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## Globalization of Biotechnology and the Public Health Challenges Accompanying It

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# LEGAL DEVELOPMENTS

## GLOBALIZATION OF BIOTECHNOLOGY AND THE PUBLIC HEALTH CHALLENGES ACCOMPANYING IT

*Michael J. Malinowski\**

### I. INTRODUCTION

The Human Genome Project (HGP) has drawn together the global biomedical science community by introducing a common prize—a map of the human genome to serve as a shared resource for scientists throughout the next millennium.<sup>1</sup> By doing so, HGP has focused the community's efforts, energy, and resources; it also has intensified competition among researchers, institutions, and countries. This combination of increased focus and competition has generated remarkable advances in biomedical science and technology development, and drawn billions of investment funds from the

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\* Copyright 1996 by *Albany Law Review* and Michael J. Malinowski, JD (Yale Law School), BA (Tufts University). Associate, Kirkpatrick & Lockhart LLP (Boston); Law and Science Research Faculty, The Eunice Kennedy Shriver Center for Mental Retardation. The opinions expressed are the author's unless attributed to others. An earlier draft of this Article was presented in July 1996 at the Joint Meetings of the Law and Society Association and the Research Committee on Sociology of Law in Glasgow, Scotland, and this Article has benefitted from those who shared their responses and suggestions. Special appreciation is due Christine Motta, Laura Silva and the editors of the *Albany Law Review*, Pat Jones (Feinstein Partners Inc.), Michaela Mahon (De Facto Consultants Ltd.), Mike Wort (Genus Communications), and Ian Leslie (Scottish Enterprise Operations) for being invaluable sources of information and sharing time, contacts, and research materials. Thanks also to Robin J.R. Blatt, Peter McIsaac, Maureen O'Rourke, and Lucia Silecchia for their helpful suggestions, Dylan Black for his research contribution, and Diane Raysan and Kirkpatrick & Lockhart for supporting this project.

<sup>1</sup> See generally ROBERT COOK-DEEGAN, *THE GENE WARS* 148-60 (1994) (discussing the emergence of HGP, including its scientific, political, and ideological background); Robert M. Cook-Deegan, *Origins of the Human Genome Project*, 5 *RISK: HEALTH, SAFETY & ENV'T.* 100 (1994) (reporting on the origins and progression of HGP); Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 *YALE J. REG.* 163, 190-93 (1996) (addressing the goals of HGP and its effect on the biotech industry).

private sector in a remarkably brief period of time.<sup>2</sup> The result is a burgeoning global industry with a myriad of products in various stages of development. The biotechnology<sup>3</sup> industry's first full generation of therapeutics and diagnostics now is reaching the world markets, and these products are simply the first drops from an immense pipeline of promising research and development (R&D) efforts.<sup>4</sup> The market for biotechnology products, which reached \$8.7 billion in 1995,<sup>5</sup> is expected to exceed \$100 billion by the year 2000.<sup>6</sup> According to many experts, "the 21st century . . . will be the century of biological science."<sup>7</sup>

The commercialization of genetic technologies, such as HGP, is accompanied by global challenges. One such immediate and profound challenge is determining the manner of reviewing and

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<sup>2</sup> See generally KENNETH B. LEE, JR. & G. STEVEN BURRILL, *BIOTECH 96: PURSUING SUSTAINABILITY*, ERNST & YOUNG'S TENTH ANNUAL REPORT ON THE BIOTECH INDUSTRY 9-25 (1995) (commenting on the amount of capital raised through public offerings, private placements, and venture capital funding); EUROPEAN BIOTECH 96: VOLATILITY AND VALUE, ERNST & YOUNG'S THIRD ANNUAL REPORT ON THE EUROPEAN BIOTECH INDUSTRY 23-31 (1996) [hereinafter EUROPEAN BIOTECH 96] (reporting on product approvals, development highlights, capitalization rates, and investment activities of biotech companies); Malinowski & O'Rourke, *supra* note 1, at 165-67 (detailing genotech discoveries of recent years attributed primarily to investments by the private sector and academia); Jennifer Lanthier, *Agricultural Biotech Seen as a Tough Sell on Wall Street*, FIN. POST, June 13, 1996, at 3 ("Of the US\$ [sic] 2.4 billion invested in 1994 in technology companies, the biggest single chunk, US\$ [sic] 973 million, went to life sciences companies like pharmaceutical firms . . . with another US\$ [sic] 1 billion split between software and information technology companies.").

<sup>3</sup> Biotechnology is a broad term that bridges several scientific disciplines and encompasses genotechnology (the commercial applications of genetic science, also known as genomics), biopharmaceuticals, bioremediation, and bioagriculture. See MICHAEL A. EPSTEIN, *MODERN INTELLECTUAL PROPERTY* § 11.01 (3d ed. 1995) (defining biotechnology broadly as to include "genetics, molecular biology, biochemistry" and other disciplines); Malinowski & O'Rourke, *supra* note 1, at 165 n.1. This Article focuses on the commercial biotechnology industry which, at the present time, is largely concentrated in genotechnology. See generally BIO 96 INTERNATIONAL BIOTECHNOLOGY MEETING & EXHIBITION, LIVE VIDEO CONFERENCE, GENOMICS: IMPACT ON HEALTH CARE (June 11, 1996) (on file with author) [hereinafter GENOMICS] (discussing various aspects of genomics, including therapeutics, gene expression, intellectual property, and ethical issues).

<sup>4</sup> See generally LEE & BURRILL, *supra* note 2, at 19-28 (detailing product successes, disappointments, and promising possibilities for the future); EUROPEAN BIOTECH 96, *supra* note 2, at 16-21 (highlighting product developments and approvals for 1995); Malinowski & O'Rourke, *supra* note 1, at 174-80 (attributing drug developments likely to be available to the public in the near future to science and entrepreneurialism).

<sup>5</sup> See LEE & BURRILL, *supra* note 2, at 9.

<sup>6</sup> See Ian Lang *Launches Biotechnology Crusade to Take Britain Into the 21st Century*, M2PW, June 19, 1996, available in 1996 WL 10345783 [hereinafter *Biotechnology Crusade*] (surmising that "[b]y the year 2000 the world market for biotechnology products is expected to reach . . . 70 billion [British pounds]").

<sup>7</sup> EUROPEAN BIOTECH 96, *supra* note 2, at ii.

regulating innovative biotechnology-based diagnostics<sup>8</sup> and therapeutics in order to maximize public health benefits, minimize delay for those who could benefit from them, and promote efficacious, responsible, and safe use. Another is determining how the deluge of new health care capabilities is going to be financed and made generally available to those in need of the technologies.<sup>9</sup> This second problem is particularly troublesome in light of the fact that modern medicine already is capable of doing much more than society is willing to pay for collectively through group or national health insurance.<sup>10</sup> The success of biotechnology, as marked by the introduction of innovative products into commerce, will exacerbate health care finance and allocation problems; price-prohibitive health insurance and rationing are realities that pre-date the widespread commercialization of biotechnology.<sup>11</sup>

This Article addresses these challenges in the context of the health care systems of the United States (U.S.) and the United Kingdom (U.K.) which have begun to facilitate the growth of significant biotechnology industries.<sup>12</sup> These countries also hold considerable influence over regulatory review and approval of genetic diagnostics and therapeutics in the major world markets. An overarching premise of this Article is that the U.S. and the U.K. could maximize

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<sup>8</sup> This challenge is exemplified by the controversy in the United States (U.S.) surrounding the availability of presymptomatic genetic testing services to detect the presence of variations of genes called BRCA1 and BRCA2 ("breast cancer 1" and "breast cancer 2") that have been linked to breast and ovarian cancer. See generally Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 TUL. L. REV. (forthcoming 1997) (manuscript at 1-7, 36-40, on file with the *Albany Law Review*). A Task Force assembled by the Ethical, Legal and Social Issues (ELSI) Working Group of HGP has issued written principles, in draft form, that recognize the scientific shortcomings of existing presymptomatic genetic testing technology and the dangers of making such tests widely available outside of the major research institutions. See TASK FORCE ON GENETIC TESTING OF THE NIH-DOE WORKING GROUP ON ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF HUMAN GENOME RESEARCH, DRAFT INTERIM PRINCIPLES (Feb. 1996) [hereinafter TASK FORCE]; see also Joan Stephenson, *Questions on Genetic Testing Services*, 274 JAMA 1661, 1661 (1995) (noting that, as genes related to diseases like breast cancer are discovered, laboratories rush to diagnose these diseases through genetic testing and to assess who is at risk).

<sup>9</sup> See generally Michael J. Malinowski, *Capitation, Advances in Medical Technology, and the Advent of a New Era in Medical Ethics*, 22 AM. J. L. & MED. 331, 337-47 (1996) [hereinafter *New Era*] (addressing this dilemma in the context of the U.S. healthcare system).

<sup>10</sup> See *id.* at 332.

<sup>11</sup> See *id.* at 343-44. See also Part II (discussing biotechnology in the United States (U.S.) and the United Kingdom (U.K.)).

<sup>12</sup> See LEE & BURRILL, *supra* note 2, at 43-45 (breaking down the U.S. biotech industry by region and year of founding); EUROPEAN BIOTECH 96, *supra* note 2, at 4 (illustrating that the U.K. has the largest biotech industry in the European Union (E.U.) by a considerable margin).

the public health benefits of biotechnology by collaborating on responses to the shared challenges of financing and regulating commercialization of biotechnology. In other words, the Article proposes that, in order to maximize the health benefits of biotechnology, the U.S. and the U.K. approach the public health challenges accompanying the commercialization of biotechnology with the same collaboration embodied in HGP. Even if this approach were only partially as successful in the regulatory and commercial arenas as it has been in the field of biomedical science, it would reduce transaction costs by: (1) eliminating duplication; (2) enabling the U.K. to benefit from the industry experience of the U.S.; (3) allowing the U.S. to benefit from the health care allocation experience of the U.K.; (4) hastening the introduction of needed health policy and other regulatory infrastructure; (5) improving the quality of that infrastructure; and (6) eliminating unnatural barriers to industry collaboration between the U.S. and the U.K. in the field of biotechnology. The latter would enable the best science in both countries to be developed commercially, thus maximizing the public health benefits of biotechnology on a global scale.

Part II presents an overview of the biotechnology industries in the U.S. and the U.K. Trends and recent advances in the development of these industries are identified and discussed. Part III addresses two profound challenges accompanying the commercialization of biotechnology. First, this section fully discusses the review and regulation of innovative biotech diagnostics and therapeutics by focusing on the increasing responsiveness of the Food and Drug Administration (FDA) to biotechnology and the impact of the recently established European Medicines Evaluation Agency (EMA) on the U.K. industry. Second, Part III addresses the impact of the forthcoming generation of genetic technologies on health care finance resources. Lastly, Part III concludes that, while the capabilities of modern medicine are on the verge of increasing dramatically, the need to ration and make more "tragic choices" will prevent some from enjoying its benefits.<sup>13</sup>

Part IV sets forth proposals both for regulating the commercialization of biotechnology and for responding to the public health challenge of financing health care in an age of rapid expansion in medical capabilities. These proposals generally arise from the observation that globalization of biotechnology and the challenges

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<sup>13</sup> See generally GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 17-28 (1978) (introducing discussion of the societal allocation of scarce resources).

accompanying it raise the importance of comparative analysis and collaboration between the U.S. and the U.K. on several levels. Although grounded in actual regulation and industry insight, the analysis presented also embodies law and economics theory.<sup>14</sup>

## II. BIOTECHNOLOGY IN THE U.S. AND THE U.K.

Biotechnology has become a major U.S. industry in "a remarkably brief period of time."<sup>15</sup> The incorporation of most biotechnology companies post-dates HGP, as does substantial venture capital and other investment in the industry.<sup>16</sup> In fact, although HGP did not commence until 1990, the U.S. biotechnology sector has matured into an industry with commercial products, powerful multinational pharmaceutical investors and allies, and enough organization to effectuate significant FDA reforms.<sup>17</sup> This accomplishment is underscored by America's long-standing and infamous ten to twelve year lab-to-market drug lag.<sup>18</sup> In March 1995, approximately

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<sup>14</sup> This analysis is grounded in fundamental law and economic principles identified and discussed by Richard A. Posner and his contemporaries. See generally ROBERT COOTER & THOMAS ULEN, *LAW AND ECONOMICS* 1-55 (1986) (pointing out, by way of examples, that legal rules deemed just and economic approaches adopted for efficiency reasons often lead to the same conclusions); RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 3-17, 19-26 (3d ed. 1986) (providing relevant chapters entitled *The Nature of Economic Reasoning* and *The Economic Approach to Law*). However, the focus of the analysis is international economic law (IEL), which increasingly is being recognized as an independent theoretical approach. See generally *infra* Part IV.

<sup>15</sup> Malinowski & O'Rourke, *supra* note 1, at 170 (discussing accomplishments such as the identification of gene sequences and the market viability achieved by genotech companies).

<sup>16</sup> Industry-wide investment from the multinational pharmaceutical industry did not begin until the second half of 1995. See LEE & BURRILL, *supra* note 2, at 10-13 (commenting upon the dearth of venture capital funding in the early part of 1995); Malinowski & O'Rourke, *supra* note 1, at 180 n.90 (describing how the genotech industry's funding has shifted from government grants to commercial investments).

<sup>17</sup> See generally, Malinowski & O'Rourke, *supra* note 1, at 165, 188, 210-12 (mentioning annual sales in the billions for the past few years and predicting sales of new products without market substitutes and investment from pharmaceutical companies will continue to rise in the future due to FDA reforms designed to accelerate approval times).

<sup>18</sup> See Stephen A. Bent & Paul M. Booth, *ICH Sets Standards for Drug Developers*, NAT'L L.J., July 8, 1996, at C1; Stephen D. Moore, *Fast Relief: Drug Companies Find EU Approval System Eases Path to Market*, WALL ST. J. (Eur.), May 6, 1996, at 1 [hereinafter *Fast Relief*]. It is too early to assess the extent to which recent FDA reforms will shorten this time lag, and many other reforms have been proposed that could reduce it further. See Jeffrey L. Fox, "Nitty-Gritty" FDA Guidelines Wanted Sooner Not Later, 14 NATURE BIOTECHNOLOGY 698 (1996) ("Officials of the . . . [FDA] have publicly promised that efforts both to simplify the regulation of well-characterized biotechnology products and to harmonize agency procedures will be completed by late summer."); see also BILL CLINTON & AL GORE, *REINVENTING REGULATION OF DRUGS AND MEDICAL DEVICES* (Apr. 1995) [hereinafter *REINVENTING REGULATION*] (outlining the Clinton Administration's proposals for self-reform); Mark Guidera,

twenty-five biotechnology drugs had reached the market.<sup>19</sup> That number now exceeds forty and is increasing rapidly.<sup>20</sup>

Alliances between prestigious non-profit research institutions—historically grant supported, independent, and aloof—and the biotech industry have become commonplace.<sup>21</sup> In fact, even the most renowned non-profit institutions engaged in biomedical R&D (for example, the Massachusetts Institute of Technology, Massachusetts General Hospital, and Johns Hopkins University) have aggressive technology transfer offices that are actively seeking out such partnerships.<sup>22</sup> Although the annual budget of the National Institutes of Health (NIH) was relatively unscathed during last year's budget cuts,<sup>23</sup> the trend in the U.S. has

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*Optimism Greeted FDA Reforms; Biotech Firms Predict Easier Medicine Trials*, THE SUN (Baltimore), Nov. 19, 1995, at 1E (“[B]iotechnology executives . . . are breathing a lot easier these days about such big up-front investments now that the Food and Drug Administration has revamped a host of regulations governing the industry.”). These reforms include proposals to: (1) eliminate requirements that force companies to seek a separate license for each facility where they plan to manufacture a drug; (2) lessen reporting requirements for adjustments in the manufacturing process; (3) eliminate the requirement that each batch of a biotech-developed drug be sent to the FDA for testing; (4) impose a 30-day deadline for the FDA to respond to a company that has submitted additional information requested after the FDA has put a clinical trial on hold; and (5) introduce more flexibility and cooperation with industry. See *id.* See also REINVENTING REGULATION, *supra*, at 32-37; Fox, *supra*, at 698. Variations of these proposals were incorporated into the FDA Reform Bill introduced in the last session of Congress by Senator Kassebaum. See S. 1477, 104th Cong. (1996); Robert Pear, *Lawyers and Lobbyists Help Guide Effort by Republicans to Speed Drug Approvals*, N.Y. TIMES, Mar. 4, 1996, at A15 (“Republicans on the Senate Committee on Labor and Human Resources and the House Commerce Committee, joined by some Democrats, have concluded that Congress must revise the F.D.A. laws to give patients swifter access to new drugs and devices.”). For a discussion of FDA Commissioner Kessler's denial of the need for such extensive reform, see *infra* note 116.

<sup>19</sup> See Malinowski & O'Rourke, *supra* note 1, at app.I n.449 (identifying biotech drugs approved by the FDA and their developers and manufacturers).

<sup>20</sup> See Lauran Neergaard, *Ethics Clash with Science: How Far is Too Far in Genetic Engineering?*, CINCINNATI ENQUIRER, June 12, 1996, at A10 (“Biotechnology is a young but fast-growing industry, with 40 medical technologies and 21 agricultural products on the market.”).

<sup>21</sup> See *Mitotix Obtains Rights to the Natural Cell Cycle Inhibitor*, 10 BIOTECH PATENT NEWS 27 (1996) (noting the grant of licenses by Memorial Sloan-Kettering Cancer Center and Fred Hutchinson Cancer Research Center, both non-profit, independent institutions, to Mitotix, Inc.). See generally *infra* note 194 and accompanying text.

<sup>22</sup> See Malinowski & O'Rourke, *supra* note 1, at 181-87 (noting the technology transfer arrangements in alliances between the genotech industry and academia). The author has observed that most of these major research institutions are staffing intensely entrepreneurial technology transfer offices with the mission of seeking out allies, enabling researchers to develop their technology in order to add value, and properly valuing technology to finance research and development, all in order to realize long-term royalty revenue streams. See *id.*

<sup>23</sup> See *id.* at 203 & n.231. The 1996 budget for NIH was approximately \$7 billion and the federal government in recent years has funded approximately 36% of R&D in the U.S. and 70% of American academic medical research. See *id.* See also *Health Policy: Managing to Care*,

been towards privatization of basic science R&D.<sup>24</sup> Ironically, the same means less in real terms, for tremendous advances in biomedical research are creating more grant-worthy science and increasing the demand for consistent funding. In addition, the money allotted by NIH is being spread more widely to reach more researchers and institutions.<sup>25</sup>

The British biotechnology industry is younger than its U.S. counterpart and lacks significant fully developed and marketed products.<sup>26</sup> Overall, the U.K. biotech industry has been slower to emerge despite the fact that British basic science in biotechnology—some of the best in the world<sup>27</sup>—has been well funded by the Wellcome Trust, the world's largest private medical research foundation.<sup>28</sup> A number of regulatory disincentives are responsible

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THE ECONOMIST (U.S.), Sept. 23, 1995, at 70; Graeme Browning, *Tense Days Down in the Lab*, 27 NAT'L J. 1005 (1995) (discussing the effects of Congressional budget cuts on scientific research).

<sup>24</sup> See Malinowski & O'Rourke, *supra* note 1, at 191 (noting private funding outstrips public funds); see also *supra* notes 21-22 and accompanying text.

<sup>25</sup> See Christopher Anderson, *Small Businesses to Get Bigger Slice of US Research Pie*, 359 NATURE 470, 470 (1992) (noting university scientists' displeasure with the Congressional decision to shift federal research funding to small businesses through the Small Business Innovation Research Program).

<sup>26</sup> See generally EUROPEAN BIOTECH 95: GATHERING MOMENTUM, ERNST & YOUNG'S SECOND ANNUAL REPORT OF THE EUROPEAN BIOTECH INDUSTRY 1, 11-21 (1995) [hereinafter EUROPEAN BIOTECH 95] (discussing biotech products launched in the U.K. and expectations for faster product approvals with the help of the EMEA).

<sup>27</sup> One of the most recent significant contributions from the U.K. is the identification by scientists in Edinburgh, Scotland of a gene linked to depression that could lead to much more effective treatment for that condition. See Nigel Hawkes, *Scientists Identify Gene Linked to Depression*, THE TIMES (London), Mar. 15, 1996, available in 1996 WL 6481302 (noting the discovery of a gene possessed by 10% of those who suffer from depression in Great Britain). Another significant contribution is an approach to cancer treatment that operates by "blocking the action of molecules known as neuropeptides, a type of hormone that also helps carry messages between nerve cells." *New Treatment Could Offer Hope for Lung Cancer Patients*, EDMONTON J., Apr. 17, 1996, at A 17 (commenting on the potential to thwart cancer growth and facilitate recovery).

<sup>28</sup> See David Dickson, *Wellcome Trust to Launch Transfer Company*, 374 NATURE 6, 6 (1995) [hereinafter *Transfer Company*]; Ian Mundell, *Wellcome Trust to Double Spending After Sale of Shares*, 358 NATURE 359, 359 (1992) (explaining that the tremendous financial holdings of the Trust are attributable to the sale of stock in Wellcome PLC, manufacturer of the AIDS drug AZT). R&D contributions from the Wellcome Trust rival those of the Medical Research Council (MRC), the U.K.'s counterpart to the NIH. See *Wellcome Cash*, THE ECONOMIST (U.K.), Apr. 6, 1996, at 58 (1996) ("The Wellcome Trust is now roughly the same size as the Medical Research Council, a body that allocates British government funds to biomedical research."); see also Peter Aldhous, *Wellcome Trust: Britain's Big Biomedical Spender*, 256 SCIENCE 1132 (1992) (stating that researchers in front-line fields like molecular biology and neuroscience are as likely to send their proposals to Wellcome Trust as to MRC). Significant contributions by the Wellcome Trust to U.K. biotechnology R&D include a loan to University College, London,



for this restrained growth, including the inability to procure patent protection for genetic discoveries<sup>29</sup> and the related unavailability of

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to purchase property for an international center for basic and clinical biotech research; a grant to fund genome research at Cambridge; an award to fund research of genetic influences on common diseases, such as diabetes and asthma, at Oxford; and a gift toward the partial price of a new laboratory at the Institute of Neurology in London. See David Dickson, *Britain's Wellcome Trust Stretches Its Financial Wings*, 363 NATURE 102, 102-03 (1993) ("The loan . . . is the latest in a series of moves by Wellcome that are intended to establish centres of excellence in biomedical research throughout Britain."). British science may become even more important in the future due to the efforts of the Wellcome Trust to preserve creativity:

The Trust, a London-based charity, is not only rich, it has proven itself innovative and adventurous, a model for what a non-governmental organi[z]ation can do. This year . . . the Trust is . . . offering individual researchers Pounds 50,000 (\$75,000) to pursue their most improbable ideas.

. . . . The Trust is flexible and imaginative in its approach to funding.

*Wellcome Cash, supra*, at 58. There is fear in the U.S. that creativity and objectivity in basic science is being lost due to the privatization of R&D. Specifically, there is concern that, rather than allowing researcher discretion and the raising of a general floor in science, basic science is being directed by corporate decisions to pursue and develop research discoveries solely according to their commercial viability. See, e.g., Malinowski & O'Rourke, *supra* note 1, at 187 (discussing the concern that the biotech industry's pressure to generate profits may "skew the course of basic science"); Christine Gorman, *Has Gene Therapy Stalled?*, TIME, Oct. 9, 1995, at 62, 62-63 (noting that, while gene therapy holds extraordinary promise, enthusiasm and financial pressures may have caused a premature push to market that is sacrificing basic science and human safety for a quick return on investment).

<sup>29</sup> See Malinowski & O'Rourke, *supra* note 1, at 200-01 (discussing how Article 53(a) of the European Patent Convention which "prohibits granting patents for inventions whose publication or exploitation would be contrary to public policy or morality," has blocked E.U. patent protection of genetic discoveries); see also *European Parliament Blocks EU Rules on Patents for Biotechnology Products*, 9 WORLD INTELL. PROP. REP. 96, 96-97 (1995) (commenting on veto of gene patents by the European Parliament); John Richards, *International Aspects of Patent Protection for Biotechnology*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 433, 443-52 (1993) (describing the guidelines of the European Patent Office). Efforts to introduce E.U. legislation aimed at making the E.U. biotechnology industry more competitive with its U.S. counterpart have been unsuccessful. See Malinowski & O'Rourke, *supra* note 1, at 198-200 (discussing the controversy surrounding the patentability of gene sequences); David Dickson, *British MPs 'Likely to Oppose Gene Patents'*, 373 NATURE 550, 550 (1995) (identifying "'growing consensus' among committee members" of the House of Commons Select Committee on Science and Technology that patenting DNA sequences could hinder the research of genetic disease). But see Gary Moss & Simon Cohen, *Patents in the Public Interest*, 372 NATURE 814, 814 (1994) (stating that the European Commission recently introduced supplemental protection certificates (SPCs) to extend patent protection for pharmaceutical products, which could be particularly beneficial to biotechnology in light of delays due to "clinical trials and regulatory approval"). See also Stef Eyckmans, *The Wheels are Finally Starting to Turn at the EMEA*, 30 MED. MARKETING & MEDIA 32 (1995) (noting that the birth of the EMEA will increase market efficiency in the field of pharmaceuticals by creating a single European market). However, the E.U. Commission now has revised a draft directive that would create common legislation throughout the E.U. for protection of biotechnology inventions. See Kerri A. Kazak et al., *European Union Directive on Biotechnology Inventions*, 3 J. PROPRIETARY RTS. 32, 32 (Mar. 1996). This revised directive restates the traditional European requirement that patents must be founded on invention rather than discovery, denies patent protection to germ-line gene

capital.<sup>30</sup> Relatively strict requirements for listing on the London Stock Exchange (LSE),<sup>31</sup> and the lack of a European Union (E.U.) equivalent to NASDAQ have augmented the latter.<sup>32</sup> Although there are almost 600 biotech companies in Europe and some of the world's largest investors in the life sciences sector are in Europe, only thirty-five to forty European biotech companies have gone

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therapy, and limits the patentability of genetically modified animals to instances where suffering caused by the genetic modification is proportionate to the benefit derived. *See id.* Still, "members of the biotechnology industry broadly favor the revised Directive because it would provide certainty and stability in the protection of biotechnology inventions through the European Union." *Id.*

<sup>30</sup> A correlation between the ability to patent scientific discoveries and the willingness of the private sector to invest in their commercial potential has been recognized by many, including Carl Feldbaum, President of the Biotechnology Industry Organization (BIO), the major U.S. biotechnology trade association. *See* Adam Marcus, *Owning a Gene: Patent Pending*, 2 *NATURE MED.* 729, 730 (1996) ("About 90 percent [of BIO members] do not have products on the market . . . . They have to raise money to fund the research. What [investors] look for are intellectual property rights.") (quoting Carl Feldbaum); *see also* Nicholas Scott-Ram, *Making More of Academic Assets*, 364 *NATURE* 666, 666 (1993) (equating the U.S. biotech industry's success in finding funding for research and in commercializing inventions to its success with technology transfer associated with patent protections). This link between the availability of capital and patent protection also was recognized by a U.K. solicitor who stated:

With safeguards for the public already in place, everything must be done to strengthen the rights of patent owners and the patent system around the world. Otherwise, potentially crucial discoveries can be lost. For example, in countries such as those of Eastern Europe, where researchers rank among the best in the world, inventions cannot be properly exploited because the necessary infrastructure for obtaining and asserting patents does not exist.

Moss & Cohen, *supra* note 29, at 814.

<sup>31</sup> *See* Karen Bernstein, *Europe's Effort to Create a NASDAQ*, *BIOCENTURY*, Mar. 6, 1996, at A1; David Dickson, *Britain Urged to Lift Barriers to Investment in Biotechnology*, 361 *NATURE* 572, 572 (1993) [hereinafter *Barriers*] (stating that the LSE "places stricter demands on fledgling companies," such as requiring "initial investors in British companies" to maintain their investments until the companies show profits); Scott-Ram, *supra* note 30, at 666 (noting that the grant of intellectual property rights is a pre-requisite to become listed on the LSE). Other conditions for listing biotech companies on the LSE include an ability to attract funds from sophisticated investors; capitalization prior to listing of at least twenty million British pounds sterling; at least two drugs in clinical trials; corporate partnerships with one or more companies that have committed at least five million British pounds sterling; and R&D expenditures of at least twenty million British pounds sterling over three or more years. *See* Bernstein, *supra*, at A5.

<sup>32</sup> *See* EUROPEAN BIOTECH 96, *supra* note 2, at iii (looking forward to the 1996 commencement of a European Exchange as a way to develop "European markets for venture capital"); *infra* notes 41-42 and accompanying text (discussing the new exchange equivalent to NASDAQ); *see also* Organization for Economic Cooperation and Development, *Venture Capital in OECD Countries*, *FIN. MARKET TRENDS*, Feb. 1996, at 15, 37 (citing the ECU 21.2 billion that was invested in portfolio companies in comparison to the meager ECU 9.4 billion that was divested as an illustration of the stagnation caused by the lack of investment exit vehicles (meaning access to security markets) which has resulted in a "liquidity crisis' in Europe").

public.<sup>33</sup> In fact, "difficulties in raising venture capital domestically . . . [have forced] small biotechnology companies into the arms of foreign investors, particularly those from the United States."<sup>34</sup>

Times are changing, however. The U.K. government has joined the U.S. in making biotechnology an economic priority,<sup>35</sup> and U.K. biotech companies now are able to raise money in financial markets in Copenhagen, London, Paris, and Vienna.<sup>36</sup> "On the London

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<sup>33</sup> See Bernstein, *supra* note 31, at A3.

<sup>34</sup> *Barriers*, *supra* note 31, at 572. But see *UK Firms Buy Into Drug Design Skills of US Start-ups*, 373 NATURE 372, 372 (1995) [hereinafter *Start-ups*] ("Two British companies have taken advantage of the relatively low price of US biotechnology shares to acquire west-coast companies that will help their plans to use advanced computing techniques to design new drugs."). This buy-up of U.K. technology is not unlike the purchase of U.S. biotech R&D by multinational pharmaceutical companies during the lean investment years of 1994 and early 1995. However, the U.S. industry was able to stay independent and vibrant by structuring alliances around specific technology, dealing with multiple pharmaceutical companies, and using the alliances with pharmaceutical companies to attract public investment. See Malinowski & O'Rourke, *supra* note 1, at 188-90 (identifying several of the above mentioned alliances and describing the benefits and problems associated with these mergers).

<sup>35</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 27, 58 ("The rest of Europe needs to wake up to the trends now being established in the UK market . . . [T]here is no argument that the UK is currently the major site for entrepreneurial European bioscience companies."). In June 1996, President of the Board of Trade, Ian Lang, launched "[a] major cross-Government drive to boost Britain's place at the forefront of global biotechnology." *Biotechnology Crusade*, *supra* note 6. Britain's "crusade" includes identification of ten priority areas: (1) "a world-class science base . . . [accompanied by] quick and effective technology transfer"; (2) a "supply of . . . qualified scientists"; (3) "protection of intellectual property"; (4) "public confidence through public understanding"; (5) "a regulatory climate" that promotes both "safety" and "competitiveness"; (6) "open markets for biotechnology products"; (7) "attract[ion] [of] internationally mobile investment"; (8) "a climate which promotes start-up and growth of new biotechnology companies"; (9) more responsiveness to biotech from "UK industry sectors"; and (10) "awareness" of the "strategic importance of biotechnology" and support from "European institutions." *Id.*; see Board of Trade, *Fresh Challenges Unveiled to Prove Biotechnology Means Business*, M2PW, June 18, 1996, available in 1996 WL 10345784 ("An expansion of the successful Biotechnology Means Business initiative was announced today by Board of Trade President Ian Lang."). The U.K. government also has set up a Human Genetics Commission to serve as a strategic body to monitor medical genetics in response to parliamentary pressure for a unified group with a strategic overview. See *UK Sets up Human Genetics Commission*, CLINICA, July 1996 (describing the commission as a non-statutory body consisting of eminent, independent experts who will report to both health and industry ministers); Dep't of Health, *Membership of Advisory Committee on Genetic Testing*, M2PW, July 10, 1996, available in 1996 WL 10348248 (listing the members of the Advisory Committee). Within the U.K., the government of Scotland has been instrumental in establishing a highly organized, entrepreneurial effort to foster the growth of the biotechnology industry that includes providing seed money and facilitating procurement of venture capital from the private sector. See LOCATE IN SCOTLAND, BIOTECHNOLOGY SCOTLAND (Spring 1996); BIOTECH SCOTLAND, BIOTECHNOLOGY IN SCOTLAND (Summer 1996) [hereinafter BIOTECHNOLOGY IN SCOTLAND].

<sup>36</sup> See Mike Ward, *Genset Sets Tone for Global Biotechnology Financing*, 14 NATURE BIOTECHNOLOGY 810, 810 (1996) [hereinafter *Genset*]; LEE & BURRILL, *supra* note 2, at 23-31. Relevant country-based European securities markets include Chapter 20 of the LSE, the

market alone, the combined capitalization of emerging bioscience companies tripled last year, to \$4.7 billion."<sup>37</sup> Investor interest has been rising recently and enabling the industry to mature. Shares in the sector rose in value thirty-nine percent during the first half of 1996, outpacing the London market's overall gains by approximately forty to one.<sup>38</sup> Favorable clinical news from the industry's leaders, most notably British Biotech,<sup>39</sup> is responsible for much of this recent surge in the appeal of U.K. biotechnology to investors.<sup>40</sup> The most prominent European effort to develop capital structures supportive of growth companies is the Brussels-based European Association of Securities Dealers Automated Quotation (EASDAQ),

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Alternative Investment Market (AIM) in London, and the Nouveau Marché in France. See Bernstein, *supra* note 31, at A1. This past March, Genset, a French genomics (genetics-based science) company, raised \$86.4 million in a dual listing on NASDAQ and the Nouveau Marché, and Genset's market capitalization now is over \$400 million. See Genset, *supra*, at 810.

<sup>37</sup> Julia Flynn, *Britain's Bedazzling Biotech Stocks*, BUS. WEEK (Int'l Ed.), June 24, 1996, at 162E2 [hereinafter *Bedazzling*]; see Julia Flynn, *Europe Catches Biotech Fever*, BUS. WEEK (Int'l Ed.), June 3, 1996, at 46 [hereinafter *Biotech Fever*] (noting that European investors are heavily investing in British Biotech).

<sup>38</sup> See *Bedazzling*, *supra* note 37, at 162E2; *Biotech Fever*, *supra* note 37, at 46.

<sup>39</sup> See Sylvia Davidson, *Is British Biotech's Marimastat a Major Cancer Drug?*, 14 NATURE BIOTECHNOLOGY 819, 819 (1996) ("On May 21, British Biotech (Oxford, UK), the UK's largest biotechnology company, became one of the four most highly valued biotechnology companies in the world."). The May 1996 disclosure by British Biotech of Phase II clinical trial results for its anticancer compound, Marimastat, increased the company's capital by \$3 billion in just three days. See *Bedazzling*, *supra* note 37, at 162E2; Stephen D. Moore, *British Biotech Surges 9.4% as New Drug Passes Key Test*, WALL ST. J. (Eur.), May 22, 1996, at 3 [hereinafter *Biotech Surges*] (noting that the drug is "designed to stop or delay cancers spreading and may encourage normal cells to wall off the tumor"); Daniel Green, *British Biotech's Shares Soar on Hopes for New Cancer Drug*, FIN. TIMES, May 22, 1996, at 21 [hereinafter *Cancer Drug*] ("[T]rials confirmed the drug's potential for treating many 'solid tumour cancers' including pancreatic, ovarian, colorectal and prostate."). British Biotech's announcement also has risen investor interest in the entire sector and facilitated public offerings by other companies. See *Bedazzling*, *supra* note 37, at 162E2 (reporting that shares in Britain's bioscience industry have increased by 39% since January 1996); Matthew Lynn, *Biotech Gets High on Hopes of Drug Bonanza*, THE TIMES (London), Feb. 18, 1996, available in 1996 WL 6475639 [hereinafter *Drug Bonanza*] (stating that British Biotech has "electrified the stock market" and, as Europe's industry leader, will impact the industry with its successes or failures); *Biotech Surges*, *supra*, at 3 (noting how the "investor frenzy" in British Biotech stock has encouraged other health-related companies to invest their stock in London markets).

<sup>40</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 24-26 (attributing the growth of the U.K. bioscience sector largely to favorable product reports from leading companies like British Biotech). Besides British Biotech, industry leaders include Celltech (developing treatment for Crohn's disease), Cortec International (developing treatment for osteoporosis), and Scotia Holdings (developing cancer drugs). See *Drug Bonanza*, *supra* note 39 (noting that stock prices for British biotech companies have been increasing); see also *Bedazzling*, *supra* note 37, at 162E2 (noting that "the combined capitalization of emerging bioscience companies tripled last year, to \$4.7 billion"); *Biotech Fever*, *supra* note 37, at 46 (listing "Britain's Booming Biotech Stocks").

which opened in September 1996.<sup>41</sup> EASDAQ is an attempt to create a European version of NASDAQ, which has brought close to 300 biotech companies to market.<sup>42</sup> "Experts estimate that by the year 2000, 22 million jobs in Europe will be affected by biotechnology."<sup>43</sup>

Despite this progress, the market appeal of U.K. biotech is "strikingly volatile."<sup>44</sup> Therefore, as has been true for the U.S. biotech industry, it is likely that there will be major fluctuations in value tied to research and regulatory events.<sup>45</sup> However, beneath the recent British Biotech-inspired surge in market value, longer-term economic stability for U.K. biotech should materialize from: (1) the escalating state of knowledge in the field of biomedical science world-wide and the leading role and contributions of U.K. researchers;<sup>46</sup> (2) the maturation and success of the U.S. biotechnology industry, which serves as a reassuring point of reference;<sup>47</sup> (3) investment from and alliance agreements with multinational pharmaceutical companies and U.S. biotech companies, and research capital from venture capitalists;<sup>48</sup> (4) the responsiveness and support of the British government;<sup>49</sup> (5) encouragement of commer-

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<sup>41</sup> See *Genset*, *supra* note 36, at 810.

<sup>42</sup> See *id.* (stating that EASDAQ has already attracted much attention from those who wish to invest in biotech); Bernstein, *supra* note 31, at A1 ("Until now, and for reasons that are often specific to each country, there has been limited private and public capital available in Europe, which has hindered the development of high-risk, growth-oriented sectors such as biotech.").

<sup>43</sup> BIOTECHNOLOGY IN SCOTLAND, *supra* note 35, at 10.

<sup>44</sup> *Drug Bonanza*, *supra* note 39 ("Earlier this month, Celltech's share price collapsed by 24% in a single day after it announced it was abandoning research on one of its most advanced asthma drugs . . .").

<sup>45</sup> See generally Malinowski & O'Rourke, *supra* note 1, at 216, 236 (explaining that clinical disappointments, expectations about new products, and regulatory policies impact not only the companies whose products are involved, but also effect the amount that investors are willing to contribute to the industry as a whole).

<sup>46</sup> See *Drug Bonanza*, *supra* note 39 (citing headway made in U.K. laboratories and interest shown by the pharmaceutical giants in potential purchases and alliances with biotech companies as key factors leading to investor interest).

<sup>47</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 30 ("The US investment community is served by highly experienced buy-side and sell-side analysts who understand the risks as well as the opportunities.").

<sup>48</sup> See *id.* (stating that pharmaceutical interest in and alliances with the biotech industry are key factors for market appeal).

<sup>49</sup> See *supra* note 35 and accompanying text; see generally JOHN ABRAHAM, SCIENCE, POLITICS AND THE PHARMACEUTICAL INDUSTRY: CONTROVERSY AND BIAS IN DRUG REGULATION 74-76, 255 (1995) (noting that the British government, after years of effective protectionism of its pharmaceutical industry, now is extending that protection to its biotechnology industry).

cialization of biotech discoveries by the Wellcome Trust;<sup>50</sup> (6) the establishment in London of the EMEA, a E.U. counterpart to the FDA that has introduced a coordinated, centralized, and timely procedure for the E.U.-wide review of biotechnology and other innovative products;<sup>51</sup> (7) new European market avenues for raising capital;<sup>52</sup> and (8) the availability of private domestic capital which, relative to the U.S., has not yet been invested in biotechnology.<sup>53</sup>

The U.S. and U.K. industries are increasingly being drawn together, especially through investment from and alliance agreements with multinational pharmaceutical companies.<sup>54</sup> This

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<sup>50</sup> The Wellcome Trust now is directly facilitating commercialization of research discoveries through the establishment of "a technology-transfer company to help the scientists it funds to find commercial outlets for the results of their research." *Transfer Company*, *supra* note 28, at 6. This decision was inspired by: (1) "anticipated guidelines from the Charity Commissioners emphasizing that charities have a duty to ensure that the research they finance is properly exploited"; and (2) "complaints from many Wellcome-funded scientists in universities about the lack of adequate support from the technology-transfer mechanisms set up by the universities for which they work." *Id.*

<sup>51</sup> See *The European Commission Background Report on the European Medicines Evaluation Agency*, M2PW, Jan. 31, 1995, available in 1995 WL 10419600 [hereinafter *Background Report*] (detailing the organization of the EMEA); United States Dep't of Commerce, *The European Medicines Evaluation Agency*, 95 NTISAFTECH, Apr. 15, 1995, available in 1995 WL 9230589 [hereinafter *EMEA*] (noting EMEA's goal of coordinating licensing procedures); Gina M. Cavalier, *Pushing Parentless Pharmaceuticals: Toward an International Home for "Orphan Drugs" and a Cure for "Zebra" Diseases*, 27 LAW & POL'Y INT'L BUS. 447, 463-64 (1996) (discussing EMEA's goal to speed up approval times without sacrificing safety); Note, *FDA Reform and the European Medicines Evaluation Agency*, 108 HARV. L. REV. 2009, 2019-21 (1995) [hereinafter *FDA Reform*] (commenting on the potential effects of the EMEA on the FDA's regulatory system); *Pharmaceuticals: "Success" in First Year for EU Medicines Agency*, EUR. ENV'T, Feb. 20, 1996, available in 1996 WL 8759045 [hereinafter *Success*] (stating that "[b]y the end of 1995, [the EMEA's] scientific committee responsible for human medicines had adopted eight positive opinions on applications for marketing authori[z]ation, leading to three authori[z]ations before the end of the year"); Eric Reguly, *Medicines Evaluation Agency Provides the Right Tonic*, THE TIMES (London), Mar. 19, 1996, available in 1996 WL 6482054 (stating that the EMEA is making London a world centre for pharmaceuticals, and that it may even emerge as a super-regulatory agency linked with the FDA and Japan). The EMEA is addressed fully below in Part III.A.

<sup>52</sup> See *Biotech Fever*, *supra* note 37, at 46 ("Now, with new bourses such as France's Nouveau Marché, London's Alternative Investment Market, and the launch of EASDAQ, a Brussels-based electronic market for high-tech startups, there could soon be more bioscience flotations . . .").

<sup>53</sup> See generally Bernstein, *supra* note 31, at A1-A2 (contrasting U.S. and European investment in biotech firms).

<sup>54</sup> See Malinowski & O'Rourke, *supra* note 1, at 188-90; *Drug Bonanza*, *supra* note 39 ("Last year, Glaxo Wellcome paid \$533 [million] for the American company, Affymax. Earlier, Ciba-Geigy of Switzerland acquired 49.9% of Chiron in a deal that valued the company at \$4.2 billion. Both deals indicated that the big players were looking to buy biotech outfits as a way of filling gaps in their own research pipelines.").

trend is likely to continue.<sup>55</sup> In the U.S. and now the U.K., the entrepreneurial quality of smaller, competitive biotech companies built around specific science and headed by talented and driven researchers has proven effective for advancing the industry.<sup>56</sup> Despite heavy pharmaceutical investment, the U.S. biotech industry has maintained its entrepreneurial quality by entering into multiple alliances with different entities, each around specific technology.<sup>57</sup> The U.K. industry should be able to do the same, especially since its companies have the option of entering into alliance agreements with mature U.S. counterparts as well as with pharmaceutical companies.<sup>58</sup> Assuming investment capital and interest remain relatively constant, the availability of more potential allies could raise the demand for the most promising U.K. biomedical research and create the opportunity to negotiate for highly favorable terms.<sup>59</sup>

In fact, the U.K. could benefit tremendously from the U.S. experience and the maturation of the U.S. biotech industry. For the purposes of commercial policy making, strategizing, and industry development, collaboration is in the best interest of the U.K.<sup>60</sup> Through collaboration and access to the insight of seasoned U.S. biotech executives, the U.K. may benefit from the U.S. experience and avoid some of its mistakes.<sup>61</sup> On a more fundamental level, the U.S. industry has raised and expended capital and dramatically advanced the state of biotechnology for the world. The U.K., therefore, is in the enviable position of tapping domestic capital and

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<sup>55</sup> See generally LEE & BURRILL, *supra* note 2, at 29-30 (describing the successes pharmaceutical companies have had in consolidating); EUROPEAN BIOTECH 96, *supra* note 2, at 41 ("US pharmaceutical companies are beginning to look at European countries."); *id.* at 15 ("The market focus of the European bioscience sector is more geared to serving large pharmaceutical, agrifood or chemical multinationals.").

<sup>56</sup> See EUROPEAN BIOTECH 95, *supra* note 26, at 7-9 (reporting, based on surveys compiled for the annual report, that seventy-five percent of biotech companies in Europe and the U.S. have less than fifty employees).

<sup>57</sup> See LEE & BURRILL, *supra* note 2, at 29-30; Malinowski & O'Rourke, *supra* note 1, at 188-90.

<sup>58</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 41-42 (noting the interest of U.S. pharmaceutical and biotech companies in European companies); Mike Ward, *Dramatic Growth Forecast for UK Biotechnology Firms*, 367 NATURE 674, 674 (1994) [hereinafter *Dramatic Growth*] (stating that access to U.S. and Japanese markets, among others, is vital to the commercialization of U.K. biotech); see also *supra* note 48 and accompanying text.

<sup>59</sup> See *Dramatic Growth*, *supra* note 58, at 674.

<sup>60</sup> See *id.*

<sup>61</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 43 ("One of the advantages European bioscience CEOs have is that they can learn from the experiences of their US counterparts.").

building a biotechnology industry with U.S. involvement.<sup>62</sup> Furthermore, the U.K. has the advantage of referring to the U.S. industry to increase credibility and confidence among investors.<sup>63</sup> These factors could temper the kind of market volatility that caused investment to dry up and a sell-off of developed biomedical science in the U.S. during 1994 and early 1995.<sup>64</sup>

In sum, the U.K. biotech industry is evolving along the growth lines of the more mature U.S. biotech industry. Globalization through, among other things, multinational pharmaceutical investment is bringing these industries together.<sup>65</sup> Growth and increased globalization of the industry in both countries is likely to continue,<sup>66</sup> and "in the future basic medical research will largely be confined to the biotech companies, with the stock market bearing the risks of success or failure, while the big drug companies will concentrate on the more controllable tasks of development and marketing."<sup>67</sup>

### III. THE IMPACT OF BIOTECHNOLOGY ON STANDARD OF CARE AND TREATMENT

The biotechnology industry in the U.S. and the U.K. is undergoing a privatization of R&D coupled with a more supportive regulatory infrastructure beneficial to commercialization.<sup>68</sup> Among the public

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<sup>62</sup> See *id.* at 41-42 (explaining that U.S. biotech and pharmaceutical companies look to European companies as sources of new ideas).

<sup>63</sup> See *Drug Bonanza*, *supra* note 39 (noting that U.S. successes have built up investor enthusiasm); *supra* note 47.

<sup>64</sup> In the U.S., a tremendous amount of domestic capital was tapped in the early 1990s and used to develop biomedical science, a great deal of which was sold to the pharmaceutical industry when private investment began to dwindle towards the end of 1994. See Malinowski & O'Rourke, *supra* note 1, at 180-90 (mentioning pharmas, academic institutions, government, and private companies as sources of funding). Though pharmaceutical investment is likely to expedite the market approval, manufacturing, and distribution of biotechnology, some U.S. companies may have liquidated significant profit and growth opportunities associated with their first generation products in order to survive into the future.

<sup>65</sup> See *supra* notes 48, 54 and accompanying text.

<sup>66</sup> See *supra* note 55 and accompanying text.

<sup>67</sup> *Drug Bonanza*, *supra* note 39; see Matthew Lynn, *Biotech Tycoon Moves into Nerve Drugs*, THE TIMES (London), Jan. 7, 1996 (profiling Cerebrus, a biotech company "concentrat[ing] on doing contract research for big pharmaceutical companies," and observing that "big drug companies are becoming keener to contract out research as the industry consolidates and as they seek ways to control the rising costs of medical research and development").

<sup>68</sup> See *supra* notes 21-24 and accompanying text (discussing privatization of R&D in the U.S.); EUROPEAN BIOTECH 95, *supra* note 26, at 1 (same); *infra* Part III.B (addressing this trend in both the U.S. and the U.K.).



health challenges accompanying the commercialization of biotechnology, two are especially immediate and profound: (1) to review and regulate a multitude of truly innovative genetic diagnostics and therapeutics to maximize public health benefits; and (2) to make the resulting deluge of new health care capabilities accessible to those likely to benefit from them.<sup>69</sup> The difficulty of the latter is underscored by the fact that limitations already have been placed on health care resources under both private group and nationalized health insurance.<sup>70</sup> These limitations are embodied in prohibitive pricing and risk assessment by insurers, coverage exclusions, and rationing.<sup>71</sup>

### A. *The Shared Challenge of Review and Regulation*

"The products regulated by the F.D.A. account for 25 percent of the nation's economic output."<sup>72</sup> Not surprisingly, the FDA has become increasingly responsive to biotechnology. Biotech therapeutics are classified biologics and subject to regulation under both the Food, Drug, and Cosmetic Act (FDCA)<sup>73</sup> and the Public Health Service Act (PHSA).<sup>74</sup> While the "objective of the FDCA is to ensure the safety and effectiveness of the final product,"<sup>75</sup> PHSA is focused on "rigid control of the manufacturing process," which reflects the particular scientific and historical characteristics of biopharmaceuticals.<sup>76</sup> The effect has been an unduly burdensome number of license and other requirements on the manufacturers of biologics.<sup>77</sup> However, in April 1995, the FDA identified reforms that could accelerate its drug review process substantially, including harmonization of FDA standards with international scientific standards, the acceptance of

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<sup>69</sup> See *New Era*, *supra* note 9, at 332.

<sup>70</sup> See *id.* at 331 (noting that efforts by insurers to contain costs have hindered people in need of services from taking advantage of advances in medical technology).

<sup>71</sup> See *id.* (discussing increased cost assessment and rationing as goals of capitation and suggesting safeguards are needed).

<sup>72</sup> Pear, *supra* note 18, at A15.

<sup>73</sup> See 21 U.S.C. §§ 321-395 (1994); see also JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 13.21 (2d ed. 1993); Gary E. Gamerman, *Regulation of Biologics Manufacturing: Questioning the Premise*, 49 FOOD & DRUG L.J. 213, 213 (1994).

<sup>74</sup> Pub. L. No. 57-244, 58 Stat. 682, 702-03 (1944) (codified at 42 U.S.C. § 262 (1994)). See Malinowski & O'Rourke, *supra* note 1, at 205-13 (discussing the regulatory climate within which the biotech industry operates).

<sup>75</sup> Malinowski & O'Rourke, *supra* note 1, at 205.

<sup>76</sup> *Id.* at 205-06 (quoting Gary E. Gamerman, *Regulation of Biologics Manufacturing: Questioning the Premise*, 49 FOOD & DRUG L.J. 213, 213 (1994)).

<sup>77</sup> See *id.* at 206-20.

a "single major clinical trial . . . as evidence that a drug works,"<sup>78</sup> privatization of review for some low-risk medical devices, and elimination of the requirement that the FDA approve facilities manufacturing all biologic drugs through the Establishment License Application (ELA) process.<sup>79</sup>

The FDA's responsiveness to biotechnology in recent years is due primarily to a combination of well-organized consumer advocacy groups and the election of a Republican Congress,<sup>80</sup> coupled with other factors.<sup>81</sup> These factors include Congressional proposals for

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<sup>78</sup> *Id.* at 218.

<sup>79</sup> *See id.* at 217-18; LEE & BURRILL, *supra* note 2, at 58; *supra* note 18 (discussing FDA reform movement).

<sup>80</sup> *See* John Schwartz, *FDA Often Blamed for Problems that Aren't Agency's Fault*, WASH. POST, July 15, 1996, at A17 (reporting that the Pharmaceutical Research and Manufacturers of America paid for approximately 140 disease victims to travel to Washington, D.C. and raise complaints about the FDA to members of Congress). *But see* Matthew Rees, *What Makes David Kessler Run?*, WKLY. STANDARD, June 3, 1996, at 25 (portraying Commissioner Kessler as "an amazingly resourceful political animal"). The voices of consumer advocacy groups representing the victims of breast cancer and AIDS have been especially strong. *See generally* Piedmont Venture Group, *Cancer Diagnostics*, MEDICAL TECHNOLOGY STOCK LETTER, no. 294, Apr. 18, 1996 (updating progress in cancer diagnostics, including reports on biotech companies, imaging procedures, and blood tests); Pear, *supra* note 18, at A15 ("Within days after the Republicans won control of Congress in 1994, some gay rights groups saw an opportunity to win speedier access to new, unapproved treatments for AIDS by rewriting Federal drug laws."). This strategy appears to be working as the FDA has already dramatically expedited approval of drugs that fight cancer and AIDS. *See* Laurie McGinley, *FDA to Quickly Clear Merck AIDS Drug, After Approving Abbott's Treatment*, WALL ST. J., Mar. 4, 1996, at B3 ("On Friday, after late-night meetings Thursday between FDA and Abbott officials, the agency approved Norvir, known generically as ritonavir. That approval came just 72 days after Abbott filed its application—the fastest drug approval in the agency's modern history. And it came just one day after the advisory panel backed its approval."); *The FDA and Shannon McDermott*, BOSTON GLOBE, Apr. 15, 1996, at 10 [hereinafter *McDermott*]. It is important to note, however, that biotechnology encompasses a multitude of products and consumer groups do not support accessibility to all of them. Some well organized consumer advocacy groups presently oppose the "premature" commercialization of predictive genetic testing services. For example:

The National Breast Cancer Coalition . . . a patients' rights group, opposes open marketing of a test for the so-called breast cancer gene, BRCA1. At the risk of sounding as paternalistic as the doctors they often fight against, members said the test's generally ambiguous results may trigger unnecessary panic in many women while reassuring others who should remain vigilant.

Rick Weiss, *Tests' Availability Tangles Ethical and Genetic Codes*, WASH. POST, May 26, 1996, at A1.

<sup>81</sup> The four primary forces driving expansion of the commercialization and availability of predictive genetic testing are: (1) the reward structure of science, which encourages immediate reporting of findings; (2) public demand for progress in battling disease; (3) biotechnology companies' objective of developing large markets, which are a pre-requisite to profits; and (4) media coverage of genetic discoveries. *See* TASK FORCE, *supra* note 8, at 4.

fundamental reform,<sup>82</sup> better organization and maturation (including more financial resources) of the biotechnology industry,<sup>83</sup> vested pharmaceutical interest in the industry,<sup>84</sup> and the involvement of the leadership of the scientific community (including the nation's major non-profit research institutions) in the biotech industry.<sup>85</sup>

It is more than mere coincidence, however, that the FDA's responsiveness has paralleled the establishment and progress of the EMEA.<sup>86</sup> The EMEA, not the FDA, now has authority over the

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<sup>82</sup> The most dramatic features of the proposed FDA reform legislation are privatization of the review process (using private companies to help review clinical data) and a six-month (180-day) time limit on the review of all drugs by 1998—a dramatic reduction compared to the current average of twelve months. See S. 1477, 104th Cong. (1996) (FDA Reform Markup introduced by Sen. Nancy Kassebaum); see also Malinowski & O'Rourke, *supra* note 1, at 210-17; Pear, *supra* note 18, at A15; Ronald Rosenberg, *Biotech Group Hits Kennedy's FDA Stance*, BOSTON GLOBE, Apr. 26, 1996, at 90 [hereinafter *Kennedy's FDA Stance*] ("Citing scientific advances over the past 50 years, the biotech industry wants to abolish the two-track approval process for biology-based drugs. That process now requires separate approvals for a biological drug, its manufacturing process and for every lot or batch produced."). Other proposed reforms include: (1) mandatory review, in four months as opposed to the present six, of all "breakthrough" drugs for fatal or incurable diseases; (2) requiring the FDA to distribute its work to private companies if it does not meet the proposed review deadlines by 1998; and (3) allowing companies, if the FDA fails to meet its deadline, to petition for automatic approval for sale in the U.S. of any therapy that is approved in certain foreign countries. If within thirty days the FDA finds the treatment "unsafe or unproven," it may ban the sale of the drug in the U.S. See Lauran Neergaard, *Speed-up in Drug Approval Could Endanger Public*, *FDA Chief Warns*, COM. APPEAL (Memphis), Feb. 22, 1996, at 8B [hereinafter *Speed-up*]. The public pressures bearing upon the FDA also have been profound. See, e.g., McDermott, *supra* note 80, at 10 ("Janet McDermott[, who was brought to Washington by a pharmaceutical trade group,] is waging a valiant struggle to get medication that will prevent the seizures suffered by her daughter Shannon. But Shannon's plight should not encourage support for a bill in Congress that would force the Food and Drug Administration to speed up the approval process for new drugs."). Appreciating the power of teamwork, drug companies have joined forces with patients in the fight to accelerate approval times. See Pear, *supra* note 18, at A15 ("Drug companies contribute substantial sums of money to patient-advocacy groups, but those groups insist that they are not unduly influenced by the money.").

<sup>83</sup> See EUROPEAN BIOTECH 96, *supra* note 2, at 43 (pointing to the relatively mature U.S. biotech industry as a model for European companies); Malinowski & O'Rourke, *supra* note 1, at 169-70 (stating that the U.S. biotech industry has made great strides in the last five years in terms of revenue earned).

<sup>84</sup> See *supra* notes 48, 54 and accompanying text (mentioning the importance of alliances with the pharmaceutical industry).

<sup>85</sup> See generally Malinowski & O'Rourke, *supra* note 1, at 180-84 (pointing to beneficial alliances with academia and research institutions).

<sup>86</sup> Prior to the EMEA, three national agencies—those of the U.S., Britain, and France—set baseline standards for the world. See Reguly, *supra* note 51 (contrasting the EMEA's procedures with those of the FDA and suggesting that there is competition between the two to make fast approvals). Commissioner Kessler's statement that the FDA is reviewing biologics as fast, if not faster, than its national European counterparts evidences a recognition of this increased competition. See Ronald Rosenberg, *Kessler Defends FDA, Says US Quicker*

world's largest unified pharmaceutical market.<sup>87</sup> The U.K., France, Germany, and Italy "account for nearly seventy-five percent of pharmaceutical consumption in the EU and thirty-five percent of global consumption."<sup>88</sup>

The EMEA, headquartered in London, was established in 1993 to implement legislation known as the Future System for the market authorization of medicinal products for both animal and human use.<sup>89</sup> There now are three procedures for market authorization within the E.U.: (1) a centralized procedure for access to the E.U. market; (2) a decentralized procedure for access to the E.U. market; and (3) national authorization for access to a country's domestic market.<sup>90</sup>

(1) *Centralized Procedure*. The centralized procedure applies to all biotechnology products.<sup>91</sup> The procedure also may be available upon request for other innovative products and new chemical entities.<sup>92</sup> Authorization, which is valid for marketing in all E.U. Member States, is granted based upon

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*at Getting Drugs Ok'd*, BOSTON GLOBE, Mar. 12, 1996, at 34 [hereinafter *Kessler Defends FDA*] (noting that in a five year period, thirty drugs were approved in the U.S. and twenty-eight in the U.K.). However, some experts suggest that

the time for NDA approval is decreasing only because the FDA is asking for substantially more clinical data before it starts its NDA review 'clock.' The Center for the Study of Drug Development at Tufts University found that from 1990 to 1992, although median review time for 'important' new drugs was 20 months instead of 31 for other products, development times for the former group were three years longer.

*FDA Reform*, *supra* note 51, at 2015 (internal citations omitted); *see also infra* note 116 and accompanying text (discussing Commissioner Kessler's concern over proposed FDA reforms).

<sup>87</sup> *See Bent & Booth*, *supra* note 18, at C3 ("[N]ow the . . . [EMEA] administers a unified regulatory system for a substantially larger population than that of the United States, and may displace the FDA as the regulatory standard-bearer.").

<sup>88</sup> Cavalier, *supra* note 51, at 459.

<sup>89</sup> *See Background Report*, *supra* note 51. The EMEA is responsible for "providing Member States and the Community institutions with the best possible advice on any question relating to the quality, safety and efficacy of medicinal products for human or veterinary use." *Id.* Other responsibilities include "improving cooperation between the Member States, the Community institutions, international organizations and third countries on the safety of medicines." *Id.* The EMEA is financed by the Community and through fees paid by the pharmaceutical industry. *See id.* For discussion of the EMEA, its procedures, and its impact on the industry, *see generally* EUROPEAN BIOTECH 96, *supra* note 2, at 19-20 (discussing approval times and the effects of the EMEA on the confidence of investors); EUROPEAN BIOTECH 95, *supra* note 26, at 16 (explaining staffing, start-up costs, and future approval procedures).

<sup>90</sup> These procedures, summarized below, are described in *Background Report*, *supra* note 51; *EMEA*, *supra* note 51; and Cavalier, *supra* note 51, at 463-64. *See also FDA Reform*, *supra* note 51, at 2012-15, 2019-21; Eyckmans, *supra* note 29, at 32.

<sup>91</sup> *See Background Report*, *supra* note 51.

<sup>92</sup> *See id.*

a single evaluation by one of the EMEA's scientific panels—the Committee for Proprietary Medicinal Products (CPMP) or the Committee for Veterinary Medicinal Products (CVMP).<sup>93</sup> An opinion must be granted within 210 days from the filing of the application, and a final decision on the application must be granted in less than 300 days.<sup>94</sup> Any applicant receiving a negative opinion has an opportunity to appeal.<sup>95</sup> When a positive opinion is rendered, E.U. Member States are obligated to recognize the new drug for sale in their borders or file a formal objection with the European Commission.<sup>96</sup> The duration of authorization is five years, with the ability to renew exclusive marketing rights for another five years if safe use can be shown.<sup>97</sup> Upon approval by the EMEA, a drug “cannot be rejected by the national regulators.”<sup>98</sup>

(2) *Decentralized Procedure.* Until January 1998, applicants also may opt for the traditional multi-state, parallel application process for conventional drugs, whereby applications are filed and reviewed by different Member States at the same time.<sup>99</sup> Authorization granted by any one Member State—which should be decided within a period of 300 days, consisting of a 210-day review period and a ninety day translation and certification period—may be extended to other Member States upon application for recognition.<sup>100</sup> A Member State receiving such an application may defer action pending the action of a Sister State, and then “base its assessment on that of the other State.”<sup>101</sup> As with the centralized procedure, unfavorable decisions may be appealed.<sup>102</sup>

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<sup>93</sup> *See id.*

<sup>94</sup> *See id.*

<sup>95</sup> *See id.*

<sup>96</sup> *See id.*

<sup>97</sup> *See id.*

<sup>98</sup> Reguly, *supra* note 51.

<sup>99</sup> *See generally Background Report, supra* note 51; *EMEA, supra* note 51.

<sup>100</sup> *See id.*

<sup>101</sup> *See EMEA, supra* note 51.

<sup>102</sup> *See id.*

(3) *National authorization.* The individual Member State application procedure remains an option. Pursuant to this procedure, a company may seek authorization for a drug from any individual Member State that is limited to the State's national market.<sup>103</sup>

Prior to the establishment of the EMEA, European drug firms were falling behind those of the U.S. and Japan.<sup>104</sup> The purpose behind the EMEA is to "exploit product licensing expertise available in the European Community."<sup>105</sup> In particular, the E.U. intends to create an efficient application process to "enhance the value of pharmaceutical advances by reducing the time necessary for technology transfer and, thus, [make] products available to the market more quickly."<sup>106</sup> The cost of E.U.-wide approval under the EMEA is expected to be just sixty percent of the cost of obtaining authorization from the fifteen individual Member States.<sup>107</sup> During its first thirteen months of operation, the EMEA, which has the capacity to approve some forty therapeutics per year, fully approved seven drugs, all biotech drugs developed by U.S. companies, and partially approved many more.<sup>108</sup> In addition to the benefits of

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<sup>103</sup> See *id.*

<sup>104</sup> See *A Drug Tsar is Born*, THE ECONOMIST, May 7, 1994, at 74. In addition to delays accompanying the need to seek approval from individual states, the pharmaceutical and biotechnology sectors of the E.U. industry also have been held back by some national hurdles that remain, such as price controls and advertising regulations. See *Fast Relief*, *supra* note 18, at 7 ("Except in the U.K. and Germany, companies can launch the [EMEA-approved] product only after elaborate bargaining with national authorities over pricing and reimbursement levels."); see also Cavalier, *supra* note 51, at 459 ("Pricing is well within the jurisdiction of the individual member country, and a unified pricing system is not likely in the near future due to 'differing socio-economic factors and reimbursement systems.'"). But see Eyckmans, *supra* note 29, at 32 (applauding a series of E.U. directives which are slowly creating a single market for pharmaceutical products); *infra* notes 208-09 and accompanying text (discussing how rules were adopted by the European Commission in 1992 to standardize labeling and harmonize requirements for patient information).

<sup>105</sup> EMEA, *supra* note 51.

<sup>106</sup> *Id.* ("Bypassing the national regulators means that drugs can reach more [sic] more markets more quickly. Today, the top companies strive to launch drugs with an annual sales potential of Pounds 500 million. Saving months of tortuous regulatory proceedings could generate hundreds of millions a year in extra sales."). See Reguly, *supra* note 51 (explaining that the EMEA will improve the efficiency of the approval process by bypassing national regulators to allow for Europe-wide clearance).

<sup>107</sup> See US GAO Views Euro Drug Approval Times, MARKETLETTER, Apr. 22, 1996, available in 1996 WL 9648419.

<sup>108</sup> See Reguly, *supra* note 51. The first drug approved by the EMEA was Gonal-F, an infertility drug manufactured by Britain's own Serono Laboratories, and the most recent was Novo-7, a therapeutic that reduces bleeding. See *id.* (stating that EMEA's start was slowed

accelerated review, companies may ask the EMEA for scientific advice long before filing applications, and the EMEA has been increasing this advisory function since its establishment.<sup>109</sup>

There are strong similarities between the Future System implemented through the EMEA and proposed FDA reforms. As stated above, EMEA application review time is limited to 210 days, whereas the Kassebaum proposal includes a 180-day time limit.<sup>110</sup> The EMEA is a lean agency with a London staff of merely 100 that contracts out essential operations to national regulatory agencies across Europe.<sup>111</sup> Similarly, the movement to reform the FDA includes strong support to privatize the review process through contracts with outside laboratories.<sup>112</sup> Even the FDA has proposed outside review for low-risk medical devices.<sup>113</sup> In addition, the EMEA and FDA reform movements each face domestic resistance.<sup>114</sup> In the U.S., resistance over the speed and extent of reform comes from the agency itself and its supporters.<sup>115</sup> According to Commissioner Kessler<sup>116</sup> and Senator Kennedy,<sup>117</sup> the FDA

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by the fact that "its use is optional except for new biotech drugs such as vaccines"). The CPMP approved fifteen drugs during the EMEA's first year of operation (all developed by U.S. companies), in comparison with twenty-eight new drugs cleared by its FDA counterpart. See *id.*; see also *Success*, *supra* note 51 (stating that, by the end of 1995, the EMEA had adopted 8 positive opinions on applications, leading to three authorizations before the end of the year).

<sup>109</sup> See *Success*, *supra* note 51.

<sup>110</sup> See S. 1477, 104th Cong. (1996).

<sup>111</sup> See EUROPEAN BIOTECH 95, *supra* note 26, at 16; *Fast Relief*, *supra* note 18, at 1; Reguly, *supra* note 51 ("Operationally, the EMEA does not work like the national regulators or the FDA. It essentially acts as a contractor, farming out most of the scientific review work to experts approved by the EU states.").

<sup>112</sup> See *supra* note 18 (regarding the FDA reform movement).

<sup>113</sup> See *id.*

<sup>114</sup> See Reguly, *supra* note 51; *Kennedy's FDA Stance*, *supra* note 82, at 90 (remarks of Senator Kennedy).

<sup>115</sup> See *Kennedy's FDA Stance*, *supra* note 82, at 90.

<sup>116</sup> See *supra* note 86. FDA Commissioner Kessler warned Congress that the proposed reforms could endanger the health of Americans. See *Legislation Puts Public Health at Risk, FDA Chief Tells Panel*, BOSTON GLOBE, May 2, 1996, at 9 [hereinafter *Legislation*]; *Speed-up*, *supra* note 82, at 8B. Commissioner Kessler has challenged the proposed FDA reforms by asserting that: (1) the FDA has accelerated its review process, as made evident by the recent approval of AIDS drugs. See *Kessler Defends FDA*, *supra* note 86, at 34; (2) the U.S. has reviewed and introduced major biotechnology drugs at least as quickly as its European counterparts. *Id.*; and (3) the FDA has often discovered problems that were missed by regulators overseas. See *Speed-up*, *supra* note 82, at 8B. As examples of the latter, Kessler cited the FDA's rejection of the blood pressure medicine dilevodol in 1989 because it caused fatal liver disease, which prompted Britain and other countries already selling the drug to ban it. See *id.*; see also *Legislation*, *supra*, at 9 ("Americans would be at risk of getting infected blood transfusions and being poisoned by the food supply under pending legislation to revamp the Food and Drug Administration, the agency's chief said yesterday."). Dr. Kessler's conclusions

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may overlook the following:

- The EMEA was established in 1993 to eliminate acknowledged inefficiencies.

- Although the biotech industry is undergoing globalization, the majority of the biotech industry is located within the borders of the U.S. See Malinowski & O'Rourke, *supra* note 1, at 169; Reguly, *supra* note 51. In terms of the first generation of biotechnology products now reaching consumers, the industry is as American in origin as the automobile industry and Microsoft. Its presence has been visible in the U.S. for years, and NIH has financed a vast amount of basic biotech research. See Malinowski & O'Rourke, *supra* note 1, at 203-04. The importance Dr. Kessler places upon collaboration and interaction between drug reviewers and industry underscores the fact that the FDA has had an incredible home-court advantage over its foreign counterparts. See *Kessler Defends FDA*, *supra* note 86, at 34. Even if Dr. Kessler's data is correct, and safe, efficacious biotech products now are reaching consumers in the U.S. at roughly the same time that those products are reaching consumers in the U.K., such an outcome certainly is no basis for declaring success. One can only wonder how Dr. Kessler's comparative data would be affected by granting the drug reviewers in the U.K. the advantage held by his staff. Also, as the EMEA hones its operation, biotech products may reach E.U. consumers much more quickly than their U.S. counterparts, regardless of where they are developed and the trials are conducted.

- Before post-HGP biotech products reached the FDA, it was expected that they would move through the approval process much more quickly than their chemical compound predecessors due to the fact that they are composed of natural molecules. Instead, there was added delay—due in part to archaic regulations for biologics and the novelty of the new products which caused a lot of second guessing by regulators. See Malinowski & O'Rourke, *supra* note 1, at 205-13. Along the same lines, simply passing a generation of novel biotech products through the FDA would result in elimination of the novelty factor and more rapid review of the biotech products that follow. In other words, even if nothing was done to remove FDA inefficiencies and excessive burdens, the time required for FDA review of biotech products should be decreasing.

- Although the FDA has made some improvements and is in the process of making more to hasten its review of needed products without abandoning prudence, the recent expedited review of AIDS drugs is not representative. See *Kessler Defends FDA*, *supra* note 86, at 34. These successes likely are more attributable to the political voice of AIDS activists and the threat of proposed Congressional reform than meaningful self-improvements by the FDA. See Malinowski & O'Rourke, *supra* note 1, at 210-13; *McDermott*, *supra* note 80, at 10 (noting that pressures placed on Congress by AIDS and cancer activists led to faster approvals for some drugs). One cannot conclude that the pace of review achieved with these AIDS drugs will be sustained for the tremendous pipeline of important biotech drugs that feeds into the FDA. Furthermore, Dr. Kessler conveniently neglected to address the costs of this accelerated review.

<sup>117</sup> See 142 Cong. Rec. S3203-01 (daily ed. Mar. 29, 1996) (statements of Sen. Edward Kennedy regarding the FDA Reform Markup); *Kennedy's FDA Stance*, *supra* note 82, at 90. In the words of Senator Kennedy:

Most recently, we reduced the delays in approving prescription drugs with user fees. As a result, we are now approving drugs faster than the United Kingdom. We have fixed the drug lag. In fact, the United States approves more important new drugs faster than any other country in the world.

. . . .

. . . The [proposed] legislation says you have to examine all of them, all of the drugs within the 6 months. . . . So now instead of bringing focus and attention of the gifted and able scientists out at FDA on those drugs that could be breakthrough drugs in cancer, in AIDS, in hepatitis, in all kinds of diseases, we are going to divert their attention to



will not be able to meet the proposed 180-day requirement and maintain quality assurance. Resistance to the EMEA is likely to come from Member State national regulators, for the EMEA's success is necessarily at their expense.<sup>118</sup>

Fundamental reforms, such as the establishment of the EMEA and enactment of some of the significant proposed FDA reforms, could mean dramatic improvements to human health and the facilitation of greater economic prosperity. As a result, public and political pressures are on the FDA and EMEA to maximize review and accelerate approval of biotechnology applications and other innovative technologies without sacrificing quality assurance. Despite the loftiness of this objective, the FDA and EMEA are both striving to obtain it—each with an eye on the other.<sup>119</sup>

### *B. The Shared Health Care Finance Challenge*

No one disputes that biotechnology can introduce diagnostic and treatment capabilities that will improve public health by adding quality and longevity to countless lives.<sup>120</sup> Biotechnology advances also may realize some immediate, short-term savings in health care costs by, among other things, improving patient diagnosis and identifying how well patients will respond to treatments.<sup>121</sup> Nevertheless, the paradox of medical technology is that, the more effectively advances in health care technology benefit public health, the more medical technology raises health care costs over time.<sup>122</sup>

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looking after the “me-too” drugs that can make extra bucks for the pharmaceutical companies.

142 Cong. Rec. S3203-01.

<sup>118</sup> See Reguly, *supra* note 51.

<sup>119</sup> See *supra* notes 51, 78-79 and accompanying text.

<sup>120</sup> See BOSTON CONSULTING GROUP INC., THE CONTRIBUTION OF PHARMACEUTICAL COMPANIES: WHAT'S AT STAKE FOR AMERICA 63, 63-65 (Sept. 1993) [hereinafter BOSTON CONSULTING GROUP] (detailing the development of drugs aimed at treating the ailments that plague society).

<sup>121</sup> “[T]he study of genetic variation will enable the identification of patient sub-populations that may respond particularly well or poorly to currently-marketed drugs.” GENOMICS, *supra* note 3, at 5. “Drugs developed using genomics technology can be expected to offer advantages in specificity that will result in therapeutics with fewer side effects.” *Id.* at 9. “The ability to eliminate ineffective therapies due to individual therapeutic response will be another way in which genomics will contribute to the reduction in health care costs . . . . Genomic diagnosis will provide physicians with a sound basis upon which to prescribe appropriate therapies.” *Id.* at 16.

<sup>122</sup> See BOSTON CONSULTING GROUP, *supra* note 120, at 3, 49 (discussing cures for disease, which have increased life expectancies, and new technology as potential causes for increases in health care costs); *New Era*, *supra* note 9, at 341-47; *EU: Pluses and Minuses of*

The reasons are multifold:<sup>123</sup>

*Susceptibility to more complex diseases.* During this century, medical technology has helped to raise life expectancy at birth from fifty-four years in 1920 to seventy-five years in the early 1990s; the death rate from disease has fallen by more than one-third during that time.<sup>124</sup> “[L]ongevity is the equivalent of susceptibility to new, more complex diseases that are more difficult to treat and require specialized, technology-intensive care.”<sup>125</sup> The most pressing diseases currently challenging medical science are no less significant, threatening, or complex than heart disease, cancer, and AIDS. “Accordingly, effective medical technology increases the need for more advances and scientific research and development (R&D), and also increases consumption of technology-intensive, specialized and expensive treatments.”<sup>126</sup>

*Increases to the ranks of the biggest consumers.* Medical technology increases both “the ranks of the elderly, the

*Pharmacoeconomics*, MARKETLETTER, July 17, 1995, available in 1995 WL 2153623 (“[A]nalyzes [sic] of the factors raising health spending always reveal that innovation is the single most important driving factor.”). The Boston Consulting Group, based upon an empirical study published in 1993, concluded that

The \$461.2 billion increase in health care costs between 1963 and 1987 has several root causes . . . . Technological innovation, increased use of medical services, and real increases in medical prices together were responsible for more than 50 percent of the increase. Additional births and immigration accounted for 6 percent, and the increase in the size of the population due to increased life expectancy contributed 2 percent. Of the remainder, 19 percent was general inflation and 21 percent was the increased cost per capita of treating the elderly, beyond the rate of increase experienced for the rest of the population.

BOSTON CONSULTING GROUP, *supra* note 120, at 48.

<sup>123</sup> See *New Era*, *supra* note 9, at 341-47 (discussing these reasons at length).

<sup>124</sup> See BOSTON CONSULTING GROUP, *supra* note 120, at 3. Pharmaceuticals have provided the treatment or means of prevention for six of the top eight categories of killer diseases of the 1920s: diphtheria; influenza; measles; pneumonia; syphilis; tuberculosis; and whooping cough. See *id.* at 4.

<sup>125</sup> *New Era*, *supra* note 9, at 341-42 (citation omitted). “Thus, paradoxically, even if another ‘penicillin’ was discovered that inexpensively cured the prevalent diseases of today, the population would eventually age to the point where some new set of diseases would be killing (much older) people at essentially the same rate.” BOSTON CONSULTING GROUP, *supra* note 120, at 12. Specialization has the potential to increase the cost of care because the lack of substitutes and high demand for services allow specialists to set high prices. See *New Era*, *supra* note 9, at 342 n.77.

<sup>126</sup> *New Era*, *supra* note 9, at 342. In 1993, “annual medical spending and indirect social costs for cardiovascular disease [reached approximately] \$110 billion.” BOSTON CONSULTING GROUP, *supra* note 120, at 46.

nation's biggest health care consumers," and the amount and complexity of the services available to them.<sup>127</sup>

*Increased services.* "When medical technology is available, it seems inevitably to be used, even in the face of objective data that it is inappropriate."<sup>128</sup> In fact, "[m]edical technology actually creates new treatable conditions."<sup>129</sup>

The field of biotechnology already is responsible for an entirely new generation of diagnostics and therapeutics now entering consumer markets. As evidenced by the burgeoning nature of biotechnology and globalization of the industry,<sup>130</sup> countless more

<sup>127</sup> *New Era*, *supra* note 9, at 342; see BOSTON CONSULTING GROUP, *supra* note 120, at 11 ("On average, the elderly consume four times as much medical care as do people under 65 . . ."). "According to the Congressional Budget Office, 64.7% of the growth in Medicare spending is attributable to increased services and use of technology, and Medicare consumed approximately 11.6% of all federal spending in 1995—meaning seventy-seven percent of the nation's health care bill for that year." *New Era*, *supra* note 9, at 342 (citation omitted).

<sup>128</sup> Henk A.M.J. ten Have, *Medical Technology Assessment and Ethics: Ambivalent Relations*, HASTINGS CENTER REP., Sept.-Oct. 1995, at 13, 16.

<sup>129</sup> *New Era*, *supra* note 9, at 342. A prime example of this effect is the impact of medical technology on short stature and infertility. See *id.*

Human growth hormone was developed initially to treat children whose bodies failed to produce it in standard amounts, a condition known as growth hormone deficiency (GHD).

Now, recombinant DNA technology has made growth hormone much more available, and there is some evidence that the physical characteristic of short stature *apart from GHD* will become a treatable condition.

*Id.* (citing Henk A.M.J. ten Have, *supra* note 128, at 16; Carol A. Tauer, *Human Growth Hormone: A Case Study in Treatment Priorities*, HASTINGS CENTER REP., May-June 1995 (Special Supp.), at S18; Gladys B. White, *Human Growth Hormone: The Dilemma of Expanded Use in Children*, 3 KENNEDY INST. ETHICS J. 401, 401-09 (1993) (emphasis added)). See Leona Cuttler et al., *Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns*, 276 JAMA 531, 531 (1996) (reporting on study findings that many pediatric endocrinologists consider GH treatment appropriate for selected non-GHD children). "Four years of GH treatment at \$20,000/year for the 37,000 children in the first height percentile at any given age would cost \$3 billion a year." Carol A. Tauer, *Human Growth Hormone: A Case Study in Treatment Priorities*, HASTINGS CENTER REP., May-June 1995 (Special Supp.), at S18, S19. Similarly, infertility has become a treatable condition despite the fact that its success rate is approximately 25% for women age thirty-seven or older. See Gail Sheehy, *Northwest Living: When Time Runs Out on Fertility*, PORTLAND OREGONIAN, Oct. 22, 1995, at L07, available in 1995 WL 9201540 (breaking success rates down by age groups). The success rate even has been reported to be as low as 10% to 18% at a cost of \$7,800 to \$15,000 per attempt. See Lisa Benavides, *Winchester Biotech Develops New Fertility Treatment*, BOSTON BUS. J., Aug. 16, 1996, at 9, available in 1996 WL 8817873. Several states, including Arkansas, Hawaii, Illinois, Maryland, Massachusetts, and Rhode Island, require insurance companies to cover fertility treatments and other states are considering similar laws. See Earl Ubell, *If You're Trying to Have a Child . . .*, PARADE MAG., Oct. 6, 1995, at 12, 12.

<sup>130</sup> See generally *supra* Part II (discussing the growth of biotechnology in the U.S. and the U.K.).

innovations will follow.<sup>131</sup> Today “a critical mass of the HGP has been completed, which suggests that the pipeline of products is about to get much fuller.”<sup>132</sup> Although “there will be some cost savings as researchers match diagnostic capabilities with therapeutic capabilities[,] . . . the first generation of genetic technologies will inundate the health care system with new costs over the next several years.”<sup>133</sup> The DNA diagnostic market is expected to exceed one billion dollars by 1998, an amount which does not include the expense of genetic counseling.<sup>134</sup> Many genetic therapeutics will be extraordinarily expensive due to their novelty and lack of market substitutes, both of which are reflected in the R&D costs of

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<sup>131</sup> See *New Era*, supra note 9, at Part II.B.3. “Genetic technologies are by no means a homogenous lot; they have varied medical and social effects, and are intended for diverse populations with distinct severity of illnesses, both actual and potential.” Philip J. Boyle, *Public Priorities for Genetic Services*, HASTINGS CENTER REP., May-June 1995 (Special Supp.), at S1, S1. “[A] plethora of population screens, diagnostic tests, and therapies will be available—perhaps commonplace—in the next decade. Conservative estimates are that some 50,000 gene markers will be developed as a result of molecular biology and translated into easy-to-employ biochemical assays, genetic tests, new drugs, and genetic therapies.” Philip J. Boyle, *Shaping Priorities in Genetic Medicine*, HASTINGS CENTER REP., May-June 1995 (Special Supp.), at S2, S2 [hereinafter *Shaping Priorities*]. The future of biotechnology is brightened by strong bipartisan support in Congress for biomedical research. See John K. Iglehart, *Politics and Public Health*, 334 NEW ENG. J. MED. 203, 203-07 (1996). See generally Malinowski & O'Rourke, supra note 1, at Part I.A. (discussing the growth of the genotech industry and the influences of government upon that growth); LEE & BURRILL, supra note 2 (discussing the future of biotechnology and the growth of new diagnostic products and drugs).

<sup>132</sup> *New Era*, supra note 9, at 343. See *Detailed Human Physical Map Published by Whitehead-MIT: STS-Based Map Represents Halfway Point to 100-kb Human Genome Project Goal*, HUM. GENOME NEWS, Jan.-Mar. 1996, at 5 (“The new map, which contains more than 15,000 STS DNA markers spaced an average of 199 kb apart, covers almost 95% of the entire genome. . . . Although originally slated for 1998, map completion by Whitehead-MIT and other groups is expected by the end of this year.”).

<sup>133</sup> *New Era*, supra note 9, at 344 (citation omitted). “Gene therapy is creating the potential for dramatic cost reduction by restoring normal function in congenital diseases like cystic fibrosis and [adenosine deaminase] deficiency.” Elizabeth O. Teisberg et al., *Making Competition in Health Care Work*, HARV. BUS. REV., July-Aug. 1994, at 131, 139. According to one study,

biomedical advances, as well as changes in lifestyles, are projected to avoid billions of dollars in total health care costs by the year 2015, including \$76 billion of costs avoided for Alzheimer's disease and \$12 billion for arthritis. . . . When economic costs are factored in—lost or inefficient work days—the costs avoided are even greater.

*New Era*, supra note 9, at 344 n.96 (citing BOSTON CONSULTING GROUP, *THE CHANGING ENVIRONMENT FOR U.S. PHARMACEUTICALS* 52 (Apr. 1993)). But see Mark J. Hanson, *The Seductive Sirens of Medical Progress: The Case of Xenotransplantation*, HASTINGS CENTER REP., Sept.-Oct. 1995, at 5, 6 (“The general irony of the cost-effectiveness argument is that because there will likely always be another cause of morbidity or mortality following the one medicine has prevented, there will always be a new investment opportunity for medicine.”).

<sup>134</sup> See Paul H. Silverman, *Commerce and Genetic Diagnostics*, HASTINGS CENTER REP., May-June 1995 (Special Supp.), at S15, S16.

developing them.<sup>135</sup> The first products are likely to generate high demand because biotech companies, most being without product lines, have focused their R&D efforts on technologies that will draw the broadest possible consumer markets.<sup>136</sup> Therefore, “[w]hen they reach market, the first generation of commercialized genetic technologies will hit health care insurers hard, especially if, as expected, many reach commerce *en masse* and over a brief period of time.”<sup>137</sup>

The challenge of financing biotechnology will have a significant impact on the health care systems of both the U.S. and the U.K. Escalating competition for limited resources will increase the pressure on health care policy-makers in both the U.S. and the U.K. to choose which research projects to support and what effective health care technologies to make available to patients. In other words, there will be trade-offs. Moreover, as shown by the cooperative nature of the industry in both countries,<sup>138</sup> the U.S. and the U.K. have already realized limitations on public funding of medical science R&D and an increase in private funding.<sup>139</sup>

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<sup>135</sup> “A case in point is Genzyme’s Ceredasae/Cerezyme, a treatment for Type 1 Gaucher’s disease. The treatment costs \$150,000 a year initially, followed by a maintenance program of monthly infusions for the rest of the patient’s life at a cost of approximately \$60,000 per year.” *New Era*, *supra* note 9, at 344 n.99 (citing Ronald Rosenberg, *Genzyme’s Plans to Beat Obsolescence*, BOSTON GLOBE, Jan. 8, 1995, at 60). See NIH Technology Assessment Panel, *Gaucher Disease: Current Issues in Diagnosis and Treatment*, 275 JAMA 548, 552 (1996) (concluding that treatment is limited by the high cost of the agent’s initial availability in the marketplace).

<sup>136</sup> See *New Era*, *supra* note 9, at 344.

<sup>137</sup> *Id.* See Malinowski & O’Rourke, *supra* note 1, at 177-78 (noting that “an entire generation of novel drugs is already visible . . . [because] the underlying science has proceeded more quickly than expected”).

<sup>138</sup> See *supra* Part II.

<sup>139</sup> See *supra* notes 24, 28 and accompanying text (discussing the privatization trend in the U.S. and the significance of the Wellcome Trust in the U.K.). In the U.K., “while the government’s contribution to industrial research spending has declined from 30 per cent in 1967 to 17 per cent in 1990, industry’s own share of the cost has remained at about 68 per cent.” John Maddox, *British Report Real Decline in Spending on Research*, 358 NATURE 359, 359 (1992). Recent cuts in medical R&D have raised an outcry from university officials. See *Wellcome Cash*, *supra* note 28, at 58 (“The Wellcome Trust is now roughly the same size as the Medical Research Council, a body that allocates British government funds to biomedical research.”); Fran Abrams, *Training Cuts Put Patients in Danger*, INDEPENDENT (London), Apr. 27, 1996, at 5, available in 1996 WL 9923611 (stating that “[u]niversity funding cuts, [including huge cuts to major research projects], have plunged medical schools into crisis”); Chris Mihill, *Cuts in Funding ‘May Cost Lives’*, GUARDIAN (London), Apr. 27, 1996, at 008, available in 1996 WL 4021902 (reporting that university officials warn that “new treatments and drugs [will] go undiscovered because of a lack of time and research facilities”); Celia Hall, *Medical School Cuts ‘Will Put Lives in Danger’*, DAILY TELEGRAPH (London), Apr. 27, 1996, at 10, available in 1996 WL 3945408 (reporting a loss of 107 million pounds “in real terms, combined with an overall grant cut of five per cent”).

The resulting introduction of intense entrepreneurialism and extensive industry interests and capital in the medical science community, set in the context of global competition, also appears to be giving rise to more incidents of fraud and abuse of patient trust.<sup>140</sup> At the same time, corporate discretion is increasing in the U.S. as biotech companies are performing research-stage presymptomatic genetic testing services in-house for consumers through primary care physicians.<sup>141</sup> One fear is that biotechnology companies increasingly will satisfy the technical laboratory requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)<sup>142</sup> by assembling their own Institutional Review Boards (IRBs)<sup>143</sup> staffed with highly-paid consultants.<sup>144</sup>

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<sup>140</sup> See Nicholas Timmins, *Call for Agency to Stop Medical Research Fraud*, INDEPENDENT (London), Mar. 29, 1996, at 6, available in 1996 WL 4065890 (providing several examples, including the forging of patient consent forms for drug company sponsored trials by Dr. Geoffrey Fairhurst, a former advisor to the British government and then vice-chairman of the General Medical Council's ethics committee in England). In March 1996, "[i]n a unique collaboration, the Lancet and the British Medical Journal produced separate leading articles demanding action as a new book detailed more than 70 proven or suspected cases of scientific dishonesty and fraud worldwide." *Id.* See Chris Mihill, *Doctors Urge Action to Curb Research Cheats*, GUARDIAN (London), Mar. 29, 1996, at 008, available in 1996 WL 4017315 (stating that "[o]ne in 250 scientific studies may be fraudulent").

<sup>141</sup> These tests are commonly known as "home brews." See Richard S. Schifreen & Cynthia Louth, *Industry View on the Regulation of Ancillary Reagents*, 51 FOOD & DRUG L.J. 155, 158-59 (1996).

<sup>142</sup> CLIA was implemented to protect human subjects. See 42 C.F.R. § 493.1 (1995) (requiring certification before laboratories perform tests on humans); Malinowski & Blatt, *supra* note 8 (manuscript at 18-19) (arguing that "there can be no reliance on state regulation to monitor . . . the quality of genetic testing services for, there too, 'the field of laboratory licensure and monitoring remains in a state of flux'" (citing ROBIN J.R. BLATT, *CONCEIVING THE FUTURE: THE X'S AND Y'S OF GENETIC TESTING IN PREGNANCY* (forthcoming 1997 Greenwood Press)). Private laboratories performing genetic testing services are also essentially immune to federal laboratory quality assurances imposed by the Health Care Finance Administration (HCFA) through CLIA, for it is easy for them to satisfy CLIA requirements. Under CLIA, "a laboratory must demonstrate *analytical* validity of its tests and their components," but there is no *clinical* validity requirement. TASK FORCE, *supra* note 8, at 14-15 (emphasis added). In other words, the CLIA validity requirement is satisfied when a test to determine the presence of a specific genetic alteration does so accurately even though the test may offer no clinical predictability (the influence of the genetic alteration tested for on the health of individual subjects has not been established with clinical reliability). See *Shaping Priorities*, *supra* note 131, at S7 (discussing the failure of CLIA to address the impact of genetic tests on patient care).

<sup>143</sup> There is no express requirement that the genetic alteration tested for has any bearing on the subject's health. The only CLIA patient care safeguard touching upon clinical quality is the requirement that the proposed clinical protocol receive Institutional Review Board (IRB) approval when an investigatory test enters the human trial phase. See Stephenson, *supra* note 8, at 1662. Academic laboratories are required to report to their standing IRB, but "[t]he situation with respect to IRBs is murkier for biotechnology companies and commercial laboratories. They also may consult an IRB of an academic institution with whom they have

The economic reality of health care coverage in both the U.S. and the U.K. dictates that many patients who probably would benefit from a given medical science capability will not be able to receive it. In the U.S., such choices necessitate abandonment of a no-concern-for-costs mentality that has governed medical ethics for decades.<sup>145</sup> This jolting change, imposed through the wildfire spread of managed care and the introduction of harsh financial incentives on providers, threatens the physician-patient relationship.<sup>146</sup> In contrast, rationing has been internalized for physicians practicing under the nationalized U.K. system, and the U.K.'s public has become used to (if not accepting of) the resource limitations of health care.<sup>147</sup>

In the long-term, however, the widespread commercialization of biotechnology advances could pose a greater challenge to the U.K. for several reasons. First, in the U.K. health care system, there is relatively less waste available to be tapped to finance more

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ties, or they may form their own IRB—a practice that has the potential for a conflict of interest.” *Id.* See ABRAHAM, *supra* note 49, at 22-25 (exploring the capture theory in the context of IRBs, suggesting that those from the medical profession who serve on IRBs reap tremendous financial rewards and may receive R&D funding from the manufacturer of the products they are reviewing); TASK FORCE, *supra* note 8, at 11 (“The Task Force recognizes that IRBs differ widely in their approach to clinical protocols and in their policies regarding what constitutes research in their purview.”).

<sup>144</sup> See Joseph Palca, *Institutional Review Boards: A Net Too Thin*, HASTINGS CENTER REP., May 15, 1996, at 4 (discussing the flawed IRB system and the initiative to introduce legislation to establish a national requirement for IRB approval for any human research).

<sup>145</sup> See *New Era*, *supra* note 9, at 359 (“The reality of modern medicine, meaning the medicine of today and tomorrow, is that costs *do matter*.”). In accordance with the professional dominance and bioethics eras in medical ethics, medical schools have trained physicians not to consider costs. There is no cost-effectiveness requirement for FDA approval, and “[o]nly in the past few years have care managers begun convincing technology suppliers regularly to incorporate cost-reduction objectives in their decision-making.” BOSTON CONSULTING GROUP, *supra* note 120, at 67.

<sup>146</sup> See David Orentlicher, *Health Care Reform and the Patient-Physician Relationship*, 5 HEALTH MATRIX 141, 142 (1995) (arguing that health care reform may cause “patients’ primary relationships [to] be with their health care insurers rather than their physicians . . . [and] would accentuate the conflict between patient needs and the physician’s personal financial interests”).

<sup>147</sup> In the U.K., “despite the severity of financial constraints—the British system spends only one-third per capita of what [the U.S.] does—physicians seldom consciously engage in explicit cost-benefit calculations.’ Moreover, ‘British doctors still profess just as strong an ethic of absolute quality.’” *New Era*, *supra* note 9, at 340 (quoting Mark A. Hall, *Rationing Health Care at the Bedside*, 69 N.Y.U. L. REV. 693, 713, 738 (1994)). “Critics of the British system point out, however, that the incentive to conserve imbedded in British doctors has limited care.” *Id.* at 340 n.68 (citing Glen C. Griffin, *MD/DO Jobs and Incomes May Shrink but There’s Good News: CLIA Office Lab Regs May Go!*, 97 POSTGRADUATE MED., May 1, 1995, at 13).

capabilities.<sup>148</sup> Second, in comparison with U.S. providers, U.K. providers prescribe more drugs and perform fewer surgeries.<sup>149</sup> Third, “[i]n the United Kingdom, nearly all drugs are reimbursed by the government’s National Health Service (NHS), and an estimated eighty-five percent of prescriptions are dispensed free of charge.”<sup>150</sup> In contrast, the U.S. government funds only twelve percent of prescriptions.<sup>151</sup>

In sum, health care technology in the U.S. “is becoming an enemy to public health because it has not been made part of a deliberate strategy for managing care.”<sup>152</sup> Advances in molecular biology and genetic medicine are changing the emphasis in advanced health care technology from machinery and complex surgical procedures to diagnostics and therapeutics.<sup>153</sup> The U.K. also faces this problem due to its pattern of heavy drug consumption, its practice of reimbursement for the costs of prescriptions, and the transaction costs (including industry disincentives) associated with negotiation

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<sup>148</sup> The British practice of rationing health care, in comparison to the American system, results in a difference in the rate of provision of certain treatments in the two countries. Each year in the U.K., 9000 people are denied renal dialysis, between 10,000 and 15,000 are denied cancer chemotherapy, between 4000 and 17,000 are denied coronary artery surgery, and 7000 are denied hip replacement surgery. See JANE M. ORIENT, *YOUR DOCTOR IS NOT IN: HEALTHY SKEPTICISM ABOUT NATIONAL HEALTH CARE* 137 (1994). At least one study suggests that British physicians already ration health care based on factors such as: (1) the age of the patient; (2) the cost of necessary equipment; (3) public information about the treatment possibilities; (4) whether the treatment is life-saving or merely life-improving; and (5) whether the patient suffers from a “dread” disease. See HENRY J. AARON & WILLIAM B. SCHWARTZ, *THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE* 97-99 (1984). There is, however, still waste in the U.K. system. See ORIENT, *supra*, at 136-37.

<sup>149</sup> See Mark A. Hall, *Rationing Health Care at the Bedside*, 69 N.Y.U. L. REV. 693, 713 (1994). Comparative study of treatment between the U.S. and Canada highlight the U.S.’ relative propensity for surgery. See Joseph White, *Health Care Reform the International Way*, *ISSUES SCI. & TECH.*, Fall 1995, at 34 (“Canadian heart attack victims have at least equal survival prospects, but 6 percent more are likely to have activity-limiting angina. The catch is that the American patients undergo twice the number of surgeries—paying twice as much—to achieve the small improvement.”).

<sup>150</sup> Cavalier, *supra* note 51, at 460 (citation omitted); see ORIENT, *supra* note 148, at 137 (“If the NHS charged patients the full costs of their sleeping pills and tranquilizers, enough money would be freed to treat 10,000 to 15,000 additional cancer patients and save the lives of 3,000 additional patients with kidney failure.”) (citation omitted). In the U.K., “[p]rices for prescription drugs are regulated by the Pharmaceutical Price Regulation Scheme (PPRS)” and negotiated by the pharmaceutical companies, NHS, and providers. Cavalier, *supra* note 51, at 460. When biotechnology arrives fully at the commercialization stage, price restraints in Europe and the transaction costs of negotiating over price could restore the competitive advantage realized by the U.S. in the early 1990s.

<sup>151</sup> See Cavalier, *supra* note 51, at 461.

<sup>152</sup> *New Era*, *supra* note 9, at 346.

<sup>153</sup> See *id.* at 343.



over price in order to sell drugs throughout Europe.<sup>154</sup> As a consequence, biotechnology could make the financing of health care technology an even greater challenge to public health officials in the U.K.

#### IV. A GLOBAL APPROACH TO THE CHALLENGES OF COMMERCIALIZING BIOTECHNOLOGY

International Economic Law (IEL) is a theoretical approach to legal scholarship responsive to industrial globalization<sup>155</sup> and increasing interdependence among national economies.<sup>156</sup> IEL, which fully embodies the fundamental elements of law and economics, has introduced "a new, cosmopolitan perspective which

<sup>154</sup> See Stephen D. Moore, *Still Some Bargaining to Do*, WALL ST. J. (Europe), May 6, 1996, at 1, available in 1996 WL 3340900 ("Except in the U.K. and Germany, companies can launch the product only after elaborate bargaining with national authorities over pricing and reimbursement levels.").

<sup>155</sup> See Curtis R. Reitz, *International Economic Law*, 17 U. PA. J. INT'L ECON. L. 29, 30 (1996) (noting that "[t]he twentieth century revolutions in communications and transportation have made it feasible for an entity to expand its activities geographically, virtually without limit. . . . The explosive growth in the number and the reach of multinational enterprises in the past few years is not yet appreciated in the legal world.").

<sup>156</sup> See John H. Jackson, *Reflections on International Economic Law*, 17 U. PA. J. INT'L ECON. L. 17, 17 (1996) [hereinafter *Reflections*] (discussing the problems that government regulation plays on the international economy); Joel P. Trachtman, *The International Economic Law Revolution*, 17 U. PA. J. INT'L ECON. L. 33, 33 (1996) [hereinafter *Economic Law Revolution*] (discussing the relationship between public and private international law, international business law, and international economic law). Ernst-Ulrich Petersmann, a leading IEL scholar, has offered the following definition for International Economic Law:

[A] conglomerate of private law (including 'law merchant' and 'transnational commercial law'), state law (including 'conflict of laws') and public international law (including supranational integration law as in the EEC) with a bewildering variety of multilateral and bilateral treaties, executive agreements, 'secondary law' enacted by international organizations, 'gentlemen's agreement,' central bank arrangements, declarations of principles, resolutions, recommendations, customary law, general principles of law, de facto-orders, parliamentary acts, governments decrees, judicial decisions, private contracts or commercial usages.

Ernst-Ulrich Petersmann, *International Economic Theory and International Economic Law: On the Tasks of a Legal Theory of International Economic Order*, in THE STRUCTURE AND PROCESS OF INTERNATIONAL LAW: ESSAYS IN LEGAL PHILOSOPHY DOCTRINE AND THEORY 227, 251 (R. St. J. MacDonald & Douglas M. Johnston eds., 1983). For another definition, see John H. Jackson, *International Economic Law: Reflections on the "Boilerroom" of International Relations*, 10 AM. U. J. INT'L L. & POL'Y 595, 596 (1995) (IEL "can cover a very broad inventory of subjects: embracing the law of economic transactions; government regulation of economic matters; and related legal relations including litigation and international institutions for economic relations."). Recognition of IEL as a field of legal study was underscored recently by a name change from what was formerly the University of Pennsylvania Journal of International Business Law to what is now the University of Pennsylvania Journal of International Economic Law. See Reitz, *supra* note 155, at 29.

may be used to understand and manage the international economic law revolution.<sup>157</sup> This perspective encompasses and is based upon the associated fields of international business law, international economic law, public international law, and private international law.<sup>158</sup> IEL relies upon the fundamental premise that, “[b]ecause decisions taken by people in one country affect people in other countries, and decisions taken in one functional area affect policy in other functional areas, we must determine to what extent and how policy formation processes can be integrated.”<sup>159</sup>

IEL “is most visible in the European Union and in the [General Agreement on Tariffs and Trade/World Trade Organization] systems, although it is growing in other regional organizations and in multilateral or plurilateral organizations with sectoral responsibilities.”<sup>160</sup> The EMEA is, itself, a prime example of the kind of multinational institution promoted by IEL to meet regulatory challenges that are beyond the scope of any single national economy. Institutions such as EMEA are founded to “allow greater communications, a wider scope for exchange, increased binding power, and greater possibilities for enforcement.”<sup>161</sup> Several factors make IEL a particularly useful tool for analyzing the shared challenges accompanying the commercialization of biotechnology. These factors include: (1) the global nature of the biomedical science community, which has been enhanced in the field of biotechnology by HGP; (2) the demand in world-wide markets for biotechnology products; (3) the cooperative nature of the biotechnology industry and involvement of multinational pharmaceutical companies in both the U.S. and the U.K. sectors,<sup>162</sup> and (4) the fact that the United Nations now is

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<sup>157</sup> *Economic Law Revolution*, *supra* note 156, at 33-34.

<sup>158</sup> *See id.* at 33.

<sup>159</sup> *Id.* at 37.

<sup>160</sup> *Id.* at 46-47; *see Reflections*, *supra* note 156, at 18-24 (discussing GATT and its role in the international economy). *But see* Robert E. Hudec, *International Economic Law: The Political Theatre Dimension*, 17 U. PA. J. INT'L ECON. L. 9, 9 (1996) (stating that IEL contains a “political theatre’ dimension [which is defined as] the tendency of governments to adopt laws and agreements that create the appearance of legal solutions when in reality no solution has been achieved”).

<sup>161</sup> *Economic Law Revolution*, *supra* note 156, at 61. As for enforcement, [w]hether it is a banking scandal such as BCCI, or the difficulty of harmonizing certain consumer or food product standards, or the differential effects of taxes, social security, medical insurance, and labor immobility, there is today hardly any subject that can be said to be effectively controlled by a single national sovereign. *Reflections*, *supra* note 156, at 25.

<sup>162</sup> *See Reflections*, *supra* note 156, at 17 (“Governments find it increasingly difficult to implement worthy policies concerning economic activity because such activity often crosses

“carving itself a role in international biotechnology regulation.”<sup>163</sup>

The following analysis is grounded in IEL and addresses the public health challenges shared by the U.S. and the U.K. of reviewing and regulating innovative biotechnology products and financing these technologies so that public health benefits may be fully realized.<sup>164</sup> This analysis follows the functionalist approach which characterizes the E.U.’s design and history.<sup>165</sup> In other words, these shared challenges are addressed in a pragmatic fashion with the objective of introducing concrete proposals to meet contemporary needs.

### A. Review and Regulation Proposal

The concept of regulatory collaboration (or “harmonization of law”<sup>166</sup>) is increasingly drawing recognition from both scholars and policy makers.<sup>167</sup> At the center of this concept is a belief that the creation of a multinational business community and maximization of

borders in ways to escape the reach of much national government control.”); Reitz, *supra* note 155, at 29-30 (“Cross-border transactions between parties located in different nations can be and are being facilitated by laws that enable efficient negotiation and performance of exchange transactions.”).

<sup>163</sup> Henry I. Miller, *Biotechnology and the UN: New Challenges, New Failures*, 14 NATURE BIOTECHNOLOGY 831, 831 (1996).

<sup>164</sup> There are, of course, other shared challenges that accompany the commercialization of biotechnology, such as preserving the safety of human subjects and biodiversity. *See id.* Agencies within the United Nations are introducing safety regulations that bridge the international science and commercial sectors in the field of biotechnology, and “[c]ertain agencies of the [UN] are vying with one another to become the world’s ‘biopolice.’” *Id.*

<sup>165</sup> *See Economic Law Revolution, supra* note 156, at 47 (“This functionalism asks: what do we need to do today, and how will we do it? It purports to eschew idealism—including one-worldism or world federalism—rolls up its sleeves, and sets about pragmatic tasks to address concrete, mostly economic, needs.”); *see also* Joel P. Trachtman, *Unilateralism, Bilateralism, Regionalism, Multilateralism, and Functionalism: A Comparison with Reference to Securities Regulation*, 4 TRANSNAT’L L. & CONTEMP. PROBS. 69, 74-75 (1994) (addressing international cooperation in securities regulation).

<sup>166</sup> *Economic Law Revolution, supra* note 156, at 61.

<sup>167</sup> *See id.* at 46 (“Increasingly, it is recognized that domestic regulation of business is within the domain of international economic law. International economic law addresses some of these concerns by promoting cooperation among states and limiting competition.”). Collaboration for greater returns is a concept long recognized by economic theorists. Consider the following illustration of this principle:

Suppose [the cattle owner’s] profits could be increased by letting the cattle roam over part of the farmer’s crops, thereby destroying them, but that the farmer has the legal right to fence her land against the cattle. The two then have an interest in striking a deal that allows the cattle to roam over part of the farmer’s land. They can do so because each can be made ordinally better off by making the deal.

Russell Hardin, *Magic on the Frontier: The Norm of Efficiency*, 144 U. PA. L. REV. 1987, 1991 (1996) (citing Ronald H. Coase, *The Problem of Social Cost*, in *THE FIRM, THE MARKET AND THE LAW* 95, 99 (1988)).

interaction and competition between industry players will realize greater market efficiencies. "With the intensification of economic relations has come the recognition that these relations can be facilitated, or made more efficient, by increased regulatory transactions between states in the area of international trade law and business regulation."<sup>168</sup> Rather than promoting cooperation for the sake of cooperation, IEL promotes cooperation as a means to realize more of what is desirable.<sup>169</sup>

For believers in IEL, the establishment of the EMEA marks the beginning of a more promising era in public health. Ideally, the EMEA and FDA will *compete* and maximize their efficiencies to attract innovative health care products to their markets while they *collaborate* to eliminate duplication, to maximize resources, to reach reliable safety and quality assessments of innovative technologies without delay, and to generally minimize the risk of error while streamlining the review and approval processes for health care products.<sup>170</sup> HGP is the model, for it has maximized efficiencies in biomedical science on the domestic and international levels by utilizing these principles of collaboration and competition.<sup>171</sup> HGP has focused the science community's efforts on a single objective—gene sequencing to construct a map of the human genome that will serve as an invaluable shared research resource for the worldwide biomedical science community.<sup>172</sup> In doing so, HGP has facilitated the exchange of information and notification of each discovery within the science community, and fostered intense competition between scientists who often are aware that contemporaries in other labs are racing to make the same discovery.<sup>173</sup>

IEL theorists recognize that national regulatory bodies possess ample domestic authority but need motivation to collaborate with their foreign counterparts.<sup>174</sup> The FDA is certainly no exception. This need for motivation is attributable to domestic pressures coupled with international competition resulting from the establish-

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<sup>168</sup> *Economic Law Revolution*, *supra* note 156, at 60-61.

<sup>169</sup> *See id.* at 61.

<sup>170</sup> *See Malinowski & O'Rourke*, *supra* note 1, at 190-92 (observing that the HGP, initiated by Congress in 1988-89, has prompted European countries to commence similar efforts).

<sup>171</sup> *See id.* at 191-92.

<sup>172</sup> *See id.*

<sup>173</sup> *See Malinowski & O'Rourke*, *supra* note 1, at 183-84 (noting that the "commercialization" of the science industry has increased competition among scientists for financial returns).

<sup>174</sup> *See Economic Law Revolution*, *supra* note 156, at 45-46.

ment of the EMEA.<sup>175</sup> The EMEA already has brought about market efficiencies both in the E.U. and globally. Within the E.U., the EMEA is drawing together resources and eliminating duplication.<sup>176</sup> To the extent that the EMEA has introduced competition and enhanced FDA efficiency, it also has benefitted the domestic interests of the U.S. The fact that the FDA and EMEA each have a counterpart and competitor should continue to improve the efficiency and effectiveness of drug approval in both countries.<sup>177</sup> This improvement is a real possibility due to the notorious inefficiencies and other shortcomings in the drug review and market approval systems of both the U.S. and the U.K.<sup>178</sup> In the U.S., “recent studies suggest that regulatory delays may have a negative impact on patient life expectancy and quality of life. . . . [O]n balance research does suggest that regulatory systems in other industrialized nations achieve a generally safe drug supply while avoiding some of the delay of the FDA process.”<sup>179</sup> Pre-EMEA inefficiencies in the U.K. are made evident by what the EMEA process is expected to accomplish. The mission of the EMEA is to enforce reliable quality controls while enabling companies to obtain E.U. market access for their products at a savings of both considerable time and forty percent of the cost of obtaining approval through the traditional multi-state system.<sup>180</sup>

Supporters of the FDA might point out that, at least to some extent, the FDA is a victim of its own success. After decades of independence and authority mushrooming out of fear of mistakes,

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<sup>175</sup> See Bent & Booth, *supra* note 18, at C3 (attributing FDA’s willingness to participate in ICH “to a fear that the [FDA] may lose its status as the world’s pre-eminent drug regulatory body”). Pursuant to one bill, FDA approval would be mandated when a drug offers significant improvement over other approved products and has been approved by the EMEA or the national U.K. authority and the U.S. fails to meet a statutory deadline. See S. 1477, 104th Cong. § 404 (1995).

<sup>176</sup> See *FDA Reform*, *supra* note 51, at 2018-19.

<sup>177</sup> See *id.* at 2017 (“[C]ollaboration and even ‘competition’ with a counterpart government agency in Europe might render the FDA more responsive to popular demand for beneficial therapies while maintaining its role as a guarantor of safety.”).

<sup>178</sup> See *id.* at 2014-15.

<sup>179</sup> *Id.* (discussing research findings of the Center for the Study of Drug Development at Tufts University); see Bent & Booth, *supra* note 18, at C1 (“It may take 12 years to bring a single new pharmaceutical to the market, at an average cost of \$359 million.”) (citing Elizabeth M. Rutherford, “The FDA and ‘Privatization’—The Drug Approval Process,” 50 *FOOD & DRUG L.J.* 203 n.2 (1995)).

<sup>180</sup> See *supra* notes 106-07 and accompanying text.

such as the U.K.'s thalidomide experience,<sup>181</sup> the FDA's authority now is being checked by public excitement over the prospects of biotechnology.<sup>182</sup> FDA supporters may further contend that the "cultural icon"<sup>183</sup> status of DNA and shortsightedness already put enough public and political pressure on the FDA and EMEA.<sup>184</sup> An international race to review and approve a multitude of biomolecular technologies generated by astonishing advances in biomolecular science, it might be added, could potentially endanger the very public that the FDA and EMEA are obligated to protect.<sup>185</sup>

Ultimately, the review and market approval of health care technology should not be unduly burdensome nor a domestic matter subject to undue pressure from shortsighted political, industrial, and public influences. The mission of *both* the FDA and EMEA is to assure quality and safety, and to protect consumers made especially desperate and vulnerable by illness.<sup>186</sup> In light of the new

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<sup>181</sup> See *FDA Reform*, *supra* note 51, at 2012; ABRAHAM, *supra* note 49, at 62-63, 66, 82. Prior to 1962, the FDA assessed only the safety of new drugs; their effectiveness was not considered. All of this changed with the discovery in 1961 by doctors in Europe that thalidomide, widely prescribed to combat morning sickness, was responsible for a significant number of birth defects. See *FDA Reform*, *supra* note 51, at 2012. The enactment of drug reform legislation followed. See *id.* (citing PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 123 (1980)).

<sup>182</sup> The public is demanding access to the technology they have been reading about. As recognized by Professor Annas, "[t]he gene has become more than a piece of information; it has become 'a cultural icon, a symbol, almost a magical force.'" George J. Annas, *Genetic Prophecy and Genetic Privacy*, TRIAL, Jan. 1996, at 19, 24-25 (quoting DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* 2 (1995)); see Richard Saltus, *Sounding the Alarm*, BOSTON GLOBE MAG., May 26, 1996, at 14, available in 1996 WL 6862982 ("No longer merely a scientific schematic, it is now a staple of pop culture. It appears time and again in op-ed pieces, newspaper and magazine articles, and books that tackle the thorny dilemmas of the genetic revolution."). Dr. Richard C. Lewontin, a Harvard scientist and affiliate of the Council for Responsible Genetics, is critical of present priorities in gene research and has coined the term "genomania," meaning "the idea that almost everything—a baby's chin or nose, someone's personality quirks, or a preponderance of men in positions of power—can be explained by genes." *Id.* at 30-31. But see Richard Saltus, *Early Alzheimer's: Do You Want to Know?*, BOSTON GLOBE, July 3, 1995, at 39 ("Recently developed gene tests for Huntington's disease and for inherited predispositions to breast cancer and other cancers have raised this issue for an increasing number of families. If any conclusion can be drawn thus far, it's that people are more hesitant and ambivalent about learning their genetic destiny than anyone expected.").

<sup>183</sup> Annas, *supra* note 182, at 25.

<sup>184</sup> See Malinowski & O'Rourke, *supra* note 1, at 210.

<sup>185</sup> The concern "is that adoption of international standards will inevitably lead to a weakening of U.S. standards, and perhaps even lead to a 'race to the bottom,' in which the FDA and EMEA compete to mollify domestic criticism or favor local manufacturers." Bent & Booth, *supra* note 18, at C3 (quoting *FDA Reform*, *supra* note 51, at 2024).

<sup>186</sup> See *FDA Reform*, *supra* note 51, at 2010, 2018. As observed by Professor Paul Starr, "[t]he very circumstances of sickness promote acceptance of [physicians'] judgment." PAUL

constraints being placed upon many providers under managed care, it is less prudent now than in the past to rely upon providers to protect consumers.<sup>187</sup> Although they should not be isolated from public and political pressures, the FDA and EMEA must not be thrown to these influences and reduced from consumer protection agencies to mechanisms primarily for domestic economic prosperity.

The products at issue include unprecedented diagnostics and therapeutics for cancers, AIDS, and other causes of immense human suffering. Accordingly, they necessitate efficient review, and the biotechnology industry innately carries a significant amount of influence.<sup>188</sup> Assuming reasonable agency accountability is effected through dissemination of accurate information to the public,<sup>189</sup>

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STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 5 (1982).

<sup>187</sup> See *FDA Reform*, *supra* note 51, at 2010 (“[P]hysicians and, increasingly, managed-care insurers are often in tension with the FDA over who is best placed to make particularized judgments about a drug’s safety and effectiveness. Although the FDA rigorously scrutinizes all new drugs before approval, the agency allows doctors wide latitude to prescribe drugs approved for one particular use in unapproved (‘unlabeled’) ways to treat other conditions.”). It is interesting to note that, “[f]or most of the FDA’s history, the agency was charged only with screening out unsafe drugs; determinations of efficacy in prescription drugs were left to prescribing physicians.” *Id.* at 2019 (citing Peter B. Hutt, *The Regulation of Pharmaceutical Products in the USA*, in *PHARMACEUTICAL MEDICINE* 211, 217 (Denis M. Burley et al. eds., 2 ed. 1994)). See also PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 123, 127-28 (1980) (stating that doctors prescribe drugs based on the “customs of the medical community,” rather than their “therapeutic effect”); *New Era*, *supra* note 9, at 351 (noting that physicians who belong to managed care networks feel pressure to “cut corners or . . . delay or omit diagnostic tests or therapeutic procedures”) (quoting Orentlicher, *supra* note 146, at 158).

<sup>188</sup> See TEMIN, *supra* note 187, at 55. Historically drug manufacturers have “had to fight for their gains. To curb the FDA’s power to classify drugs, [they] had to enter into explicit negotiations. Their success in these negotiations is hardly surprising.” *Id.*

<sup>189</sup> The FDA’s authority to regulate advertising of health care technologies has not and cannot stop researchers from informing the public about their genetic discoveries nor the general media from reporting on these highly newsworthy advances. See *supra* note 182 (citing media sources reporting and commenting on the so-called “genetic revolution”). Although advertising *laissez faire* is a troubling proposition, according to some accounts, FDA officials have all the power and discretion they need, and this discretion is enhanced by the ambiguity of the regulations they enforce. See, e.g., James G. Dickinson, *Will Anybody Sue FDA?*, *MED. MARKETING & MEDIA*, Oct. 1, 1993, at 100, 101 (“The Food, Drug and Cosmetic Act’s failure to address pharmaceutical marketing activities that are neither ‘advertisements’ nor ‘labeling’ created the gray zone in which both industry and FDA take liberties. Congress simply failed to foresee the innovations that modern communication technologies could spawn.”). As explained by Dr. Dickinson,

[a]dvertising alone is defined as ‘commercial speech’ and is thus subject to less First Amendment protection than labeling or non-commercial speech. But FDA has been able to tie advertising’s statutory dependence on the content of approved labeling to a broad array of ‘labeling’ materials in such a way that companies have no freedom of speech rights when it comes to advertising prescription drugs, compared to the way in which those rights are commonly understood and interpreted by the courts for other industries.

ongoing public demand for health care technology should keep the EMEA and FDA in check.<sup>190</sup> The alliance nature of the biotech industry and privatization of health care R&D are additional assurances that these agencies will not become distant, independent, and nonresponsive.<sup>191</sup> In fact, the alliance nature of the biotechnology industry may have weakened the FDA's most important resource for legitimizing tough and controversial decisions.<sup>192</sup> Historically, the FDA has relied upon the top echelon of medical academia to justify its controversial stances with industry.<sup>193</sup> Now, however, influential non-profit research centers, academic institutions, and the world's top biomedical scientists all have a direct and meaningful stake in the success of the biotechnology

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*Id.* at 102 (quoting BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (Richard T. Kaplar ed. 1993)). Dr. Dickinson alleges that “[b]ecause FDA has excessive coercive power in its ability to approve an advertiser’s products for market, and Congress has shown no interest in balancing FDA’s First Amendment incursions, the regulation of drug advertising and promotion should be handed over to the Federal Trade Commission.” *Id.* at 103-04. Dr. Dickinson contends that the FDA’s definition of “deception” is “the basis for the mischief created by the FDA’s regulation of advertising.” *Id.* (quoting BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (Richard T. Kaplar ed. 1993)). Dickinson noted that “[t]he [FDA] says ads or promotional materials are deceptive unless they contain ‘fair balance.’” *Id.* (quoting BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (Richard T. Kaplar ed. 1993)). In practice, according to Dr. Dickinson, “any message promoting some pharmaceutical must also present virtually all negative information about the product. . . .” *Id.* (quoting BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (Richard T. Kaplar ed. 1993)). Dickinson sets forth the following proposals for reform:

FDA should (1) cancel all recent initiatives restricting promotion of off-label uses; (2) allow manufacturers to advertise any reasonable claim for which reliable scientific evidence exists; (3) abolish the ‘brief summary’ requirement for consumer advertising; and (4) allow unrestricted advertising of drugs, subject only to regulation for ‘falsity’ but not for ‘deception’ as currently defined.

*Id.* (citing BAD PRESCRIPTION FOR THE FIRST AMENDMENT: FDA CENSORSHIP OF DRUG ADVERTISING AND PROMOTION (Richard T. Kaplar ed. 1993)). Nevertheless, there also is evidence that hyping of health care product features by their manufacturers is a pervasive problem:

So endemic is the practice of hyping product features the facts clearly don’t support that FDA deputy commissioner Mary K. Pendergast, speaking in October 1994 before the House Subcommittee on Regulation, Business Opportunities, and Technology, was moved to uncharacteristically straightforward language. “Promotion of unapproved uses by company sales representatives,” she stated, “is a major problem.”

Greg Critser, *Oh, How Happy We Will Be: Pills, Paradise, and the Profits of the Drug Companies*, HARPER’S MAG., June 1996, at 39, 47.

<sup>190</sup> See *FDA Reform*, *supra* note 51, at 2024.

<sup>191</sup> See *id.* at 2010.

<sup>192</sup> See *id.* at 2014-15.

<sup>193</sup> See *id.* at 2016.



industry due to the privatization of medical R&D and the alliance nature of the industry.<sup>194</sup>

Ideally, domestic pressures and international competition will bring the resources of the EMEA and FDA together to maximize the speed and quality of their review.<sup>195</sup> This may already be happening, for the U.S., Japan, and the E.U. (even prior to the founding of the EMEA) have been working to harmonize their respective requirements for new drug research and applications:

The EU, Japan, and the United States, which together account for most of the world's drug consumption, participated in the International Conferences on Harmonization in 1991 and 1993. These conferences examined regulatory differences between the three blocs and began to draft international guidelines on procedure, quality, safety, and efficacy to be incorporated into each country's legal scheme because pharmaceutical industry and government regulators agree that harmonization of drug authorization is necessary.<sup>196</sup>

"The fundamental goals of the ICH are to reduce the costs associated with gaining regulatory approval . . . and to increase patient access to new drugs. . . . The FDA has [actively participated] in the harmonization process,"<sup>197</sup> and the establishment of the EMEA

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<sup>194</sup> See *supra* notes 21-22. See generally Malinowski & O'Rourke, *supra* note 1 (discussing numerous examples of scientists from public and private universities, as well as the universities themselves, entering into joint ventures with genotech firms).

<sup>196</sup> The presence of the EMEA, which now oversees the world's largest integrated pharmaceutical market, should be enough to compel FDA collaboration. See Eric M. Katz, *Europe's Centralized New Drug Procedures: Is the United States Prepared to Keep Pace?*, 48 FOOD & DRUG L.J. 577, 578-79 (1993). "The existence of this huge integrated market threatens to undermine the FDA's position of regulatory leadership, and U.S. patients ultimately may suffer from an even greater 'drug lag' if [the U.S. market becomes a secondary priority and] pharmaceutical manufacturers tailor their clinical research and new drug applications to satisfy EMEA standards." *FDA Reform*, *supra* note 51, at 2021.

<sup>196</sup> Cavalier, *supra* note 51, at 466 (citations omitted); see Bent & Booth, *supra* note 18, at C1, C3-C4. A comparison of the drug review and approval processes of the U.S., Europe, and Japan is presented in Rosemarie Kanusky, Comment, *Pharmaceutical Harmonization: Standardizing Regulations Among the United States, the European Economic Community, and Japan*, 16 HOUS. J. INT'L L. 665 (1994).

<sup>197</sup> Bent & Booth, *supra* note 18, at C1, C3 (citation omitted). The ICH process consists of five steps: (1) the expert working group "forwards a consensus draft of a guideline . . . to the steering committee"; (2) "the steering committee transmits the draft to the [U.S., U.K., and Japanese] regulatory agencies for formal consultation"; (3) "a designated rapporteur amends the draft document to [incorporate] comments"; (4) "the final draft is endorsed by the steering committee"; and (5) the final document is implemented domestically by the members. *Id.* at C1, C3.

should ensure future participation.<sup>198</sup> Also, the FDA has entered into several memoranda of understanding with foreign regulatory bodies regarding the monitoring and inspection of foreign data<sup>199</sup> and, in some instances, the FDA is permitting approval of drugs based solely on foreign clinical data.<sup>200</sup> “More recently, the EMEA has stated that it will continue to explore the development of harmonization and mutual recognition programs with the United States and Japan.”<sup>201</sup>

Collaboration and standardization of product review and approval could further join the U.S. and E.U. industries, thereby enabling market forces to work more effectively on a global level.<sup>202</sup> First, if a single, carefully designed clinical trial (accompanied by necessary post-marketing checks) could result in approval on the major world markets, at least theoretically, the costs of the resulting products would be lower and more resources would be made available for R&D.<sup>203</sup> Second, eliminating barriers between markets could make it economically feasible to manufacture drugs otherwise designated orphan drugs.<sup>204</sup> Third, a more unified world market may be the best way to distribute the philanthropy of the multinational pharmaceutical companies which, though sporadic, has been substantial

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<sup>198</sup> “The agency to date has published 39 notices concerning various topics addressed by the ICH, as well as three notices concerning related harmonization efforts.” Bent & Booth, *supra* note 18, at C3 n.12 (citing 60 Fed. Reg. 53078 (1995) (Policy on Standards); 60 Fed. Reg. 31485 (1995) (International Memorandum of Understanding, New Compliance Policy Guide); 60 Fed. Reg. 25920 (1995) (Viral Testing)). FDA Commissioner Kessler has stated that biotechnology drugs may be a means to harmonize regulations since their novelty sets them apart. *See id.* at C3 n.10 (citing Keynote Address by Commissioner David A. Kessler, M.D. at the Proceedings of the Second International Conference on Harmonisation (Orlando, Fla. 1993)).

<sup>199</sup> *See* Philip B. White, *International Memoranda of Understanding on Inspections*, 49 FOOD & DRUG L.J. 171, 171 (1994) (stating, however, that these memoranda have been problematic in practice).

<sup>200</sup> *See, e.g.*, Food and Drugs, 21 C.F.R. § 314.106 (1995) (explaining the requirements of foreign data as the sole basis for marketing approval).

<sup>201</sup> *FDA Reform*, *supra* note 51, at 2021; White, *supra* note 199, at 171 (stating that “[m]utual agreements with other countries in the area of GMPs [international good manufacturing practices] are an important priority for . . . the FDA”); *see* Reguly, *supra* note 51, at 1 (“In time, [the EMEA] may even emerge as part of a super-regulator, linked with the FDA and Japan to create an international agency that would allow pharmaceuticals groups to clear medicines in three of the world’s biggest markets in one go.”).

<sup>202</sup> *See* Cavalier, *supra* note 51, at 447.

<sup>203</sup> *See id.*

<sup>204</sup> To be designated an orphan drug means that the anticipated consumer market for the drug is too small to justify production without market exclusivity under programs such as the U.S. Orphan Drug Act. *See* Orphan Drug Amendments of 1988, 21 U.S.C. §§ 360aa, 360bb, 360ee (1988); 42 U.S.C. § 236 (1988). *See generally* Cavalier, *supra* note 51 (discussing the history of the Orphan Drug Acts in the U.S., Japan, and Europe).

in recent years.<sup>205</sup> This possibility is underscored by the fact that pharmaceutical corporations also are joining the U.S. and the U.K. biotech industries by entering into multiple alliances with biotech counterparts on both sides of the Atlantic.<sup>206</sup> Fourth, collaboration for review and approval also could result in uniform standards for labeling and patient information.<sup>207</sup> This already has been achieved to some extent in the E.U.<sup>208</sup>

More generally, mutually beneficial alliance formation between the U.S. and the U.K. biotech industries already is apparent.<sup>209</sup> Greater market unification and alliance freedom on a multinational level should maximize intellectual and financial resources.<sup>210</sup> The rationale is that expanded cooperation eliminates duplicative research and, therefore, better concentrates the energies of research-

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<sup>205</sup> See, e.g., Luther Turmelle, *Merck & Co., Paul Newman Win Humanitarian Awards*, COURIER NEWS, Apr. 23, 1993, at 1, available in 1993 WL 3181546 ("Merck and its philanthropic arm, the Merck Company Foundation, have donated more than \$153.4 million in cash and products between 1990 and 1992."); *Company to Give Medicine to Uninsured Poor*, N.Y. TIMES, Aug. 15, 1993, § 1, at 1, available in 1993 WL 2111517 ("Pfizer Inc. announced on Aug. 14, 1993 that it would offer 11 of its products free to community health centers that provide medical care to poor patients who have no health insurance. The company estimated the program would cost \$10 million to \$12 million in its first year.").

<sup>206</sup> See Cavalier, *supra* note 51, at 458 ("[V]irtually all pharmaceutical companies have indigent patient programs that provide free drug therapy to those who specify in writing that the drug will not be reimbursed by Medicaid or insurance.").

<sup>207</sup> See Eyckmans, *supra* note 29, at 36.

<sup>208</sup> Specifically, back in March 1992,

the [E.U.] Commission adopted rules to standardize labeling and harmonize the requirements for patient information. These rules spell out the information that must be included on the product's packaging and in the—now compulsory—patient leaflet. This information must be provided "in clear and understandable terms" and in the official languages of the member states where it is marketed.

*Id.*

<sup>209</sup> British pharmaceutical companies also merge with U.S. firms to take advantage of their advanced technologies, and vice versa. The desire for computer-designed molecules led Glaxo plc to purchase Affymax for \$533 million in January, 1995, and led to Oxford Molecular's agreement to purchase CAChe Scientific, Inc. earlier that month. See *Start-ups*, *supra* note 34, at 372. The computer technology offered by the U.S. firms allowed pharmaceutical researchers to use "computer-designed molecules, rather than those produced through chemical experimentation, as the basis of a new generation of drugs." *Id.* Also, several smaller British start-up biotech ventures have merged with U.S. firms to take advantage of U.S. venture capital. See *Barriers*, *supra* note 31, at 572. For example, Scotgen Biopharmaceuticals, Inc., the result of a merger between Scotland-based Scotgen and California's Vasacor, Inc., was able to raise \$7 million in capital from U.S. investors for use in clinical trials. See *id.*

<sup>210</sup> See Manning Gilbert Warren III, *Global Harmonization of Securities Law: The Achievements of the European Communities*, 31 HARV. INT'L L.J. 185, 225 (1990) (stating that when markets combine, cost of capital decreases resulting in an increase of financial resources).

ers and the funds that support them on specific R&D projects.<sup>211</sup> Furthermore, unifying the world markets to better enable the most suitable allies to find each other can only help to stabilize investor interest<sup>212</sup> and improve science and product applications.<sup>213</sup> This already is happening within the E.U. "Certainly, the statistics suggest that E.C. firms are actively seeking new sources of competitive strength in domestic and international markets and are more willing than in the past to conclude alliances that promise an infusion of international capital and new ideas."<sup>214</sup>

There should be two overarching objectives to the review and regulation of biotechnology products—realizing the most economical use of human and other resources and expediting patient access to beneficial products without compromising safety. Many of the products at issue in the biotech sector provide the means to alleviate tremendous human suffering, and the importance of realizing such an improvement to public health certainly is as global as the challenges accompanying the commercialization of biotechnology.

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<sup>211</sup> See Joseph G. Contrera, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious will International Pharmaceutical Relations Become?*, 8 ADMIN. L.J. AM. U. 927, 957 (1995) (stating that harmonization will allow countries to spend their money more productively and avoid costly duplicative research and development).

<sup>212</sup> See *Barriers*, *supra* note 31, at 572. For the U.K., alliances with more mature U.S. counterparts could help to stabilize investment appeal while its biotech industry moves through the extremely volatile no-products-on-market stage. See *id.*

<sup>213</sup> U.S. antitrust policy is supportive of cooperation for research endeavors. See Cooperative Research Act, 15 U.S.C. §§ 4301-02 (1994); U.S. DEPT OF JUSTICE ANTITRUST ENFORCEMENT GUIDELINES FOR INTERNATIONAL OPERATIONS (1988), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,109. IEL, the strength of which rests in collaboration, is also an approach to overcome the limitations of domestic antitrust policy meaning, among other things, the doctrine of comity and the act-of-state doctrine. See 1 PHILLIP AREEDA & DONALD F. TURNER, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 239, at 271-76 (1978 & Supp. 1996) (discussing American antitrust policy towards foreign restraints on U.S. Commerce). Collaboration between the FDA and EMEA should include enforcement of antitrust principles to prevent industry over-consolidation orchestrated by the multinational pharmaceutical industry. Also, national industry influence over both the FDA and its European counterparts, fostered by the incestuous nature of the science community, has given credence to a theory that these agencies have, to some extent, been "captured" by industry. See ABRAHAM, *supra* note 49, at 22-23 (stating that "a regulatory commission . . . [i]nitially . . . tends to be aggressive and adversarial towards its regulatees, but . . . [e]ventually it is progressively 'captured' by, and comes to share the perspectives of, the regulated industry"). The danger that such influence could be used to exploit access to world markets must be offset by maintaining checks and balances between the FDA and EMEA despite collaboration to eliminate duplication and establish uniform, scientifically reliable standards. See AREEDA & TURNER, *supra*.

<sup>214</sup> Paul J. De Rosa, *Cooperative Joint Ventures in European Community Competition Law*, 41 BUFF. L. REV. 993, 1044 (1993).

The removal of unnatural barriers between the markets, made accessible through FDA and EMEA collaboration, would bring both the U.S. and the U.K. closer to realizing the full public health potential of biotechnology.

### B. Health Care Finance Proposal

The spread of managed care in the U.S. suggests at least some recognition by public health officials that the law of economics governing consumer goods, such as food, shelter, and transportation, applies to health care.<sup>215</sup> In fact, because health care is part of the commercial sector (the largest industrial sector in the U.S.), the law of economics is a means to maximize the allocation of health care resources and improve public health.<sup>216</sup> Similarly, fundamental differences between the U.S. and the U.K. health care systems make comparative law useful for identifying the relatively beneficial and detrimental features of each system. As discussed in Part II of this Article, the inundation of health care capabilities from advances in biotechnology, absent a parallel increase in the resources allocated to health care, will make care rationing<sup>217</sup> and tragic choices more prevalent in both the U.S. and the U.K.<sup>218</sup> As suggested above,

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<sup>215</sup> See ORIENT, *supra* note 148, at 151-59; *New Era*, *supra* note 9, at 360 (proposing “numerous reforms and uses of legal and regulatory mechanisms to promote socially responsible allocation of health care resource and to ensure that capitation does not result in substandard care”).

<sup>216</sup> See David L. Kaserman, *Reimbursement Rates and Quality of Care in the Dialysis Industry: A Policy Discussion*, 8 ISSUES LAW & MED. 81, 97-99 (1992-93). “[H]ealth care markets are not exempt from the laws of economics. The sooner public policy begins to recognize this fact, the sooner we can begin to resolve these problems through more sensible regulatory approaches.” *Id.* at 99. See ORIENT, *supra* note 148, at 173-85 (stating that guidelines are necessary to contain costs and to ensure quality). For discussion of the size and growth of the U.S. health care industry, see ROSS PEROT, *INTENSIVE CARE* (1995).

<sup>217</sup> Presently in the U.S., there is a call for universal coverage accompanied by recognition of the need for graduated care—as made evident by a recent survey of health policy specialists. See Peter J. Howe, *Poll: Health Care Will be a Key Election Issue*, BOSTON GLOBE, July 15, 1996, at A5. While 83% of those surveyed said that the country should strive to provide universal health coverage and 62% said they want universal coverage by the year 2000, only 27% supported equal access to the same quality of care regardless of ability to pay. See *id.*

<sup>218</sup> See *supra* Part III.B (discussing the increased costs associated with new advances in medical technology). Excluding elective procedures, virtually all cost containment measures in the field of medicine decrease quality of care for individuals and increase mortality rates. See Kaserman, *supra* note 216, at 82 (“Indeed, such trade-offs are inescapable in a world of limited resources.”). This resource dilemma associated with advances in medical technology is vividly illustrated by new “cocktail” AIDS therapies, which involve the combination of a series of drugs. See Richard A. Knox, *AIDS Remedies Give Little Hope to World’s Poor*, BOSTON GLOBE, July 14, 1996, at 1, available in 1996 WL 6869331 [hereinafter *Little Hope*] (“The gap

IEL is an especially useful approach to this problem, for the challenge is shared by the U.S. and the U.K. and arises out of globalized science and industry sectors.<sup>219</sup>

The myriad of biotechnology capabilities now reaching commerce cannot be made sufficiently available to maximize improvements to public health without cost-benefit analysis.<sup>220</sup> “Theoretically, there is an efficiency frontier or lower boundary that, given current technology, traces out a locus of minimum expenditures for a given number of deaths or a minimum number of deaths for a given expenditure.”<sup>221</sup> Finding the balance between per-patient resource allocation and quality requires an intensive inquiry and sizable transaction cost (meaning the consumption of considerable resources) regardless of the particular features of the health care system.<sup>222</sup>

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between the world’s haves and have-nots widened with each report about the new therapies, which hold the virus in check with from two to four costly drugs.”). This therapy proved so effective in clinical trials that the study was concluded prematurely on the grounds that “patients on experimental therapy were doing so much better that it became unethical to withhold it from other study subjects.” Richard A. Knox, *Success of a New AIDS Treatment Brings Study to Early End*, BOSTON GLOBE, July 24, 1996, at A3, available in 1996 WL 6870599. The “[t]riple-drug treatment can cost \$20,000 a year and more, plus the expense of regular blood tests at \$150 to \$250 apiece.” Richard A. Knox, *Successes Offer Hope on AIDS*, BOSTON GLOBE, July 7, 1996, at 1, available in 1996 WL 6868464 [hereinafter *Successes Offer Hope*]; see Brian MacQuarrie, *Treatments for AIDS Met by Hope, Wariness*, BOSTON GLOBE, July 15, 1996, at B1 (“The high cost of the treatment, estimated to be as much as \$20,000 annually per person, concerns physicians and gay activists who question whether the public will be willing to help foot the bill for such expensive therapy.”). Presently, “no more than 10 percent of the estimated 600,000 to 900,000 Americans with HIV infections are now on aggressive treatment, raising a question of whether society will be willing to spend the billions of dollars it would take to carry out the new treatment guidelines.” *Successes Offer Hope*, *supra*, at 1. “Already, questions are being raised about who should be treated and when, and about the multibillion-dollar potential cost of making the new drug therapies widely available.” *Id.* In the “new world” of managed care, “[h]eaven help your bottom line if during your contract year a new drug or expensive laboratory test is approved, as you will have to absorb this by a reduced income or by delivering fewer services than you had planned to other patients.” *Little Hope*, *supra*, at 1 (quoting Dr. Paul Volberding of San Francisco General Hospital). See generally CALABRESI & BOBBITT, *supra* note 13 (discussing the difficulty that cultures around the world must endure due to the scarcity of resources).

<sup>219</sup> See *supra* notes 162-63 and accompanying text.

<sup>220</sup> See Kaserman, *supra* note 216, at 82.

<sup>221</sup> *Id.*

<sup>222</sup> For example, based upon one case study, the considerations to make an optimal reimbursement and regulatory assessment regarding dialysis for end-stage renal disease (ESRD) include:

- (1) the rate at which clinics are willing to . . . preserve treatment quality[;]
- (2) the costs of specifying and enforcing quality standards . . . [;]
- (3) the ability of patients to enforce . . . liability rules . . . [;]
- (4) the potential for improving patient information . . . [;]
- (5) the effect on entry, capacity expansion, and quality of a rule prohibiting physician ownership of dialysis clinics[;]
- (6) the feasibility of tying reimbursement rates to treatment

This is attributable to the need for substantial input from experts and consumers with varying perspectives, the premium on accuracy necessitated by the emotionally charged nature of allocating health care resources, and the fact that the outcomes will constitute a basis for denying treatment. Also, reliable quality assessment focuses on outcomes and involves thoughtful inquiries made in an intelligent manner, which necessitates compilation and interpretation of considerable follow-up data.<sup>223</sup>

The U.S. health care system, a "prepaid system for consumption,"<sup>224</sup> is particularly ill-suited for such determinations—as has been made apparent by the legal, professional, and social resistance to the Oregon plan<sup>225</sup> and the performance of the U.S. health care system in comparison to the systems of other in-

duration[;] and (7) society's willingness [or unwillingness] to devote additional resources to the ESRD program.

*Id.* at 95. The high transaction costs of quality and cost-benefit analysis are exemplified by the recognized evidentiary difficulties associated with efficiency analysis in the context of antitrust law:

These evidentiary problems led then-Professors Posner and Bork, the two most influential exponents of the Chicago School's efficiency-based antitrust analysis, to argue against recognizing any kind of an efficiencies defense. Although the two share the view that mergers are generally efficiency-enhancing, they have argued against an efficiencies defense out of a belief that courts lack the tools to measure efficiencies and gauge their effect on prices against the countervailing anticompetitive propensities of a merger.

Joseph Kattan, Comment, *Efficiencies and Merger Analysis*, 62 ANTITRUST L.J. 513, 520 (1993-94); see RICHARD A. POSNER, ANTITRUST LAW: AN ECONOMIC PERSPECTIVE 112 (1976) (noting that "the measurement of efficiency [is] an intractable subject for litigation"); ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 126 (1978) (noting that it is "the productive efficiency factor that renders the problem utterly insoluble").

<sup>223</sup> For more health care cost-effectiveness materials and citations to other sources, see generally, NEW ENGLAND REGIONAL GENETICS GROUP, COST-BENEFIT/COST-EFFECTIVENESS ANALYSES IN GENETICS, Mar. 30, 1996 (These materials were distributed during a conference held at the Whitehead Institute for Biomolecular Research in Cambridge, MA and are on-file with the author.).

<sup>224</sup> ORIENT, *supra* note 148, at 237-45 (arguing that insurance is for catastrophes, and that, rather than insurance, the U.S. has a "prepaid, tax subsidized plan[] for the use of medical services").

<sup>225</sup> These impediments were explained by Dr. Michael Garland in his presentation, Role of Economics in Setting Health Practices and Priorities: The Oregon Plan, at the Cost-Benefit/Cost-Effectiveness Analysis in Genetics conference sponsored by the Social and Ethical Concerns Committee of the New England Regional Genetics Group. See NEW ENGLAND REGIONAL GENETICS GROUP, *supra* note 223 (transcript on file with author). The legal prohibition to quality of life considerations according to the HCFA's interpretation of the Americans with Disabilities Act (ADA), 42 U.S.C. §§ 12112-12113 (1994), is discussed in *New Era*, *supra* note 9, at 339-40 & n.64. For comparison, consider that the U.K. and Canada have acknowledged the need to engage in cost assessment. See generally ORIENT, *supra* note 148 (highlighting some pros and cons of both the British and Canadian system of socialized medicine).

dustrialized countries.<sup>226</sup> One of the significant differences between the U.S. and the U.K. health care systems is that, for decades, U.S. health care providers have been both patient advocates for care without concern for costs and private practice entrepreneurs.<sup>227</sup> Although entrepreneurialism generally has a positive impact on quality and efficiency, it has not had this effect in a prepaid health care system that lacks specific quality requirements and compensates physicians according to the amount of health care resources they expend. When physicians have personally invested in specialized training and medical technology for advanced procedures, too often there have been conflicts of interest on the part of physicians that have encouraged the wasteful expenditure of society's health care resources.<sup>228</sup> In some instances, despite the tremendous consumption of health care resources in the U.S., perverse rate-setting incentives and the absence of firm quality of care standards have

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<sup>226</sup> See White, *supra* note 149, at 34 ("Every other industrialized nation guarantees a high standard of care to virtually every citizen, at much lower cost than that of the U.S. system.").

<sup>227</sup> See *New Era*, *supra* note 9, at 334-47. It is important to note, however, that managed care is bringing about tremendous change in the U.S., including consolidation within the health care industry and the buyout of private physician practices. See Phillip R. Kletke et al., *Current Trends in Physicians' Practice Arrangements: From Owners to Employees*, 276 *JAMA* 555, 555 (1996) (reporting that "[b]etween 1983 and 1994, the proportion of patient care physicians practicing as employees rose from 24.2% to 42.3% . . . , the proportion self-employed in solo practices fell from 40.5% to 29.3% . . . , and the proportion self-employed in group practices fell from 35.3% to 28.4%").

<sup>228</sup> The impact of perverse incentives on the U.S. health care system have been illustrated through a case study addressing end-stage renal disease (ESRD). See Kaserman, *supra* note 216, at 85-86. Reimbursement levels for ESRD fell approximately 64% during the 1980s and early 1990s. See *id.* at 82. The case study made evident that these savings were attributable primarily to shortening the duration of patients' ESRD dialysis running times. See *id.* This lowers costs by allowing "existing machines [to] be used more intensively" and "labor costs per treatment [are] reduced commensurately." *Id.* at 83. Under a "fixed price per treatment" payment scheme, ESRD "clinics' profits are unambiguously increased with reduced treatment times." *Id.* at 83-84. However, "[e]mpirical evidence suggests that lower treatment duration causes increased mortality among dialysis patients." *Id.* at 84 (citing Philip J. Held et al., *Mortality and Duration of Hemodialysis Treatment*, 265 *JAMA* 871 (1991)). "Therefore, a definite trade-off exists between profitability and quality of care in the dialysis industry." *Id.* The conclusion reached by Kaserman was that "there is strong evidence to suggest that the cost savings attributable to reduced reimbursement rates are being gained at the expense of patients' lives." *Id.* at 82. It is important to note, however, that this case study was based upon data gathered in the 1980s and early 1990s. This was prior to the advent of widespread managed care, and at a time when a "substantial portion of dialysis clinics [were] owned by the physicians that [ran] them." *Id.* at 84. "These physicians/owners controll[ed] patients' [dialysis] running times through the treatment prescriptions they [wrote]." *Id.* Under capitation, however, physician compensation (as well as their very employment by a managed care system) still may be tied to profitability. See *New Era*, *supra* note 9, at 348.



resulted in sub-standard treatment.<sup>229</sup> In addition, there is remarkable inconsistency in both treatment and coverage, especially for state-of-the-art medical technologies.<sup>230</sup> In contrast, U.K. providers are civil servants employed by the NHS.<sup>231</sup> Like members of the U.S. judiciary, who have a professional obligation to the parties before them as well as to the judiciary itself, physicians in the U.K. are professionally obligated to their patients and to the health care system they are a part of.<sup>232</sup>

Just as the U.K. industry may benefit from the U.S. experience in allocating capital and joining the science and industry sectors to build a biotech industry, the U.S. could benefit from the U.K.'s experience in systematically and more honestly allocating health care resources.<sup>233</sup> Although consolidation and managed care are significantly impacting both U.S. health care delivery and regulation,<sup>234</sup> the U.S. system's no-concern-for-costs mentality is

<sup>229</sup> The skewed incentives that arise from the rate-setting aspect of the U.S. health care system have also been addressed in the ESRD case study discussed in note 222. See Kaserman, *supra* note 216, at 85. Kaserman noted that the Health Care Finance Administration's "reimbursement rates are set on the basis of observed (audited) costs." *Id.* Each time the rates were adjusted, the incentive to lower costs would take over. See *id.* When the treatment was audited again, the rate would be lowered. See *id.* "This process of adjustment and readjustment by the clinics and the regulators creates a downward spiral of reimbursement rates and quality of care." *Id.* Kaserman also noted that HFCA's practice of checking entry to the industry to provide the service as an indicator of adequate rate setting is not reliable, for those entering the industry may be offering substandard care. See *id.* at 86. "Consequently, observations on entry—or, for that matter, profitability—cannot be used to make inferences about the financial health of the industry in the absence of quality considerations." *Id.*

<sup>230</sup> The absence of uniform guidelines has resulted in deference to providers, the private insurance sector, and to the courts to determine coverage. See Karen L. Illuzzi Gallinari, *The State of the Law on Insurance Coverage for State of the Art Medical Treatments*, 12 MEALEY'S LITIG. REP.: BAD FAITH 16 (1995) (discussing the use of specific exclusions to deny coverage). See, e.g., William P. Peters & Mark C. Rogers, *Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer*, 330 NEW ENG. J. MED. 473, 476 (1994) (compiling data on decisions of whether or not to provide coverage for Autologous Bone Marrow Transplantation for breast cancer).

<sup>231</sup> See ORIENT, *supra* note 148, at 136-38.

<sup>232</sup> The U.K. physicians' civil servant status may enable them to more objectively and effectively assess the relative quality of advances in medical science and analyze costs and benefits. See *id.*; *New Era*, *supra* note 9, at 340 & nn.67-68.

<sup>233</sup> See ORIENT, *supra* note 148, at 136-38.

<sup>234</sup> See *New Era*, *supra* note 9, at 331 & nn.1-4; Mark Kadzielski et al., *Peer Review and Practice Guidelines Under Health Care Reform*, 16 WHITTIER L. REV. 157, 157-60 (1995) (discussing the need for clinical practice guidelines as a result of the managed care industry's focus upon the cost and effectiveness of health care services provided to patients).

decades old.<sup>235</sup> Relative to the U.K. and many other industrialized nations, the U.S. health care system generally lacks mechanisms for open, honest, and socially and professionally acceptable quality and cost-benefit assessment; rationing is taboo.<sup>236</sup>

While the U.S. health care system is now in a state of change,<sup>237</sup> and before the first full generation of biotechnology products reaches market, U.S. health care policy makers should consider and adopt modifications of the U.K.'s allocation and treatment mechanisms that have been effective. For example, the U.S. should examine the U.K.'s experience and success with treatment-coverage guidelines.<sup>238</sup> First, such an approach takes advantage of the

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<sup>235</sup> See *New Era*, *supra* note 9, at 334-35 (noting that delivery of medical care has proceeded "without concern for costs").

<sup>236</sup> See generally ORIENT, *supra* note 148 (discussing the inefficient practice in the U.S. health care system); DAVID U. HIMMELSTEIN & STEFFIE WOOLHANDLER, *THE NATIONAL HEALTH PROGRAM BOOK* (1994) (promoting a national health program that is comparable to the Canadian system); PEROT, *supra* note 216 (stressing the importance of Medicare and Medicaid for the U.S. health care system).

<sup>237</sup> See *New Era*, *supra* note 9, at 337 (stating that "[t]he advent of widespread managed care," acting in concert with "economic limitations" and "enhanced medical capabilities," has resulted in a "new approach to medical ethics"). See also, e.g., White, *supra* note 149, at 34 (taking note of the federal government's effort to reform and reduce the cost of health care).

<sup>238</sup> See White, *supra* note 149, at 36-39 (referencing the higher reliance on treatment and other guidelines in the health care systems of other industrialized countries); Robert H. Brook, et al., *Health System Reform and Quality*, 276 *JAMA* 476, 476 (1996) ("Physicians should also use tools and guidelines both to coordinate care and to determine what care is to be provided in a population-based, multiprovider managed care system."); Sean Milmo, *European Drug Sales are Up. (Pharmaceuticals '95)*, 248 *CHEMICAL MARKETING REP. SR30* (1995). France, Europe's biggest consumer of medicine, now is attempting to reduce use by "tightening" and "extending prescription guidelines for doctors." *Id.* The U.K. has developed guidelines for everything from standards for good practice to waiting times for outpatient therapy, to the appropriate uses of gene therapy. See *UK Issues Guidelines for Gene Therapy*, *MARKETLETTER*, Sept. 19, 1994; *International Healthcare News*, *BUS. CONF. & MGMT. REP.*, Mar. 1, 1996, at 7 (covering "new [U.K.] guidelines for health professionals on the management of waiting lists"). The use of peer review and guidelines in the U.S. health care system is addressed in *New Era*, *supra* note 9, at 352-53 & n.147; William M. Sage & James M. Jorling, *A World that Won't Stand Still: Enterprise Liability by Private Contract*, 43 *DEPAUL L. REV.* 1007, 1029-30 (1994); Kadzielski, *supra* note 234, at 157-60. At the present time, the U.S. is still experimenting and some efforts are already underway. See, e.g., *ME. REV. STAT. ANN.* tit. 24, §§ 2504-11 (West 1990 & Supp. 1995) (establishing "professional competence committee[s]"). Perhaps the highest-profile federal efforts are the Acute Physiology and Chronic Evaluation system (APACHE), an experiment to standardize diagnosis and treatment through computerization, and the compilation and publication of two volumes of treatment guidelines based primarily on outcomes and effectiveness of research prepared by the Agency for Health Care Policy and Research with assistance from the Institutes of Medicine. See 42 *U.S.C.* §§ 299-299a-1 (1994). There also is precedent for international collaboration in constructing guidelines along the lines of the approach proposed in this Article. See, e.g., C. Patterson & Larry W. Chambers, *Preventative Health Care*, *LANCET*, June 24, 1995, at 1611 (summarizing "clinical preventive health care guidelines [drawn up by expert panels in Canada, the U.S., and U.K.] using an evidence-

opportunity to modify and use practical and effective (meaning *proven* effective through practice) clinical guidelines developed in the U.K. through the expenditure of significant resources.<sup>239</sup> AIDS prevention guidelines are one illustration of how the U.S. may benefit from such an approach.<sup>240</sup> Another example is guidelines for determining when comfort care is more appropriate than aggressive life-extending treatment.<sup>241</sup> Second, comparative analysis could help U.S. public health officials to better understand the incentives and disincentives prevalent in both systems and improve health policy and regulation. Consider that doctors in the U.S. have been much more resistant to implementing prevention guidelines than their contemporaries in the U.K. and Canada.<sup>242</sup> Through IEL analysis, it may be possible to identify the reasons why U.S. physicians resist guidelines by identifying the relevant incentives and disincentives in both systems responsible for the difference in physician receptiveness to guidelines. The understanding resulting from such analysis may enable the U.S. to construct mechanisms that utilize influential incentives to bring about the implementation of guidelines. As a result of such analysis, U.S. policy makers might decide to instill some of the health care professional and social norms from the U.K. system into their U.S. counterparts through changes in medical and public education.

More fundamentally, an IEL approach would enable health care policy makers in both systems to share quality assessment data, and

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based approach . . . with strict attention to the quality of published trials”).

<sup>239</sup> Treatment guidelines have long been a part of the U.K.'s NHS system. Further, NHS is now launching an initiative to introduce more comprehensive quality assessment by, among other things, expanding the input and decision making authority of providers who have the most direct contact with patients—namely nurses and social workers. In other words, NHS hopes to dismantle the current hierarchy and increase the influence of nurses and other providers who have the most contact with patients and their families over guideline drafting. See (BBC Broadcast, July 5, 1996 (aired in London)).

<sup>240</sup> See Richard A. Knox, *Prevention Guide Set for US Doctors*, BOSTON GLOBE, July 7, 1996, at 17, available in 1996 WL 6868362 (reporting that in July 1996, the U.S. adopted guidelines for AIDS prevention that urge doctors to talk to every patient about AIDS risks—guidelines Canada has had since 1988).

<sup>241</sup> The U.K. has extensive experience with openly providing comfort care (also called palliative care) at the end of life, though the concept is new to the U.S. See Franklin G. Miller & Joseph J. Fins, *A Proposal to Restructure Hospital Care for Dying Patients*, 334 NEW ENG. J. MED. 1740, 1740 (1996).

<sup>242</sup> See Knox, *supra* note 240, at 17 (“Dr. Nancy Dickey, chairwoman of the AMA’s board of trustees, said a recent survey indicated that 40 percent of doctors will read prevention guidelines and about one in five of those will modify their examining-room behavior in response.”); HIMMELSTEIN & WOOLHANDLER, *supra* note 236, at 91-119. See generally *New Era*, *supra* note 9 (discussing reasons why health care resources should be rationed).

it would give them the ability to coordinate efforts to compile necessary clinical information to fully assess new technologies. Such an approach, beyond being prudent in the short-run, is a necessary means to maximize resource allocation choices and benefits from the biotechnology products and capabilities that are being commercialized and will continue to enter consumer markets in significant numbers well into the next millennium.

## V. CONCLUSION

Biotechnology holds great promise for improving public health, and the U.S. and the U.K. have much to gain from the success of their biotechnology industries. However, each of these countries also face the daunting complications that accompany the commercialization of biotechnology. This Article has explored the status of the U.S. and the U.K. biotechnology industries and two major regulatory challenges: (1) to review and regulate a multitude of truly innovative genetic diagnostics and therapeutics to maximize public health benefits; and (2) to make the deluge of new health care capabilities available to those likely to benefit from them.

The transnational nature of the biotechnology industry draws the U.S. and the U.K. together—just as the world's science community has been united through HGP. The miraculous advances in biomedical science of recent years could not have been accomplished without collaboration within the science community and between the science and industry sectors. Now the major world markets for pharmaceutical products are moving closer together through the establishment and work of the EMEA and domestic pressures on both the EMEA and the FDA.

This Article has applied IEL to analyze regulatory dilemmas brought about by the commercialization of biotechnology. These are complications that must be confronted by public health officials in both the U.S. and the U.K. The central premise of this Article is that cooperation between the U.S. and the U.K. on the regulatory level will remove unnatural barriers between their national industrial sectors and will maximize the talent and entrepreneurialism of both countries to best meet these challenges. Although the regulatory difficulties brought about by biotechnology may appear overwhelming, one only has to look at what has been accomplished in biomedical research and genetic medicine in recent years to realize that, through collaboration, they are surmountable.