blum underscores this intrinsic function of telemedicine as he believes telemedicine's biggest area for growth is in the urban neighborhoods where there is a shortage of physicians treating poor and indigent communities. He stresses that there is great opportunity to reach these underserved populations through telemedicine, and pushes for a concerted development in this area.[23] Notwithstanding the enormous potential for growth in communities like the one mentioned by Blum, it is telemedicine's effect on liability which requires greater examination if its eventual assimilation into healthcare is to be ubiquitous.[24]

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[20] TELEMEDICINE REPORT TO CONGRESS, PRIVACY, SECURITY AND CONFIDENTIALITY IN TELEMEDICINE (1997), http://www.ntia.doc.gov/reports/telemed/privacy.htm.
[21] Glenn W. Wachter, *Malpractice and Telemedicine Liability: The Uncharted Waters of Medical Risk*, TELEMEDICINE INFORMATION EXCHANGE July 2002, *available at* http://tie.telemed.org/articles/article.asp?path=articles&article=malpracticeLiability_gw_tie02.xml.
[22] *Id.*
[23] Interview with John D. Blum, *supra* note 4.
[24] Wachter, s*upra* note 21.

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Grey's Anatomy Meets Star Trek: How the Tele-ICU Has Forever Changed Critical Care

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A medical revolution in critical care is upon us. Since 2000, more than 200 hospitals and over forty healthcare systems in the United States have instituted active Telemedicine Intensive Care Unit (Tele-ICU) programs.[1] These Tele-ICU programs serve over 300,000 ICU patients annually in over twenty-eight states, yet this figure amounts to only four percent of the total number of ICU patients.[2] Both Dr. Michael Ries, Director of Tele-ICU at Advocate Hospital, and Dr. Neil Rosenberg, Director of Tele-ICU at Resurrection Hospital, have seen first-hand how the dramatic changes in the field of critical care since the inception of the first Tele-ICU program in 2000.[3]

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[1] VISICU, Inc., Data from 185,000 ICU Admissions Show Significant Reductions in Mortality, May 20, 2008, http://www.prnewswire.com/mnr/visicu/33159/; NEW ENG. HEALTHCARE INST., MASS. TECH. COLLABORATIVE, HEALTH TECH. CTR., TELE-ICUS: REMOTE MANAGEMENT IN INTENSIVE CARE UNITS 5, http://www.masstech.org/ehealth/cmyk_tele_icu.pdf (last visited Nov. 8, 2008) [hereinafter REMOTE MANAGEMENT].
[2] VISICU, Inc., *supra* note 1; REMOTE MANAGEMENT, *supra* note 1, at 5.
[3] Telephone Interview with Dr. Michael Ries, Director of Tele-ICU, Advocate Hospital, in Chicago, Ill. (Oct. 9, 2008); Telephone Interview with Dr. Neil Rosenberg, Director of Tele-ICU, Resurrection Hospital, in Chicago, Ill. (Oct. 8, 2008); REMOTE MANAGEMENT, *supra* note 1, at 5.

I. THE ICU'S CHANGING LANDSCAPE

Dr. Ries mentioned that even the layout and appearance of a Tele-ICU may shock a new visitor whose exposure to such a device is limited to seeing it on Grey's Anatomy.[4] Advocate's staff of physicians – called intensivists – critical care nurses, and health care assistants monitor all 212 adult ICU beds across eight Chicago area hospitals.[5] Each intensivist may make rounds on 120 patients by watching six separate computer monitors during a ten-hour shift.[6] This visual seems more reminiscent of Captain Kirk's chair on the bridge of the "Starship Enterprise" more so than a traditional ICU. When asked whether he could have foreseen this technological shift in critical health care, Dr. Rosenberg stated "maybe not twenty-five years ago, but . . . ten to fifteen years ago . . . definitely, yes."[7]

Despite the recent growth in Tele-ICU programs, telemedicine is not as novel as one might think. The American Telemedicine Association defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve patients' health status."[8] Telemedicine technology has been available since at least 1959, but the adoption rate of this technology in an effort to provide health services has been slow.[9] Not until 1982, over twenty years later, did literature first mention the use of telemedicine for ICU patients.[10] Thus, the question becomes: what delayed this large-scale proliferation of telemedicine and specifically Tele-ICU programs?

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[4] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[5] Advocate Health Care, The Electronic Intensive Care Unit (eICU), http://www.advocatehealth.com/system/info/tvspots/eicu.html#q3 (last visited Nov. 8, 2008).
[6] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[7] Telephone Interview with Dr. Neil Rosenberg, *supra* note 3.
[8] American Telemedicine Association, What is Telemedicine & Telehealth? 1, http://www.americantelemed.org/news/What%20Is%20Telemedicine.pdf (last visited Nov. 8, 2008).
[9] Phoebe Lindsey Barton et al., *Specialist Physicians' Knowledge and Beliefs About Telemedicine: A Comparison of Users and Nonusers of the Technology*, 13 TELEMEDICINE & E-HEALTH 487, 488 (2007).
[10] Telephone Interview with Dr. Michael Ries, *supra* note 3 (citing to B.L. Grundy et al., *Telemedicine in Critical Care: Problems in Design, Implementation, and Assessment*, 10 CRITICAL CARE MED. 471, 471 (1982)).

II. THE SLOW DIFFUSION OF TELEMEDICINE

Institutions and practitioners alike generally acknowledge that the paucity of definitive findings regarding effectiveness is likely one of the most prominent factors accounting for the slow diffusion of telemedicine.[11] Dr. Ries averred that there is "no question that [Tele-ICUs] have been beneficial," while warning that "there are no good scientific studies" affirming the benefits of telemedicine.[12]

With respect to Tele-ICUs, Dr. Ries and Dr. Rosenberg noted that the difficulty in measuring the specific benefits attributed to telemedicine arises in part because of the program's collaborative nature.[13] Since the introduction of Tele-ICU programs, protocols on "both sides of the camera" have been improved.[14] Additionally, checklists have been established for physicians and nurses working at the patient's bedside, while Tele-ICUs provide real-time patient vital signs and alert systems powered by complex algorithms for faster evaluation of the most critical patients.[15] These improvements work in tandem to advance the quality of critical care.[16] Thus, it remains challenging to isolate the exact benefits specific to Tele-ICUs.

Additionally, complications in locating accurate statistics of Tele-ICU benefits lie in the fact that the authors of these reports tend to have vested interests in the results. In 2004, Sentara Healthcare System, in collaboration with VISICU (the company that sells the Tele-ICU software program) reported results of a twenty-seven percent decrease in mortality for medical ICU patients, a seventeen percent decrease in average patient length-of-stay, and a savings of $2,150 per patient or three million dollars above program costs.[17] However, Dr.

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[11] Jim Grigsby et al., *The Evaluation of Telemedicine and Health Services Research*, 11 TELEMEDICINE & E-HEALTH 317, 318 (2005).
[12] Telephone Interview with Dr. Michael Ries, *supra* note 3; Telephone Interview with Dr. Neil Rosenberg, *supra* note 3.
[13] *Id*.
[14] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[15] *Id.*
[16] *Id.*
[17] *Id.*; VISICU, Inc. Factsheet, http://www.visicu.com/company/factsheet.html (last visited Nov. 8, 2008).

Ries highlighted how the potential conflict of interest by VISICU cannot be ignored and may color these disarmingly positive results.[18]

Most recently, Advocate Healthcare System has compiled a soon-to-be-released study of the first 5,000 patients treated in Advocate's Tele-ICU program.[19] The Advocate statistics demonstrate no improvement in mortality.[20] However, Dr. Ries cautioned that, " [W]hat [Tele-ICUs] were doing then is not what they are doing now," meaning that Advocate now has access to updated clinical information systems, has instituted more efficient bedside protocols, and has stronger support from its caregivers.[21] Dr. Ries noted that this study also included two hospitals that were most resistant to telemedicine integration but have since embraced the Tele-ICU.[22] This Advocate study further showcases the difficulty in publishing findings that accurately depict Tele-ICU benefits.[23]

In sum, the difficulty of demonstrating the specific advantages attributed to Tele-ICUs has hindered the proliferation of telemedicine into ICUs.[24] However, with time, Dr. Ries suggests that the quality of published literature will improve to fuel this medical revolution in critical care.[25]

III. LEGAL AND REGULATORY BARRIERS

With the advancement of telemedicine, five major legal issues have emerged: 1) licensure, 2) malpractice liability and standard of care, 3) reimbursement, 4) informed consent, and 5) confidentiality and privacy.[26]

Generally, Illinois requires a physician treating a patient located within the state to be licensed by the state's licensing body.[27] Not only do physicians need

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[18] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[25] *Id.*
[26] Roman J. Kupchynsky II & Cheryl S. Camin, *Legal Considerations of Telemedicine*, 64 TEX. B.J. 20, 22 (2001).
[27] *See, e.g.*, Medical Practice Act of 1987, 225 ILL. COMP. STAT. 60/49.5 (1987).

to comply with state licensure requirements, but physicians also must offer proof of malpractice insurance that includes coverage for Tele-ICUs.[28] In Illinois, corporations, such as Advocate Healthcare Corporation, will commonly pay for a physician's medical malpractice insurance.[29] Dr. Ries approached the Illinois State Medical Inter-Insurance Exchange (ISMIE) to act as the universal carrier for Tele-ICU coverage.[30] This universal carrier, ISMIE, has eliminated the due diligence complications by ensuring that each separate physician's insurance carrier complies with industry standards.[31]

Also, sparse reimbursements have also been cited as barriers to the rapid spread of telemedicine.[32] Only nineteen states (including Illinois) currently offer reimbursement for telemedicine services.[33] Further, each state has its own guidelines for dealing with reimbursement matters.[34] However, according to Dr. Ries, reimbursements remain non-existent for most Tele-ICU services.[35]

Currently, Congress has excluded Tele-ICU services from reimbursement under Medicare, but that may change soon. On July 15, 2008, the Medicare Improvement for Patients and Providers Act of 2008 was successfully enacted into law after both the Senate and the House successfully overrode President Bush's veto.[36] Introduced by Representative Charles Rangel (D-NY) on June 20, 2008, the Act contained several payment-related provisions, including one to expand the list of eligible originating sites for telemedicine services.[37] Section

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[28] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] Barton et al., *supra* note 9, at 488; U.S. DEP'T. OF HEALTH & HUMAN SERVS., 2001 TELEMEDICINE REPORT TO CONGRESS 1 (2001) *available at* ftp://ftp.hrsa.gov/telehealth/report2001.pdf.
[33] Alan Naditz, *Medicare's and Medicaid's New Reimbursement Policies for Telemedicine*, 14 TELEMEDICINE & E-HEALTH 21, 21 (2008).
[34] *Id.*
[35] Telephone Interview with Dr. Michael Ries, *supra* note 3.
[36] Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008); Thomas (Library of Congress), Search Results, http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR06331:@@@R|TOM:/bss/d110query.html (last visited Nov. 8, 2008).
[37] Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 149, 122 Stat. 2494 (2008); Thomas (Library of Congress) *supra* note 36.

149 of the Act outlines three new sites eligible for payment of telemedicine services beginning on or after January 1, 2009: (1) hospital-based or critical access hospital-based renal dialysis centers, (2) skilled nursing facilities, and (3) community mental health centers.[38] This expansion of originating sites facilitates the dissemination of telemedicine services across the U.S. and increases Medicare patient access to vital health care services that are not ordinarily available on a local basis.[39]

A newly proposed bill further expands the list of telemedicine providers to include physical therapists, occupational therapists and speech-language pathologists.[40] This bill also would enhance the Centers for Medicare and Medicaid Services' process of updating the list of covered telemedicine services by creating an advisory committee to make recommendations on the addition or deletion of such services.[41] Dr. Rosenberg even suggested that a logical step would be to include reimbursements for Tele-ICU services.[42]

IV. PALPABLE BENEFITS GIVE RISE TO TELE-ICU ADOPTION

Regardless of the dearth of scientific studies compounded by the various legal and regulatory barriers, the practical benefits of Tele-ICUs are palpable. Dr. Rosenberg described how Tele-ICUs have standardized patient care while augmenting the level of crisis intervention.[43] At Resurrection, telemedicine technology allows for physicians to simultaneously monitor 170 ICU beds in eight different hospitals for nineteen hours a day.[44] Without Tele-ICUs, Resurrection could not afford to staff these hospitals with trained physicians and

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[38] Medicare Improvements for Patients and Providers Act § 149.
[39] Center for Telehealth and E-Health Law, New Medicare Legislation Increases List of Eligible Originating Telehealth Sites, http://www.telehealthlawcenter.org/?c=175&a=1911 (last visited Nov. 11, 2008).
[40] S. 2812, 110th Cong. § 3 (2008).
[41] *Id.*
[42] Telephone Interview with Dr. Neil Rosenberg, *supra* note 3.
[43] *Id.*
[44] *Id.*

nurses.[45] Also, common sense suggests that the ability of a fully rested physician responding to urgent needs of sick patients will produce a higher level of care than a physician who has been working a twenty-hour shift in the ICU.[46] Finally, Tele-ICUs have opened up job opportunities for individuals, such that physically handicapped individuals with the requisite knowledge may have a successful medical career they otherwise may not have had.[47] In effect, pioneering Tele-ICU programs, such as those at Resurrection and Advocate, have not only dramatically improved patients' access to critical care services but also serve as a model for the integration of telemedicine into modern medical practice across the country.

[45] *Id.*
[46] *Id.*
[47] *Id.*