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## INTERNATIONAL ARBITRAGE OF CONTROVERSIAL MEDICAL TECHNOLOGIES: AN INTRODUCTION

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During the 2002-2003 academic year, the Case Western Reserve University Journal of International Law (the “Journal”) and the Frederick K. Cox International Law Center (the “Cox Center”) invited a series of experts to explore the difficulties in global regulation of new bio-medical technologies. We entitled the symposium *International Arbitrage of Controversial Medical Technologies* in order to capture the intersection of two significant developments.

First, we endeavored to investigate the rapid proliferation of bio-medical technologies that create deep moral and ethical dilemmas for lawmakers, e.g., genetic engineering, germ line gene therapy, somatic cell gene therapy, untested, risky pharmaceuticals for terrible illnesses, and even biological weapons, and the diverse national approaches to regulating such activity. Such approaches vary widely: from laissez-faire, market-oriented self-regulation<sup>1</sup> in South Korea;<sup>2</sup> to strong regulation by states (e.g. the United Kingdom and Sweden)<sup>3</sup> that endeavor simultaneously to maximize benefits and minimizing risks;<sup>4</sup> to absolute bans (e.g., in France and Germany) based on the view that some medical technologies (e.g., cloning)

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<sup>1</sup> See generally Arthur Caplan, *If Science Becomes Politicized, Where Do We Go For Truth*, THE PHILADELPHIA INQUIRER, Sept. 23, 2002 (asserting that politicians should not set the standards for new biotechnologies; rather, if policy is needed it should be created by panels that are not accountable to the political party in power).

<sup>2</sup> B.J. Lee, *Cloning College: South Korea's Biomedical Researchers, Unhindered by Politics, Do World-Class Research on the Cheap*, NEWSWEEK INTERNATIONAL, Mar. 1, 2004, available at 2004 WL 65299408.

<sup>3</sup> See Human Reproductive Act of 2001 c. 23 §1 et. seq. (2001) (U.K.) (United Kingdom national law allowing cloning of human embryos for medical and therapeutic purposes); See also *Sweden Backs Research Into Therapeutic Cloning*, AGENCE FRANCE PRESSE, Mar. 25, 2004, available at 2004 WL 74002656 (stating that new law would allow therapeutic research on early stage human embryos, but not on embryos for reproductive research)

<sup>4</sup> See Sarah Kate Templeton, *Clone Ban Will Not Last*, THE SUNDAY HERALD July 28, 2002. at 11.

should be banned for moral or ethical reasons.<sup>5</sup> Absent any overarching global regime, each national community (from England<sup>6</sup> to Australia<sup>7</sup>) must choose a particular approach somewhere along this regulatory spectrum in order to answer the troubling questions posed by each controversial technology.

Second, and in relation to myriad national differences, we wondered whether the decisions of any one national community could be easily circumvented. Bio-medical researchers and enterprises and their activities are not hermetically and unalterably sealed into any one national jurisdiction. The increasingly primed channels of global exchange (commerce, technology, information, finance, migration) make it increasingly easy for those potentially subject to bans or regulations in one place of operation to choose another, more favorable, less constraining venue. The combination of primarily national (and divergent) decision-making and the ease of cross-border transfer give rise to a process of international legal arbitrage.

A concept derived from the context of securities and commodities exchange, legal arbitrage is an emerging concept of scholarly investigation.<sup>8</sup> Arbitrage is "the simultaneous purchase in one market and sale in another of a security or commodity in hope of making a profit on price differences in the differing markets."<sup>9</sup> This allows an investor to make a profit by exploiting the differences in price from one market to another. Legal arbitrage is a variant of the economic practice: those subject to the law of any one national jurisdiction may alter the location of their activities in order to take advantage of the legal difference.

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<sup>5</sup> See George J. Annas, *Human Cloning: A Choice or an Echo?*, 23 U. DAYTON L. REV. 247, 249-250 (1998) (explaining the problem with cloning, by stating, "The danger is that through human cloning we will lose something vital to out humanity, the uniqueness of every human. Cloning a human is also uniquely disturbing because it is the manufacture of a person made to order, it represents the potential loss of individuality and freedom, and symbolizes science's unrestrained quest for mastery over nature for the sake of knowledge, power, and profits.")

<sup>6</sup> Steve Connor, *Cloned Human Embryo in Britain by End of This Year*, THE INDEPENDENT, May 8, 2004, available at 2004 WL 78362376 (reporting that group of researchers at Newcastle University have applied for a license, likely to be approved, to create the first cloned human embryo for the purpose of cloning stem cells).

<sup>7</sup> Deborah Smith, *Stem-Cell Extraction Becomes a Reality*, THE SYDNEY MORNING HERALD, Apr. 17, 2004, available at 2004 WL 74952802 (reporting that Australia has just issued its first license to extract stem cells from excess IVF embryos).

<sup>8</sup> See, e.g., Pamela Samuelson, *Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Relations*, 71 U. CHI. L. REV. 223 (2004); Douglas M. Branson, *The Very Uncertain Prospect of "Global" Convergence in Corporate Governance*, 34 CORNELL INT'L L. J. 321, 358 (2001).

<sup>9</sup> BLACK'S LAW DICTIONARY 95 (5th ed. 1979).

Theoretically, arbitration decisions may be made on the substantive law (or lack thereof) or the strength (or weakness) of the institutions responsible for enforcing it. Furthermore, legal arbitration does not necessarily imply the choice of *weaker* legal regimes—the so-called race to the bottom—for two reasons. First, private researchers or enterprises may choose to operate in an environment that provides greater legal protection, for example, through strong patent law. Second, arbitration decisions are complex; they involve more than one applicable legal regime (e.g., intellectual property, drug regulation, labor and employment law, etc.) and also involve non-legal arbitration decision-making based on the quality of the telecommunications infrastructure, the labor force, the financial system, etc. Finally, the concept of international legal arbitration involves *public* as well as private decision-making. National systems may increasingly make regulatory decisions in anticipation of these private choices.<sup>10</sup> For example, South Korea appears to have provided an attractive environment for labs and researchers who would be under more invasive scrutiny in the U.S. and Europe, where they are “hamstrung by political backlash.”<sup>11</sup> The country has thus attempted strategically to meet the demand for bio-medical research banned in other countries.<sup>12</sup> Seoul National University’s campus is now home to several world-renowned scientists and boasts of the highest in-vitro fertilization success rate in the world.<sup>13</sup>

International legal arbitration may be easier to grasp theoretically than to document empirically. A number of notorious cases, however, invite further attention. For example, in 1996 Pfizer used an experimental drug, Trovan, to treat close to a hundred children with spinal meningitis in Nigeria.<sup>14</sup> The drug had never been tested on children before. Six weeks later, Pfizer left and shortly thereafter, “locals began reporting severe health problems, including death, resulting from their involvement with Pfizer’s research.”<sup>15</sup> Or take the unverified claims that Clonaid researchers helped a Florida woman birth to a cloned child dubbed “Eve.” Rumors that the mother had returned to Florida gave rise to a lawsuit against her, which was

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<sup>10</sup> For a recent exposition of the multiple strategies available to national legal systems to regulate increasingly global activity, see Hiram E. Chodosh, *Globalizing the U.S. Law Curriculum: The Saja Paradigm*, 37 U.C. DAVIS L. REV. 843, 853-859 (2004) (outlining the strategies states may employ to address cross-border arbitration problems, e.g., restrictions on cross-border transfer, extraterritoriality, comparative law reform, public international law, and international institutions).

<sup>11</sup> Lee, *supra* note 2.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> David Carr, *Pfizer’s Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries*, 35 CASE J. INT’L L. 15 (2003).

<sup>15</sup> *Id.*

later dismissed.<sup>16</sup> Clonaid also claimed to have helped a patient from The Netherlands, where cloning is banned. The Dutch patient announced that she had given birth to the second cloned baby on January 4, 2003.<sup>17</sup> Similarly, the emergence of genetic engineering for athletes, "designer babies,"<sup>18</sup> germ line therapy,<sup>19</sup> or new classes of people, coined *Genobility*<sup>20</sup> or *GenRich*<sup>21</sup> each simultaneously raise significant arbitrage opportunities and problems. Strong regulation in one place may push research to more weakly regulated venues, and some countries may seek to take advantage of the arbitrage process.<sup>22</sup> China has persuaded numerous Western-educated scientists "to return to a homeland where research on human embryos is lavishly funded at dozens of laboratories."<sup>23</sup> Singapore recently completed a new biotech complex called "Biopolis" that has attracted a British Nobel laureate, a researcher from the group that cloned Dolly the sheep, and an entire division from the medical school at Johns Hopkins.<sup>24</sup> These are among the many reports of international legal arbitrage of controversial medical technologies that demand greater attention.

With these interests in mind, and with the guidance of Professor Max Mehlman, Director of the school's Law-Medicine Center, the Cox Center and the Journal have committed themselves to continuing this collaborative research. As a first phase in pursuit of this long-term commitment, we invited three world-class experts, Dr. Arthur Caplan,<sup>25</sup> Bartha-Maria

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<sup>16</sup> CNN, *Rael: No DNA test for baby Eve*, Jan. 3, 2003, available at <http://www.cnn.com/2003/HEALTH/01/03/clone.claims/indez.html>.

<sup>17</sup> See Toby Sterling, *Sec Claims It's Clone Another Human*, ASSOCIATED PRESS, available at [http://customwire.ap.org/dynamic/stories/N/NETHERLANDS\\_HUMAN\\_CLONING?SITE=INSHE&SECTION=HOME](http://customwire.ap.org/dynamic/stories/N/NETHERLANDS_HUMAN_CLONING?SITE=INSHE&SECTION=HOME).

<sup>18</sup> See Caroline S. Wagner, *The Weapons of Mass Creation: Are We Ready for Genetically Enhanced 'Designer People'? If So, Who Will Make the Titanic Decisions Involved?*, L.A. TIMES, Feb. 13, 2003, available at 2003 WL 2386264.

<sup>19</sup> Lee Silver, *The God Effect: America's Religious Conservatives Are Not the Only Ones who Object to Science on Spiritual Grounds—so do Europe's Greens. The Big Winner is Asia*, NEWSWEEK INTERNATIONAL, Apr. 5, 2004, available at 2004 WL 65299497. See also George Annas, *Resolved: GLGT Should be Prohibited*, Remarks at the Case Western Reserve University Law-Medicine Center 50<sup>th</sup> Anniversary debate, (Oct. 8, 2003).

<sup>20</sup> Maxwell J. Mehlman, *The Law Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517, 533 (2000).

<sup>21</sup> Silver, *supra* note 19.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Arthur L. Caplan has been the director of the Center for Bioethics and Trustee Professor of Bioethics at the University of Pennsylvania since 1994. He is currently chairman of the Advisory Committee to the Department of Health and Human Services, Centers for Disease Control and Food and Drug Administration on Blood Safety and Availability.

Knoppers,<sup>26</sup> and George Annas,<sup>27</sup> to explore these issues, with a particular focus on human cloning. In a lecture entitled *What If Anything Is Wrong with Cloning a Human Being?*,<sup>28</sup> Dr. Caplan allays many common fears about human cloning, providing an expert's perspective on the different technologies, uses, benefits and risks, as well as the limitations and foreseeable consequences of the technology. In the end, he favors therapeutic but rejects reproductive cloning. In her lecture, *Human Dignity: In Danger of Banality? (The Case of Cloning)*,<sup>29</sup> Professor Knoppers proposes a human rights model based on the concept of human dignity. She recommends that the international regime balance any current ban on cloning against the need to continue research and proposes a more multifaceted, complex systems approach to the internalization of human dignity as a fundamental norm. In the final lecture entitled *Arbitrage, Bioethics, and Cloning: the ABC's of Gestating a United Nations Cloning Convention*,<sup>30</sup> Professor George Annas, along with Rosario M. Isasi, examines recent attempts to create a U.N. Convention to ban human cloning and observes that mainstream researchers are engaged in regulatory arbitrage: the infertility industry still has not set any limits as to where U.S. researchers can go to "evade our almost nonexistent legal and ethical constraints."<sup>31</sup> In order to solve the arbitrage problem, he argues for an international cloning treaty that would recognize cloning as an "offense against humanity." Notwithstanding the breadth, complexity, or novelty of international legal arbitrage as an area of sustained scholarly attention, this volume thus takes an important step forward in recording the observations of these leading voices on the global regulation of controversial technologies.

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<sup>27</sup> George J. Annas is the Edward R. Uteley Professor and Chair of the Department of Health Law, Bioethics & Human Rights of Boston University School of Public Health, and Professor in the Boston University School of Medicine and School of Law. He is the cofounder of Global Lawyers and Physicians, a transnational professional association of lawyers and physicians working together to promote human rights and health. He has degrees from Harvard College (A.B.), Harvard Law School (J.D.) and Harvard School of Public Health (M.P.H.).

<sup>28</sup> Arthur L. Caplan, *What if Anything is Wrong with Human Cloning?*, 35 CASE J. INT'L L 369 (2003).

<sup>29</sup> Bartha-Maria Knoppers, *Human Dignity: In Danger of Banality? (THE CASE OF CLONING)*, 35 CASE J. INT'L L 385 (2003).

<sup>30</sup> George J. Annas & Rosario M. Isasi, *Arbitrage, Bioethics, and Cloning: The ABCs of Gestating a United Nations Cloning Convention*, 35 CASE J. INT'L L 397 (2003).

<sup>31</sup> *Id.* at 398.

