

# FACE/OFF: THE STRUGGLE BETWEEN INFORMED CONSENT AND PATIENT WELFARE IN FACIAL TRANSPLANT SURGERY

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## I. INTRODUCTION

*“The standards for consent should be highest in those settings in which other mechanisms for protecting patients from harm are absent; namely, innovative therapy.”<sup>1</sup>*

In the rapidly advancing field of medicine, surgeries involving the removal and transplantation<sup>2</sup> of human organs are not only possible, but in some areas have become commonplace.<sup>3</sup> Due to the experience and knowledge gained by performing these procedures, as well as advances in medical equipment, physicians today constantly push the limits of transplant medicine.<sup>4</sup> Specifically, the realm of transplant medicine has expanded from organs essential to life function into procedures that may improve quality of life, but are by no means vital. Before any transplant procedure can be initiated, consent to the procedure must be obtained from either the organ donor or the donor’s legal guardian.<sup>5</sup> Organ donor cards on the back of a driver’s license are a common form of donor consent for situations in which a

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1. Norman Fost, *Waived Consent for Emergency Research*, 24 AM. J.L. & MED. 163, 177 (1998).

2. *Organ Transplant*, WIKIPEDIA: THE FREE ENCYCLOPEDIA, Oct. 15, 2007, [http://en.wikipedia.org/wiki/Organ\\_transplant](http://en.wikipedia.org/wiki/Organ_transplant). “An organ transplant is the transplantation of a whole or partial organ from one body to another . . . for the purpose of replacing the recipient’s damaged or failing organ with a working one from the donor. Organ donors can be *living*, or *deceased* . . .” *Id.*

3. 26,689 organ transplants have been performed between January and November of 2006 alone. The Organ Procurement and Transplantation Network, Data, <http://www.optn.org/data> (last visited Feb. 7, 2007). About 80 people receive an organ transplant every day in the United States. *Id.*

4. “While the technology to perform [a face transplant procedure] has been available for some time, ethical concerns have delayed the implementation of such procedures.” Jim Bittermann, *Face patient wants ‘normal life’*, CNN.COM, Feb. 6, 2006, <http://www.cnn.com/2006/HEALTH/02/06/face.transplant/index.html> [hereinafter *Normal Life*].

5. See, e.g., Gift of Hope Organ & Tissue Donor Network, *How Donation Works*, <http://www.giftofhope.org/understanding-donation/how-donation-works.htm> (last visited Feb. 7, 2007).

vital organ is harvested.<sup>6</sup> Certain ethical concerns, however, are inevitable when the consent necessary to begin the procedure must be obtained. The chief ethical concern in cutting edge surgical procedures is whether either the donor or the recipient can truly give “informed consent.”<sup>7</sup> The extreme nature of new experimental procedures such as nerve transplants and facial transplants cater to individuals so desperate for treatment that obtaining informed consent is impossible.

This Note proposes that physicians cannot possibly explain certain transplant procedures in a way that will clearly inform the patient of the risks and consequences involved in undergoing the procedure. Under modern informed consent requirements, physicians are not required to disclose information regarding their own interests in performing the procedure to patients that lack the mental capacity to give informed consent under the rational patient standard. Additionally, this Note recommends that the best policy to assure that the best interests of the patient are fully considered is appointing a guardian for the patient. This guardian can perform an unbiased cost-benefit analysis regarding the likelihood of the operation’s success versus the consequences attached to failure. Part II of this Note lays out the interests of the parties involved in advanced medical procedures. An understanding of the positions of each of the parties involved, from the doctors, to the treating hospital, to the recipient and the donor, will lead to an understanding of why traditional notions of informed consent do not apply to proposed face transplants.

Finally, Part II will detail the consequences facing the parties if the transplant procedure is not a success. Part III of the Note analyzes current notions of informed consent, and will apply these concepts to the new procedure gaining notoriety in the medical world. Part IV of this Note suggests that traditional definitions of informed consent cannot be applied to procedures like facial or nerve transplants. Part IV concludes that a solution to this problem may be reached with the appointment of a guardian that can make an informed decision on behalf of the patient after a careful analysis of the entire situation, including the risks of the transplant being rejected by the patient’s body. This solution is advantageous because it protects the treating doctor and hospital from liability and puts the decision in the hands of a party capable of decision-making under the reasonable patient standard, uninfluenced by the strong emotions at work in the mind of the transplant recipient.

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6. *Id.*

7. The doctrine of informed consent has never been reduced to a single sentence definition. “[L]aw has neither defined sufficiently well the substance and ambit of informed consent in therapeutic settings nor determined clearly its functional relevance for human experimentation.” JAY KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* 523 (1972). “The doctrine of informed consent developed out of strong judicial deference to individual autonomy, reflecting a prevalent belief in American jurisprudence that an individual has a right to be free from nonconsensual interference with his or her person.” 1 BARRY R. FURROW ET AL., *HEALTH LAW* § 6-9, at 315. “[Informed consent] has become one of the forces altering the attitudes of a new generation of doctors toward their patients, and its requirements are now reflected in consent forms that health care institutions require patients to sign upon admission and before various procedures are performed.” *Id.*

## II. BACKGROUND

### A. *The Function of Informed Consent*

The critical inquiry one may have when looking into cutting edge or experimental surgical procedures is “why do I care about informed consent?” or “aren’t I paying the doctor to make these decisions for me?” The doctrine of informed consent functions to promote individual autonomy and encourage rational decision making in situations where the patient does not have the expertise necessary to determine his or her own course of treatment.<sup>8</sup>

The concept of informed consent is a legal hybrid.<sup>9</sup> “The modern law of informed consent to medical care has contributed to a fundamental shift in the relationship between physicians and patients.”<sup>10</sup> The doctrine of informed consent has developed in doctor-patient relations as a result of the widely held American belief in individual autonomy, as well as the principle that it is wrong to force another person to act against his or her will. As it has developed through the last century, the informed consent doctrine has guided medical decision-making policy by establishing the boundaries of the doctor-patient relationship; resulting in health care providers issuing mandatory “consent to treatment” forms the patient must sign before admission or before various procedures are performed.

The first United States case that clearly recognized a patient’s right to participate in medical decision-making was *DeMay v. Roberts*,<sup>11</sup> in 1881. In that case, a young pregnant woman had gone into labor and summoned a doctor to assist her.<sup>12</sup> The doctor arrived in the company of a man that not only did the woman not know, but who had no medical knowledge or experience.<sup>13</sup> The doctor did not inform the woman as to the identity of his friend, but the friend proceeded to assist with the delivery.<sup>14</sup> The patient assumed that the stranger was another doctor, but eventually discovered that he was not.<sup>15</sup> The court found that both the doctor and his friend, the defendants in the case, were guilty of deceit and owed the plaintiff a duty to completely inform her as to the nature of the second person and ask her to consent to his staying in the room.<sup>16</sup> Anything else, the court found, would be an invasion of privacy.<sup>17</sup> The court’s analysis, however, was more consistent with an action for assault and battery, rather than the negligence and malpractice based theory of modern times.

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8. See FURROW ET AL., *supra* note 7, at § 10-4, at 523–24.

9. *Id.* § 10-4 at 523.

10. INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (2002).

11. 9 N.W. 146 (Mich. 1881).

12. *Id.*

13. *Id.* at 146–47.

14. *Id.* at 148.

15. *Id.*

16. *Id.* at 149.

17. *Id.*

In his opinion in *Schloendorff v. Society of New York Hospital*,<sup>18</sup> Justice Cardozo articulated the modern concept of informed consent. In that opinion, Justice Cardozo stated that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”<sup>19</sup> While Cardozo articulated the idea that led to the development of the modern concept of informed consent in 1914, the phrase “informed consent” did not appear until several decades later. From *Schloendorff* through the first half of the twentieth century, there was not any requirement that specific types of information be given to patients before they agreed to surgery or other medical treatment.<sup>20</sup>

The phrase “informed consent” was first put to paper in *Salgo v. Leland Stanford Jr. University Board of Trustees*.<sup>21</sup> The holding in *Salgo* united the principles discussed above in *DeMay* and *Schloendorff*. The court held that written consent is ineffective if the patient failed to understand material information about the procedure to be performed.<sup>22</sup> Moreover, the Court held that “[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”<sup>23</sup> The holding in *Salgo* therefore established the baseline rule that before any procedure is to be performed, the treating physician must take measures to ensure that the patient clearly understands everything the procedure entails.<sup>24</sup> The *Salgo* ruling, however, gave rise to the question of what standard of disclosure was applicable in such situations. In this area, *Salgo* only offers the guidance that the “physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action.”<sup>25</sup>

The holding in *Salgo* gave rise to two competing judicial standards of physician information disclosure dealing with the minimum amount of information necessary to shield the physician from liability.<sup>26</sup> First, the

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18. 105 N.E. 92 (N.Y. App. 1914).

19. *Id.* at 93.

20. INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, *supra* note 10, at 121.

21. 317 P.2d 170 (Cal. App. 1957).

22. *Id.* at 181.

23. *Id.* The court did not stop there; the opinion went on to lay out several other courses of conduct that a physician must follow when caring for a patient: “Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient’s consent.” *Id.*

24. *Id.*

25. *Id.* at 181. The court laid out two courses of action for a careful physician to follow. “One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; . . . it may also result in actually increasing the risks by reason of the psychological results of the apprehension itself.” *Id.* The other method proposed by the court was to recognize that “each patient presents a separate problem, the patient’s mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.” *Id.*

26. Only the physician based and reasonable patient standards have been adopted by state law. The third, the “subjective patient standard,” has not been adopted by the courts “because of deep-rooted fears that the patient, with hindsight, will say that the information not disclosed was indeed important to her and that she would have declined treatment.” FURROW ET AL., *supra* note 7, § 6-9 at 319.

“physician based” standard measured the duty to disclose by the standard of a reasonable doctor acting in a similar situation.<sup>27</sup> The second was the “reasonable patient” standard, which makes the level of information required by a reasonable patient in the same situation the proper level of disclosure.<sup>28</sup>

Until the holding in *Canterbury v. Spence*,<sup>29</sup> it was assumed that the standard of care for obtaining informed consent, like other medical standards of care, was set by medical custom.<sup>30</sup> Thus, the physician-based standard of care was the majority view in cases involving a patient’s informed consent to a medical treatment or procedure. After *Canterbury*, however, the reasonable patient standard has become the majority standard applied by state courts.

*Canterbury* built upon the *Salgo* opinion and continued to shape the modern notions of what constitutes a patient’s informed consent to a medical procedure. In its opinion, the court acknowledged that “the physician’s noncompliance with a professional custom to reveal, like any other departure from prevailing medical practice, may give rise to liability to the patient.”<sup>31</sup> This is where the court parted ways with prior holdings in other jurisdictions,<sup>32</sup> stating that it believed that there “are formidable obstacles to acceptance of the notion that the physician’s obligation to disclose is either germinated or limited by medical practice.”<sup>33</sup> The court defined a standard that revolved around the needs of the patient, and established the reasonable patient standard. The *Canterbury* court required disclosure “when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.”<sup>34</sup> In essence, the court found that a doctor must disclose information if he or she believes that a reasonable person in the patient’s situation would deem that information significant enough to affect the patient’s decision to follow the doctor’s proposed course of treatment. This blazed a new standard that other jurisdictions have adopted within the last 30 years.<sup>35</sup> Some courts have characterized this patient-oriented characterization of medical decision making as “patient sovereignty.”<sup>36</sup>

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27. *Id.* at 318.

28. *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972).

29. *Id.*

30. *Canterbury* “was a ground-breaking departure from the usual manner of determining what disclosures a physician must make to a patient.” CARL COLEMAN, ET AL., *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* 299 (2005). The plaintiff in *Canterbury* brought a medical malpractice action, a type of negligence claim. “[M]alpractice actions typically require proof that the physician deviated from the ‘standard of care,’ and the standard of care has traditionally been determined by looking at the medical community’s customary practices.” *Id.*

31. *Canterbury*, 464 F.2d at 783.

32. *Id.* (“We do not agree that the patient’s cause of action is dependent upon the existence and nonperformance of a relevant professional tradition.”)

33. *Id.* Furthermore, “[i]n our view, the patient’s right of self-decision shapes the boundaries of the duty to reveal.” *Id.* at 786.

34. *Id.* at 787 (quoting Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U. L. REV. 628, 640 (1970)).

35. See, e.g., *Korman v. Mallin*, 858 P.2d 1145, 1149 (Alaska 1993) (adopting the reasonable patient standard, or what it considered to be the “modern trend”); *Carr v. Strode*, 904 P.2d 489, 494 (Haw. 1995).

36. See, e.g., *Backlund v. University of Washington*, 975 P.2d 950, 956 n.3 (Wash. 1999). (defining

Today, “informed consent” connotes slightly different ideas in different jurisdictions.<sup>37</sup> Across the United States, this notion includes a list of informational items that must be passed from doctor to patient. The American Medical Association (“AMA”) Web site contains information regarding informed consent to advise practicing physicians.<sup>38</sup> The AMA defines informed consent as “more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.”<sup>39</sup>

The AMA has drafted a list of discussion items that a physician should go over with a patient when determining if the patient would like to proceed with

patient sovereignty as entitling a patient to sufficient information to make an informed health care decision).

37. For instance, the state of Illinois defines written informed consent as follows:

“Written informed consent” means an agreement in writing executed by the subject of a test or the subject’s legally authorized representative without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion, which entails at least the following:

- (1) a fair explanation of the test, including its purpose, potential uses, limitations and the meaning of its results; and
- (2) a fair explanation of the procedures to be followed, including the voluntary nature of the test, the right to withdraw consent to the testing process at any time, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of information identifying the subject of the test and the results of the test, to the extent provided by law.

410 ILL. COMP. STAT. 305/3(d) (2005).

Illinois has additional requirements in cases where experimental procedures are involved:

Sec. 3.1. (a) Any patient who is the subject of a research program or an experimental procedure, as defined under the rules and regulations of the Hospital Licensing Act [210 ILL. COMP. STAT. 85/1 et seq. (2006)], shall have, at a minimum, the right to receive an explanation of the nature and possible consequences of such research or experiment before the research or experiment is conducted, and to consent to or reject it.

(b) No physician may conduct any research program or experimental procedure on a patient without the prior informed consent of the patient or, if the patient is unable to consent, the patient’s guardian, spouse, parent, or authorized agent.

(c) This Section shall not apply to any research program or medical experimental procedure for patients subject to a life-threatening emergency that is conducted in accordance with Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations.

410 ILL. COMP. STAT. 50/3.1 (2005).

The state of Washington uses a more specific definition:

If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:

- (1) A description, in language the patient could reasonably be expected to understand, of:
  - (a) The nature and character of the proposed treatment;
  - (b) The anticipated results of the proposed treatment;
  - (c) The recognized possible alternative forms of treatment; and
  - (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;
- (2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section. Failure to use a form shall not be admissible as evidence of failure to obtain informed consent.

WASH. REV. CODE § 7.70.060 (2006).

38. American Medical Association, Informed Consent, <http://www.ama-assn.org/ama/pub/category/4608.html> (last visited Oct. 15, 2007).

39. *Id.*

a certain procedure.<sup>40</sup> Finally, an excerpt from the AMA's Council on Ethical and Judicial Affairs crystallizes the AMA's position on the requirements of the treating physician; "[t]he physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice."<sup>41</sup> The AMA guidelines attempt to guide physicians in recommending procedures in an ethical manner while providing patients with an understanding of their treatment.

The legal requirements of informed consent vary from state to state, but several statutory requirements are usually present.<sup>42</sup> For example, Illinois courts, when reviewing claims based on a lack of informed consent, require a plaintiff to show

- (1) the physician had a duty to disclose material risks; (2) he failed to disclose or inadequately disclosed those risks; (3) as a result of this failure to disclose, the plaintiff consented to treatment to which he would not otherwise have consented; and (4) the treatment caused the plaintiff injury.<sup>43</sup>

Other states require "a physician to reveal the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment."<sup>44</sup> The majority of states apply the rational patient standard when determining the proper level of physician disclosure. These standards apply not only to routine procedures necessary for a patient's treatment, but also include experimental and research procedures, such as facial transplant surgeries.<sup>45</sup>

40. "In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention." *Id.*

41. CODE OF MEDICAL ETHICS § 8.08 (Council on Ethical and Judicial Affairs, Am. Med. Assoc. 2002).

42. "The focus is on whether a reasonable person in the patient's position probably would attach significance to the risk. The crucial indicator is the patient's need." *Harbeson v. Parke Davis, Inc.*, 746 F.2d 517, 523 (9th Cir. 1984) (quoting *Miller v. Kennedy*, 522 P.2d 852, 863 (Wash. Ct. App. 1974)).

43. *Welton v. Ambrose*, 814 N.E.2d 970, 978 (Ill. App. Ct. 2004). Illinois operates under the physician-based standard of disclosure in regard to informed consent. "[A] physician must disclose to the patient the risks that a reasonable medical practitioner would have disclosed in similar circumstances." *Id.*

44. *Wachter v. U.S.*, 877 F.2d 257, 260 (4th Cir. 1989). The Fourth Circuit applied Maryland law, which operates under the rational patient based standard of disclosure. "As to what data are significant enough to warrant disclosure, [the standard is] whether a reasonable person in the patient's position would consider the data significant to the decision whether to submit to a particular treatment or procedure." *Id.* (citation omitted).

45. See RONALD MUNSON, INTERVENTION AND REFLECTION: BASIC ISSUES IN MEDICAL ETHICS 474 (6th ed. 2000) ("The notion of informed consent is also considered a requirement that has to be satisfied before a

### B. *The Face Transplant Procedure*

The idea of taking the face off of a donor body and grafting it to another recipient has been present in tales of science fiction for some time.<sup>46</sup> In the past few years, the face transplant has begun to make a splash in mainstream media. In November 2005, the F/X station's fictional drama "Nip/Tuck" devoted an episode to the topic.<sup>47</sup> Specifically, the mother of a young woman whose face had been horribly scarred solicited the services of two plastic surgeons.<sup>48</sup> With the woman was another mother, whose own daughter was in a persistent vegetative state, with no hope of ever waking from the coma.<sup>49</sup> The women asked the surgeons to remove the facial tissue of the daughter in the coma and graft it on to replace the other daughter's burned tissue.<sup>50</sup> This type of surgical procedure is at the center of controversy in the real world as well, due to scientific advancements in transplant surgeries.

The technology and techniques being applied by doctors to facial transplants is drawn from more established transplant techniques involving other body parts. "With the advance of microsurgical techniques and immunosuppressant drug therapies that have allowed successful transplantation of hands and lower limbs, a number of plastic surgeons have been quietly working in recent years toward applying the same skills to the face."<sup>51</sup> Dr. Warren Briedenbach is a leading surgeon working on the perfection of facial transplant techniques.<sup>52</sup> His experimentation has allowed a time estimate of the procedure to be established.<sup>53</sup>

"Once removed from the donor, a face, much like a heart, can survive without adequate blood supply for only a matter of hours before it begins to suffer tissue damage."<sup>54</sup> Thus, there is a strict time limit between when the donor tissue is harvested and when it must be attached to the recipient. If the recipient changes his mind, then it is unlikely that another adequate recipient

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person can legitimately be subjected to medical treatment. Thus, people are asked to agree to submit themselves to ordinary medical procedures such as blood transfusions, or to other procedures such as surgical operations or radiation therapy.")

46. Face transplants played a central role in the successful 1997 film titled *FACE/OFF* (Paramount Pictures 1997), starring Nicholas Cage and John Travolta. The plot of the film revolved around a procedure that grafted the facial tissue of the character played by Nicholas Cage onto the head of the character played by John Travolta. The rest of the movie predictably revolved around the confusion resulting from such a procedure. While at the time this sort of idea was purely science fiction, medical technology has advanced to the point where such procedures are being seriously considered. However, the transplants discussed in this Note would not result in such confusion due to differences in the underlying facial structure of the patient and donor.

47. *Nip/Tuck: Hannah Tedesco* (FX television broadcast Nov. 15, 2005).

48. *Id.*

49. *Id.*

50. *Id.*

51. Do Face Transplants Make You Nervous? Outspoken Proponent Explains All in New York Times Interview, <http://www.allbusiness.com/health-care-social-ambulatory-health-services/524907-1.html> (last visited Oct. 15, 2007) [hereinafter *Nervous*].

52. *Id.*

53. "Having done trial procedures with cadavers, Butler estimates that the harvesting or 'degloving' of a face would take approximately two hours, depending on the depth of the excision. *Id.*

54. *Id.*

could be found and prepped for surgery. “With the recipient’s scar tissue removed and the essential arteries and veins exposed, surgeons would attach them to the corresponding arteries and veins in the harvested face in order to supply both nourishment and drainage.”<sup>55</sup> The complexity of the attachment to the recipient’s head becomes more complicated as the level of damage increases.<sup>56</sup> Thus, the complexity and ultimate success of the transplant depend on the unique circumstances presented by each potential patient.

Another integral component to the success of facial tissue transplants is the debilitating drug cocktail that the recipient is subsequently prescribed.<sup>57</sup> After a successful transplant of facial tissue, the anti-rejection drug cocktail must be taken by the recipient for the rest of his or her life.<sup>58</sup> If the patient does not follow this strict drug regime, there is a significant possibility that the recipient’s immune system will reject the donor tissue.<sup>59</sup> In the event of a tissue rejection, the patient is left worse off than if the procedure had never occurred because no skin tissue remains on the patient’s face and a skin graft surgery must then be performed.<sup>60</sup> Thus, the immune suppression drugs become a critical element of the patient’s decision.<sup>61</sup>

### C. The Patient

The recipient of a cutting-edge facial transplant is not a science-fiction character or a government agent sent to infiltrate a terrorist organization.<sup>62</sup> The facial transplant procedure is not elective.<sup>63</sup> The procedure is aimed at those who have suffered severe facial scarring as a result of trauma.<sup>64</sup> Doctors hope to significantly improve the quality of life of such individuals by performing the complicated transplants.<sup>65</sup> A face transplant would permit surgeons to mold an actual face and underlying tissue, which proponents say is closer to what nature intended.<sup>66</sup> Doctors want their patients to regain the ability to eat, drink and communicate with others through the vast array of facial expressions that few people think about unless they are lost.<sup>67</sup>

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55. *Id.*

56. “The deeper the cut, the more complex becomes reattachment.” *Id.*

57. Jon Bowen, *Gaining Face*, SALON, May 19, 1999, [http://www.salon.com/health/feature/1999/05/19/face\\_transplants/print.html](http://www.salon.com/health/feature/1999/05/19/face_transplants/print.html).

58. *Id.*

59. *Woman Has First Face Transplant*, BBC NEWS, Nov. 30, 2005, <http://news.bbc.co.uk/1/hi/health/4484728.stm> [hereinafter *First Woman*].

60. *U.S. Plans First Face Transplant*, BBC NEWS, Sept. 19, 2005, <http://www.news.bbc.co.uk/2/hi/health/14259538.stm>.

61. *See infra* Part III.A.

62. This was the plot of the motion picture *FACE/OFF*. *FACE/OFF* (Paramount Pictures 1997).

63. ‘*Face Transplant*’ Sparks Concerns, CNN.COM, Dec. 1 2005, <http://www.cnn.com/2005/HEALTH/12/01/france.face/index.html>.

64. The goal is helping people who often say they are shunned by society and lead extremely unhappy lives. *Normal Life*, *supra* note 4.

65. *See generally* Craig S. Smith, *As a Face Transplant Heals, Flurries of Questions Arise*, N.Y. TIMES, Dec. 14, 2005, at A1 (reporting on the first partial face transplant).

66. Peter Gerner, *Surgery’s Next Step: Face Transplants*, CHI. TRIB., June 12, 2005, at 1, available at <http://www.chicagotribune.com/features/health/chi-0506120244jun12,1,1875144.story>.

67. *See generally id.*

As stated earlier, the patients considered to benefit from facial transplants are typically victims of a catastrophic accident, leaving faces horribly burned or scarred, or without any remaining sensation. “The typical candidates under consideration by [Dr.] Butler[,] [a physician preparing to perform a facial transplant surgery,] and his team for their initial attempt are people with severe facial burns that have lost not merely appearance but also normal facial function. [The patient’s] face is disintegrated . . . They have no nose. No ears. The eyes won’t properly close, leaving them open to infection. They aren’t able to open their mouths.”<sup>68</sup>

Several issues are at the forefront of the patient’s decision process when considering whether to go through with the surgery. One of the biggest concerns is what the recipient will look like upon completion.<sup>69</sup> One closely held patient fear is that he or she will no longer be able to recognize the stranger staring back at them in the mirror, and be forced to live their life looking like someone else. This may not necessarily be the case, however. Dr. Butler believes that the end result of the surgery would be a cross between the donor’s skin and the recipient’s underlying facial structure.<sup>70</sup> While this is a best-case scenario, the fact is that the procedure may not be everything for which the patient hopes.

The potential for a negative outcome is high; Dr. Butler proceeds carefully in considering if the procedure is truly in the best interests of the patient.<sup>71</sup> “My gut reaction is that we are pressing too far, too fast with ideas that impinge on our understanding of what normality is. I’m concerned that it’s actually one step further down the route of not accepting anything abnormal in this society.”<sup>72</sup> This raises the question of whether performing such procedures is truly in the best interest of the patient at all, or if the procedures are being advanced by doctors eager to see if they can actually succeed, or if, as Dr. Butler fears, facial transplants are being considered largely due to society’s revulsion towards individuals with such extensive scarring.

Another major consideration before the patient is the procedure’s likelihood of success, which currently is around 50%.<sup>73</sup> This is the same percentage of success that surgeons for the Cleveland Clinic in Ohio are quoting to patients while preparing for the Clinic’s first face transplant.<sup>74</sup> Dr.

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68. *Nervous*, *supra* note 51.

69. Jane Elliot, *Do Not Rush into Cosmetic Surgery*, BBC NEWS, Oct. 29, 2004, <http://news.bbc.co.uk/2/hi/health/3964135.stm>.

70. *Nervous*, *supra* note 51. (“What we’re proposing is taking the skin envelope with or without some muscle. So if I were to transplant my face onto you, it would look much more like you than me, because the skin envelope is elastic. The things you would have of mine are skin tone, texture, eyebrow color, beard, things of that nature.”).

71. *Ethical Minefield Dogs Face Transplant Pioneer*, ABC NEWS ONLINE, Dec. 30, 2002, [http://abc.net.au/news/scitech/2002/12/item20021226154247\\_1.htm](http://abc.net.au/news/scitech/2002/12/item20021226154247_1.htm).

72. *Id.*

73. *Clinic Gets OK on Face Transplants*, CBS NEWS, Nov. 1, 2004, <http://www.cbsnews.com/stories/2004/09/17/health/main644116.shtml> [hereinafter *Clinic Gets OK*].

74. *Id.*

Maria Siemionow will lead the surgical team.<sup>75</sup> The team will remove skin and underlying tissues from the patient, and then replace those tissues with those from a matched cadaver.<sup>76</sup> While these types of operations give hope to patients who have already suffered a great deal in life, based on this percentage, there is a great chance that such patients will go through with the surgery for nothing.

Furthermore, even if the surgeries are a success, anti-rejection drugs must be ingested by the patient for his or her lifetime in order to prevent the body's immune system from rejecting the new tissues.<sup>77</sup> For those whose need for a transplant stems from scarring related to facial tissue cancers, the continued ingestion of anti-rejection drugs greatly increases the likelihood of cancer returning.<sup>78</sup> Ironically, this leaves the patient with a decision to either live with disfigurement, or risk another bout with cancer or another serious illness. Finally, if the patient does not stay on the drugs, the body could reject the donor facial tissue, resulting in "a transplanted face . . . sloughing away, leaving the patient worse off than before."<sup>79</sup>

At this stage experts have difficulty clearly explaining what "worse off than before" really means. Some doctors have described the rejection as "leav[ing] the patient with an extensive facial wound with potentially serious physical and psychological consequences."<sup>80</sup> The only solution at that point would be to perform a more traditional skin graft using skin taken from the patient's own body, often inch by inch from the back, abdomen, legs, arms, and buttocks.<sup>81</sup> Understandably, there has been a considerable amount of hesitation and debate within the medical community as to whether facial transplants should be attempted at all.<sup>82</sup>

#### D. The Physicians

Physicians are another party with a significant interest in the application of new surgical techniques. Physicians are unique in that they want what is best for the patient, but at the same time desire advancing surgical procedures in their fields. The debate on whether facial tissue transplants should be attempted continues to rage in the United States and Europe. Another debate pertains to the characteristics that should be presented in the ideal transplant candidate.<sup>83</sup> One point of agreement between doctors is that facial tissue

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75. *Id.*

76. *Id.*

77. Michael Smith, *Rare Transplant Aims to 'Rewire' Nerves*, CNN.COM, Nov. 18, 2005, <http://www.cnn.com/2005/HEALTH/11/17/nerve.transplant/index.html>.

78. *Id.*

79. *Id.*

80. *Id.* (statement of bioethicist Carson Stronger).

81. *See generally id.* (describing a nerve transplant that involved traditional skin grafts).

82. *See Face Transplant Battled Tissue Rejection*, MSNBC.COM, Jan. 18, 2006, <http://www.msnbc.com/id/1096232> ("American doctors . . . said they would attempt a face transplant only as a last resort for a severely disfigured patient.").

83. "A number of us here are interested in making this a widespread procedure available to the public. It's the future, and could benefit millions of people." *New Face, New Lips, Old Habit*, CBS NEWS, Jan. 19,

transplants are not within the realm of “traditional” cosmetic surgery.<sup>84</sup> Due to this, facial transplants are not only a lightning rod for ethical debate in the medical community, but also represent an opportunity for individual professional achievement.<sup>85</sup>

In the instance of facial transplant surgery, the interest that surgeons have in upholding the Hippocratic oath seems to be in conflict with their underlying interests in achievement within their field and specialty, and gaining fame and success amongst professional peers and the public as a whole. Requiring a patient to provide informed consent to such a procedure also clashes with the traditional role of the physician. As the Institute of Medicine has observed, “[t]he ethical ideal of informed consent, grounded in the philosophical concept of autonomy, represents a departure from the paternalistic traditions of medicine revealed in the Hippocratic text, in which physicians were told to direct their commitment to the health and well-being of their patients, but were not instructed to foster their independence of thought or individual choice.”<sup>86</sup>

While the medical community has worked to resolve the conflict between the traditional Hippocratic patient care system and the idea of informed patient choice,<sup>87</sup> there is an additional conflict found with experimental procedures. If a facial transplant surgery is performed in the United States, then a physician also has the underlying interest in being the first physician or team to attempt such a transplant and complete it successfully.<sup>88</sup> This leads to pressure on the patient to consent to the procedure before he or she fully understands the consequences, for fear that the physicians will move on to another candidate. The physicians’ competing interests give rise to the concern that in the rush to successfully perfect a new cutting edge medical technique, physicians may lose sight of the patient’s best interests. This is evidenced by the media frenzy surrounding “Isabelle,” the first recipient of a *partial* facial tissue transplant procedure.<sup>89</sup> At a news conference revealing the results of Isabelle’s procedure, “some American doctors said it is time to stop debating whether the French operation was ethical or wise and focus now on making such transplants as safe and widely available as possible.”<sup>90</sup>

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2006, <http://www.cbsnews.com/stories/2006/01/19/health/main1219318.shtml> (statement of Dr. Suzanne Ildstad) [hereinafter *New Face*].

84. See *Normal Life*, *supra* note 4 (“While the surgery to perform it has been available for some time, ethical concerns have delayed the implementation of such procedures.”).

85. See *generally id.* (highlighting the publicity surrounding face transplant surgery).

86. INSTITUTE OF MEDICINE, RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS 120 (The National Academics Press 2002).

87. “The result of that discussion, in the context of the legal opinions and scholarship, was the general agreement that paternalism was no longer appropriate as the guiding philosophy of medicine and physician practice.” *Id.* at 121.

88. There are several units attempting to perform facial transplants around the world. For instance, besides Dr. Sieminow and Dr. Butler, a team led by Dr. Warren Breidenbach (lead surgeon of the first successful hand transplant) and a surgical team based in Australia are all in the planning stages of performing a procedure. *Nervous*, *supra* note 51.

89. The only portion of Isabelle’s face replaced with donor material was the area consisting of her nose, mouth and chin. *New Face*, note 83 (explaining that donor cadavers are the primary source of facial skin tissue).

90. *Id.*

While some of the interests presented by patient and doctor tend to overlap when applied to the mechanics of the actual surgery, the risks of performing facial or nerve tissue transplants are readily apparent as well as highly significant. If a procedure is not a success, not only is the patient left worse off than before the surgery took place, but the tissue donated by the donor is left completely useless. Thus, if the surgery is not a success, the donor and the patient are left worse off.<sup>91</sup> While in the case of a facial transplant from a cadaver this may not be particularly relevant, it still results in the need of a cremation or closed casket funeral for the deceased. Thus, the ramifications of a facial transplant procedure do not only effect the patient, but also the donor and treating physicians.

### III. ANALYSIS

#### A. *The Shortcomings of Current Informed Consent Requirements*

This section of the Note examines and applies principles of informed consent to the physicians and patients involved in facial tissue and nerve tissue transplantation procedures. This section includes a discussion of whether current informed consent principles adequately cover the types of new cutting-edge surgeries in the media today. Finally, this section determines that shortcomings regarding disclosures by the physician to the patient under current informed consent standards do not provide the patient with enough information to make an informed decision to undergo a facial transplant.

Due to the gravity and incredible risk involved in experimental procedures like facial tissue transplants, as well as the physical and mental states the patients are in when considering the procedure, many experts feel that obtaining informed consent is impossible. "Doctors not infrequently offer patients new or unproven interventions as part of a patient's medical care. These situations are similar to research in that the patient is being asked to consent to something whose safety and efficacy have not yet been established."<sup>92</sup> Other commentators think that obtaining informed consent from a patient is

an empty ritual not only because it does not require physicians to disclose the uncertainties inherent in their interventions . . . but also because the doctrine remains so inattentive to its underlying *idea* that patients and physicians must make decisions jointly, with ultimate decision making authority residing in the patient and *not* in the physician.<sup>93</sup>

Attempts have been made to draft an informed consent document for these new types of patients and procedures, but the wording does not truly

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91. While technically the donor is left worse off than prior to the surgery, this harm is usually minimized since donors in facial transplants are recently deceased. See *Clinic Gets OK*, *supra* note 73.

92. COLEMAN ET AL., *supra* note 30, at 304.

93. Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 13 (1993).

communicate the multitude and severity of risks involved.<sup>94</sup> Here is a sample consent form presented to a potential facial transplant patient:

Your face will be removed and replaced with one from a cadaver, matched for tissue type, age, sex and skin color. Surgery should last 8 to 10 hours; the hospital stay, 10 to 14 days.

Complications could include infections that discolor your new face and require a second transplant or reconstruction with skin grafts. Drugs to prevent rejection will be needed lifelong, and they raise the risk of kidney damage and cancer.

After the transplant you might feel remorse, disappointment, or grief or guilt toward the donor. The clinic will try to shield your identity, but the media likely will discover it.<sup>95</sup>

These few gentle reminders are not enough to paint a true picture of what could happen if the patient decides to go through with the procedure. The form contains no statistical data regarding the likelihood of failure, or the development of infection or other diseases. Moreover, it leaves the reader with a suggestion of potential fame and notoriety as a result of undergoing the procedure.

There are several critical factors that many jurisdictions agree must be included in the information that the physician presents to the patient before the patient can be deemed to have given informed consent to treatment.<sup>96</sup> The federal government lays out the elements of informed consent regarding experimental procedures in 45 C.F.R. § 46.116 as the following:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research and research

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94. See Anthony Renshaw et al., *Informed Consent for Facial Transplantation*, 19 *TRANSPLANT INT'L* 861, 861–62 (2006), available at <http://www.blackwell-synergy.com/action/showPdf?submitPDF=Full+Text+PDF+%2874+KB%29&doi=10.1111%2Fj.1432-2277.2006.00358.x> (attributing uncertainty and a general lack of data as primary difficulties in obtaining informed consent).

95. Associated Press, *Facing Up to Ultimate Transplant*, *WIRED.COM*, Sept. 19, 2005, <http://www.wired.com/news/medtech/0,1286,68907,00.html> [hereinafter *Facing Up*].

96. See FURROW ET AL., *supra* note 7, at 319–36.

subjects' rights, and whom to contact in the event of a research-related injury to the subject; and (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.<sup>97</sup>

“Although jurisdictions differ over interpretation of the fine details of disclosure standards, there is general agreement on the basic elements constituting a valid consent.”<sup>98</sup> These factors include a diagnosis of the patient's condition, the nature and purpose of treatment, a disclosure of the physician's skill or any status risks, alternatives to the physician's proposed course of treatment, the patient's prognosis if treatment is declined, the patient's prognosis with treatment, and disclosure of any potential conflicts of interest on the part of the physician.<sup>99</sup> While certain jurisdictions may weigh some elements more heavily than others, most agree that proper informed consent disclosures must address them all. Finally, a written informed consent document can be fully accurate and cover every aspect of the procedure, but it will still be rendered ineffective if the patient lacks the mental capacity to provide consent.<sup>100</sup> This portion of the Note will examine not only the disclosure requirements applied to the physician, but also the factors influencing a facial transplant patient's mental capacity to consent.

Applying the above listed factors to the world of experimental surgical techniques leads one to question whether the patients involved are truly giving the treating physician a clear and intelligent consent to treatment “free from imposition”<sup>101</sup> by the physician. Of chief concern to physicians about to perform an experimental or high-risk surgical procedure is whether the patient truly gave informed consent. In regard to Isabelle, the French woman who received the world's first partial face transplant, several doctors have voiced opinions that they feel the French doctors did not act ethically in deciding to perform the procedure.<sup>102</sup> The doctors most pressing an inquiry ask “[d]id the patient give adequately informed consent to the procedure? Did she understand the risks and implications of the transplant?”<sup>103</sup> These questions illustrate the concern and the divide in the medical community as to whether those patients constituting ideal candidates for facial transplant procedures are mentally stable enough to rationally analyze the information provided by the physician.

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97. 45 C.F.R. § 46.116(a) (2005).

98. FAY A. ROZOVSKY, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* 12 (2d ed. 1990).

99. See FURROW ET AL., *supra* note 7, at 319–36.

100. See *id.* at 317–18.

101. *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C. Cir. 1972).

102. Michael Mason & Lawrence K. Altman, *Ethical Concerns on Face Transplant Grow*, N.Y. TIMES, Dec. 6, 2005, at A4.

103. CNN.com, *Woman Has First 'Face Transplant'*, CNN.COM, Dec. 1, 2005, <http://edition.cnn.com/2005/HEALTH/11/30/france.face> [hereinafter *Woman Has First 'Face Transplant'*].

### 1. Complete Diagnosis

The physician's diagnosis of the patient's condition is the first element of proper informed consent to treatment.<sup>104</sup> In this regard, there is not much concern that the physician will not be able to communicate to the patient the medical condition that can be treated with a facial tissue transplant. Most often, the ideal candidates that United States physicians would consider are the victims of severe facial trauma, either caused by cancer of the mouth or severe third degree burns, or as the victim of an animal attack.<sup>105</sup> Diagnosis of such injuries is relatively straightforward, and in the case of facial transplants, the patient has been given an original diagnosis when the original injuries occurred.

Fortunately, most jurisdictions only require the physician to describe the diagnosis, including any preceding tests and their alternatives.<sup>106</sup> Applied to the arena of facial transplants, very few complications are immediately evident.<sup>107</sup> Essentially, "a physician must first describe the diagnosis, including the medical steps preceding diagnosis, including tests and their alternatives."<sup>108</sup> Thus, a physician's duty is fulfilled if he or she makes an accurate presentation of the facts uncovered as a result of testing.<sup>109</sup> As in other diagnoses, identifying what needs to be disclosed by the physician when dealing with severe burns, cancer wounds, or animal attacks is not particularly complicated. As a result, few physicians fail to discuss their diagnosis with patients, and courts have rarely considered physician liability for a failure to disclose a diagnosis.<sup>110</sup>

### 2. Nature and Purpose of Treatment

Another element courts look at in determining whether a treating physician has presented all elements necessary for the patient to make an informed choice is whether the physician has informed the patient as to the nature of and purpose behind the proposed course of treatment.<sup>111</sup> In essence, this is the "sales pitch" the surgeon makes to the patient. This element is not a clear-cut requirement, as its exact parameters are still being developed.<sup>112</sup> Generally, this element requires that the physician inform the patient as to what

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104. FURROW ET AL., *supra* note 7, at 319-20.

105. Samuel Bern, *Is the World Ready for Audacious Face Transplants?*, VENTURA COUNTY STAR (Cal.), Dec. 11, 2005, at 11.

106. State court informed consent decisions "follow a pattern, including such details as the risks and benefits associated with a particular procedure and reasonable alternatives to it." ROZOVSKY, *supra* note 98, at 44-45.

107. See Renshaw et al., *supra* note 94, at 862 (laying out in detail a methodology for disclosure of information to the patient).

108. FURROW ET AL., *supra* note 7, at 319-20.

109. CODE OF MED. ETHICS § 8.08 (Council on Ethical and Judicial Affairs, Am. Med. Ass'n 2002) ("The physician's obligation is to present the medical facts accurately to the patient . . . and to make recommendations for management in accordance with good medical practice.").

110. FURROW ET AL., *supra* note 7, at 320.

111. See *id.*

112. See *id.*

the proposed procedure involves, as well as why the physician feels it needs to be performed.<sup>113</sup> This requirement is somewhat fulfilled by the informed consent document presented to facial transplant candidates laid out above.<sup>114</sup> The true nature of the procedure, however, is only briefly discussed in the document. So far, courts have not given a clear description of the level of physician disclosure required regarding the nature of the proposed treatment, i.e., how detailed and graphic the physician must be. When a physician proposes to totally surgically remove the facial tissue of the patient, the argument can be made that the level of disclosure must go beyond a simple sentence stating that one's facial tissue will be removed and replaced with that of a donor.<sup>115</sup> The physician should also disclose details regarding the extent of area to be removed and how deep incisions into the underlying facial tissue will be.

Recently, there has been a greater emphasis placed on the probability of the proposed treatment being completed successfully.<sup>116</sup> Informing the patient of the probability of success is clearly a critical issue in experimental surgical procedures. It is a critical issue because there are obviously no prior procedures to base a probable outcome upon. Were the physician and patient to discuss the procedure successfully completed in France, it would provide the patient with a technically accurate, yet deceptive, past success rate of 100%.<sup>117</sup> This statistic would inappropriately skew the patient towards believing the odds of success are extremely high when they may not be so. Indeed, Dr. Maria Siemionow of the Cleveland Clinic in Ohio, the only United States institution with an internal review board that has granted approval to attempt a face transplant,<sup>118</sup> is screening patients to undergo the procedure. She herself has stated that there is only a 50% chance of a successful transplant should she find an adequate candidate and proceed.<sup>119</sup> In considering the probability of successful surgeries in experimental procedures, courts have consistently required that patients be informed of the "probability of success of the contemplated therapy."<sup>120</sup> While few courts have discussed the requirement directly, there has been much consideration of the necessary corollaries to disclosure of the probability of success: the physician's level of skill and the probability of failure and harm as a result of the procedure being performed.<sup>121</sup>

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113. *See id.*

114. *See supra* note 95 and accompanying text.

115. *See supra* notes 92-93 and accompanying text.

116. "[T]he production of comparative outcomes data by the government, insurers, and providers makes more likely a requirement in the future that probabilities of success and failure be disclosed." FURROW ET AL., *supra* note 7, at 320.

117. As the only attempted surgery and the only success, the ratio would be 1:1, resulting in a percentage of 100%.

118. *Normal Life*, *supra* note 4.

119. *Clinic Gets OK*, *supra* note 73.

120. *Goodman v. United States*, 298 F.3d 1048, 1058 (9th Cir. 2002).

121. *Id.*

### 3. *Disclosure of Skill Level*

“Informed consent doctrine can be interpreted to require a physician to disclose differential success rates, forcing the physician into the awkward position of presenting his or her ‘batting average.’”<sup>122</sup> The physician’s disclosure of his skill level in facial transplant procedures is an obvious area of concern to the patient, and one that is not adequately covered by current informed consent requirements. The reason a physician is required to disclose his or her success rate relates to the idea that institutions and surgeons should disclose their successes and failures so that the public can choose the best provider available.<sup>123</sup> In surgeries involving the transplantation of facial tissue, all the doctors in the world, save one,<sup>124</sup> cannot tell the patient that he or she has ever successfully performed the procedure. Thus, they come to the plate with a “batting average” of .000. No doctor to date has attempted a full facial tissue transplant; the transplant procedure recently successful in France involved the area of the face around the nose, lips and chin.<sup>125</sup> Consequently, as far as facial transplant procedures as a whole are concerned, there is a success rate of 100%.

The danger in the field of facial transplant surgery arises from the fact that surgeons are, by their very nature, confident individuals. Indeed, a great level of confidence in one’s abilities is required to overcome the rigors of the medical profession and rise to be a pioneer in the medical community. This confidence is a necessary component of being a physician; allowing a patient to see doubt or uncertainty in his doctor can cause the patient unnecessary stress at a critical time. Thus, a fine balance is necessary, and has been recognized by the courts, in holding that physicians should disclose the general success rate for a proposed procedure across the medical community, as well as the physician’s particular experience with that procedure.<sup>126</sup> Many of the surgeons in the United States eager to perform the country’s first facial transplant are experienced transplant surgeons, albeit not in the realm of full facial tissue.<sup>127</sup> It is here the current informed consent doctrine falls short.

*Johnson v. Kokemoor*,<sup>128</sup> a Wisconsin decision, illustrates the shortcomings of the current informed consent requirement regarding the physician’s disclosure of skill level. In *Johnson*, plaintiff Donna Johnson sued

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122. FURROW ET AL., *supra* note 7, at 321.

123. Duncan Newhauser, *Ernest Armory Codman, M.D. and End Results of Medical Care*, 6 INTERN. J. TECH. ASS. IN HEALTH CARE 307 (1990).

124. The French doctor who performed Isabelle’s partial face transplant technically has a success rate of 100%. The physician’s name is Dr. Bernard Devauchelle. *Normal Life*, *supra* note 4.

125. *Woman Has First ‘Face Transplant’*, *supra* note 103.

126. *Hales v. Pittman*, 576 P.2d 493, 498-500 (Ariz. 1978) (en banc).

127. As an example, Dr. Warren Breidenbach is working to perform a facial transplant. *Nervous*, *supra* note 51. Dr. Breidenbach is the surgeon who performed the first hand transplant in the United States in 1999. *Id.* His required disclosure in this area of informed consent would be to inform the patient of the fact that he has yet to perform a facial transplant, but that he has had considerable success in performing transplant surgeries in general. *See generally* FURROW ET AL., *supra* note 7, at 321.

128. 545 N.W.2d 495 (Wis. 1996).

her surgeon for failure to obtain informed consent to surgery.<sup>129</sup> As a result of the surgery performed, Johnson was left unable to walk or control her bowel and bladder movements.<sup>130</sup> The court held that “[h]ad a reasonable person in the plaintiff’s position been made aware that the risks associated with surgery were significantly greater than the risks [associated with a less complicated version of a similar surgery], that person might well have elected to forego surgery altogether.”<sup>131</sup> While the court held for the plaintiff, it relied on the fact that the defendant surgeon had skewed the data he presented in order to push the patient to elect to undergo the surgery.<sup>132</sup> Thus, the court’s decision stands for the proposition that the physician should not skew success and failure information if asked. The decision, however, ultimately left the disclosure issue to a case-by-case analysis, rather than setting a bright-line rule of mandatory disclosure across the board.<sup>133</sup>

The danger posed to patients is that while other states have considered the holding in *Johnson*, not all have agreed to follow it. In *Whiteside v. Lukson*,<sup>134</sup> the defendant surgeon did not disclose to the patient that he had never performed a laparoscopic cholecystectomy on a human.<sup>135</sup> The court acknowledged the holding in *Johnson*, but concluded “that a surgeon’s lack of experience in performing a particular surgical procedure is not a material fact for purposes of finding liability predicated on failure to secure an informed consent.”<sup>136</sup> The rejection of the *Johnson* ruling and explicit pronouncement that a physician need not disclose lack of experience leaves the patient considering a facial transplant in a dangerous situation. While it may be widely known now that no United States surgeon has completed a surgery, the rejection of *Johnson* allows eager surgeons to downplay their inexperience with facial transplants and place greater emphasis on their more extensive experience with other transplant surgeries.<sup>137</sup> Thus, the patient places greater than deserved confidence in the prognosis of the surgeon, resurrecting the old “doctor knows best” physician based standard of informed consent, by transferring a key decision from the patient back to the physician. This leaves the ultimate decision of the patient as somewhat hollow, as the facts the patient relies upon are influenced and skewed by the physician.

Some commentators argue that a bright-line rule requiring physicians to disclose their inexperience would do more harm than good.<sup>138</sup> The possibility that a patient may ask the physician about his medical school grades, however,

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129. *Id.* at 497.

130. *Id.* at 499.

131. *Id.* at 506–07.

132. The defendant doctor likened the risks of a highly difficult neurosurgery procedure to simpler, more routine procedures, like a tonsillectomy, appendectomy, or gall bladder operation. *Id.*

133. *Id.* at 504–05.

134. 947 P.2d 1263 (Wash. Ct. App. 1997).

135. *Id.* at 1264.

136. *Id.* at 1265.

137. See *Woman Has First ‘Face Transplant’*, *supra* note 103.

138. “In theory, the physician’s own health, financial situation, even medical school grades, could be considered material facts a patient would want to consider in consenting to treatment by that physician.” *Whiteside*, 947 P.2d at 1265.

should not result in a physician being able to conceal the amount of experience he has acquired. Additionally, it is hard to imagine a circumstance where a court would find a lack of informed consent based on the patient not knowing the physician's grade point average. Moreover, not having a bright-line rule requiring disclosure of inexperience fails the facial transplant surgical patient because it relates back to the old physician-based standard of informed consent, placing all the decision making power back into the hands of the surgeon.

#### 4. Alternatives for Proposed Treatment

Courts heavily weigh the informed consent factor of whether the treating physician fully informed the patient of all the viable alternatives to the proposed course of treatment.<sup>139</sup> While the number of alternative treatments to be disclosed is up for debate, at a minimum, the physician should disclose alternative methods of treatment generally acknowledged within the medical community as feasible.<sup>140</sup> Those alternatives that the physician considers to be feasible and reasonable will depend upon the circumstances of a patient's case.<sup>141</sup> When a physician and patient discuss the idea of a facial transplant, a problem arises—there are no alternative treatments that would achieve the same results.<sup>142</sup> The only true alternatives would be to forego the surgery or endure a much longer facial reconstruction procedure consisting of skin grafts taken from other areas of the patient's body.<sup>143</sup> Thus, a problem arises due to the fact that if someone is so devastatingly injured that a facial transplant surgery is required, foregoing the surgery will not be considered an alternative, but rather a lack of treatment.

Thus there exists a substantial risk that the physician will not discuss foregoing surgery as a valid alternative to a facial transplant. In reviewing cases involving a physician's disclosure of alternatives to proposed treatment, courts have held that an alternative need not be discussed if it is not within the standard of care.<sup>144</sup> Foregoing surgery is technically not within the standard of care because it does not involve any actual medical treatment. Additionally,

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139. See, e.g., *Goodman v. United States*, 298 F.3d 1048, 1058 (9th Cir. 2002); *Wachter v. United States*, 877 F.2d 257, 260 (4th Cir. 1989); *Cowman v. Hornaday*, 329 N.W.2d 422, 425 (Iowa 1983).

140. ROZOVSKY, *supra* note 98, at 42 ("In addition to risk and benefit information, a patient should be told of the availability of reasonable alternative procedures.").

141. *Id.*

142. See Naomi Austin, 'My Face Transplant Saved Me', BBC NEWS, Oct. 17, 2006, <http://news.bbc.co.uk/1/health/6058696.stm>.

143. Press Release, Am. Soc'y of Plastic Surgeons, Plastic Surgeons Countdown First Full Facial Transplantation (Mar. 3, 2006), available at <http://www.sciencedaily.com/releases/2006/03/060303111744.htm>.

144. See, e.g., *Madsen v. Park Nicollet Med. Ctr.*, 431 N.W.2d 855, 861 (Minn. 1988) (holding that disclosure is not required when managing a pregnancy at home rather than in the hospital because it is not a choice between alternative methods of treatment). Standard of care is defined as "the level at which the average, prudent provider in a given community would practice. It is how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances." MedicineNet.com, Definition of Standard of Care, <http://www.medterms.com/script/main/art.asp?articlekey=33263> (last visited Oct. 15, 2007).

the medical standard to determine the feasibility of an alternative course of treatment raises issues. For instance, as discussed above, Dr. Sieminow is informing potential candidates for her surgical procedure that the success rate is only 50%.<sup>145</sup> In this situation, it is hard to even consider an untested procedure as feasible when it is just as likely to fail as to succeed.

On the other hand, physicians promoting widespread availability of facial transplants base their position on the feeling that such procedures are not elective, but medically essential.<sup>146</sup> With this point of view, physicians see living with injuries as a non-option, which again takes the decision out of the patient's hands, or at the very least influences it significantly. This leads one to question the rationale behind these transplants. Carried to its logical extent, transplants following loss of limbs would also be considered essential to the continuance of life. Thus, patients considering undergoing a facial transplant procedure with only a 50% chance of success are not legally entitled to be informed that foregoing the surgery, and for example undergoing counseling and therapy, is a safe, viable treatment alternative.

Finally, if the surgery does not succeed and the patient sues her physician for malpractice based on a lack of informed consent, there is evidence that the patient would not prevail.<sup>147</sup> In cases involving untested or alternative procedures, courts have found that patients have assumed a portion of the risk associated with the procedure.<sup>148</sup> Additionally, courts have granted treating physicians some "wiggle room" in cases concerning experimental procedures, based on the fact that in experimental procedures, there is a higher level of unknown factors affecting the procedure's outcome.<sup>149</sup> In *Goodman v. United States*,<sup>150</sup> the court found the patient had given informed consent to the experimental treatment even though the treating doctors did not disclose the complications experienced by the three previous experimental subjects, and that "there is no legal requirement that the consent form developed for [the experimental] study must be amended as each group of patients proceeds through the study."<sup>151</sup> This bears special significance in the case of facial transplant procedures because surgeons will not be legally required to change their assessment of risk for subsequent patients based on previous failures. Considering this, one realizes that current standards of informed consent are lacking, leaving the patient with the dangerous possibility of undergoing a surgical procedure the extent of which is not truly understood.

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145. MedicalNewsToday.com, First Human Face Transplant, Ohio Clinic Starts Screening Patients, <http://www.medicalnewstoday.com/articles/15719.php> (last visited Oct. 15, 2007).

146. *Woman Has First 'Face Transplant'*, *supra* note 103.

147. See *Charell v. Gonzalez*, 673 N.Y.S.2d 685, 686 (N.Y. App. Div. 1998) (finding that patient had assumed 49% of the risk based on the fact she agreed to forego conventional medical treatment in favor of an alternative therapy).

148. *Id.*

149. "It is tragic when death occurs following risky medical procedures based on complications. But in the battle against deadly diseases, progress often will be made only when medical experimentation is permitted." *Goodman v. United States*, 298 F.3d 1048, 1058 (9th Cir. 2002).

150. 298 F.3d 1048.

151. *Id.* at 1058.

### 5. *The Patient's Prognosis*

Many jurisdictions require the physician to include disclosures to the patient of not only the consequences of treatment, but also the consequences associated with foregoing the procedure. For facial transplant patients, this simply means the physician must make the patient aware of living with the condition that has made them a candidate for facial transplant surgery.<sup>152</sup> In essence, this means telling the patient to expect more of the same, but could also include information such as life expectancy<sup>153</sup> and any risks associated with foregoing the procedure. It does not require the physician to consider this a valid alternative to treatment. The uniqueness of facial transplant procedures does not bring to light any shortcomings of this facet of informed consent doctrine. The physician in this case simply informs the patient what can be expected if the surgery is not elected, as he or she would were it any other proposed procedure.<sup>154</sup>

An area where issues can arise is the detail of the physician's disclosure regarding the extent of further medically necessary treatments in order to ensure the facial transplant procedure remains a success. Once the facial tissue is grafted onto the patient's facial structure, precautions must be taken to ensure the tissue remains in place. In this area, informed consent waivers issued by the United States surgeons hoping to attempt a transplant fall short of fully explaining to the patient the serious risks associated with a successful procedure. The example form above mentions that taking the immune suppression drugs raises the risk of cancer, but does not disclose the probability.<sup>155</sup> It deals with the issue in a rather brisk manner, brushing over what is a critical component of the patient's decision—especially those whose facial features may have already been devastated once by cancer.

The closest correlation to the type of procedure discussed in this Note is a procedure that has recently been performed on a woman who was attacked and mauled by her pet Labrador in France.<sup>156</sup> Isabelle underwent surgery for a partial facial tissue transplant involving a new nose, lips and chin.<sup>157</sup> She had "lesions that were extremely difficult and nearly impossible to repair using standard facial surgery methods."<sup>158</sup> "The grafted tissue came from another woman who had been declared brain-dead."<sup>159</sup> This transplant has been successful so far, in that the grafted tissue has not been rejected by the recipient's body.<sup>160</sup> In the time since the procedure was performed, however, several interesting issues have arisen.

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152. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 142–55 (1984).

153. *Id.* at 213–29.

154. *See, e.g., id.*

155. "Drugs to prevent rejection will be needed lifelong, and they raise the risk of kidney damage and cancer." *Facing Up*, *supra* note 95.

156. *Normal Life*, *supra* note 4.

157. *Woman Has First Face Transplant*, *supra* note 103.

158. *Id.*

159. *Id.*

160. *Id.*

First, there is a significant risk that the immune-suppression drugs that the patient is required to take for the rest of her life will cause cancer.<sup>161</sup> These drugs reduce the risk that the graft will be rejected, but significantly increase the recipient's chances of developing cancer.<sup>162</sup> This had led many in the medical community to question whether the long-term risks associated with the transplant outweigh the long-term benefits.<sup>163</sup> Isabelle, while showing great signs of progress,<sup>164</sup> is also showing signs that she was not fully aware or fully informed of the severity of the ongoing risk factors associated with the transplant.<sup>165</sup> It has been recently reported that Isabelle has resumed her smoking habit, now that she sufficiently recovered from the surgery itself.<sup>166</sup> Her doctors are especially concerned by this smoking habit because it not only increases her already elevated risk of developing cancer, but also because smoking increases the risk of tissue rejection by restricting the circulation of blood to bodily tissues.<sup>167</sup>

The physician properly explaining what will happen if the transplant is rejected poses a second critical issue in the area of prognosis with treatment. Many experts are unsure what will happen beyond the point of the patient having a severe head wound open to infection.<sup>168</sup> Other physicians feel that the only alternative is to take sections of skin from the patient's body and perform a more traditional skin graft, but this will result in severe discomfort because of the tissue removal as well as multiple extensive surgeries before the wound is completely closed.<sup>169</sup> These are just two issues where doctors have a hard time imparting the gravity of the situation on the patients. Such horrific consequences may seem so terrible to the patients that they may simply not believe that it will happen to them or that it could be true.

## 6. Conflict of Interest

When considering experimental surgical procedures the patient must necessarily place a great deal of faith in the knowledge of the physician. It rarely occurs to patients to consider the economic interests of the physicians beyond the hospital bill, however. A case illustrating the secondary interests of physicians is *Moore v. Regents of the University of California*.<sup>170</sup> In *Moore*, the treating physician did not disclose his economic interests in the spleen that he extracted from his patient.<sup>171</sup> The court noted that there is a conflict between the patient and physician when the physician has an interest in the

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161. *Id.*

162. *Id.*

163. *Id.*

164. She has recently regained the ability to feel sensation in the transplanted portions of tissue. *See Normal Life, supra* note 4.

165. Smith, *supra* note 65.

166. *In Brief/Arizona; Face Transplant Patient Has Resumed Smoking*, L.A. TIMES, Jan. 19, 2006, at 19.

167. *Id.*

168. *Nervous, supra* note 51.

169. *Id.*

170. 793 P.2d 479 (Cal. 1990).

171. *Id.* at 480.

procedure aside from treating the patient. The court stated that this was “because medical treatment decisions are made on the basis of proportionality—weighing the benefits *to the patient* against the risks *to the patient*. . . . [A] physician who adds his own research interest to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient.”<sup>172</sup> This concept was taken further in the case of *Estrada v. Jaques*,<sup>173</sup> where the court recognized “[t]he psychology of the doctor-patient relation, and the rewards, financial and professional, attendant upon recognition of experimental success, increase the potential for abuse and strengthen the rationale for uniform disclosure.”<sup>174</sup>

This danger of abuse is nearly self-evident when viewing the competing facial transplant procedures being considered throughout the United States. The conflict arises in that the surgeons rush to be the first to gain the fame and notoriety associated with being the first surgeon to successfully complete a procedure in the United States. Indeed, this can be evidenced through the sentiments of members of the medical community itself. “Some American doctors at the conference said it is time to stop debating whether the French operation was ethical or wise and focus now on making such transplants as safe and widely available as possible.”<sup>175</sup> These sorts of statements illustrate the fact that some physicians may be more concerned with the fact that transplants *can* be done instead of whether ethically they *should* be done.<sup>176</sup> Along with the fame and notoriety of performing the first face transplant, there is also a great economic interest at stake. The facility and surgeon that completes the first successful procedure will have a significant advantage in recruiting subsequent patients, swelling the profits of the treating institution.

Additionally, as briefly discussed above, the surgeons attempting facial transplants are by their nature confident individuals. This may lead to an additional conflict of interest in that the physicians may be willing to attempt the procedure even if it is not in the best interest of the patient, because the physicians are eager to see if they can do it—to see where their own limitations lie. While *Moore* requires disclosure of economic interests in medical materials,<sup>177</sup> the conflicts associated with experimental procedures such as facial transplants are more difficult to articulate, and thus may not be required to be disclosed to the patient.

Finally, a real life example is available to illustrate the risks posed by potential conflicts of interest. After Isabelle’s transplant surgery was completed, there was an incident in which her body attempted to reject the tissue that had been grafted.<sup>178</sup> The details regarding this episode were not

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172. *Id.* at 494.

173. 321 S.E.2d 240 (N.C. Ct. App. 1984).

174. *Id.* at 255.

175. *New Face*, *supra* note 83.

176. *Id.* “Face transplants can be done and should be done.” *Id.* (statement of Dr. Warren Breidenbach).

177. *Moore*, 793 P.2d at 485.

178. News-Medical.Net, French Face Transplant Patient in Fight to Stop Tissue Rejection, <http://www.news-medical.net/?id=15487> (last visited Oct. 15, 2007).

immediately revealed by the treating institution, perhaps for fear of ethical criticism should the rejection not be stopped. Even more appalling is that her treating physician arranged the sale of the rights to take and sell photographs of Isabelle's face to a long-time friend of his.<sup>179</sup> While the physician insists he arranged the sale to prevent others from taking advantage of Isabelle, it is evident that such arrangements call for greater scrutiny of physician motivations, as well as reforms in the requirements of informed consent to adequately protect the rights of the patient.

The areas of the informed consent doctrine discussed above revolve around the physician side of the doctor-patient relationship and illustrate that in some areas, current notions of informed consent do not require physicians to disclose as much information to the facial transplant patient as society would prefer. Even if the assumption is made that the current disclosure requirements adequately inform the patient of all the information relevant to agree to undergo a facial transplant, there is still a serious issue as to whether patients meeting the requirements of such a procedure are capable of giving their informed consent.

### *B. Patient Capacity to Consent*

As to patients making the decision to undergo a procedure, “[t]he law presumes that a person possesses the requisite mental capacity to reach an informed choice.”<sup>180</sup> Due to the extreme condition of the patient involved in facial tissue transplants, it is hard to gauge whether the patient is fully capable of making an informed decision regarding whether to undergo a procedure. Typically, the injuries giving rise to the need for such a procedure are quite horrific.<sup>181</sup> Again, the facial transplant procedure is aimed at “people with severe facial burns that have lost not merely appearance but normal facial function.”<sup>182</sup> This can put patients in need of a facial transplant in a mental state where they would be willing to undergo any treatment just to have a small chance to rectify the situation. For instance, doctors cannot explain to the patients what they will look like once the surgery is completed because no one really knows—there are no previous results to show them.<sup>183</sup> There is also no evidence as to how much sensation and function will be regained as a result of the procedure.<sup>184</sup>

Additionally, it is difficult for many patients to overcome the notion that “doctor knows best,” and voice their true concerns. One commentator has stated that “informed consent notwithstanding, the physician-patient encounter continues to be shaped by the belief, shared by doctors and patients, that in

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179. *Id.*

180. ROZOVSKY, *supra* note 98, at 21.

181. *Nervous*, *supra* note 51.

182. *Id.*

183. *See Clinic Gets OK*, *supra* note 73.

184. *See Nervous*, *supra* note 51 (describing a condition called dyskinesia, an internal misfiring of nerve signals that could leave patients twitching uncontrollably or smiling when they mean to frown).

therapeutic settings doctors at least try to do their level best for the individual patient who seeks their help and, therefore, the doctor's recommendations can be trusted."<sup>185</sup> The glimmer of hope offered by a physician offering a treatment previously only considered in science-fiction, combined with the psychological effects associated with injuries requiring a facial transplant leave the patient unable to make a rational, criteria-based decision as to whether to undergo a facial transplant surgery. Thus, it is easy to imagine a situation where a patient is so despondent and desperate over the physical condition of his face that he would be willing to jump at any chance of improvement, no matter the risk involved.

Mental capacity to give valid consent "is the ability to understand the nature and consequences of authorizing treatment."<sup>186</sup> There are several reasons that a patient may lack the capacity to give an informed consent. "Mental illness is not the only reason for lack of such capacity: shock or trauma, a crippling physical injury or illness, or alcohol or drug abuse can be responsible for a mental incapacity that temporarily or permanently impedes the patient's ability to consent to treatment."<sup>187</sup> In the media whirlwind surrounding the announcement that Isabelle's transplant surgery was a success, news agencies discovered that Isabelle had attempted suicide prior to undergoing the procedure.<sup>188</sup> Reports of this kind call into question whether she possessed the requisite mental state to consent to the procedure in a rational manner. If Isabelle was so psychologically distraught prior to the surgery that she attempted suicide, it is not logical to assume that she was acting as a reasonable patient. It seems more likely that she was so upset about her appearance that she would have jumped at any chance of resuming a "normal life." This leads one to the conclusion that patients undergoing experimental facial transplant procedures may not be fit under the reasonable patient standard. If the patient is so desperate, he will place greater emphasis on the chance of success than the probability of failure. This begs the question of whether a patient in this type of situation can even be compared to a reasonable patient, i.e., can there be such a thing as a person acting rationally in the same type of situation? Can doctors expect a person to act rationally when suffering from wounds that traditional plastic surgery techniques cannot currently fix? The evidence shows they cannot.

Evidence presented in other transplant procedures illustrates the fact that transplant patients may be consenting to procedures where they do not fully grasp the details involved, or lack the capacity to understand what they are being told. For instance, in the relatively small new field of hand transplants,

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185. Katz, *supra* note 93.

186. ROZOVSKY, *supra* note 98, at 21.

187. *Id.*

188. Smith, *supra* note 65. "Among the most disturbing aspects of the debate are conflicting reports from doctors about whether the transplant was the result of two suicide attempts, one successful by the donor, and one failed by the recipient." *Id.* Some doctors question "[Isabelle's] psychological fitness for the operation because of reports that she had taken sleeping pills in a possible suicide attempt when the dog attack occurred." *New Face*, *supra* note 82. However, her doctors have repeatedly and vehemently denied these allegations. *Id.*

there are several instances of patients reacting negatively once the surgery is completed.<sup>189</sup> These surgical candidates match the same profile as facial transplant candidates, i.e., they may lack the mental capacity required for consent due to the shock and trauma associated with sustaining the loss of a limb.<sup>190</sup> In one case, a Belgian patient also attempted to end his own life after receiving a new hand.<sup>191</sup> Moreover, the treating doctors deemed the patient psychologically able to give consent even though he had also attempted suicide prior to the surgery.<sup>192</sup> Additionally, despite having attempted suicide, Isabelle was deemed competent to make the decision to undergo the surgery.<sup>193</sup> Finally, at a recent medical conference focused on surgical transplant procedures, a Chinese surgeon revealed that nine of his patients have since rejected the new body parts for failure to consistently take the drugs required to prevent the body rejecting the tissue.<sup>194</sup> These examples highlight the fact that the patients are not in a mental state where they can truly appreciate the lifelong commitment these surgeries necessitate.

Another issue arises from the patients themselves. Going into such a procedure, the patient lives with an extremely disfigured face, so much so that having a successful operation would cause “a considerable improvement in quality of life.”<sup>195</sup> Thus, it is conceivable that the patients approach the surgery with a sort of irrational desperation that could easily lead to acceptance of chances of success that a rational person would reject. Many patients simply do not want their doctors to inform them of bad news, and courts generally have not forced the treating physicians to inform them in such a case.<sup>196</sup> This aversion to bad news is evidenced not only by the fact that patients who have completed hand transplant procedures are unable to keep up the drug regimen that is required, but also by the fact that the patients seem completely focused on resuming a “normal life.” This leads to the conclusion that patients involved in experimental transplant procedures tend to focus on the completion of the procedure, and ignore the consequences associated with a longer time frame.

In fact, the requirements necessary to maintain the transplant for the rest of the patient’s life are anything but normal. For example, Isabelle has recently resumed her smoking habit despite the fact that the drugs she is required to take increase the risk of cancer by a significant amount.<sup>197</sup> This lends support to the notion that facial transplant patients would focus only on

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189. The first hand transplant was performed in the United States in 1999. News Release, Pioneers in Medical Innovation, World’s First Successful Hand Transplant Recipient Reaches Seventh Year (Feb. 6, 2006), available at [http://www.handtransplant.com/news\\_release/020606.html](http://www.handtransplant.com/news_release/020606.html).

190. See ROZOVSKY, *supra* note 98, at 21.

191. *New Face*, *supra* note 82.

192. *Id.*

193. *Id.*

194. *Id.* Another patient even asked him to surgically remove the hand once the year-long period in which the hospital provided the medicine for free had expired. *Id.*

195. *Nervous*, *supra* note 51.

196. See, e.g., Lawrence K. Altman, *The Doctor’s World; A Short, Speckled History of a Transplanted Hand*, N.Y. TIMES, Feb. 27, 2001, at F1.

197. *New Face*, *supra* note 82.

changing their appearance in the short term, instead of considering the long-term consequences. Additionally, there is a certain amount of celebrity associated with undergoing such a highly publicized procedure. Isabelle has been made an international celebrity with every aspect of her life exposed to the media.<sup>198</sup>

Based on this information, it is evident that there is a serious question as to whether informed consent requirements adequately protect the patient in the field of advanced surgical procedures. The need for reform is evidenced by the fact that patients requiring facial transplant procedures have undergone such trauma that they are no longer mentally capable of make a rational, informed decision to undergo the procedure.

#### IV. RECOMMENDATION

While the above information makes it evident that there is a problem applying current notions of informed consent to the field of facial transplants, the question of how to rectify the problem is difficult to resolve. An instinctual response would be to involve the patient's relatives in the decision-making process, akin to procedures used to assist senior citizens when mental capacity is diminished. In this situation, however, asking a relative to function as the patient's medical guardian and decision-maker would be inadequate. Family members would be susceptible to several of the same factors affecting the mental stability of the surgical candidate. For instance, delegating decision-making responsibilities to a family member does nothing to reduce the risks associated with a physician's disclosures regarding conflicts of interest or the non-disclosure of the benefits to foregoing such an experimental and potentially dangerous surgical procedure.

In order to correct the current shortcomings of informed consent when applied to facial transplant patients, state courts should appoint impartial medical guardians with the power to determine whether the facial transplant procedure is truly in the best interests of the patient. The guardian should also assess whether the patient has the ability to understand the possibility of failure and the responsibilities associated with the success of the procedure—namely the requirement of taking immune suppression drugs, the length of time the drugs are required, and the elevated risks of disease associated. Ideally, the profession best suited for this job would be a court-appointed psychologist; such professionals have a general understanding of the medical field and can accurately gauge the mental capacity of the patient charged to their care. Additionally, having the court appoint a guardian reduces some of the power the treating physician has in the doctor-patient relationship, and works to reduce the interest the treating facility has in seeing the operation performed. This facility could have exerted influence through its board members on the treating surgeon, which he could exert on the patient in turn; this tactic would

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198. "According to one report, she has signed agreements worth nearly \$1 million for a book, a documentary and a feature film about her story." *Normal Life*, *supra* note 4.

be rendered ineffective by the appointment of an independent guardian. Moreover, the guardian would be much less eager than the patient, affording the opportunity for greater research into past transplant failures, as well as the individual success rate of the treating surgeon.

A psychologist appointed as guardian in the informed consent process would also be much better suited to gauge the patient's mental capacity, as well as determine the effects the surgery would be likely to have on the patient's mental status. This will significantly reduce the chances of patients voluntarily rejecting their transplants later on by not taking the required drugs.<sup>199</sup> Under this proposed method, only the patients that are truly serious about undertaking the surgery, and are able to fully comprehend what they will have to live with for the rest of their lives will undergo the surgery. Overall, this would work to greatly increase the odds of successful procedures around the country.

The only potential drawback to this procedure is the possibility that appointing an overworked court guardian would lead to sloppy review and a lesser standard of care than was originally provided by the treating physician. The imposition on the physician patient relationship by the appointment of a guardian, however, would reduce more potential for harm that it would engender. The reduction of physician and facility based conflicts of interest, and the assurance that the decision maker is actually acting under the rational patient standard outweighs the possibility that one patient would be "lost in the shuffle."

Finally, the possibility of guardians taking on too many patients to give each the proper amount of consideration is also limited by the relatively small number of people requiring facial transplant surgery, and could also be reduced by the imposition of a state determined maximum patient to guardian ratio. The high profile nature of facial transplant procedures would also work to ensure that the guardian was carefully considering all factors and making a rational decision because of the high social interest and media scrutiny of the surgeries.

The appointment of only psychologists as guardians would work to ensure that the mental needs of the patient would be put first and foremost. Not only would the guardian be acting as a rational patient in making the election to undergo the procedure, but would also be able to establish a personal bond with the patient, providing counseling both before and after the procedure. Additionally, the guardian would be able to offer therapeutic assistance to the patient if the guardian felt the surgery was not the best option, or that the patient would not be able to endure the stresses associated with the procedure. Finally, using a court appointed guardian to determine whether the patient should undergo a facial transplant would eliminate the pressures faced by other potential decision makers, namely the desperation faced by the patients themselves, and the sympathetic feelings and pressures exerted upon

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199. See *supra* Part III.A.

family members that may be trying to act in the best interests of their relative.

#### V. CONCLUSION

This Note illustrates some of the unique issues facing patients with injuries so extensive that traditional plastic surgery techniques are of no avail and the only treatment option available is the replacement of all facial tissue. Under the current requirements of informed consent to surgery, facial transplant patients are left exposed to dangerous procedures of which they are unable to comprehend the full extent. This lack of comprehension makes it impossible for the potential facial transplant patient to act as a reasonable person would in electing to undergo the procedure, creating a need for reform where informed consent and facial transplant procedures meet. The appointment of an individual guardian to act as decision maker for the purposes of the facial transplant surgery corrects the deficiency created by the application of current informed consent requirements. The guardian acts as a perfect model of the reasonable patient standard, considering all the risks and acting as a reasonable person would when in the situation of the transplant patient. Therefore, before a single facial transplant is performed, states should require the appointment of an independent guardian to assist the facial transplant patient in making a life-altering decision.