Health & Welfare

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A patient arrives at a hospital emergency room with severe head injuries. Immediately the emergency room staff tries to reduce the pressure on the patient's brain. The treatment does not work and the patient dies. Now imagine that the patient would have had a better chance of survival if the emergency room doctor had been able to use a new experimental therapy.

Critically ill patients are often denied new experimental treatments because they are unable to provide the necessary "informed consent" to participate in clinical trials and experimental therapies which may benefit them.

I. INTRODUCTION

The doctrine of informed consent requires a doctor to inform the patient of the risks and benefits of the proposed medical treatment and any alternative courses of treatment. The failure of the doctor to obtain the proper consent results in battery.

1. See Lynn Marek, Ethical Dilemma in the ER: Experiment on Patients?, CHI. TRIB., May 23, 1994, at 1 (stating that reducing pressure on the brain is a commonly accepted treatment for patient's suffering from severe head injuries).

2. See id. (reporting that Dr. John Barrett, director of Cook County Hospital's trauma unit, is unable to use a promising new treatment on patients suffering from severe head injuries because of the inability to obtain informed consent and because of potential liability issues).

3. See CAL. HEALTH & SAFETY CODE § 24173 (West 1990) (stating that the patient must be given an explanation of the proposed medical treatment and the potential benefits and risks of the procedure so that the patient can make an informed decision); see also Arato v. Avedon, 5 Cal. 4th 1172, 1183, 858 P.2d 598, 604, 23 Cal. Rptr. 2d 131, 137 n.5 (1993) (noting that the phrase "informed consent" is often thought to have been coined by Justice Bray in Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees); see also Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1957) (holding that a physician violates his duty to his patient if he fails to disclose any information which is necessary for the patient to make an informed decision).

4. See Richard S. Hamburg, Public Policy Solutions Sought for Emergency Care, 10 J. CARDIOVASCULAR NURSING 85, 85 (1996) (stating that patients in life-threatening situations are often denied new treatments because they are unable to provide "informed consent").

5. See CAL. HEALTH & SAFETY CODE § 24175 (West 1990) (establishing the informed consent doctrine that requires a medical professional to advise the patient of the risks, benefits, and alternatives to the proposed treatment); see also Luka v. Lowrie, 136 N.W. 1106, 1110 (Mich. 1912) (holding that a physician is justified in treating a patient in an emergency situation, and a surgeon may lawfully perform a potentially life-saving operation
Although there is a recognized emergency exception to the doctrine of informed consent, it is unclear whether the use of experimental therapies falls within this exception.

The emergency exception exists because, in a life-threatening situation, the patient's right to know of the risks, benefits and alternatives of the proposed medical treatment is supplanted by the gravity of the situation. Chapter 68 places the use of experimental therapies within the emergency exception under a narrow set of conditions.

Chapter 68 relaxes the informed consent doctrine to conform with recent Food and Drug Administration (FDA) regulations and to allow doctors to administer investigational therapies where their patients are in life-threatening situations. The American Association of Critical Care Nurses supports Chapter 68 because they believe that a patient in a life-threatening situation should not be denied a promising investigational therapy. Also, they assert that Chapter 68 conforms with federal regulations that require extensive studies of investigatory procedures before they are administered on patients. In addition, the hospital Institutional Review Boards

6. CAL. HEALTH & SAFETY CODE § 24178(a) (West 1990) (setting forth penalties for the person who negligently allows or performs medical treatment conducted without informed consent).

7. See CAL. BUS. & PROF. CODE § 2397 (West 1990) (declaring that a licensee is not liable for civil damages for injury or death caused by an emergency situation in which the patient has not provided informed consent). The rationale is that a patient is unable to give his informed consent when he is facing a life-threatening situation. In addition, in an emergency situation it is not feasible to try to contact the patient's legal representative to obtain their consent, because of the time constraints. Id. § 2397; see also Halle Fine Terrion, Informed Choice: Physicians’ Duty to Disclose Nonreadily Available Alternatives, 43 CASE W. RES. L. REV. 491, 506-07 (1993) (explaining that the term “emergency” is ambiguous). Some commentators think that the emergency exception to the informed consent doctrine should only apply when the patient is unconscious, and that the harm that would result from nontreatment overrides the risk involved from the medical treatment. Another author suggests that the emergency exception should apply when the patient is unable to give his consent to receive information. Id. 507.

8. See Richard S. Saver, Critical Care Research and Informed Consent, 75 N.C. L. REV. 205, 231 (1996) (explaining the ambiguities of the informed consent doctrine); see also Richard Delgado and Helen Leškovač, Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice, 34 UCLA L. REV. 67, 67-68 n.1 (1986) (stating that unorthodox therapies are often controversial even when patients are in a life-threatening situation, or the doctor administers the therapy as a last resort).

9. See Terrion, supra note 7, at 506 (explaining that a physician’s inability to obtain informed consent from their patient often prevents lives from being saved).

10. CAL. HEALTH & SAFETY CODE § 24177.5 (enacted by Chapter 68); see SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 2 (Mar. 11, 1997) (stating that Chapter 68 provides an exception to the Protection of Human Subjects in Medical Experimentation Act when a person is in a life-threatening situation and is unable to give informed consent). In addition, a number of safeguards have been included in the law to protect the patient's rights, including a requirement that valid scientific studies must be conducted on the experimental therapy before administering the proposed medical treatment. Id.

11. CAL. HEALTH & SAFETY CODE § 24177.5 (enacted by Chapter 68); see SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 3 (Mar. 11, 1997) (acknowledging that proponents of Chapter 68 argue that this law is needed to bring California law into conformity with federal regulations).

12. See SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 3 (Mar. 11, 1997) (explaining that, as an organization which represents 76,000 critical care nurses, the members are familiar with situations in which lives are lost because investigational procedures were not used).
(IRBs) retain the power to approve or stop the proposed treatment from being implemented.\textsuperscript{13} The proponents of Chapter 68 assert that the narrowly drafted exception protects patients’ rights while at the same time increasing the ability of doctors to administer experimental therapies which may save a greater number of lives.\textsuperscript{14}

However, Chapter 68 poses constitutional and ethical problems. Free will, an individual’s autonomy, and respect for bodily integrity all underlie the doctrine of informed consent.\textsuperscript{15} There is a tension between respecting and valuing an individual’s personal autonomy and the need to advance emergency medical procedures and technologies.\textsuperscript{16}

II. LEGAL BACKGROUND

An individual’s right to make choices affecting what happens to his body is a highly valued principle in our society.\textsuperscript{17} The law has evolved to reflect this principle. After World War II, there was an increasing awareness of the negative impacts that human experimentation could have on society.\textsuperscript{18} In the 1970s, measures were taken to further protect patients rights against experimentation.\textsuperscript{19} In response to the public’s outrage at the discovery that patient’s rights were being violated in order to conduct medical research,\textsuperscript{20} Congress enacted the National Research Act.
The NRA authorized the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which issued the influential Belmont Report. The Belmont Report set forth guidelines and ethical principles for the protection of human subjects in medical research, and has influenced the enactment of federal agency regulations.

There are four reasons why it is important to obtain individuals’ informed consent when they are the subject of a medical experiment. First, the risks and side-effects of experimentation cannot be known in advance. Second, there are no experts in the field of medical experimentation. Third, experimentation usually provides the subject with few benefits. Finally, the interests of the researcher and the subject are often in conflict. Yet, the recent trend is to relax some of these laws with the hope of saving more lives while advancing medical research.

A. Existing Law

Prior to the enactment of Chapter 68, existing law required that physicians obtain informed consent before conducting any experimental medical procedures on human beings. In addition, although existing law included an emergency exception to the informed consent doctrine, it did not allow the administration of potentially beneficial experimental therapies to patients in life-threatening situations.

22. See Saver, supra note 8, at 215 (providing background on the increase of legislation dealing with patient’s rights).
23. See id. (recognizing the influence of the Belmont Report on the Food and Drug Administration and Health and Human Services revisions of their regulations).
26. See Delgado & Leskovac, supra note 8, at 87 (explaining that courts and scholars have provided us with four reasons why our society should protect subjects of human experimentation).
27. See id. (explaining that the outcomes of experimental procedures and treatments are uncertain and often pose high risks).
28. See id. at 89 (explaining that because the researcher is uncertain of the outcome of the experiment, he offers no greater expertise to help the patient decide what to do with his body).
29. See id. at 90 (stating that medical treatment is meant to help a patient; whereas the purpose of medical experimentation is to aid people in the future).
30. Id. at 91.
31. See ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (June 17, 1997) (stating that the purpose of Chapter 68 is to improve the care of patients in life-threatening situations).
32. CAL. HEALTH & SAFETY CODE § 24172 (West 1992); see SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 2 (Mar. 18, 1997) (explaining that existing law did not provide a qualified immunity to the informed consent doctrine making it easier for doctors to administer investigational therapies in life-threatening situations).
33. See CAL. HEALTH & SAFETY CODE §§ 24173, 24175 (West 1992) (propounding an informed consent doctrine which requires advising a patient of the procedures, risks, benefits and alternatives, and the right to decline consent); see also id. §§ 26678, 26679 (West 1992) (relating to the use of experimental drugs); see also Review of Selected 1978 California Legislation, 10 PAC. L.J. 510, 510 (1979) (providing legislative intent relating to the informed consent doctrine).
Prior to the enactment of Chapter 68, there had been a trend to relax the doctrine of informed consent on the federal level. Recent FDA and National Institute of Health (NIH) regulations waive the informed consent requirement in life-threatening situations. The FDA measures were introduced to help people in critical care who may benefit from experimental treatments but are unable to give their informed consent. Under the new FDA regulations, a doctor may rely on implied consent where the patient will die without intervention.

The FDA regulations, issued on October 2, 1996, stem from a need to advance medical research and save a greater number of lives. The FDA regulations are an attempt to remove the barriers hindering critical research in a limited number of situations, while protecting the patient’s rights.

B. Chapter 68

Chapter 68 expands the ability of medical professionals to develop, analyze, and refine investigational therapies for the treatment of patients in life-threatening situations.

34. See 21 C.F.R. §§ 50.23, 50.24 (1997) (setting forth an emergency exception to the informed consent doctrine which allows consent to be waived under a narrow set of conditions).

35. See Saver, supra note 8, at 249 (noting that FDA regulations permit informed consent to be waived where: (1) The patient is in a life-threatening situation; (2) available treatments are unproven or unsatisfactory; (3) the patient is unable to consent because of their medical condition; (4) intervention must be administered before consent can be obtained from a legal representative; and (5) the risk of intervention is reasonable in light of what is known about the medical condition, current treatment, and the proposed treatment).

36. See Baruch A. Brody, New Perspectives on Emergency Room Research; Change in Informed Consent Laws; In Case of Emergency: No Need for Consent, THE HASTINGS CENTER REP., Jan. 11, 1997, at 7 (identifying four reasons for the new FDA regulations: (1) The social need for research in emergency settings; (2) the potential benefit to patients of promising new therapies; (3) the need to keep strict controls on the administration of experimental therapies in order to prevent the abuse of patient’s rights; and (4) the need to safeguard patients from experimental therapies that turn out to be harmful); see also FDA, NIH Ease Rules on Experiments in Emergencies, PUB. HEALTH REP., Jan./Feb. 1997, at 6 (observing that the new FDA rules make it easier for doctors to use promising experimental drugs on patients facing life-threatening situations who because of their medical condition, are unable to give informed consent).

37. See ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (Mar. 18, 1997).

38. See John Schwartz, Rules Eased for Emergency Therapy; Some Experimental Devices to Be Used Without Patient’s Consent, WASH. POST, Sept. 27, 1997, at A11 (stating that the FDA regulations protect patients who may be saved by an investigational procedure); see also Saver, supra note 8, at 206-207 (commenting that approximately 350,000 people suffer from heart attacks each year, and the majority of them die). There is a question whether accepted and standard CPR techniques are adequate. A new CPR device has been created called the "cardiopump," and it has potentially promising benefits. Yet, the FDA stopped the "cardiopump" clinical trials because doctors were unable to obtain the required consent from their patients. This is an example of a situation in which a device may prove to save lives, but it cannot be used because of the rigid informed consent rules. The new FDA regulations are designed to make it easier to use experimental therapies such as the "cardiopump" in life-threatening situations.

39. See Schwartz, supra note 16, at A11 (reporting the tension between people’s fear of being used in experiments because of abuses in the past, and the need for new therapies which will benefit society).
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Chapter 68 is designed to allow critically ill or injured people to have access to life-saving therapies when informed consent cannot be obtained.41 Chapter 68 amends existing law to allow the use of experimental therapies on patients in life-threatening situations who are unable to give their informed consent.42 This exception to the Human Subjects in Medical Experimentation Act has been narrowly drafted to apply in limited situations in order to protect the bodily integrity of the patient.43

III. CONSTITUTIONAL AND ETHICAL ISSUES

The constitutional right to control medical decisions is still evolving in medical jurisprudence and is a highly debated issue among legal scholars.44 Western ethics place a high value on the principle of individual autonomy. Indeed, individual autonomy is a fundamental right in our society implicit in the Constitution.45 The Supreme Court recognizes rights to bodily integrity, liberty, and self-determination that stem from the principles set forth in the Constitution.46

The concept of personal autonomy favors the individual over the community,47 and can be traced back to the works of Western philosophers Locke and Mill.48

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40. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 3 (Mar. 1, 1997); see ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (June 17, 1997) (declaring that the intent of Chapter 68 is to expand doctor’s abilities to administer investigational therapies).
41. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 160, at 2 (Mar. 11, 1997); see ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (June 17, 1997) (explaining that Chapter 68 provides an exception to the requirements of the Protection of Human Subjects in Medical Experimentation Act for the treatment of a patient in a life-threatening situation).
42. See CAL. HEALTH & SAFETY CODE § 24177.5 (enacted by Chapter 68).
43. See id. (permitting the exception when the following conditions are met: (1) The patient is in a life-threatening situation; (2) the patient is unable to give informed consent; (3) obtaining informed consent from a legal representative is not feasible because of time constraints; and (4) valid scientific studies have been conducted that support the potential for the intervention to provide a direct benefit to the patient).
44. Saver, supra note 8, at 232.
45. See Elysa Gordon, Multiculturalism in Medical Decisionmaking: The Notion of Informed Waiver, 23 FORDHAM URB. L.J. 1321, 1321 (1996) (providing a history of the ideals of autonomy and the doctrine of informed consent according to Western principles).
46. See U.S. CONST. amend. XIV (stating that no State shall deprive any person of life, liberty, or property without due process of law); see also Roe v. Wade, 410 U.S. 113, 152 (1973) (finding that a woman’s right to have an abortion is based upon the constitutional right to bodily privacy).
47. See Gordon, supra note 45, at 1325 (explaining the importance American society places on the individual and the principles of privacy and self-determination); id. at 1343 (stating that the emphasis on the individual in our society has influenced laws which provide for patient autonomy).
48. See JOHN LOCKE, TWO TREATISES OF GOVERNMENT 283 (Cambridge Univ. Press 1988) (writing that “the natural liberty of man is to be free from any superior power on earth and not to be under the will or legislative authority of man, but to have only the law of nature for his rule”); see also JOHN STUART MILL, ON LIBERTY (E. Rapaport ed., 1978).
These Western philosophers influenced American jurisprudence, and their ideals and theories are embodied in the Constitution.49

The concept of patient autonomy emerged as a response to the civil rights movement in the 1960s.50 Yet, it can also be seen in the early 1900s in the case of Schloendorf v. Soc'y of New York Hosp.,51 which held that a patient has a right to make decisions concerning his body except in the case of an emergency when the patient is unconscious and is unable to give informed consent.52 In 1972, the American Hospital Association issued A Patient’s Bill of Rights to convey the importance of patient autonomy.53

Informed consent initially developed as a safeguard to unauthorized touching, but it has been extended by the courts.54 The doctrine of informed consent embraces the ideas of autonomy, liberty, and privacy,55 and stems from a patient’s right to make decisions regarding his own body.56 The problem the medical community faces is how to advance emergency medical treatments without violating a patient’s autonomy.57 Can we justify the waiver of informed consent if it will save a person’s

49. See Gordon, supra note 45, at 1327 (stating that the concept of personal autonomy is a fundamental right which is supported by the right to bodily integrity, liberty and self determination which is interpreted by the courts to be in the Constitution).
50. Gordon, supra note 45, at 1327.
52. Id.
53. See Nancy E. Brazell, The Significance and Application of Informed Consent, 65 ASS’N OPERATING ROOM NURSES J. 377, 377 (1997) (noting that the Patient’s Bill of Rights includes statements that declare that a patient has a right to receive information regarding the risks, benefits and prognoses of the proposed treatment).
54. See Mohr v. Williams, 104 N.W. 12, 15 (Minn. 1905) (holding that patients have the right to weigh the risks and benefits of the proposed medical treatment); see also Pratt v. Davis, 79 N.E. 562, 564 (Ill. 1906) (holding that a physician should be required to obtain a patient’s informed consent before performing surgery if the patient is conscious and is in good mental health); see generally Cobbs v. Grant, 8 Cal. 3d 229, 242, 502 P.2d 1, 9, 104 Cal. Rptr. 505, 513 (1972) (enunciating four postulates related to the doctrine of informed consent: (1) Patients generally do not have the same knowledge as their physician; (2) competent adults have a right to make decisions with regard to their bodies; (3) patient consent must be an informed consent; and (4) patient puts trust in a physician because they have training and knowledge in the medical field).
55. Gordon, supra note 45, at 1327.
56. See Schloendorf, 105 N.E. at 129 (stating that “every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent, commits an assault”); see also Gordon, supra note 45, at 1328 (explaining that informed consent emphasizes the right of an individual to make decisions that affect their body). The doctrine of informed consent embodies four principles: (1) Emphasizes the right of an individual to make decisions regarding medical treatment; (2) encourages physicians to be forthright regarding the proposed treatment, risks, benefits and prognosis; (3) stresses secularism over spirituality; and (4) emphasizes the participation of an individual in medical decision making. Id.
57. See Saver, supra note 8, at 233 (acknowledging that there may be constitutional limits placed on attempts to relax or reform the informed consent doctrine, and that the right to privacy regarding medical treatment may be infringed by changes in the informed consent doctrine); see also Peter H. Schuk, Rethinking Informed Consent, 103 YALE L.J. 899, 924 (1994) (commenting on the fact that the principle of autonomy is deeply rooted in our society).
life? Can we reasonably assume that a patient would consent to an experimental therapy?58

One alternative is eliminating the informed consent doctrine altogether in critical care situations.59 The argument behind this proposal is that the medical community is ethically bound to do what is best for the patient, and if the doctor believes that he will have greater success saving the patient's life by administrating an experimental therapy, then he should be able to do so.60 The downside to implementing this alternative is that it opens the door to abuse.61

Another alternative is deferred consent in which a patient or patient's representative is told of the risks and benefits as soon as possible after the treatment has been administered.62 At this point, the patient or his representative can withdraw or decline further treatment.63 Another alternative is to seek consent from potential patients before they are in a life-threatening situation.64 The variety of alternatives signifies the conflict in the medical community between protecting a patient's autonomy and advancing medical research.

One of the main purposes of Chapter 68 is to improve the care of patients in life-threatening situations.65 A person who enters an emergency room unconscious or suffering from a cardiac arrest or a stroke is not in a position to weigh the risks and benefits of the proposed medical treatment.66 Time is of the essence; and, if the person's life is to be saved, it is important for the physician to have the authorization to act immediately in the best interest of the patient. The administration of an experimental therapy or drug may have a greater chance of saving a person's life

58. See Saver, supra note 8, at 231 (remarking that when the proposed treatment is experimental it is difficult to ascertain whether a reasonable person in the same circumstances would choose the experimental therapy over the standard treatment).

59. Id. at 241.

60. Id. at 241.

61. Id.; see Marek, supra note 1, at 2 (illustrating examples of abuse in the use of experimental therapies). For example, in Minnesota a hospital research review board permitted a cardiac resuscitation device to be tested on young children even though the device was intended for adults. Id. See generally MARY SHELLEY, FRANKENSTEIN (Bantam Books 1997) (1818) (illustrating a fabled example of a medical experiment that went awry).

62. See Saver, supra note 8, at 244 (explaining that under this approach the experimental therapy is used without obtaining informed consent, but as soon as the patient regains consciousness or the patient's legal representative is available, they are told of the procedure and have the option of withdrawing from the treatment).

63. Id.

64. See id. (commenting that, in theory high risk patients could be identified and contacted to seek their informed consent in the case that they are in a life-threatening situation and are unable to make decisions because of their medical condition).

65. CAL. HEALTH & SAFETY CODE § 24177.5(2) (enacted by Chapter 68); see ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (June 17, 1997) (stating that the Society of Critical Care Medicine asserts that without the passage of this bill, patients in emergency situations who might be saved by an investigational therapy will probably die).

66. See ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 160, at 2 (June 17, 1997) (stating that the California Health Care Association (CHCA) asserts that communication between a physician and his patient is difficult or impossible if the patient is facing a life-threatening situation).
than a standard therapy that does not have proven success. Chapter 68 was not established to compromise bodily integrity, autonomy or privacy; it was established to help save a greater number of lives.

IV. CONCLUSION

In order to improve the care of critically ill patients, the government needs to relax the rigidity of the informed consent doctrine while protecting an individual from abuse in the name of medical research. Chapter 68 and the FDA regulations are a step toward making it easier for medical professionals to use promising new therapies that may increase the number of lives saved of people suffering from strokes, comas, severe head injuries, and heart attacks where there are no proven satisfactory medical treatments. At the same time, however, these provisions are narrowly tailored to ensure effective protection of the critically ill patient's personal autonomy. In this way, advances in necessary medical research are possible without jeopardizing valuable patient rights.

67. *See* CAL. HEALTH & SAFETY CODE § 24177.5(6) (enacted by Chapter 68) (requiring that valid scientific studies of the experimental therapy be conducted to show that the administration of the therapy will be potentially beneficial to the patient).

68. *See* Saver, *supra* note 8, at 239 (acknowledging that inflexible rules can interfere with principles of beneficence and justice).

69. *See* Terence Burns, M.D., *CPR Advances Stymied by Informed Consent*, BUFFALO NEWS, Nov. 30, 1994, at 3 (declaring that if the doctrine of informed consent is not relaxed then the “treatment of cardiac arrest in 2000 will be the same as in 1994, with no advances, no progress and no improvement in survival rates”).

70. *See supra* note 43 and accompanying text (discussing the narrow requirements for consent to be waived in emergency situations).
Successful Animal Cloning Raises Questions About Human Cloning Possibilities: Science Fiction No Longer

Erin M. Stepno

Code Sections Affected
- Business and Professions Code §§ 2260.5, 16004, 16105 (added and repealed).
  SB 1344 (Johnston); 1997 STAT. Ch. 688
  SB 1344 (Johnston); 1997 STAT. Ch. 688

I. INTRODUCTION

[L]ike the splitting of the atom, this is a discovery that carries burdens as well as benefits.

–President Bill Clinton

In the February 27, 1997, issue of the science journal Nature, Dr. Ian Wilmut and his colleagues at the Roslin Institute in Edinburgh, Scotland, reported to the world that their laboratory had successfully cloned a sheep from an udder cell of an adult ewe. The cloned sheep, known as “Dolly,” triggered a worldwide debate as to the ethical, legal, moral, and religious implications surrounding the scientific breakthrough. Immediately, President Bill Clinton, on March 4, 1997, banned the use of federal monies for human cloning research and requested that the private sector voluntarily comply with the moratorium. President Clinton also requested that the National Bioethics Advisory Commission review the cloning situation and report back within ninety days.

On June 9, 1997, President Clinton accepted the recommendations of the Commission and asked Congress to ban human cloning for a minimum of five years, but also asked to allow scientists to pursue research involving recreation of human cells

2. Dr. Ian Wilmut et al., Viable Offspring Derived from Fetal and Adult Mammalian Cells, Nature, Feb. 27, 1997, at 310.
3. See Cimons & Peterson, supra note 1, at A1 (indicating that President Clinton wished for the cloning situation to be investigated further before any actual experiments take place).
and tissues. Since the cloning breakthrough was reported, national leaders in many fields have tried to propose a workable balance between the advancement of science and the facets of life that such breakthroughs affect. Lawmakers have striven to memorialize such a balance into legislation so that foreseeable problems with the research can be avoided.

In California, one such law has been adopted, Chapter 688, which mandates a five year moratorium on human cloning. The California Legislature believes, as does Congress, that the five year period will allow the legal, ethical, moral and religious fields to investigate foreseeable situations that may arise in light of the cloning breakthrough that occurred in Scotland.

II. WHAT IS ClONING?

The term "cloning" has, in recent years, become a part of our vernacular—easily found in literature, news broadcasts, and radio programs. However, while some citizens may consider "cloning" to be a procedure limited to producing many identical humans or complete organisms, scientists generally do not consider this to be the true use of the word. A biologist would define a "clone" to be a collection of genetically identical organisms, cells, viruses, or DNA derived from the reproduction of a virus, single cell, or DNA molecule. There are three common types of cloning techniques: molecular cloning, cellular cloning, and nuclear transplantation cloning.


6. See Senate Subcommittee on Public Health and Safety—Scientific Discoveries in Cloning: Challenges for Public Policy (1997) (statement of Bill Frist) (describing the purpose of the Congressional hearing as investigation into the public policy implications created by the cloning breakthrough); Charles Krauthammer, A Special Report on Cloning, TIME, Mar. 10, 1997, at 60 (listing medical advancement as one major facet of life that cloning may effect, such as insights into spinal cords, heart muscles, and brain tissues which do not regenerate after injury, as well as the growth patterns of cancer cells).

7. See News Release from Jim Battin, Assemblyman of Eightieth District (Apr. 16, 1997) (copy on file with the McGeorge Law Review) (stating that the cloning legislation, "[g]oes strictly to prohibiting the cloning of entire human beings and does not preclude potential beneficial uses such as regenerating spinal cord tissue for accident victims or skin tissue for burn victims").

8. LEGISLATIVE COUNSEL'S DIGEST, ANALYSIS OF SB 1344, at 1-3 (Oct. 4, 1997).

9. SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES, COMMITTEE ANALYSIS OF SB 1344, at 2-3 (Apr. 16, 1997).


11. LUBERT STRYER, BIOCHEMISTRY 71 (W.H. Freeman & Co., 3d ed. 1988) (defining “DNA” as “Deoxyribonucleic Acid which is a very long, threadlike macromolecule comprised of deoxyribonucleotides (each comprised of a base, sugar, and phosphate group) whose bases carry genetic information and whose sugar and phosphate groups give the molecule its characteristic double-helical structure”).

12. See BERG & SINGER, supra note 10, at 89 (clarifying the distinction between what scientists consider to be cloning and what others may perceive it as).

The first two types of cloning do not carry the possibility of developing another entire organism, as neither egg nor sperm cells are used, however both techniques have other applications. Molecular cloning has become an invaluable way for recombinant DNA technology to produce vital medical substances, such as insulin; while cellular cloning has enabled scientists to grow specific cells in a culture which results in a cell line that is identical to the original cell, an invaluable resource in studying the nature of many medical maladies. The latter method of cloning, nuclear transplantation cloning, is often referred to as "blastomere separation," and is capable of producing a genetically identical child or animal. It is this type of cloning that is the subject of Chapter 688.

III. THE OCCURRENCE IN SCOTLAND

In a most simplistic description, the scientists from the Roslin Institute and PPL Therapeutics in Midlothian, United Kingdom, successfully transferred the nucleus from an udder cell of an adult sheep into an egg whose DNA had been removed. The researchers reduced the nutrient-laden serum given to the donor cells in order for them to behave more like the inactive DNA found in an unfertilized egg or sperm. An electric current was then used to fuse the donor cell with an egg whose chromosomes had been removed. That fusion gave the egg a full compliment of new DNA and initiated the development process. Ironically, none of the scientists are certain as to how the DNA from the udder cell was able to direct the development of an entire new organism. Researchers are also uncertain as to how effective this procedure will prove in other organisms.

14. Id.
15. Id.
16. Id.
17. See BERG & SINGER, supra note 10, at 248 (defining "nucleus" as the sac within a eukaryotic cell that contains chromosomes).
19. Id.
20. Id.
21. Id.
22. Id.
23. Id. See generally Scientists Grow Monkeys from Cloned Embryos (visited July 26, 1997) <http://www.cnn.com/TECH/9703/02/monkey.monkey/index.html> (describing how scientists at the Oregon Regional Primate Research Center successfully produced two sibling rhesus monkeys using cloned embryos. These two monkeys are not genetically identical, as cells from different embryos were used, but set the stage for producing genetically identical animals).
IV. SOCIETAL ISSUES THAT CLONING AFFECTS

A. The Idea of Each Human Being as a Unique Individual

If the cloning procedures that made the existence of Dolly possible are refined to a point where the procedure is safe and effective for human beings, there would then be the possibility of creating an infinite number of genetically identical persons. Each cell of a human body contains the same genetic material, and thus provides an infinite supply of starting material for the cloning procedure. If many clones result from one person, both the original person and its clones will lack the concept of individuality that is such an important aspect of human life. The researchers in Scotland realized that their successfully cloned sheep may be seen as simply a scientific commodity and in all press releases referred to the sheep as “Dolly” to give the sheep an individual character, as opposed to “6LL3,” the title that she received in the scientific reports of which she was the subject. On the other hand, it must be noted that both genetic composition and environmental factors are what shape the existence of a human. Thus, like identical twins, the clones will share genetic material, but they may manifest this material in differing ways depending on their lifestyle and environment.

B. Choosing Traits and “Designing” Humans

Successful sexual reproduction results in an offspring that has inherited from its parents an unpredictable mix of the traits that they themselves express or carry within their genetic material. However, with cloning one may choose as the starting material of life a cell from a human who possess traits that they find attractive for various reasons. Such a concept brings to mind eugenic practices of the past that strove to propagate traits that were viewed as superior. Opponents of human cloning fear that if clones express only the most-beautiful attributes, then those individuals with disabilities of any sort would be greatly discriminated against and entirely devalued. In addition, some opponents fear that certain persons would arrange it so that they could clone the most intriguing persons of the time, not only

25. Id.
27. Id.
30. Id.
31. See Scientific Hearings, supra note 24 (detailing problems that may arise due to perfecting a person to a degree not currently possible).
to have a “child” potentially displaying such attributes, but solely for the notoriety of having done so.32

C. Reversal of Gender Roles, Notions of Surrogacy, and the “Family” Dynamic

With the advent of cloning, no longer is the union of males and females necessary in order to produce an offspring.33 Theoretically, only females are necessary for the propagation of the human race, because they alone have the ability to carry the clone to term.34 This notion has profound consequences for the orientation of gender roles and the idea of parental responsibility.35 Two possible situations exist that may remedy such a female-dominated hypothetical situation: (1) The use of surrogate “mothers,” and (2) the development of artificial wombs.36 To this day, surrogacy, as used for non-cloning reproductive technology, is unregulated at the federal level and only addressed in few states’ legislation.37 The creation of the necessary artificial womb for human gestation is long from being a reality and would present its own legal and moral debate.

In addition, as previously mentioned, the donor of the cell from whom the clone is produced will be a genetic copy of the clone.38 This genetic “twin” fits more closely the definition of a sibling to the cell donor, rather than its child.39 Thus, if human cloning advances to this point the legal and psychological ramifications of such technology will need to be addressed.

V. LEGAL ISSUES RAISED BY HUMAN CLONING

In addition to the moral and ethical concerns, there are many areas of law greatly affected by human cloning. The law has to this point failed to sufficiently address many scientific breakthroughs. For example, in vitro fertilization [IVF] technology raised questions of parental identity, posthumous reproduction, and embryo disposition that have yet to be legally settled.40 Suddenly, human cloning

32. See Wachbroit, supra note 29 (explaining one of the unlikely, yet not impossible, situations that cloning brings about).
33. See Scientific Hearings, supra note 24 (discussing how cloning would affect males and females differently).
34. Id.
35. Id.
36. Id.
37. Id.
39. Id.
40. Annas, supra note 26, at 80.
has surfaced and lawmakers seek to avoid the pattern of history and address foreseeable situations that this breakthrough presents.

A. Is the Ban on Cloning Constitutional?

As mentioned previously, President Bill Clinton banned the use of federal monies for human cloning on March 4, 1997, in light of the Dolly controversy. Ironically, according to the British Science Journal, *Lancet*, at that time no United States federal money was even being expended to such an endeavor. Legal experts have noted that such a ban raises many novel constitutional questions that need to be addressed with respect to the First, Fifth, and Fourteenth amendments as well as the interstate commerce clause.

Despite the outcome of these Constitutional inquiries, it must be noted that the role of the U.S. government in funding scientific projects has been on the decline for many years, and one must question the effect of such a ban. While the federal government continues to play a major role in its own laboratories and academic research, industry now outspends the U.S. Treasury by a ratio of approximately two to one. Moreover, many note that if a market for human cloning develops, despite "presidential grandstanding" and legislative enactments, people will be able to work around such rules.

B. Who Would Hold the Property Rights Over Cloning Material?

In 1992, a team of scientists from George Washington University successfully completed what is now known as "blastomere separation." In that experiment, polyploid embryos (embryos rendered non-viable due to the fact that they were fertilized by more than one sperm) at the two to eight cell stage of development were separated into single-celled organisms. Much like the situation regarding embryos created via blastomere separation, the legal community is puzzled by how cloning material should be classified.

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42. See Cloning Challenges Hearings, supra note 38 (stating that the constitutionality of a federal ban on human cloning research would need to be assessed in light of federal jurisdiction over private research. Such jurisdiction may be based on the Interstate Commerce Clause or the Fifth and Fourteenth Amendments of the United States Constitution, yet such jurisdiction would likely be subjected to opposition, including First Amendment freedom of inquiry claims).
43. See Greenberg, supra note 41, at 1850.
44. Id.
45. Id.
47. Id. at 1664.
48. Id. at 1660.
With respect to IVF, courts generally consider the created embryos to be the property of the parents of that embryo. Yet, the notion that children produced by a successful IVF procedure should themselves have property rights over the remaining embryos has not been tested in a court of law. This question arises because if a remaining embryo was allowed to go to term, it would be a genetic copy, much like the cloning procedure, of the initial successful embryo. Normally an individual possesses the DNA in his body, which is a unique entity of that individual and under their personal control. One state, Louisiana, has remedied this legal difficulty by classifying embryos created via IVF technology not as property, but as judicial persons until they are implanted, and prohibits intentional destruction of a viable embryo.

C. Current Forensic Techniques May Become Obsolete

In arguably one of the most fascinating aspects of human cloning, it has been noted that the current forensic method of DNA identification may be ruined by the cloning breakthrough. The DNA identification procedure currently operates on the notion that every individual's genetic makeup is unique and reliable in terms of determining who matches a given biological sample. Clones, as mentioned previously, will possess genetically identical material and render the procedure much less valuable.

VI. CALIFORNIA LEGISLATION DIRECTED TOWARD HUMAN CLONING

Within two weeks of the announcement of Dolly's existence, a bill was introduced in the California legislature that addressed the human cloning situation. It was observed that existing law did not address the notion of human cloning. Existing law covered only the act of knowingly using ova, sperm, or embryos in reproduction technology against the wishes indicated by the provider of that ova, sperm, or embryo. Existing law also prohibited the implantation of ova, sperm, or embryos via reproductive technology into a recipient who was not the provider of the implant material without having received the written consent of both the pro-

49. Id. at 1661.
50. Id.
51. Id.
52. Id. at 1668.
55. Id.
56. SB 1344 (listing its introduction date as March 11, 1997).
57. ASSEMBLY FLOOR, COMMITTEE ANALYSIS OF AB 1251, at 2 (July 8, 1997).
vider and the recipient. Violation of those laws was punishable by either a fine not to exceed $50,000, imprisonment from three to five years, or both a fine and imprisonment. In addition, unprofessional conduct complaints by either physicians or surgeons resulted in the matter being initially heard by the Medical Board which has the ability to revoke a doctor’s certificate, prohibit or suspend a doctor from practicing medicine, place that person on probation, reprimand publicly, or take any other action necessary to discipline the individual. The Division of Medical Quality of the Medical Board, an Administrative Law Judge, or the local District Attorney may also hear violations and pursue them as they see fit.

A. Chapter 688

Chapter 688 defines “clone” as the practice of:

Creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human egg cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.

This definition may not be entirely effective because technology may advance to a point where the “implantation” of the product is not necessary—effectually it will be ex vivo production of a viable embryo, and thus would render this definition too narrow to prohibit the conduct it intends to prohibit.

Chapter 688 states that its intent is to prohibit the cloning of an entire human being for a period of five years. This chapter will expire on January 1, 2003, which will allow the legislature to then review, update, and amend the provisions as deemed necessary at that time. This chapter does not hinder cloning of human cells, tissue, or organs, but instead only applies to the cloning of an entire human. During the five year period, Chapter 688 states that a panel of medical, religious, biotechnology and genetics representatives will be established to review the cloning situation and will then advise the Legislature and Governor regarding their findings.

59. Id. § 367g(b) (West 1988 & Supp. 1998).
60. Id. § 367g(c) (West 1988 & Supp. 1998).
62. Id.
63. CAL. HEALTH & SAFETY CODE § 24185(c) (added by Chapter 688).
64. Id.
66. CAL. BUS. & PROF. CODE § 2260.5(b) (added by Chapter 688).
68. Id.
Chapter 688 states that if the cloning prohibition is violated, penalties of between $250,000 and $1 million will be levied. Further, if the violator derives pecuniary gain from his conduct, he may be assessed a civil penalty up to twice the amount of the pecuniary gain, all monies being paid to the General Fund.

B. Gaps in Chapter 688

Though Chapter 688 attempts valiantly to address the human cloning situation, it leaves crucial gaps that may be exploited to the detriment of the State of California. For example, Chapter 688's fines may prove to be entirely too small if there indeed develops a market for cloned humans. It is entirely possible that even Chapter 688's highest penalty of twice the pecuniary gain from the endeavor would be but a fraction of the monetary gain incurred via successful cloning in that there is ambiguity as to how that amount will be determined. For example, if one was paid $10,000 to clone a human, the penalty would be $20,000. Yet, the one who completed the cloning procedure may then receive endorsement contracts or other types of compensation that are not directly related to the single cloning procedure which may greatly exceed the $20,000 fine. In that case, one may consider violating the law, recognizing that later compensation would eclipse the fine imposed.

In addition, the creation of Dolly by the Scottish researchers was preceded by 276 unsuccessful attempts. Chapter 688 does not address what is to be done with such unsuccessful attempts. Another ambiguity in Chapter 688 is its definition of "clone" which describes an activity that "could result in the birth of a human being." If a researcher could produce clones that fell short of satisfying Chapter 688's definition of human being (say, by not having reproduced all of the physical and mental attributes of the human cloned), that researcher may be able to argue that Chapter 688 was indeed not violated.

VII. CONCLUSION

The successful cloning of the sheep Dolly from the udder cell of an adult ewe catapulted the world into the reality of human cloning possibility. Such a scientific breakthrough carries with it tremendous promise, and at the same time tremendous moral, religious, ethical, and legal questions. As a nation we must decide if and how to proceed with cloning technology. More importantly, we must decide what exactly to proceed with. Cloning of human DNA in order to more easily manipulate

69. CAL. HEALTH & SAFETY CODE § 2418.7(a)(b) (added by Chapter 688).
70. Id. § 24187(c)-(d) (added by Chapter 688).
71. See Wilmut, supra note 2, at 810.
72. CAL. HEALTH & SAFETY CODE § 2418 (added by Chapter 688).
73. See supra note 2 and accompanying text.
74. See supra notes 3, 4 and accompanying text.
genes, replace diseased tissue, and conduct vital research has not been affected by Chapter 688. However, as with most areas of law, it may not always be easy to determine the bright line that distinguishes when Chapter 688 has been breeched. As advances occur in prenatal medicine and neonatal care, the need for a uterus (the "implantation" phase of Chapter 688) drops drastically and comes closer to rendering the chapter less efficient. The cloning breakthrough is an unprecedented intersection of science, morality, and law. The five year moratorium on human cloning is designed to allow such morality and law to catch-up with the scientific breakthrough and is essential to proceeding with this technology responsibly.