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## Should There Be Another Ewe? A Critical Analysis of the European Union Cloning Legislation

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## Comments

# Should There Be Another Ewe? A Critical Analysis of the European Union Cloning Legislation

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What would the world be like if we accepted that human 'creators' could assume the right to generate creatures in their own likeness, beings whose every biological characteristics would be subjugated to an outside will, copies of bodies that have already lived, half slaves, half fantasies of immortalities?<sup>1</sup>

## I. Introduction

It was the bleat<sup>2</sup> heard around the world when the birth of Dolly,<sup>3</sup> the first successful clone of an adult mammal,<sup>4</sup> was

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\* Special thanks to Dr. Robert O'Donnell whose insight and integrity remain with me; and to my parents, Melissa, Christopher, Megan, Christopher, Jennifer, and John whose love and loyalty are constant sources of encouragement.

1. Axel Kahn, *Clone Mammals . . . Clone Man?* (visited Oct. 26, 1997) <<http://www.nature.com/Nature2/serv>>. Kahn's article was specially commissioned by *Nature* to accompany the Web publication of the articles on sheep cloning.

2. Bleat is defined as "the cry of a sheep, goat or calf." WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY 194 (deluxe 2d ed. 1983).

3. See Michael Specter & Gina Kolata, *A New Creation: The Path to Cloning — A Special Report.; After Decades of Missteps, How Cloning Succeeded*, N.Y. TIMES, Mar. 3, 1997, at A1. Dolly was born at 4 P.M. on July 5, 1997 and weighed 6.6 kilograms. *Id.* The birth was normal, with her head and forelegs emerging first. *Id.*; see also Charles Marwick, *Scientists Flock to Hear Cloner Wilmut at NIH*, 277 JAMA 1102, 1103 (1997)(quoting Dr. Wilmut as saying, "I'm pleased to say that Dolly is still healthy and well and, like me struggling to cope with the T.V. cameras").

announced on February 23, 1997.<sup>5</sup> Dr. Ian Wilmut<sup>6</sup> of the Roslin Institute<sup>7</sup> in Edinburgh, Scotland and creator of Dolly,<sup>8</sup> instantly found himself<sup>9</sup> in the throes of an international debate regarding the ethics of mammal cloning.<sup>10</sup> Shock, and soon fear,<sup>11</sup> permeated the scientific community as the implications of Dolly's creation were extrapolated—human cloning was a biological possibility.<sup>12</sup>

Although Dolly's conception brought cloning to the forefront of modern day science, it is not a new concept by any means. It was first envisioned in 1938 when Hans Spemann proposed a "fantastical experiment"<sup>13</sup> in which a nucleus from an embryo, juvenile, or adult cell (a donor cell) would be transplanted into an

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4. See *Cloning Researcher to Speak Online; GW Medical Center and HELIX (SM)* ([www.HELIX.com](http://www.HELIX.com)) to Host Dr. Ian Wilmut; *Continuing Medical Education Credit Available*, PR NEWSWIRE, June 20, 1997.

5. See Robin McKie, *Scientists Clone Adult Sheep*, THE OBSERVER (London), Feb. 23, 1997, at 1. The Roslin Institute sent various ethical committees briefing notes on the cloning technique before its publication; however, the successful cloning of Dolly was prematurely published by THE OBSERVER (London). Harry Griffin, *Dollymania* (visited Oct. 26, 1997) <<http://www.ri.bbsrc.ac.uk/cloning/dollymania.html>>. Further, an e-mail was received by NATURE shortly before the article on cloning was published, urging that the paper be withdrawn so that the information could not be accessed until additional ethical concerns were considered. *Caught Napping by Clones*, 385 NATURE 810 (1997).

6. See Youssef M. Ibrahim, *Man in the News; Ian Wilmut; Secrecy Gives Way to Spotlight for Scientist*, N.Y. TIMES (London), Feb. 24, 1997, at B8. Dr. Wilmut is a husband and father who enjoys "a good single-malt Scottish whiskey," lives in a very small town outside of Edinburgh and has worked at the Roslin Institute for the past 23 years. *Id.*

7. See J. Madeline Nash, *The Age of Cloning; A Line Has Been Crossed, and Reproductive Biology Will Never Be the Same for People or for Sheep*, TIME, Mar. 10, 1997, at 62. Although the Roslin Institute performed the actual cloning procedure, PPL Therapeutics, a small biotechnical company also located in Edinburgh, funded one-third of the project to create Dolly. *Id.*; see also *infra* note 112 and accompanying text.

8. See Specter & Kolata, *supra* note 3, at A1.

9. See *Fear Made Flesh: Dolly's Creators Find Wolf in Sheep's Cloning; Scientists at Center of Global Panic Attack*, THE DALLAS MORNING NEWS, Mar. 8, 1997, at A44.

10. "The calm center of a storm over the science and morality of cloning is . . . Ian Wilmut who . . . is trying to reassure a world frightened by the shadows in his experiments." *Id.*

11. See Mark Honigsbaum, *Inside Story: The Price of Life*, THE GUARDIAN (London), Oct. 21, 1997. Societal fear of cloning stems from a belief that scientific advances are "running ahead of our ability to deal with the ethical consequences." *Id.*

12. See *Cloning of Humans "Quite Inhuman" Says Scientist Who Created Dolly*, AGENCE FRANCE PRESSE, Mar. 12, 1997. Dr. Wilmut believes that human cloning will be possible in less than two years. *Id.*

13. See Specter & Kolata, *supra* note 3, at A1.

oocyte (egg cell) that was lacking a nucleus (a recipient cell).<sup>14</sup> Almost fifty years and several unsuccessful cloning attempts later, a scientist cloned a live lamb from an early-stage sheep embryo cell in 1984.<sup>15</sup>

Embryo cells were initially used in cloning, because they did not have the specialized functioning<sup>16</sup> that adult cells had. Adult cell specialization presented additional difficulties in cloning, because an adult cell does not express all of the genes necessary for the functioning of the entire organism.<sup>17</sup> Thus, it was feasible that the cloning of an adult cell would only yield specialized adult cell progeny, and not an entire organism. Further, as no successful clones had ever been derived from adult cells,<sup>18</sup> many scientists did not believe that cloning an organism from an adult mammal cell was even a viable possibility.<sup>19</sup> Others, however, believed that the difficulties could be surmounted if the adult cell could be reverted back to an embryo cell; it then could express all its genetic components.<sup>20</sup> This could be done, it was thought, if the donor and recipient cell cycles were synchronized at the time of their fusion,<sup>21</sup> but the synchronization would only occur if both cells were in a similar stage of development.<sup>22</sup> Despite this theory, the scientific community remained divided on the feasibility of adult mammal cell cloning until the birth of Dolly.

Dolly's emergence as the first clone from an adult mammal cell found the world unprepared for the Pandora's box<sup>23</sup> of legal and ethical issues that accompanied her. Few laws were in place to

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14. *Id.*

15. *Id.*

16. *Id.*

17. *See infra* text accompanying note 89.

18. *See* Marwick, *supra* note 3, at 1103.

19. *See* J. Travis, *Ewe again? Cloning from Adult DNA* (visited Oct. 26, 1997) <[http://www.sciencenews.org/sn\\_arc97/3\\_1\\_97/fob1.htm](http://www.sciencenews.org/sn_arc97/3_1_97/fob1.htm)>. Many scientists had concluded that cloning an adult cell was impossible because of the irreversible changes a cell undergoes as it ages. *Id.*

20. *See* J. Madeleine Nash, et al., *The Age of Cloning; A Line Has Been Crossed, and Reproductive Biology Will Never Be the Same for People or for Sheep*, *TIME*, Mar. 10, 1997 at 62.

21. *See id.*

22. *See* I. Wilmut, et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 *NATURE* 810, 810 (1997). Specifically, the donor cell needed to exit its growth state and enter the G0 phase of the cell cycle in order to more closely resemble the embryonic state of the recipient cell. *Id.*

23. *See* Paula Bouonadonna, *MEPs 'No' to Human Cloning*, *THE EUROPEAN*, Mar. 13, 1997, at 2.

govern mammal, and more specifically, human cloning or research<sup>24</sup> at the time of her birth. Motivated primarily by the fear of human embryo cloning, countries rushed to research the implications of mammal cloning and the viability of human cloning.<sup>25</sup> Many countries, including the United States<sup>26</sup> and the countries of Europe<sup>27</sup>, implemented or proposed subsequent bans on human embryo cloning and research.

In an effort to integrate a single legislative initiative within its member countries, the European Union (hereinafter "EU") began to develop cloning legislation. The European Parliament urged the European Union to adopt laws strictly regulating animal cloning and research, and concurrently prohibiting human cloning or research.<sup>28</sup> To this end, the European Commission generated a biotechnology Directive<sup>29</sup> pursuant to a report from the Group of Advisors on the Ethical Implications of Biotechnology.<sup>30</sup> The Directive governs biotechnical inventions by refusing to grant patents for human cloning processes, but granting patents for animal cloning processes.<sup>31</sup> The Directive became effective on July 30, 1998 and must be implemented by the EU member states

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24. See Gina Kolata, *Scientist Reports First Cloning Ever of Adult Mammal*, N.Y. TIMES, Feb. 23, 1997, at § 1, at 1. Although Britain, Spain, Denmark, Germany and Australia had very general legislation prohibiting the cloning of humans, the United States did not. *Id.* Further, any laws restricting research with human embryos would likely not apply, because human cloning utilizes human eggs, not embryos. *Id.* See, e.g., Ehsan Masood, *Cloning Technique 'Reveals Legal Loophole,'* (visited Oct. 26, 1997) <<http://www.nature.com/Nature2/>> (stating that the cloning of humans may not be covered by the Human Fertilization and Embryology Act of 1990 (UK law), because cloning utilizes adult cells and not embryos).

25. See Joan Stephenson, *Threatened Bans on Human Cloning Research Could Hamper Advances*, 277 JAMA 1023,1023 (1997).

26. Marwick, *supra* note 3, at 1102. United States President Bill Clinton has prohibited the use of any Federal funds for research involving human cloning or research. *Id.*

27. See *Council of Europe Decides Against Cloning*, AGENCE FRANCE PRESSE, Sept. 23, 1997.

28. See Gillian Handyside, *EU Parliament Demands Ban on Human Cloning*, THE REUTER EUR. COMMUNITY REP., Mar. 12, 1997.

29. European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) [hereinafter "Directive"].

30. Opinion of the Group of Advisors on the Ethical Implications of Biotechnology to the European Commission, Report No. 9, May 28, 1997. A copy of the Opinion can be obtained from: European Commission, General Secretariat, Secretariat of the Group of Advisors on the Ethical Implications of Biotechnology, 200 rue de la Loi (BREY 7/320), B-1049 Brussels, Fax# 32-2-2994565.

31. *Id.*

by July 30, 2000.<sup>32</sup> Further, the Council of Europe recently approved a Protocol<sup>33</sup> to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine.<sup>34</sup> The Protocol expressly bans the use of cloning technology in conjunction with humans.<sup>35</sup> It was signed by nineteen European countries on January 12, 1998, and became the "first binding international ban on human cloning."<sup>36</sup>

As the European Union is the first assembly of countries to develop an integrated legislative plan for cloning technology, its influence on the international community will be considerable. This Comment addresses the ramifications of cloning technology and the development of the European Union cloning legislation. Part II discusses the structure of the European Union and its influence over the fifteen member states. Part III explains the legislative process in the European Union. Part IV is a preliminary discussion of the mechanics of cloning and the creation of the adult-cloned sheep, Dolly. Part V discusses the current legislation and proposals regarding cloning in the European Union. Part VI presents the benefits of cloning, including such areas as organ and tissue transplants, human disease treatment and disease prevention. Part VII describes the potential negative aspects of cloning. Finally, Part VIII examines the EU's proposed cloning legislation and its potential effect on society.

## II. The Structure of the European Union

The European Union,<sup>37</sup> originally known as the European Coal and Steel Community, was established in April of 1951 with the signing of the Treaty of Paris.<sup>38</sup> Although it was initially

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32. *Id.*

33. Protocol to the Convention for the Protection of the Human Rights and Dignity with Regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, *opened for signature* Jan. 22, 1998, Europ. T.S. No. 164 [hereinafter "Protocol"].

34. *See Council of Europe Prepares to Prohibit Cloning of Humans*, WALL ST. J., Nov. 7, 1997, available in 1997 WL-WSJ 14172898.

35. *See* Protocol, *supra* note 33, art. 1.

36. *See* Jeremy Laurance, *Human Rights Convention Embraces Ban on Cloning*, THE INDEPENDENT (London), January 13, 1998, at 11.

37. The terms 'European Union' and 'European Community' are used interchangeably. *See* P.S.R.F. MATHIJSEN, A GUIDE TO EUROPEAN UNION LAW 3 (6th ed. 1995).

38. *See* NEILL NUGENT, THE GOVERNMENT AND POLITICS OF THE EUROPEAN COMMUNITY 35 (2d ed. 1991).

composed of only six countries,<sup>39</sup> the EU currently consists of fifteen member states.<sup>40</sup> The aims of the EU include the unification of the people of Europe, the promotion of social and economic progress, and a common defense policy including the protection of the rights and interests of its member states and citizens.<sup>41</sup> The EU is composed of several institutions that were initiated to accomplish these aims.<sup>42</sup>

EU legislation is perhaps the tie that binds the member states together. The EU member states surrender the right to exercise independent determination over public policy issues if the issues are incorporated into EU legislation.<sup>43</sup> In theory, the member states are not required to accept and implement decisions contrary to vital national interest.<sup>44</sup> In practice, however, European law is supreme over national law.<sup>45</sup> Ideally, the EU law and national law should co-exist as an overall legal framework.<sup>46</sup> The European Parliament, the European Commission (hereinafter the "Commission"), and the European Council (hereinafter the "Council") are the central figures in creating the legislation for the EU.<sup>47</sup>

#### A. *The European Parliament*

The European Parliament is the only democratically elected international institution in the world.<sup>48</sup> It currently has 626 members elected to office by some 370 million citizens.<sup>49</sup> Al-

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39. The six original countries of the EU were Belgium, France, West Germany, Italy, Luxembourg and The Netherlands. *Id.* at 25.

40. See *What Is the European Union?* (last modified Aug. 23, 1996) <[http://www.europarl.eu.int/dg7/survol/en/bro\\_en1.htm](http://www.europarl.eu.int/dg7/survol/en/bro_en1.htm)>(listing the fifteen member states as Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom).

41. See *id.*

42. The EU institutions and bodies are the European Parliament, the Commission, the Council of the European Union, the European Council, the Court of Justice, the Court of Auditors, the Economic and Social Committee, and the Committee of the Regions. *Id.*

43. See NUGENT, *supra* note 38, at 166.

44. Shirley Williams, *Sovereignty and Accountability in the European Community*, in *THE NEW EUROPEAN COMMUNITY: DECISIONMAKING AND INSTITUTIONAL CHANGE* 155, 156 (Robert O. Keohane & Stanley Hoffmann eds., Westview Press 1991). The member states acknowledge that they can exercise veto power if an EU proposal is directly contrary to national interests. *Id.*

45. See *id.* (citing case 6/64, *Costa v. Enel*, 1964 E.C.R. 585).

46. See NUGENT, *supra* note 38, at 176.

47. See *What Is the European Union?*, *supra* note 40.

48. See *id.*

49. *Id.*

though the powers of Parliament were initially quite limited, the Single European Act of 1986<sup>50</sup> significantly enlarged the role of Parliament in the EU.<sup>51</sup> The many significant roles of the Parliament in the EU<sup>52</sup> include the adoption of community legislation and the EU budget, the supervision of the Commission and the Council, and the appointment of the European Ombudsman.<sup>53</sup> Traditionally, however, the Parliament acts as an "advisory body"<sup>54</sup> that exerts a substantial influence over EU lawmaking.<sup>55</sup>

### B. *The European Commission*

The European Commission, consisting of twenty Commissioners,<sup>56</sup> proposes European legislation and implements the policies of the EU.<sup>57</sup> It is the Commission's responsibility to ensure that all who are governed by the EU comply with EU legislation.<sup>58</sup> Further, the Commission is bound by the terms of the Treaties<sup>59</sup> to ensure that the provisions it develops are incorporated into European policy.<sup>60</sup>

### C. *The European Council*

The Heads of Government<sup>61</sup> of the EU member states comprise the European Council and act on the instruction of the governments they represent.<sup>62</sup> The Council is the center of EU

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50. See G. Federico Mancini, *The Making of a Constitution for Europe*, in *THE NEW EUROPEAN COMMUNITY: DECISIONMAKING AND INSTITUTIONAL CHANGE*, 177, 189 (Robert O. Keohane & Stanley Hoffmann eds., Westview Press 1991).

51. *Id.* at 189.

52. The European Parliament has "a number of opportunities to influence" EU legislation. NUGENT, *supra*, note 38 at 129.

53. See *What Is the European Union?* *supra*, note 40.

54. See NUGENT, *supra* note 38, at 165. Although the European Parliament does not have the strong constitutional powers of national parliaments, its influence over the affairs of the EU is greater than that of most national parliaments over their respective states. *Id.*

55. See Mancini, *supra* note 50, at 189.

56. See *What Is the European Union?*, *supra* note 40.

57. *Id.*

58. See MATHIJSEN, *supra* note 37, at 66.

59. See Peter Ludlow, *The European Commission*, in *THE NEW EUROPEAN COMMUNITY: DECISIONMAKING AND INSTITUTIONAL CHANGE* 85, 87 (Robert O. Keohane & Stanley Hoffmann eds., Westview Press 1991). The Treaties define the European Union as a "system". *Id.*

60. *Id.* at 96.

61. There are 40 Heads of State and Government of the European Council. *Council of Europe: 18-Point Plan Adopted by 40 European Leaders*, EUR. REP., Oct. 15, 1997.

62. See MATHIJSEN, *supra* note 37, at 50.



decision-making<sup>63</sup> and is also jointly responsible with the Parliament for the adoption of Commission-proposed legislation.<sup>64</sup> The Council has the power to make general guidelines binding upon the member states for the benefit of the EU.<sup>65</sup>

### III. European Union Legislation

The three institutions of the EU, the Parliament, the Commission, and the Council, work in concert to enact EU legislation.<sup>66</sup> Ultimately, however, either the Commission or the Council adopts the legislation.<sup>67</sup> There are four types of EU legislation: 1) regulations 2) directives 3) decisions, and 4) recommendations and opinions.<sup>68</sup> Each type of legislation differs in its effect upon the EU member states.

#### A. Types of Legislation

Regulations are fully binding upon the member states<sup>69</sup> without any subsequent national measures.<sup>70</sup> Directives allow national authorities to accept legislation with modifications in its form;<sup>71</sup> however, the intended result of the legislation must remain the same in every member state.<sup>72</sup> Decisions resemble regulations in that they are binding upon the member states and cannot be modified.<sup>73</sup> Usually, however, they deal with administrative, and not legislative acts.<sup>74</sup> Finally, recommendations and opinions are developed as guidelines to harmonize the member states' behaviors

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63. See Wolfgang Wessels, *The EC Council: The Community's Decisionmaking Center*, in *THE NEW EUROPEAN COMMUNITY: DECISIONMAKING AND INSTITUTIONAL CHANGE* 133, 141 (Robert O. Keohane & Stanley Hoffmann eds., Westview Press 1991). "[V]ital decisions" regarding the future of the EU are normally made by the Council. *Id.* at 145.

64. See *What Is the European Union?*, *supra* note 40.

65. See MATHIJSEN, *supra* note 37, at 50.

66. See *What Is the European Union?*, *supra* note 40.

67. See NUGENT, *supra* note 38, at 168. The legislation is not exclusively the product of either the Commission or the Council. *Id.* Generally, however, legislation originating from the Commission is administrative in nature, whereas legislation originating from the Council is broader and deals with more controversial issues. *Id.*

68. *Id.*

69. *Id.* at 169.

70. See MATHIJSEN, *supra* note 37, at 138.

71. See NUGENT, *supra* note 38, at 169.

72. See Mancini, *supra* note 50, at 182.

73. See NUGENT, *supra* note 38, at 171.

74. *Id.*

on particular issues.<sup>75</sup> As such, they have no binding effect upon the member states.<sup>76</sup>

### *B. The Legislative Process*

In what is known as the Cooperation Procedure,<sup>77</sup> a Proposal for legislation is introduced to the Council by the Commission.<sup>78</sup> The Council, in turn, presents the Proposal to the European Parliament and to the Economic and Social Committee for their subsequent critiques and appraisals.<sup>79</sup> The Proposal is then returned to the Commission for amendment.<sup>80</sup>

The Council reads the newly amended Proposal twice before presenting it again to the European Parliament for its review.<sup>81</sup> The Proposal is then returned to the Commission for its second, and final opportunity for amendment.<sup>82</sup> Lastly, the Council determines whether the Proposal will be adopted as either a Regulation or a Directive.<sup>83</sup>

## IV. Cloning

In order to understand the EU legislation for mammal cloning, a better understanding of the cloning technology is essential. The following Section should prove helpful in achieving this end.

### *A. The Cell*

The cell is the most basic and fundamental component of an organism; every living entity is composed of cells. A single fertilized egg, which contains all of the information needed to create an entire organism,<sup>84</sup> gives rise to every other cell in the human body.<sup>85</sup> The cell is controlled by its nucleus,<sup>86</sup> which

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75. See MATHJSEN, *supra* note 37, at 140.

76. See NUGENT, *supra* note 38, at 171.

77. See Ludlow, *supra* note 59, at 99. There are two basic types of legislative procedures in the EU, known as the Consultation Procedure and the Cooperation Procedure. *Id.* at 98-99. The Cooperation Procedure is an extended form of the original legislative process, the Consultation Procedure, created by the original treaties. *Id.* For the purposes of this comment, only the Cooperation Procedure is explained, as the proposed cloning legislation has utilized this procedure.

78. *Id.*

79. *Id.*

80. See Ludlow, *supra* note 59, at 99.

81. *Id.*

82. *Id.*

83. *Id.*

84. See Specter & Kolata, *supra* note 3, at A1.

85. *Id.*

occupies approximately 10% of the total cell volume and contains most of the cellular DNA.<sup>87</sup>

The cells of complex organisms often go through a series of divisions and developmental changes in order to become an organism.<sup>88</sup> These cells undergo a process known as differentiation<sup>89</sup> in which any gene not necessary for the functioning of that particular cell is "switched off,"<sup>90</sup> although it still remains present. For example, once a cell has become a retina cell, it can only express those genes involved in the structure and functioning of the retina. This is despite the fact that the retina cell contains all of the DNA necessary to become any type of cell.

The scientific community used to accept the theory that as cells aged, they differentiated and irreversibly specialized.<sup>91</sup> Thus, all embryo cells had the potential to become any type of cell. In contrast, older cells (fetal and adult cells) that had already undergone substantial differentiation could only express genes that had been "turned on."<sup>92</sup> Consequently, previous cloning experiments utilized only undifferentiated, embryonic cells.<sup>93</sup>

### B. *The Process of Cloning*

The process of cloning is actually based upon an older, fairly simple<sup>94</sup> process known as nuclear transfer.<sup>95</sup> Two genetically

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86. See BRUCE ALBERTS, ET AL., *MOLECULAR BIOLOGY OF THE CELL* 408 (2d ed. 1989). DNA and RNA synthesis occurs primarily in the nucleus. *Id.*

87. *Id.* at 481.

88. See Specter & Kolata, *supra* note 3, at A1. In humans, gene expression is turned on after only two cell divisions. Sharon Begley, et al., *Little Lamb, Who Made Thee?*, *NEWSWEEK*, Mar. 10, 1997, at 52.

89. See Nash, *supra* note 7, at 62. Differentiation causes the folding of the gene strand, otherwise known as DNA, which facilitates the expression of some genes while suppressing the expression of others. *Id.* at 64. Proteins contribute to the differentiation process by covering and hence, blocking genes from expression. See Begley et al., *supra* note 88, at 52. The proteins cannot be stripped off the DNA without shattering it. Kolata, *supra* note 24, § 1, at 1.

90. See Begley, et al., *supra* note 88, at 52. As a result of differentiation, a brain cell cannot secrete insulin and a skin cell cannot generate estrogen. *Id.*

91. *Id.*

92. *Pittsburgh's Biomedical Business Network to Feature Scottish Geneticist Ian Wilmut in Its Inaugural Forum*, PR NEWSWIRE, June 20, 1997, (stating that evidence from past studies showed that the genetic material of a mature mammal does not have the ability to grow and divide).

93. K.H.S. Campbell, et al., *Sheep Cloned by Nuclear Transfer from a Cultured Cell Line*, 380 *NATURE* 64, 64 (1996).

94. See Nash, *supra* note 7, at 62. The simplicity of cloning is also what makes the technology dangerous. *Id.*

different cells are utilized in the process: an unfertilized egg and a donor cell.<sup>96</sup> The egg cell is enucleated<sup>97</sup> via micromanipulation<sup>98</sup> so that only the “nutrients”<sup>99</sup> of the egg remain. The nucleus of the donor cell is subsequently removed and fused with the recipient egg cell by a pulse of electrical current.<sup>100</sup> The electrical pulse stimulates the recipient cell to accept the donor DNA as its own.<sup>101</sup> This same current is then used to activate and propel the newly formed cell into a growth cycle.<sup>102</sup>

While nuclear transfer had been successfully performed with adult cells in the past, the success was limited in duration. None of the resulting organisms was viable for an extended period of time.<sup>103</sup> Inevitably, at some point in the organism’s development, it reverted to an embryonic state and died.<sup>104</sup> The process was successful only if the donor cell (i.e., the nucleus used) was that of an embryo.<sup>105</sup>

The idea of a clone derived from an adult cell, the idea of Dolly, seemed biologically impossible given its completed cellular differentiation.<sup>106</sup> Dolly, however, became more than a glint in the eyes of her laboratory parents, Keith Campbell and Ian Wilmut (both of the Roslin Institute), in February of 1995.<sup>107</sup> Campbell had discovered a way to unlock the silent genes that resulted from the differentiation of adult cells. Thus, the adult cell could express all of its genes, the “genetic blueprint” of a complete organism.<sup>108</sup>

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95. Nuclear transfer differs from twinning, because it is a form of asexual reproduction; likewise, cloning is a method of asexual reproduction). *Genetic Cloning vs. Gentic Twinning*, (last modified Aug. 7, 1997) <[http://www.ncgr.org/gpi/odyssey/dolly-cloning/cloning\\_twinning.html](http://www.ncgr.org/gpi/odyssey/dolly-cloning/cloning_twinning.html)>.

96. See Campbell, et al., *supra* note 93, at 64.

97. An enucleated cell is defined as one that has had its nucleus removed. Dr. Ray Bohlin, *The Little Lamb That Made a Monkey of Us All - Can Humans Be Cloned Like Sheep?*, PROBE MINISTRIES, (Probe Ministries Corporation, Richardson, TX), Mar. 7, 1997.

98. See Campbell, et al., *supra* note 93, at 64.

99. The nutrients of the egg cell, the RNA and proteins present in the egg, control early development of the fused cell. *Id.*

100. *Id.*

101. See Nash, *supra* note 7, at 62.

102. See Campbell et al., *supra* note 93, at 64.

103. See Specter & Kolata, *supra* note 3, at A1.

104. *Id.*

105. See Campbell et al., *supra* note 93, at 64.

106. See Nash, *supra* note 7, at 62.

107. Campbell explained his theory on gene reprogramming to Dr. Wilmut, and the two of them agreed to remain silent about the technique until its success was established. Begley, et al., *supra* note 88, at 52.

108. *Id.*

By starving adult cells of needed nutrients, the cells entered an inactive state known as quiescence.<sup>109</sup> Subsequently introducing the quiescent cells to special proteins that activated the cells' genetic material<sup>110</sup> allowed the cells to express all of the information needed for a complete organism.<sup>111</sup> Armed with this new discovery, Campbell and Wilmut began the process that eventually led to the birth of Dolly in July, 1996.

Dolly was created with the nucleus from a mammary<sup>112</sup> cell of a Finn Dorset ewe<sup>113</sup> (the donor cell) and an oocyte of a Scottish Blackface ewe (the recipient cell).<sup>114</sup> The mammary cell was induced into quiescence by decreasing the cell's nutrients to one twentieth of what it needed to grow.<sup>115</sup> After five days, the cell was open to the "reprogramming of gene expression"<sup>116</sup> and was fused with the oocyte through the technique of nuclear transfer.<sup>117</sup> One hundred and forty-eight days later, Dolly emerged healthy, genetically-identical to the Finn Dorset she was derived from, and forever embedded in the annals of scientific discovery.

## V. Cloning Legislation in the European Union

On March 12, 1997, the European Parliament reacted to the successful creation of Dolly by passing a resolution calling for a worldwide ban on human cloning with strict regulatory controls on

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109. *Id.*

110. *See* Campbell et al., *supra* note 93, at 64.

111. *See* Specter & Kolata, *supra* note 3, at A1 (stating that each cell carries a "complete blueprint for an organism" through its DNA).

112. *See* Kolata, *supra* note 24, § 1, at 1. Dr. Wilmut used mammary cells to create Dolly, because PPL Therapeutics, a company that partially sponsored his work, donated the cells from research it was performing on genetically-altered milk proteins of sheep. *Id.* The mammary cells also provided Dolly with her name; Dr. Wilmut stated that he could think of no mammary cells more famous than those of the country singer, Dolly Parton. Specter & Kolata, *supra* note 3, at A1.

113. Animal welfare organizations have been very critical of the Roslin Institute for the use of the blackface sheep as the mother, because it is a much smaller breed than the Dorset. *Cloning Miscarriages & Genetic Alterations*, AGBIOTECH NEWS & INFO., (visited Nov. 11, 1997) <<http://www.cabi.org/whatsnew/cloneani.htm#13>>. As such, the birth is more apt to be very painful for the recipient mother. *Id.*

114. *See* I. Wilmut, et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810, 811 (1997).

115. *Id.* at 812. The concentration of the growth medium that the cells were suspended in was reduced from 10 to 0.5% for five days in order to force the cells into the quiescent state. *Id.*

116. *Id.* at 810.

117. *Id.*

animal cloning.<sup>118</sup> As a result, all three legislative pillars of the European Union—the Parliament, the Commission, and the Council—have subsequently had a role in determining the future use of cloning technology.

The European Parliament suggested that all funding for cloning research should be stopped immediately,<sup>119</sup> and that penal sanctions should result from any violation of the ban.<sup>120</sup> Parliament further stressed in its resolution that every individual was entitled to his or her own genetic identity without interference from cloning.<sup>121</sup> Moreover, Parliament urged the European Commission to carefully consider the ethical implications of the cloning technique, especially the possibility of human cloning.<sup>122</sup>

The European Commission held a much more favorable view of cloning as a “leap forward towards the better understanding of living things.”<sup>123</sup> The Commission seemed to prefer the regulation of cloning technology, as opposed to a complete ban. It organized a nine member group, the Advisory Group on Ethics and Biotechnology,<sup>124</sup> to investigate the legal, ethical and scientific ramifications of cloning technology.<sup>125</sup> The rejection of human cloning by the Parliament was accepted by the majority of the Commission.<sup>126</sup> But, the Commission also condoned the use of cloning on other animals as having great potential for medical, economic and agricultural benefits.<sup>127</sup>

The Commission’s Advisory Group on Ethics and Biotechnology reported its findings on May 31, 1997.<sup>128</sup> The Group found a clear distinction between the cloning of animals and the cloning of

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118. See Buonadonna, *supra* note 23, at 2.

119. See Handyside, *supra* note 28.

120. *Id.*

121. *Id.*

122. See *Biotechnology: EU to Consider Ethical Implications of Animal Cloning*, EUR. REP., Mar. 1, 1997.

123. See *EU: EP/Biotechnology - Animal Cloning* REUTER TEXTLINE AGENCE EUR., Mar. 12, 1997.

124. See *Biotechnology: EU to Consider Ethical Implications of Animal Cloning*, *supra* note 122. The Advisory Group was chaired by Noelle Lenoir and was convened on Feb. 27, 1997. *Id.* The Group is comprised of scientific, legal and ethical experts that did not participate in the development of the cloning technology. See Suzanne Perry, *Commission Studying Ban on Human Cloning*, THE REUTER EUR. COMMUNITY REP., May 30, 1997.

125. See *Biotechnology: Worldwide Ban on Cloning of Humans in View*, EUR. REP., Apr. 23, 1997.

126. See Perry, *supra* note 124.

127. *Id.*

128. *EU: EU/Cloning - Content of Opinion*, AGENCE EUR., June 3, 1997.

humans.<sup>129</sup> Human cloning was found to be a “subject of unequivocal condemnation at the European level”.<sup>130</sup> Further, because of the potential misuse of the technology, the Group advised that a complete ban on human cloning was warranted.<sup>131</sup> Animal cloning, however, was found to be acceptable because of its potential contribution to the limited knowledge of certain human biological processes, such as aging.<sup>132</sup> Subject to certain limitations, the Group determined that cloning technology should be utilized with animals, but only if both the aim and the method were ethically justifiable.<sup>133</sup>

In conjunction with the Advisory Group’s findings and subject to amendment suggestions by the Parliament, the Commission proposed a Directive for the Legal Protection of Biotechnological Inventions.<sup>134</sup> The Directive prohibits the patenting of any cloning procedure for human reproduction or for any process designed to modify the human genome.<sup>135</sup> Further, it provides for the creation of an Ethics Committee with the purpose of assessing all of the ethical aspects of the utilization of biotechnology.<sup>136</sup> The Directive was passed by the European Council after its second reading by the Parliament and became effective on July 30, 1998.

On April 4, 1997, the European Council signed the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (hereinafter “the Convention”).<sup>137</sup> It is currently non-binding legislation<sup>138</sup> and will remain so until at least five states, four of which must be EU member states, express their intent to be bound by the Convention’s terms.<sup>139</sup> Although the Convention included an implicit prohibition on any human genome modification,<sup>140</sup>

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129. *See id.*

130. *Id.*

131. *Id.*

132. *See Perry, supra* note 124.

133. *EU: EU/Cloning - Content of Opinion, supra* note 128. The limitations for animal cloning include the duty to prevent unwarranted animal suffering, to preserve genetic diversity and to limit the utilization of the technology. *Id.*

134. *See Directive, supra* note 29.

135. *Id.* art. 6.

136. *Id.* art. 7.

137. Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, Apr. 4, 1997, Europ. T.S. No. 164 [hereinafter “Convention”].

138. *See NUGENT, supra* note 38, at 171.

139. *See Convention, supra* note 137, art. 33.

140. Arthur Rogers, *Europe Takes Steps to Outlaw Human Cloning*, THE LANCET, Oct. 4, 1997. The main Convention currently permits “an intervention

cloning technology had not been developed at the time of the Convention's writing. Hence, human cloning was not expressly included in the Convention.

Thus, the European Council subsequently approved a draft Protocol<sup>141</sup> to the Convention banning human cloning on September 23, 1997.<sup>142</sup> The Protocol took the prohibition of human cloning one step further<sup>143</sup> than the Convention by strictly forbidding "any operation with the aim of creating a human being genetically identical to another human, living or dead", as defined by having "the whole of nuclear genes" in common."<sup>144</sup> Although the word 'cloning' is not mentioned anywhere in the Protocol,<sup>145</sup> it prohibits the result of cloning, and not simply the technology.<sup>146</sup> The Protocol is the first and only legally binding international document regarding cloning.<sup>147</sup> As an addendum to the main Convention, however, the Protocol must ultimately be approved individually by five signatories to the Convention before it becomes binding.<sup>148</sup>

## VI. Benefits of Cloning

What has become one of the most controversial scientific discoveries of all time began with a much humbler objective—better milk.<sup>149</sup> Dr. Wilmut and his colleagues developed the cloning technology to modify the genome of cows and sheep. These modifications would allow the animals to secrete human

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seeking to modify the human genome only if its aim is not to introduce any modification in the genome of any descendants." *Id.*

141. Pursuant to Article 32 of the Convention for the Protection of Human Rights and Dignity, Protocols may be added to the Convention with subsequent ratification, acceptance or approval by those signatories of the Convention. Convention, *supra* note 137, art. 31.

142. See *Council of Europe Decides Against Cloning*, *supra* note 27.

143. See Rogers, *supra* note 140.

144. See *Council of Europe Decides Against Cloning*, *supra* note 27.

145. See Rogers, *supra* note 140.

146. *Id.* By prohibiting the creation of any genetically identical human being, whether dead or alive, the Proposal goes beyond its United States counterpart in regulating cloning technology. *Id.*

147. See *Council of Europe Prepares to Prohibit Cloning of Humans*, *supra* note 34.

148. See *id.* The member states began signing the Directive on January 12, 1998, at a conference of the national-ethics committees. *Id.* Great Britain, through its Prime Minister, Tony Blair, voiced its intent to back the European Council's ban of human cloning. See *Blair Demonstrates Commitment to Rights by Incorporating European Convention into UK Law*, THE HERALD (GLASGOW), Oct. 11, 1997, at 7.

149. See *supra* text accompanying note 112.



proteins such as alpha-lactalbumin<sup>150</sup> in their milk.<sup>151</sup> These proteins, even though generated by an animal, have proven highly useful in many different areas of human disease and malfunction. For example, premature infants, who often cannot nurse, would greatly benefit from cow milk containing alpha-lactalbumin, an essential amino acid<sup>152</sup> which serves as a building block for proteins. Cloning technology would allow the *en masse* generation of these proteins for human benefit.<sup>153</sup> Although the extent of such benefits from utilization of cloning technology is not yet known, the Roslin Institute has cited several potential areas of benefit, including xenotransplantation, cell therapy, animals and use of animals as models of disease,<sup>154</sup> and alternative approaches to production of human proteins.<sup>155</sup>

#### A. Xenotransplantation

Xenotransplantation was developed as a response to the shortage of organs for transplantation into humans.<sup>156</sup> It involves the transplant of an animal organ, usually a kidney or heart, into a human.<sup>157</sup> In the past, the human immune system has generated many problems in reaction to these transfers. Although the transplants often prolong the life of the human, the success is often short-lived.<sup>158</sup> Eventually, the immune system recognizes the

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150. Alpha-lactalbumin is an essential human protein and contains amino acids that serve as the building blocks for other proteins. *Pittsburgh's Biomedical Business Network to Feature Scottish Geneticist Ian Wilmut in Its Inaugural Forum*, *supra* note 92.

151. *See id.*

152. *Id.*

153. *The Future of Cloning* (CNN Morning News, Mar. 12, 1997) (quoting Dr. Wilmut as stating, "The reason why we were trying to develop this technique was because we believe it will offer important new opportunities").

154. Dr. Wilmut has stated, "There are a number of genetic diseases for which there isn't a cure at the present time. Serious diseases. And [cloning] will enable us to carry out research into the causes of those diseases and perhaps develop methods to treat them." *Id.*

155. *See Dolly: Intellectual Property* (visited Oct. 26, 1997) <[http://www.ri.bbsrc.ac.uk/cloning/intellectual\\_property.html](http://www.ri.bbsrc.ac.uk/cloning/intellectual_property.html)>.

156. *See Benefits from Cloning/Nuclear Transfer* (visited Oct. 26, 1997) <<http://www.ri.bbsrc.ac.uk/cloning/benefits.html>>.

157. *See Robert Finn, Reports Give Boost to Xenotransplantation as Researchers Wait for Federal Guidelines* (visited Nov. 21, 1997) <[http://www.thescientist.library.upenn.edu/yr1996/august/xeno\\_960819.html](http://www.thescientist.library.upenn.edu/yr1996/august/xeno_960819.html)>.

158. In 1994, the three year survival rate for transplants from human donors to human recipients was about 75% and was dependent upon a variety of factors. Alan H. Berger, *Xenotransplantation: The Ethics, the Science, the Risks* (visited Nov. 18, 1997) <[http://envirolink.org/arrs/essays/xeno\\_risks.html](http://envirolink.org/arrs/essays/xeno_risks.html)>.

animal's organ and its corresponding proteins as foreign, and consequently, it rejects the organ.<sup>159</sup>

Cloning technology could prevent this organ rejection problem through the creation of 'transgenics.'<sup>160</sup> Transgenics are animals whose genome has been engineered by the insertion of single or multiple genes.<sup>161</sup> Human genes can be added to the genome of animals used for organ donation. As a result of the human genetic component, the animal's organ is coated with human proteins (not the animal's)<sup>162</sup> and thus, may not be recognized by the human immune system as foreign. Because recognition by the human immune system is less likely, an animal's organ coated with human proteins will also be much less likely to be rejected. Transgenic xenotransplantations have the potential to eradicate the shortage of organs for transplantation into humans.<sup>163</sup>

### B. Cell Therapy

Cell therapy<sup>164</sup> is another form of organ transplant, but the entire organ is not transplanted. Instead, cell therapy utilizes the cells of a fetal or juvenile animal organ to revitalize<sup>165</sup> and possibly even extend the life of older cells.<sup>166</sup> The animal cells are suspended in a physiological medium and injected into the human body.<sup>167</sup>

Although the exact reason or method is not known, the animal cells seem to target their corresponding counterpart organs in the human body.<sup>168</sup> Thus, if the animal cells were derived from the

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159. See *Benefits from Cloning/Nuclear Transfer*, *supra* note 156.

160. Transgenics will pass their genetic modifications onto their offspring. Mercedes Tira Andrei, *Cloning Can Help Feed the World*, BUSINESSWORLD (MANILA), Oct. 13, 1997.

161. See *Benefits from Cloning/Nuclear Transfer*, *supra* note 156.

162. *Id.*

163. In the United States alone, only 7,600 people donated organs in 1994 for the 37,000 individuals needing transplants; nearly fifty percent of those on a waiting list for an organ donation die before it becomes available. Finn, *supra* note 157.

164. See *How Does Cell Therapy Work?* (visited Nov. 21, 1997) <<http://www.icbr.com/icbr3.htm>> (finding that is accepted by most civilized countries, excepting the United States and Canada); *What Is Cell Therapy?* (visited Nov. 21, 1997) <<http://www.icbr.com/icbr.htm>> (stating that cell therapy is widely accepted in Europe as an effective form of treatment for many illnesses).

165. See *How Does Cell Therapy Work?*, *supra* note 164.

166. See *What Can You Expect from Cell Therapy?* (visited Nov. 21, 1997) <<http://www.icbr.com/icbr2.htm>>.

167. See *How Does Cell Therapy Work?*, *supra* note 164.

168. *Id.*

animal's liver, the suspension-cells will find their way to the human liver. This result is perplexing, given that the animal cells used are generally fetal cells, and thus, undifferentiated. This phenomenon accounts, however, for the human immune system's inability to recognize and reject the cells.<sup>169</sup>

Cell therapy is viewed by much of the medical community as an effective method of healing, because it harnesses the body's own revitalizing and curative abilities.<sup>170</sup> The benefits of cell therapy take many forms, and include the rapid dispersal of cell components throughout the body, reduced cell damage during the dispersion because of an adequate blood supply for the cells (organ rejection typically occurs as a result of inadequate blood supply to the cells), as well as the maintenance of greater control over the selection of the various fetal cells used in the dispersion.<sup>171</sup>

Cell therapy is already used in the treatment of several diseases, including leukemia and Parkinson's disease.<sup>172</sup> Utilization of the cloning technique, however, could further the development of cell therapy and its use in disease treatment. A beneficial cell—one with therapeutic value—could be created *en masse* via the nuclear transfer technique.<sup>173</sup> Moreover, this technique would ease genome modification and increase the utilization of the modified cells by the patient's immune system.<sup>174</sup> For instance, a cancerous cell could be removed from a patient and the cancerous component of the genome could be repaired and re-injected into the patient.<sup>175</sup> This form of treatment is much kinder to the body than treatments currently in use (such as chemotherapy or radiation), because it targets only the desired cells and does not injure or remove any of the patient's healthy cells.<sup>176</sup>

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169. *Id.*

170. *See What Is Cell Therapy?*, *supra* note 164.

171. *See How Does Cell Therapy Work?*, *supra* note 164.

172. *See Benefits from Cloning/Nuclear Transfer*, *supra* note 156.

173. Through utilization of nuclear transfer technology, a virtually unlimited number of "genetically identical animals" could be produced; the same applies to individual cells that are cloned. *Cloning in Farm Animal Production* (visited Oct. 26, 1997) <[http://www.ri.bbsrc.ac.uk/cloning/cloning\\_uses.html](http://www.ri.bbsrc.ac.uk/cloning/cloning_uses.html)>.

174. *See Benefits from Cloning/Nuclear Transfer*, *supra* note 156.

175. Various diseases could be treated this way, including degenerative disorders, viral, inflammatory or genetic diseases. Kahn, *supra* note 1.

176. *See How Does Cell Therapy Work?*, *supra* note 164. Unwanted or unnecessary cells are not harmful to the body and are simply rejected. *Id.*

### C. *Animals and Livestock*

There are various ways in which farmers and the subsequent consumers of farm products can benefit from cloning technology as well. As previously mentioned, the genome of milk-secreting animals can be altered by the cloning technique to include human genes; thus, the animal's milk will contain human proteins. A cow's genome could likewise be altered to produce a fat-free milk by reducing the enzymatic activity in the animal's udder.<sup>177</sup>

With cloning technology, animals that have a genetic advantage over other animals of the same species could be cloned, and an entire herd of the "most productive" animals could become a reality for wealthier farmers.<sup>178</sup> Through a gene insertion and/or deletion process, animals could be made more disease-resistant.<sup>179</sup> As carriers of human genes, animals would have a therapeutic value for humans by becoming factories for missing or malfunctioning proteins.<sup>180</sup> Certain human diseases could be introduced into the genome of smaller animals, such as mice, in an attempt to determine the effects of the disease and possible methods of treatment.<sup>181</sup> Cloning could also be utilized to increase the populations of many endangered species<sup>182</sup> and to increase the number of livestock<sup>183</sup> available as food to the undernourished and poverty-stricken countries of the world.<sup>184</sup>

## VII. Potential Negative Aspects of Cloning

Despite the many benefits of cloning, there are some known detriments, many of which cannot be explained with the current state of technology. Perhaps even more unsettling are the

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177. See Campbell et al., *supra* note 93.

178. *Cloning in Farm Animal Production*, *supra* note 173.

179. See Specter & Kolata, *supra* note 3, at A1.

180. Charles Arthur, *After Dolly Comes Polly, the Sheep With Human Genes*, THE INDEPENDENT (LONDON), July 25, 1997. For example, PPL, the company that funded the Dolly project, has modified sheep genomes to produce alpha-1-antitrypsin, "a blood protein used to treat the symptoms of cystic fibrosis." *Id.*

181. See *Benefits from Cloning/Nuclear Transfer*, *supra* note 156.

182. See *Cloning in Farm Animal Production*, *supra* note 173.

183. In principle, cloning would allow for the production of unlimited numbers of genetically identical animals. *Id.*

184. See Andrei, *supra* note 160. The current availability of land and water cannot accommodate the world's three billion hungry people; the cloning of livestock and agriculture that are disease-resistant and have increased nutritional value may be an answer to this challenge. *Id.*

unknown detriments, conceivably discoverable from the life and observation of Dolly.

The cloning procedure is extremely inefficient.<sup>185</sup> In the case of Dolly's genesis, there were initially 277 cell fusions of which 29 were viable enough for implantation into recipient sheep.<sup>186</sup> Only one sheep, Dolly, was born.<sup>187</sup> This is a success rate of 3.4%, compared with the 33 - 50% success rate mother nature achieves with fertilized eggs.<sup>188</sup> Further, the cloning procedure can damage the DNA.<sup>189</sup> This damage could be the cause of the inefficiency of the procedure and could lead to increased disease development in the viable clone.<sup>190</sup>

Additional cloning procedural problems include an increased birth weight of the clone,<sup>191</sup> an increased duration of pregnancy,<sup>192</sup> and the lack of controlled and repeated trials of the procedure.<sup>193</sup> Further, although there is evidence that a clone is capable of reproducing,<sup>194</sup> it is too early to determine the health of the offspring or even its cellular age! This uncertainty is due to the fact that a clone's age must be determined from the DNA of the donor cell animal. Thus, as the sheep that donated the DNA for the creation of Dolly was six years old,<sup>195</sup> it is not certain whether Dolly's DNA is that of a newborn lamb or of a six year old sheep.<sup>196</sup> The same uncertainty applies to the offspring of clones. Only the continued development of Dolly, her daughter, and additional cloning experiments will be able to provide insight into these very critical issues.<sup>197</sup>

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185. See Marwick, *supra* note 3, at 1103.

186. See Wilmut et al., *supra* note 114, at 811.

187. *Id.*

188. See Bohlin, *supra* note 97.

189. See Nash, *supra* note 7, at 62.

190. *Id.*

191. See Marwick, *supra* note 3, at 1103. Dolly, a Finn Dorset lamb, weighed 6.6 kg. at her birth; the average weight for Finn Dorset lambs is between 1.2 and 5.0 kg. *Id.*

192. *Id.* The recipient sheep's pregnancy with Dolly was 148 days, compared to the average duration of 143 days. *Id.*

193. See *The Commercial Potential for Mammalian Cloning*, AGBIOTECH NEWS & INFO., Aug., 1997, available in <<http://www.cabi.org/whatsnew/cloneani.htm#13>>.

194. The Roslin Institute announced that Dolly gave birth to a daughter named Bonnie on April 13, 1998.

195. See Marwick, *supra* note 3, at 1103.

196. See Specter & Kolata, *supra* note 3, at A1. When asked how old Dolly is, Dr. Wilmut responded, "I can't answer that. We just don't know. There are many things here we will have to find out." *Id.*

197. New cloning techniques have already been developed, including one technique developed at the University of Hawaii by Dr. Ryuzo Yanagimachi and

### VIII. Responses to the Proposed Cloning Legislation in the European Union

Cloning benefits and detriments were most certainly among the considerations in the EU's development of legislation for cloning technology. But how can a technology so vehemently opposed by the majority of those involved in its potential effects be concurrently regulated and banned? The Directive and the Protocol attempt to create just such a legislative dichotomy.

The Directive and the Protocol were developed as a direct response to the cloning of an adult mammal. Because adult cell cloning had never occurred—and indeed, many in the scientific community did not believe it even possible—there was no recognized need for legislation. Once the technology became a reality, however, its potential widespread and significant effects highlighted the need for immediate legislation.

The Directive was written with the intent of harnessing the technology's power while preventing its abuse. It prohibits the patenting of any procedure for human cloning or human genome modification.<sup>198</sup> Subject to certain limitations, however, the Directive allows for the patenting of cloning or genetic modifications of animals.<sup>199</sup>

The Protocol prohibits the creation of a genetically identical human being from another living or dead human being.<sup>200</sup> In theory, the Directive reinforces the Protocol's prohibition of human cloning by refusing to allow patents for any human cloning procedure. In practice, however, both the Directive and the Protocol condone the use of the cloning technology by recognizing the use of that technology in conjunction with animals. The Directive's refusal to grant patents for human cloning procedures is coupled with a corresponding grant of patents for animal cloning procedures. The Protocol's ban on the use of cloning technology on humans is coupled with a corresponding allowance of the

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his postdoctoral student, Dr. Teruhiko Wakayama. Gina Kolata, *In Big Advance, Cloning Creates Dozens of Mice*, N.Y. TIMES, July 23, 1998, at A1. This technique differs from the fusion technique developed by Wilmut in that it simply injects the donor genetic material into a recipient egg, without the electric current used in the fusion. Michael D. Lemonick, *Dolly, You're History*, TIME, August 3, 1998. The results have suggested that the Honolulu technique has a much greater success rate, and hence, fewer failed attempts occur. *Id.*

198. See Directive, *supra* note 29, art. 1.

199. *Id.*

200. See Protocol, *supra* note 33, art. 1.

technology on animals. Thus, the Directive and the Protocol open the door for the use of cloning technology and ultimately render the ban on human cloning unenforceable.

Human cloning and animal cloning both utilize the nuclear transfer technique developed by the Roslin Institute. By allowing for the use of the technology and the grant of patents in conjunction with animals, the same technology cannot then be banned if its use is on humans. Therein lies the inherent contradiction in the execution of the Directive and the Protocol - the same technology is both banned and regulated. As a result, enforcement of the Directive and the Protocol could only be executed to fruition in a society devoid of any dishonesty or intellectual curiosity—a society much unlike the one that currently exists.

Both the Directive and the Protocol initially appear to be assets to European Union legislation. They attempt to reflect Dr. Wilmut's intent not to use the technology for human cloning, while simultaneously allowing for utilization of the benefits of the technology. In this way, the Directive and the Protocol encourage necessary technological development, but within the confines of generous, ethical boundaries; merely the effect is encumbered, not the technology. Moreover, the Directive calls for the creation of an Ethics Committee which has the role of assessing the development and utilization of biotechnology.<sup>201</sup> This Committee would most likely attempt to maintain the use of cloning technology in conjunction with the purposes of the Directive and the Protocol.

Unfortunately, the approval of animal cloning is an implicit approval of the technology, regardless of its intended participants. It is not reasonable to believe that the technology will be used only in the manner prescribed by the Protocol and reinforced through the Directive's grant of patents. Invariably, the cloning of humans will occur through the use of the approved technology. Disturbingly, neither the Directive nor the Protocol establishes, or even addresses, any preventative measures for the cloning of humans. Only the Protocol provides for "penal sanctions"<sup>202</sup> upon the occurrence of human cloning. Unfortunately, there is little redemption in an after-the-fact penalty, especially with the far-reaching implications and lasting effects of a successful human clone.

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201. See Directive, *supra* note 29, art. 8.

202. See Protocol, *supra* note 33, art. 3.

Perhaps the fatal flaw in the EU's cloning legislation results more from the simplicity of the cloning procedure itself than from a weakness in either the Protocol or the Directive. Cloning is very simple. So simple, in fact, that a thirteen year old boy from Honeoye Falls, New York produced three sets of identical frogs with very rudimentary equipment: an aquarium, glass tubes, petri dishes, and highly reproductive African frogs.<sup>203</sup> Although the boy did not create actual clones, but rather twins (identical frogs generated by the splitting of the fertilized eggs),<sup>204</sup> the theory behind his accomplishment is much the same as the theory behind cloning technology. If the ability to create identical organisms exists within the mental capacity and access of a thirteen year old child, surely a Directive aimed at the mere regulation of cloning cannot prevent its exploitation by the creative, scientific minds across the world.<sup>205</sup> And if a thirteen year-old can create identical frogs, surely many people, despite a Protocol ban to the contrary, will create identical humans.<sup>206</sup>

The regulation of animal cloning in conjunction with a concurrent ban on human cloning is a naive, if not implausible, attempt to prevent human cloning. Because of the interest in cloning, its potential benefits and its simplistic methodology, the technology is not policeable.<sup>207</sup> Legislation against the inevitable cloning of humans will not tighten the reigns on the frantic pace of scientific discovery. The cloning of humans is already within its domain.

So, what is the answer? The progression of society through the progression of technology should not, and probably could not, be stopped. Moreover, the mere fact that legislation is most likely not enforceable in practice does not mean it should not exist. Perhaps the focus on whether cloning *should* be allowed is poorly placed. The technology has developed, and its use is inevitable. Instead, perhaps the focus should shift to the *people* utilizing the

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203. See *13-Year-Old Makes Twin Frogs in Lab*, ST. LOUIS POST-DISPATCH, Mar. 9, 1997, at O6A.

204. *Id.*

205. In January of 1997, despite a ban on human embryo research with government funds, a biologist at George Washington University resigned after his research on human embryos was discovered. Begley et al., *supra* note 88, at 52. A Chicago physicist, Dr. Richard Seed, recently announced his intention to open a human cloning clinic in order to provide human clones to infertile couples. Robert Winston, *Beware the Charlatans of Cloning; As a U.S. Doctor Announces Human Cloning Clinic*, DAILY MAIL (London), January 8, 1998, at 8.

206. *See id.*

207. *See* Kolata, *supra* note 24, § 1, at 1.



cloning technique. They alone will determine the future of cloning technology. Directives and Protocols are not enough to monitor the progression of science or the ethics of humans. Humans themselves need to learn to weigh the benefits and costs of the answers they seek.

## IX. Conclusion

The development of the cloning technology is perhaps one of the most controversial, and potentially powerful scientific discoveries of the late twentieth century. Its implications extend into many areas of agricultural, medical, and human development. The main concern generated by cloning technology surrounds its use—the maximization of its benefits with the concurrent minimization of its potential abuse.

The European Union has responded efficiently to the development of cloning technology. EU legislation will inevitably have an enormous impact on the worldwide regulation of cloning technology. Non-member states are allowed to become signatories to the Proposal to the Convention for the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine,<sup>208</sup> and thus the potential for a world-wide regulation of cloning technology is possible.

Legislation, however, regardless of its origin, will not be a sufficient safeguard against the potential abuses of cloning technology. Inevitably, the use of the technology under one set of circumstances will implicitly allow for the use under any set of circumstances. Those utilizing the technique must assume the responsibility to act within the confines of ethical considerations.

Currently, scientific advances have surpassed society's ability to deal with the ethical consequences.<sup>209</sup> Although science fiction should not determine science policy,<sup>210</sup> it is the responsibility of society to consider the regulation of the scientific applications it develops. Therein lies the future of scientific progression, but perhaps more importantly, the future of ethical progression.

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208. See Protocol, *supra* note 33, art. 3.

209. See Honigsbaum, *supra* note 11.

210. See Stephenson, *supra* note 25, at 1027.