COMMENTARY

HUMAN EXPERIMENTATION AND THE DOUBLE FACELESSNESS OF A MERCILESS EPOCH

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When you take an idea or a concept and turn it into an abstraction, that opens the way to take human beings and turn them, also, into abstractions. When human beings become abstractions, what is left?[1]

The image is remarkable and unforgettable: Former SS Gruppenführer, Waffen SS Generalleutnant, Reich Commissioner for Health and Sanitation, and personal physician to Adolf Hitler, Dr. Karl Brandt, a chillingly handsome man with precisely correct posture even under the weight of defeat and condemnation, has just been sentenced to death by the court in Tribunal No. 1, Case 1 of the Nuremberg trials.[2] He very slowly and very carefully removes the headphones through which he has heard his death sentence translated into German, raises his hand to his head, and smoothes back his hair. One hand, one stroke, front to back. Having heard the court's judgment that he bears a significant share of the responsibility for some of the worst human rights abuses in history, committed in the name of biomedical science, his first reaction is to straighten his hair, to correct his appearance. Even at the end, Karl Brandt's movement is reflexive, from his own face and hair outward. The man who

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1. ELIE WIESEL, *Foreword* to THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION vii, ix (George J. Annas & Michael A. Grodin eds., 1992) [hereinafter NAZI DOCTORS].

2. Brandt's trial was conducted under the conditions created by the Allied Powers for the prosecution of war criminals. *See* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, OCTOBER 1946 – APRIL 1949, 171 (1950) (documenting these conditions). Brandt and others were tried in Military Tribunal 1. *See* NAZI DOCTORS, *supra* note 1, at 67–104 (reprinting excerpts of United States v. Brandt).

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helped ensure the suffering, mutilation, and death of countless innocents shows no awareness of anyone but himself.[3]

When faced with the charges against him at the Nuremberg Doctors Trial, Brandt offered the following argument as justification: "Do you think that one can obtain any worthwhile, fundamental results without a definite toll of lives? The same goes for technological development. You cannot build a great bridge, a gigantic building—you cannot establish a speed record without deaths!"[4]

What Brandt so clearly did not understand was that the reason for his conviction (and eventual execution) was less the *deaths* of the subjects in his experiments than the fact that they were unwilling and unconsenting *objects* of experimentation. That he would compare biomedical research to buildings and bridges shows that he was blind to humanity and autonomy, to what Emmanuel Levinas refers to as the "heteronomic alterity" of his subjects.[5] That he would compare subjects to race-car drivers shows his indifference to the unwilling and unconsenting status of those subjects.

Doctors Trial eyewitness Alexander Mitscherlich, representative of the West German Chamber of Physicians, describes how doctors such as Brandt had functioned:

> Before such monstrous deeds and thoughts shape everyday routine and real life, the disaster must have originated from many sources. Only in the crossing of two currents could the doctor turn into a licensed killer and publicly employed torturer: at the point where his aggressive search for the truth met with the ideology of the dictatorship. It is almost the same, if one sees a human being as a "case" or as a number tattooed on his arm. This is the double facelessness of a merciless epoch.[6]

In 1938, Ernst Hiemer, editor of the anti-Semitic newspaper *Der Stürmer*,[7] published the story "Der Giftpilz." In that story we read about Inge: "Inge sits in the Jew doctor's reception room. . . . The door opens.

3. Videotape containing archive footage of Karl Brandt's sentencing (shown at Conference, The Nuremberg Code and Human Rights: Fiftieth Anniversary of the Doctors' Trial, United States Holocaust Memorial Museum, Washington, D.C., Dec. 9, 1996).

4. Leo Alexander, *War Crimes: Their Social-Psychological Aspects*, 105 AM. J. OF PSYCHIATRY 3, 172 (1948), *quoted in* Paul Ramsey, *Judgement on Willowbrook*, *in* INTERVENTION AND REFLECTION: BASIC ISSUES IN MEDICAL ETHICS 511, 515 n.5 (Ronald Munson ed., 6th ed. 2000).

5. *See generally* EMMANUEL LEVINAS, TOTALITY AND INFINITY: AN ESSAY ON EXTERIORITY (Alphonso Lingis trans., 1969) (1961).

6. ALEXANDER MITSCHERLICH, *Preface* to DAS DIKTAT DER MENSCHENVERACHTUNG, *quoted in* Christian Pross, *Nazi Doctors, German Medicine, and Historical Truth*, *in* NAZI DOCTORS, *supra* note 1, at 32, 38–39.

7. *Der Stürmer* was founded in 1923 and published anti-Semitic propoganda over the next two decades. Prosecutors at Nuremberg, as well as others, argued that the newspaper's articles incited the genocide of Jews under the Nazi regime. *See generally* TELFORD TAYLOR, THE ANATOMY OF THE NUREMBERG TRIALS 264, 375–76 (1992).

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Inge looks up. There stands the Jew. She screams. . . . She jumps up in terror. Her eyes stare into the Jewish doctor's face. His face is the face of a devil."[8] When the crude anti-Semitic propaganda of *Der Stürmer* and its editor portrayed the Jewish doctor's face as the "face of a devil," the ideology of the dictatorship sought to demonize a "race" condemned as inferior and degenerate according to its Nordic-variant racial hygiene theory. It was the *face*, above all, that gave the outward sign of the inferiority deemed unchangeable by a combination of Mendelian genetics and Weismann's theory of the immutable germ plasm.[9] When Michael Grodin introduced Mengele twin experiment[10] survivor Eva Mozes-Kor at a conference in late 1996, it was her *face* (and her name) that Grodin offered as a reminder of the existential context of all moral debate.

In this essay I will explore some of the ways in which the human face serves as both a marker of moral value and a call of moral duty. Where the marker is abandoned and the call ignored, we find that particular intersection of ethics, ideological power, and biomedicine that Mitscherlich identified as the "double facelessness of a merciless epoch."[11] In the defacing and effacing of the human subject under Nazi biomedicine and in important cases of biomedical research since 1945, seeing another person as just a case or a number made it impossible see her as you, as my friend, as me.

I.
NUREMBERG FIFTY YEARS ON

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force,

8. Ernst Hiemer, *Der Giftpilz, reprinted in* DOCUMENTS ON NAZISM 1919–1945, at 470 (Jeremy Noakes & Geoffrey Pridham eds., 1974).

9. Weismann theorized that organisms produce two types of cells: somatic cells, which develop and do not affect heredity, and germ cells, which do not develop but do transmit genetic material. *See* ROBERT PROCTOR, RACIAL HYGIENE: MEDICINE UNDER THE NAZIS 30–38 (1988).

10. Nazi doctor Josef Mengele conducted medical experiments in concentration camps on at least 3000 twins, of which only 160 individuals survived. Among other things, these twins, who were mostly children, were subjected to germ experiments (in which one twin would be infected with a germ, and if she died, the other twin would be killed to conduct comparative autopsies on the twins' bodies), surgeries without anesthesia, "surgeries" attempting to create conjoined twins, and genetic experiments attempting to change the individual's biological sex. Eva Mozes-Kor, *The Mengele Twins and Human Experimentation: A Personal Account, in* NAZI DOCTORS, *supra* note 1, at 53–57. *See generally* Lucette Matalon Lagnado, CHILDREN OF THE FLAMES: DR. JOSEF MENGELE AND THE UNTOLD STORY OF THE TWINS OF AUSCHWITZ (1992).

11. *See supra* text accompanying note 6.

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fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[12]

Adolf Hitler declared with a sense of impending triumph in 1937 that the ascendance of racial hygiene theory in German race policy would be the most decisive action for the future of Germany, since those laws would help create *the new man.* While few societies have emulated Hitler's attempt to create a new man (although Cambodia in the 1970s comes most horribly to mind as one that did),[13] many societies and the international community have stepped back from the ringing language of informed consent and from respect for the autonomy of heteronomic alterity found in the Nuremberg Code, both in principle and in practice. More than fifty years after the Doctors Trial, the legacy of the Nuremberg Code and related codes in biomedical ethics is distinctly mixed, especially with regard to the most important aspect of the Code: its insistence on informed consent. That "most fundamental tenet of medical ethics and human decency," embodied in the first principle of the Nuremberg Code, stands as a fundamental ethical principle that has not been observed on a regular basis since 1947.[14]

Although the World Medical Association (WMA) was established largely as the professional medical community's response to the Code and the Nazi medical experiments, the WMA's restatement of the Nuremberg principles in its Helsinki Declaration: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (Helsinki Declaration) reflects a more general vision of ethical responsibilities.[15] While the first two versions of the Helsinki Declaration contain provisions supporting informed consent, no version adopts it as an unconditional principle. The current version (October 2000) of the Helsinki Declaration has

12. Nuremberg Code, *reprinted in* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, OCTOBER 1946 – APRIL 1949, 181 (1950) [hereinafter Nuremberg Code].

13. The Khmer Rouge guerilla army led by Pol Pot ruled Cambodia from April 1975 to early 1979, when it was overthrown by forces from neighboring Vietnam. During its time in power the Khmer Rouge leadership attempted to eliminate "foreign" influences from Cambodian society, purifying Cambodia so as to institute a socialist agrarian society. During this period, approximately 1.7 million Cambodians were murdered or died from the effects of slave labor or starvation. *See generally* GENOCIDE IN CAMBODIA: DOCUMENTS FROM THE TRIAL OF POL POT AND IENG SARY (John Quigley, Kenneth J. Robinson & Howard J. De Nike eds., 2000).

14. James McHaney, Prosecution's Closing Argument, United States v. Brandt, July 14, 1947, *quoted in* Michael A. Grodin, *Historical Origins of the Nuremberg Code, in* NAZI DOCTORS, *supra* note 1, at 121, 137.

15. NAZI DOCTORS, *supra* note 1, at 331–33, 339–423. *See generally* Claire A. Milner, *Gulf War Guinea Pigs: Is Informed Consent Optional During War,* 13 J. CONTEMP. HEALTH L. & POL'Y 199, 209–11 (1996).

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maintained the policy of the 1989 and 1996 versions, stating: "each potential subject must be adequately informed of the aims, methods . . . anticipated benefits and potential risks of the study and the discomfort it may entail. . . . [T]he physician should then obtain the subject's freely-given informed consent, preferably in writing."[16] This pronouncement comes only in the twenty-second principle, rather than in the first, however, and is closely followed by an exception for potential subjects who are legally incompetent.[17] Here the WMA provides, as a justification for experimenting on the legally incompetent, a researcher's claim that "the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons."[18] In these circumstances and when the subject is neither a minor child nor other incompetent capable of assenting to (to be carefully distinguished from consenting to)[19] the research, substituted consent is deemed sufficient by the WMA.[20] The 1996 version of the WMA code had allowed an even stronger exception in cases of medical research combined with clinical care, which allowed the physician to bypass informed consent if the physician deemed the omission "essential."[21] Finally, the last principle in the section on nonclinical biomedical research in the 1996 version states that: "In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject."[22] As Jay Katz has observed, this closing comment is a subtle reminder that the spirit of the Nuremberg Code has faded: what the principle fails to state is *what* sense of well-being is at work here and *who* will be the judge of that

16. WORLD MED ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS § B-22 (2000), *at* http://www.wma.net/e/policy/17-c_e.html [hereinafter DECLARATION OF HELSINKI 2000].

17. *Id.* § B-24.

18. *Id.* The complete text of this provision reads:

> For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

Id.

19. The difference between assent and consent is a philosophical one. In assenting, one agrees to something, often signified by a lack of resistance or by formalized approval, for example, signing a form. In consenting, one goes beyond agreement, adding subjective approval from one competent to give such approval. Thus, children are capable of assenting to medical procedures but are incompetent to consent to them.

20. DECLARATION OF HELSINKI, *supra* note 16, § B-25. This provision states, "[w]hen a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative." *Id.*

21. WORLD MED. ASS'N, DECLARATION OF HELSINKI, RECOMMENDATIONS GUIDING PHYSICIANS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS § II.5 (1996), *at* http://www.etikkom.no/NEM/REK/declaration96.htm [hereinafter DECLARATION OF HELSINKI 1996].

22. *Id.* § III.4.

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well-being. Katz proposes a modification: "In research on man and woman, the interest of science and society should never take precedence over considerations related to the well-being of the subject *as determined by the subject, after having been fully informed by the physician-scientist, so that both can* make an understanding and enlightened decision."[23]

Some examples of recent and contemporary biomedical research in the United States, from the so-called Cold War Radiation Experiments[24] to current gene therapy, have confirmed Katz's suspicions that anything short of an unconditional demand for informed consent invites even more exceptions.

In American law, the first Nuremberg principle has been mentioned in several cases involving both military and civilian experiments, experimental treatments, and medical procedures, but as George J. Annas has noted, "no U.S. court has ever awarded damages to an injured experimental subject, or punished an experimenter, on the basis of a violation of the Code."[25] In *United States v. Stanley*,[26] Justice Scalia's opinion for the U.S. Supreme Court effectively rejected the first principle of the Nuremberg Code in a way that specifically rejected the heteronomic alterity at stake in the case.

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23. Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, *in* NAZI DOCTORS, *supra* note 1, at 227, 232–33 (emphasis in original).

24. In January 1994, President Clinton established the Advisory Committee on Human Radiation Experiments. The Committee's final report based on a review of thousands of government documents indicated that the federal government had sponsored almost 4000 human radiation experiments across the country between 1944 and 1974. These experiments included feeding radioactive cereal to teenagers at a school for the mentally retarded, subjecting prisoners in Washington and Oregon to blasts of direct radiation, and secretly injecting patients afflicted with long-term and terminal illnesses with large doses of plutonium and monitoring their condition. *See generally* ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, THE HUMAN RADIATION EXPERIMENTS: FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS (1996) [hereinafter ADVISORY COMMITTEE]; EILEEN WELSOM, THE PLUTONIUM FILES: AMERICA'S SECRET MEDICAL EXPERIMENTS IN THE COLD WAR (1999).

25. George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics Versus Expediency*, *in* NAZI DOCTORS, *supra* note 1, at 201. Most of the cases that have mentioned the Nuremberg Code or have occasioned public comment referring to the Code have focused on its first principle. *See, e.g.*, Jaffee v. United States, 663 F.2d 1226 (3d Cir. 1981) (considering constitutional tort claim on behalf of former soldier whom the U.S. government deliberately exposed to radiation in 1950s nuclear weapon test); Karp v. Cooley, 493 F.2d 408 (5th Cir. 1974) *aff'g* 349 F. Supp. 827 (S.D. Tex. 1972) (considering malpractice suit following first use of artificial heart); Doe v. Sullivan, 756 F. Supp. 12 (D.D.C. 1991) (reviewing use of unapproved vaccines on Gulf War soldiers without informed consent); Whitlock v. Duke Univ., 637 F. Supp. 1463 (M.D.N.C. 1986) (reviewing allegation of fraudulent and negligent failure to warn of risk in deep sea diving experiment); Begay v. United States, 591 F. Supp. 991 (D. Ariz. 1984) (considering 1949–1960 epidemiological study of Navajo uranium miners conducted without disclosing its aims or mining risks); Strunk v. Strunk, 445 S.W.2d 145 (Ky. Ct. App. 1969) (considering removal of institutionalized, mentally retarded adult's kidney for transplantation); Pierce v. Ortho Pharm. Corp., 417 A.2d 505 (N.J. 1980) (considering allegation of wrongful discharge from employment following researcher's objection to participation in development of new drug).

26. United States v. Stanley, 483 U.S. 669 (1987).

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James Stanley had been given the drug LSD as part of a U.S. Army experiment in 1958.[27] He was not informed that he was a subject in this experiment; in fact, he believed that he was a volunteer in a test of clothing and equipment designed to protect against chemical warfare agents.[28] Stanley suffered a severe and long-term reaction to LSD, one that ended his military service and, at least in part due to personality changes, ended his marriage.[29] After learning in 1975 of his involuntary participation in the drug study, Stanley sued for damages.[30]

Justice Scalia's opinion is complex but the result is not. The Court effectively granted the Army immunity for its conduct, ruling that Stanley as a soldier was subject to military discipline and decisions that must be free from the scrutiny and review of a lawsuit.[31] The four dissenting justices in this case focused on the violation of Stanley's basic autonomy.[32] Both Justice Brennan (joined by Justice Marshall and in part by Justice Stevens) and Justice O'Connor specifically mention the first principle of the Nuremberg Code, arguing that Stanley had suffered a grievous wrong. Justice Brennan wrote: "The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable."[33] Brennan quoted from an internal Army staff study from 1959 revealing that leaders in the Army recognized the scope of their violation:

> It was always a tenet of Army Intelligence that the basic American principle of dignity and welfare of the individual will not be violated. . . . In intelligence, the stakes involved and the interests of national security may permit a more tolerant interpretation of moral-ethical values, but not legal limits. . . . Proper security and appropriate operational techniques can protect the fact of employment of [LSD].[34]

In other words, the Army report acknowledged a violation of basic dignity and welfare but sought to avoid legal liability by hiding that violation behind a curtain of secrecy.

Justice O'Connor highlighted the importance of the first Nuremberg Principle in her dissent: "If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can

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27. *Id.* at 671.

28. *Id.*

29. *Id.*

30. *Id.* at 672.

31. *Id.* at 681.

32. *Id.* at 686, 710.

33. *Id.* at 687.

34. *Id.* at 688–89 (quoting United States Army Intelligence Corps, Staff Study, Material Testing Program EA 1729, at 26 (Oct. 15, 1959)).

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be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much."[35] In invoking the promise of due process, Justice O'Connor also invoked the notion of fundamental moral equality found more generally at the heart of heteronomic alterity and autonomy. Justice Brennan made this clear in his condemnation of Justice Scalia's "talismanic invocation" of "military discipline" as an excuse for allowing a violation of human dignity to go uncompensated.[36] Brennan remarked, "[s]oldiers ought not be asked to defend a Constitution indifferent to their essential human dignity."[37] Such indifference occurs when the experimental subject is treated as "an object, a sample"[38] or, as Eva Mozes-Kor put it, as "a mass of living, breathing cells."[39] In a recent essay on the Nuremberg Code, George J. Annas noted that in a 1991 congressional hearing on a private bill to compensate Stanley, "it was alleged that some of the researchers who subjected Stanley to the LSD experiments were former Nazis brought to the U.S. under Operation Paperclip,"[40] the secret U.S. government operation to employ German scientists without scrupulous regard for their wartime activities.

The *Stanley* decision and especially Justice Scalia's arguments remind one of the importance of arguments for autonomy and heteronomic alterity. Both in the codes and practices of international biomedical research organizations and in relatively recent developments in United States law, the protection of this autonomy has not received consistent and thorough protection, even though awareness of the importance of such protection has begun to inform and affect both biomedical research and United States law. In Part III, I will discuss one example from recent U.S. biomedical research practice and law, other than the *Stanley* case, to illustrate this point.

II.
POSTMODERNITY AND POST-AUSCHWITZ VALUES

> *It is incumbent upon us to set forth with conspicuous clarity the ideas and motives which moved these defendants to treat their fellow men as less than beasts.*[41]

35. *Id.* at 710.

36. *Id.* at 708.

37. *Id.*

38. *Id.* (citing Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 219 (1969)).

39. Eva Mozes-Kor, Address at the Conference, The Nuremberg Code and Human Rights: Fiftieth Anniversary of the Doctors' Trial, United States Holocaust Memorial Museum, Washington, D.C. (Dec. 9, 1996) (notes on file with author).

40. Annas, *supra* note 25, at 215.

41. Telford Taylor, Prosecution's Opening Statement, United States v. Brandt, Dec. 9, 1946, *reprinted in* NAZI DOCTORS, *supra* note 1, at 67, 68.

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The philosophical, political, and historical connections between the Nazis' practice of biomedicine, the ideological and moral commitments of those who participated in or supported the worst practices of the Nazi doctors and researchers, and the post-Auschwitz culture are many and labyrinthine. What are the conceptual and moral bases for evaluating these practices and thus for understanding biomedical ethics in post-Auschwitz culture? What are the moral presuppositions and implications, what is the *wrong* of Mengele's experiments, of Becker-Freyseng's (among others) sea-water experiments at Dachau,[42] of Rose and Mrugowsky's typhus experiments at Buchenwald,[43] of dozens of others that could be listed? One possible set of answers can be found in the works of Jean-François Lyotard and Emmanuel Levinas.

Lyotard has suggested an answer to the question of the wrong of Auschwitz in his discussion of the interlocutory silences imposed by the Holocaust. For Lyotard, the wrong of Auschwitz is the silence imposed when the speaker is excluded from the speech community not as a criminal person or an enemy person but as refuse. Lyotard claims that the silences imposed by the Holocaust are silences imposed on knowledge and on the lived experiences of victims and survivors alike. Thus, "the shades of those to whom had been refused not only life but also the expression of the wrong done to them by the Final Solution continue to wander in their indeterminacy."[44] While Lyotard's view is insightful and provides a partial answer to the question of the wrong of the Holocaust and Nazi biomedicine, that view needs to be supplemented by a phenomenological and aesthetic understanding of the lived reality of moral judgment found in the experience of heteronomic alterity, of the Other as encountered in the gaze of a human face.

While it is possible to trace the origins of the Nuremberg Code's placement of informed consent as the first ethical (and international legal) principle of biomedical practice to a Kantian approach to systematic ethics

42. From late 1942 through May 1943, several physicians operating at the Dachau concentration camp conducted experiments on behalf of the German Air Force to investigate the effects of exposure to freezing water, a matter of some importance to German aviators downed over the North Sea. Ten researchers, including Hermann Becker-Freyseng, were charged with special responsibility for these experiments. In the summer of 1944, many of the same researchers conducted experiments at Dachau on behalf of the German Air Force and Navy, studying the effectiveness of processes for chemically treating sea-water, in order to make it potable. Twelve researchers were charged in these experiments. *See* Indictment, Counts Two and Three, United States v. Brandt, *reprinted in* NAZI DOCTORS, *supra* note 1, at 96–100.

43. From late 1941 through early 1945, investigators such as Gerhard Rose and Joachim Mrugowsky conducted research on the effectiveness of experimental vaccines for "Spotted Fever" (i.e., *Fleckfieber*, typhus) at the Natzweiler and Buchenwald concentration camps. Thirteen researchers were charged in these experiments. *Id.*

44. JEAN-FRANÇOIS LYOTARD, THE DIFFEREND: PHRASES IN DISPUTE 56 (Georges Van Den Abbeele trans., 1988) (1983).

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based on respect for persons,[45] an even more subtle understanding of the moral significance of informed consent as ethically primary can be found in Levinas's notion of heteronomic alterity.[46] Here ethics is first philosophy, and one finds at the center of ethics the *Other*—understood as a call to the self, a demand on the self, and a kind of moral marker, or a fundamental responsibility of the self. This is an ethics of the interhuman, resting—as does Kant's—on a conception of the Other as singular, irreducible to the "same," and a unique locus of value. Emmanuel Levinas moves beyond the Kantian notion, however, in seeing this Other as a precondition of and as a constant challenge to the self. As heteronomic alterity, there is something inherently foreign, inherently other about the Other, while at the same time moral subjectivity is possible only because of its presence. As Levinas writes,

> The absolutely foreign alone can instruct us. And it is only man who could be absolutely foreign to me—refractory to every typology, to every genus, to every characterology, to every classification—and consequently the term of a "knowledge" finally penetrating beyond the object. The strangeness of the Other, his very freedom![47]

and

> I am defined as a subjectivity, as a singular person, as an 'I,' precisely because I am exposed to the other. It is my inescapable and incontrovertible answerability to the other that makes me an individual 'I.' . . . The ethical 'I' is subjectivity precisely in so far as it kneels before the other, sacrificing its own liberty to the more primordial call of the other.[48]

One sees the connection between the sense of autonomy central to heteronomic alterity and the first principle of the Nuremberg Code in the rejection of the importance of this autonomy found in the racial hygiene theory underlying much of the biomedical abuse practiced under the Nazis. The origins of racial hygiene theory are complex, traceable in part to the social Darwinism of the late nineteenth and early twentieth centuries, but having other important scientific and political origins as well. The principles and results of racial hygiene theory, however, are clear. Racial hygiene theory rejected the Lamarckian hypothesis of the inheritance of acquired characteristics in favor of the Mendelian genetic model, combined with Weismann's view of the immutability of germ plasm. Mendel's and

45. *See, e.g.*, Ruth Macklin, *Universality of the Nuremberg Code*, *in* NAZI DOCTORS, *supra* note 1, at 245 (noting that Kantian tradition refers to one formulation of ultimate moral principle as respect for persons).

46. LEVINAS, *supra* note 5.

47. *Id.* at 73.

48. Emmanuel Levinas, *Ethics of the Infinite*, *in* STATES OF MIND: DIALOGUES WITH CONTEMPORARY THINKERS 177, 192 (Richard Kearney ed., 1995).

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Wiesmann's ideas, brought together in the Nazi's racial hygiene theory, were extended to cover the most important intellectual, social, and moral characteristics identified with specific "races." National Socialist racial policy was governed by the organicist implications of this rejection of both the heritability of acquired characteristics and of the ability of the environment to produce significant change in racial characteristics. The Nazis ridiculed the Lamarckian and environmental views as weak liberal views characteristic of Jews, Free Masons, liberals, and Marxists. Identification with liberalism was also and importantly an identification with individualism; for example, one of the founding figures of German racial hygiene theory, Alfred Ploetz, argued that birth control must be distributed in a way that seeks the good of the race, not just that of the individual.[49]

Devaluing the good of the individual because the locus of value has been shifted to the race or genetic line is evident in all of the racial hygiene theories influential under the Nazis. Eugen Fischer praised National Socialism for its concern with the health of the family as opposed to the (Marxist) concern for the health of the individual.[50] Fritz Lenz, a student of both medicine and philosophy, was quite clear about the ethical implications of this view, arguing that the most basic moral category and concept and the ultimate referent of value is the race, and not the individual.[51]

If the first principle of value is race, or at least the genetic family, then silencing the voices of inferior individuals is a necessary step in the scientific improvement of society. The interlocutory silences Lyotard condemns then become praiseworthy, since the voice of the racially or genetically inferior is a discordant tone obstructing the march of social progress through racially hygienic medicine and social policy. The recognition of the Other in the heteronomic alterity of Levinas never arises, since the *alterity* of the inferior individual is never acknowledged. The racially inferior Other is not the primary source of value, no more than the racially superior Other is. Both are valuable only in a derivative sense, one negative, the other positive. Thus, one need not acknowledge another person as Other, since she is not—in the morally primary sense—the ground of my own moral subjectivity. The racial inferior for the racial hygienist is *not* you, *not* my friend, *not* me. The racial inferior is other *simpliciter*, a radical heteronomy that knows no alterity. When National Socialist medicine combined that radical heteronomy with a value hierarchy that treated Jews and other "inferior types" as inherently and inevitably moral and social degenerates, it almost invariably viewed the subjects of the biomedical practice and experimentation condemned at Nuremberg as expendable living, breathing cells, and not as the moral Other. One need not obtain informed consent from these mere cells, since they are *ex hypothesi* beings whose autonomous

49. *See* PROCTOR, *supra* note 9, at 19.
50. *Id.* at 40–41.
51. *Id.* at 48–50.

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ends and continued existence are harmful to the race. Such beings, in the phrase introduced to the euthanasia debate in the 1920 work of Karl Binding and Alfred Hoche, are "not a life worth living."[52] When those cells are no longer useful, they are refuse. As Lyotard wrote, "it is the destiny of refuse to be incinerated."[53]

It is this rejection of heteronomic alterity in Nazi biomedical practice that produced Mitscherlich's "double facelessness of a merciless epoch," and it is the condemnation of this conception of the Other that lies at the heart of the first principle of the Nuremberg Code. The moral importance of informed consent is in the recognition of the other as Other—i.e., as autonomous and a heteronomic alterity.

III.
A DEATH IN PHILADELPHIA

Recent genetic research and gene therapy trials have been beset by a number of social, legal, ethical, economic, and political difficulties involving the autonomy of research subjects. While no responsible critic would compare the efforts, motives, and methods of gene therapy researchers to those of the Nazi doctors, incidents arising from alleged violations of ethical principles of autonomy, beneficence, and justice at the macro and micro levels—especially as they apply to experimental protocols and studies and are found in international codes, treaties, and conventions—have led to a number of protests against genetic research and therapy, both in specific cases and as a general practice.[54] These protests have helped lead to the curtailment of many gene therapy trials and to an extensive restructuring of the federal regulatory system overseeing gene therapy and genetic research.[55] This restructuring has extended to the oversight system for all research involving human subjects in the United States.[56]

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52. *Id.* at 178.

53. Jean-Francois Lyotard, *The Other's Rights, in* ON HUMAN RIGHTS: THE OXFORD AMNESTY LECTURES 1993, at 144 (Stephen Shute & Susan Hurley eds., 1993).

54. *See* Pete Hartogs, *Gene Therapy Researchers Defend Trial After Death of Patient* (Dec. 10, 1999), *at* http://www.cnn.com/1999/HEALTH/12/10/gene.therapy.01/index.html; Kristen Philipkoski, *Gene Therapy Progress Report* (June 1, 2000), *at* http://www.wired.com/news/technology/0,1282,36673,00.html; Kristen Philipkoski, *Smells Like Gene Spirit* (Dec. 6, 2000), *at* http://www.wired.com/news.technology/0,1282,36674,00 [hereinafter Philipkoski, *Gene Spirit*]; Eugene Russo, *Monitoring Human Subjects and Clinical Trials*, 14 THE SCIENTIST 6 (2000), *at* http://www.the-scientist.com/yr2000/may/russo_p6000515.html.

55. *See* Sheryl Gay Stolberg, *Fines Proposed for Violations of Human Research Rules*, N.Y. TIMES, May 24, 2000, at A1; Press Release, U.S. Dep't of Health & Human Servs., New Office for Human Research Protections Created, Dr. Greg Koski Named Director U.S. Department of Health and Human Services (June 6, 2000), *at* http://www.hhs.gov/news/press/2000pres/20000606.html; Press Release, U.S. Dep't of Health & Human Servs., Secretary Shalala Bolsters Protections for Human Research Subjects (June 6, 2000), *at* http://www.hhs.gov/news/press/2000pres/20000523.html.

56. Gene therapy trials, genetic research, and other research involving human subjects have been halted in the past year at research centers including the Institute for Human

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On September 18, 2000, the family of Jesse Gelsinger filed suit in the First Judicial District of Pennsylvania, Civil Trial Division, against the University of Pennsylvania, the University's Institute for Human Gene Therapy, researchers from the Institute, medical centers involved in the research project in question, and Arthur Caplan, a bioethicist and head of the University's Center for Bioethics.[57] On November 3, 2000, the University of Pennsylvania agreed to settle the case out of court.[58]

On January 21, 2000, the U.S. Food and Drug Administration (FDA) had issued an order halting eight human gene therapy experimental trials at the University of Pennsylvania's Institute for Human Gene Therapy in Philadelphia.[59] The order (technically a "clinical hold") was the first of its kind in terms of severity and extent but was not the only action restraining researchers in recent years. It temporarily stopped the expansion and, in some cases, the continuation of therapy in five active clinical trials and three other experiments, including valuable experiments in the treatment of breast cancer, cystic fibrosis, and brain disease.[60] Since that time, many other gene therapy trials and some other research programs in the United States have been halted or modified, and the Institute for Human Gene

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Gene Therapy at the University of Pennsylvania, St. Elizabeth's Medical Center (cosponsored by Tufts University), Virginia Commonwealth University, Duke University, and Charles R. Drew University of Medicine and Science/Martin Luther King, Jr. Hospital. *See* Dave Amber, *Case at VCU Brings Ethics to Forefront*, 14 THE SCIENTIST 1 (2000), *at* http://www.the-scientist.com/yr2000/may/amber_p1_000501.html (describing temporary suspension of all human subject research at Virginia Commonwealth University under order of Office for Protection from Research Risks and FDA); Philip J. Hilts, *FDA Says Researchers Failed to Report a Second Death Linked to Gene Therapy*, N.Y. TIMES, May 4, 2000, at A20, *available at* http://www.nytimes.com/library/national/science/health/050400hth-gene-therapy.html; Nicholas Riccardi & Terence Monmaney, *King/Drew Medical Research Suspended*, L.A. TIMES, April 27, 2000, at A1 (describing suspension of all clinical trials at Charles R. Drew University of Medicine and Science and affiliate Martin Luther King, Jr. Hospital after federal Office for Protection from Research Risks discovered more than two dozen violations of regulations protecting human subjects); Rick Weiss & Deborah Nelson, *FDA Lists Violations by Gene Therapy Director at U-Penn*, WASH. POST, Mar. 4, 2000, at A04; Press Release, University of Pennsylvania Health System, University of Pennsylvania Announces Series of Actions to Strengthen Oversight and Monitoring of its Clinical Trials (May 24 2000), *at* http://www.med.upenn.edu/news/News_Releases/may00/clintri.shtml; Letter from Steven A. Masiello, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, to Jeffrey M. Isner, Chief of Vascular Medicine, St. Elizabeth's Medical Center (Apr. 28, 2000), *at* http://www.fda.gov/foi/warning_letters/m3661n.pdf (informing Dr. Isner of investigator's conclusion that clinical trial under Isner's authority violated "regulations governing the proper conduct of clinical studies involving investigational new drugs and the protection of human subjects" and warning of possible enforcement action by FDA).

57. Gelsinger v. Trustees of Univ. of Pa., No. 000901885 (Pa. Dist. Ct. filed Sept. 18, 2000).

58. Michael Rubinkam, *Family of Dead Gene Therapy Patient Settles with Penn*, PHILA. INQUIRER, Nov. 3, 2000, *at* http://inq.philly.com/content/inquirer/2000/11/03/city/03GENE.htm.

59. Sheryl Gay Stolberg, *Gene Therapy Ordered Halted at University*, N.Y. TIMES, Jan. 22, 2000, at A1 [hereinafter Stolberg, *Gene Therapy*].

60. *Id.*

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Therapy in Philadelphia has undergone a radical restructuring of its research mission, including a discontinuation of clinical trials, as ordered by the University of Pennsylvania.[61]

The FDA's original order halting the trials was issued after discovery of a number of serious problems in the Institute's informed consent procedures and, more generally, a lapse in the researchers' ethical responsibilities to experimental subjects. The FDA cited eighteen specific violations of federal experimental (and especially informed consent) guidelines,[62] but the impetus for the investigation was actually the death of eighteen-year-old Jesse Gelsinger on September 17, 1999. Gelsinger was a key participant in a clinical trial testing gene therapy for a genetically-linked enzyme deficiency called ornithine transcarbamylase deficiency (OTC) disease, a disorder that limits the liver's ability to process ammonia, which is a toxic by-product of the breakdown of food in humans.[63] The exact problem in OTC is that genes deficient in ornithine transcarbamylase are unable to break down nitrogen, which leads to the accumulation of ammonia and other toxic substances. The OTC trial used a weakened adenovirus (common-cold virus) as the "vector" or delivery system to introduce trillions of particles of the OTC gene into Jesse Gelsinger's hepatic artery and thus directly to his liver. Gelsinger had a massive, catastrophic immune system reaction to the introduction of the virus, causing his death.[64]

The Gelsinger case brought to light the complex interplay of cutting-edge genetic research regulated by the government but funded largely by the capital-hungry private biotechnology industry. Some of the ethical problems that emerged reflect in some ways the blindness and disregard witnessed in the Karl Brandt case.

Jesse Gelsinger and his father were aware of the risk of harm and even death, but the informed consent procedures in their case were compromised by misunderstandings and maybe even misstatements. Gelsinger's form of OTC was under control through diet and drugs, and there was virtually no chance that the experiment—which researchers insisted on calling a *therapy* trial—would provide him with any therapeutic benefit. In fact, the trial was testing a proposed treatment for infants suffering from a different and fatal form of the OTC mutation.[65]

This Phase I clinical trial was designed to test the safety of the procedure (in particular the safety of the vector), not the efficacy of the treatment. Neither Gelsinger nor his father were told that at the time the study

61. *See* sources cited *supra* notes 54, 56.

62. One violation, for example, was that the Pennsylvania researchers enrolled all eighteen patients without filling out eligibility forms. In addition, consent was not well documented for nine of the eighteen. *See* Stolberg, *supra* note 58, at A1.

63. *Id.*

64. *Id.*

65. *Id.*

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commenced, in more than 390 clinical trials of gene therapy in the last decade, no one had ever been cured.[66] The informed consent form given to the Gelsingers did not disclose that in earlier versions of the same experiments on monkeys, the monkeys had died.[67] This omission is contrary to federal guidelines, which require a strict risk-benefit disclosure.[68] In a warning letter from the FDA to the University of Pennsylvania released July 11, 2000, the FDA noted that a pathology report characterized one of the monkey deaths as a euthanization, when in fact the monkey had been found dead.[69] That same warning letter stated that the adenovirus vectors used in the animal studies were two years old and past their expiration date, and may have been less than half as toxic as the fresh virus used in the human trial, thus calling into question the validity of the animal studies in testing the safety of the treatment.[70]

When four other patients in the trial experienced elevated liver enzymes, the researchers should have stopped the trial immediately, notified both the University's Institutional Review Board and two federal regulatory agencies, and revised the consent form.[71] Moreover, it is possible that Jesse Gelsinger was medically ineligible to participate in the study due to ammonia levels exceeding protocol maximums prior to the infusion.[72] Gelsinger had been hospitalized with a liver crisis requiring respiratory assistance just weeks before.[73] Even though Gelsinger's ammonia level was within protocol limits at the time of his enrollment in the trial, his levels exceeded those limits just prior to infusion, according to reports.[74] The protocol's ammonia threshold maximum was seventy. A change in the experimental protocol to allow sicker patients (in terms of liver function) to participate in the experiment—a change that should have been reported and reviewed and made part of the consent process—was not so authorized. According to the FDA, protocol changes were recorded as "amendments" to the protocol, even though they were written after the completion of the experiments.[75]

Is this just a case of rogue experimenters giving a bad name to all genetic research? Not at all. The program in Philadelphia is (or at least was) one of the most prestigious in the world and the researchers there

66. Gina Kolata, *Scientists Report the First Success of Gene Therapy*, N.Y. TIMES, Apr. 28, 2000, at A1.

67. Rick Weiss, *FDA Seeks to Penalize Gene Scientist*, WASH. POST, Dec. 12, 2000, at A14.

68. 45 C.F.R. § 46.116 (2000) (listing general requirements for informed consent).

69. Rick Weiss & Deborah Nelson, *FDA Faults Penn Animal Tests That Led to Fatal Human Trial; Genetic Research Killed Teenager*, WASH. POST, July 12, 2000, at A9.

70. *Id.*

71. *Id.*

72. Hartogs, *supra* note 54.

73. *Id.*

74. *Id.*

75. *See* Weiss & Nelson, *supra* note 69, at A9.

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were first-rate. Rather, the problems with that program are indicative of systemic problems with genetic research and informed consent as a protection of the autonomy of research subjects.

In the past year, researchers in the United States have been "catching up" on their reporting to regulators, and it now appears that at least 691 serious side effects—ranging from high fevers to serious infections and even seizures—have been experienced by experimental subjects in U.S. gene therapy trials using modified adenovirus vectors.[76] Researchers claim that most of these side-effects were caused by the subjects' underlying medical conditions, and undoubtedly this is so. Still, of the 691 serious side effects, only thirty-nine were reported—as regulations require—when they happened.[77] The others were reported in the wake of Pennsylvania's program shutting down, no doubt because of fear of the same fate. More than 500 serious side effects were reported just this year, of which 130 occurred in the year 2000.[78] This represents a noncompliance rate of approximately five percent, or put another way, a rate of failure to comply of almost ninety-five percent.

Why are there such serious problems with informed consent in some of these trials, and why is there almost total noncompliance with regulations concerning serious side effects? The answers to these questions are related. Informed consent has suffered from pressure to get results—as quickly as possible. Despite the receipt of more and more venture capital from biotechnology companies which fund much of the research, genetic therapy had been singularly unsucccessful in producing positive results until just recently.[79] To complicate matters, many key researchers in this area hold patents for their own work, which gives them a significant financial interest in the success of their own experiments, often founding biotech companies for this purpose. Informed consent procedures, properly followed, are troublesome, time-consuming, costly, and may even threaten proprietary information valuable to the biotech companies. The ethical face of the research subject can be obscured by such factors.

Jesse Gelsinger's father, a handyman by trade, who, like most people, did not bring an extensive knowledge of genetics or gene therapy to the informed consent process, has stated that no party independent of his son's experiment explained "the whole process of gene therapy," and that he and his son *trusted* the researchers.[80] He explained: "I didn't research it. But I

76. Deborah Nelson & Rick Weiss, *Earlier Gene Test Deaths Not Reported; NIH Was Unaware of 'Adverse Events,'* WASH. POST, Jan. 31, 2000, at A1.

77. *Id.*

78. Philipkoski, *Gene Spirit*, *supra* note 54.

79. Recent promising results in treating certain forms of hemophilia B (in the production of Factor IX) and especially in treating SCID-X1 (severe combined immunodeficiency-X1) have been reported. *See* Nicholas Wade, *Hint of Success in Gene Therapy Study*, N.Y. TIMES, Mar. 2, 2000, at A20; *see also* Kolata, *supra* note 66.

80. Both the Gelsingers and the Browns, the first subjects of successful *in vitro* fertilization (that is, the first subjects of an *in vitro* fertilization brought to term) are members of the

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shouldn't have to research it. I believed these guys, everything they were telling me."[81] Gelsinger claimed that he and his son were led to believe that Jesse might derive some therapeutic benefit from the trial, that the principal researcher stated that the treatment had worked in others, and that Jesse Gelsinger's particular form of the disorder would let researchers "show exactly how well this works."[82] That is an important claim, since if Mr. Gelsinger is correct, he and his son were clearly misled.[83] It is possible, of course, that the Gelsingers *heard* something more promising than what the researchers said, which illustrates the difficulty of using the seriously ill in research where there is almost no chance of therapeutic benefit. Mr. Gelsinger is convinced that the informed consent requirements were not satisfied in his son's case because the researchers were anxious to make sure that Jesse Gelsinger would not choose to leave the trial. This seems like a reasonable explanation, given recent sociological research about the competitive pressures on researchers to produce success and to produce it quickly.

Paul Root Wolpe, a bioethicist at the Center for Bioethics of the University of Pennsylvania, has studied these problems in detail.[84] In the wake of the Gelsinger controversy he commented that, in observing the disclosure process in one experiment, he witnessed researchers telling subjects that the injection they would receive was so small that it could not harm them.[85] What the subjects were not told was that it was so small that it could not possibly help them. When Wolpe confronted the researchers, one of them responded, "Well, of course we do that. No one would do this if we didn't spin it that way."[86]

In that admission lies a clue to one of the systemic problems of informed consent in contemporary genetic research. Experimental subjects—who are often patients as well—bring limited understanding of genetics and almost limitless, sometimes desperate, hope to the consent

working class. That the working class bears a heavy share of research risks has been a problematic feature of many societies, including ours, for more than two centuries. The information gained from such research becomes a valuable asset to the multinational pharmaceutical corporations who often fund the research, and also for for-profit clinics in the case of infertility treatment techniques. While the parents of the first *in vitro* baby and the child herself, Louise Brown, bore the risks of being experimental subjects, the result of that risk-bearing is now sold at very high prices (e.g., prices charged by pharmaceutical companies for drugs used in fertility treatments and fees charged by fertility clinics).

81. *See* Sheryl Gay Stolberg, *Teenager's Death Is Shaking Up Field of Human Gene-Therapy Experiments*, N.Y. TIMES, Jan. 27, 2000, at A20.

82. *Id.*

83. Mr. Gelsinger claims that University of Pennsylvania researchers told him that an earlier study participant underwent a fifty percent improvement in liver function. Such improvement, however, was never documented. *See* Rick Weiss & Deborah Nelson, *Victim's Dad Faults Gene Therapy Team*, WASH. POST, Feb. 3, 2000, at A2.

84. Stolberg, *Gene Therapy*, *supra* note 59, at A1.

85. *Id.*

86. *Id.*

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process. Researchers, under competitive pressure and also financial pressure from corporate backers, operate under a paternalistic approach to research subjects, asserting professional expertise and arguing experimental necessity while minimizing the right to self-determination—a key aspect of the exercise of autonomy—of their subjects. The result is a greater or lesser degree of ethical effacement.

The noncompliance with institutional and federal reporting requirements can be understood in a similar way. First, as some researchers have admitted, disclosing adverse events in these experiments, whether or not the events are caused by the gene therapy, "can shake investor confidence in a gene therapy company."[87] Bioethicist George Annas has commented that "[a] lot of these companies may have too much at stake. They may think [stopping gene therapy trials after adverse events is] wrong for their stockholders. . . . When researchers worry more about share values than about patients, we're in trouble."[88] Second, the reporting procedure in the United States prior to recent revisions required that adverse events in gene therapy trials be reported to both the FDA and the National Institutes of Health's Recombinant DNA Advisory Committee (RAC). The difference between the two agencies is that, by law, the FDA must keep such reports secret, because they involve trade secrets of the biotechnology and pharmaceutical companies funding the research, while the RAC is required to make the reports public, to guard the public welfare and guide other researchers. (This dual reporting scheme was a legacy of political compromise.) What has emerged is that in many cases the worst adverse events—including some deaths—were reported to the FDA (the secret side) but not to the RAC (the public side).[89]

In the past, biotechnology companies were quite open about their opposition to public reports about the details of gene therapy trials, including "adverse events." (They lobby through the Biotechnology Industry Organization, the BIO.) At least one pharmaceutical company, Schering-Plough, has sought to protect information about adverse events as "trade secrets." The particular adverse event that Schering-Plough wanted to protect as a trade secret was the death of a man with advanced heart disease in a clinical trial. A Schering-Plough spokesperson stated late last year that the company regards both the design of the experiments in gene therapy and data about patient/subject safety as proprietary trade secrets. According to the spokesperson, "[t]hat is the same information that goes to the FDA and remains confidential there."[90] The RAC, however, rejected such attempts to shroud gene therapy risks in secrecy. It is quite possible that the past

87. *See* Nelson & Weiss, *supra* note 76, at A1.

88. Michael Lasalandra, *Medical Ethicist Says Halt Gene Therapy,* BOSTON HERALD, Feb. 8, 2000, at 18.

89. Sheryl Gay Stolberg, *U.S. Panel Moves to Force Disclosure in Gene Testing,* N.Y. TIMES, Oct. 30, 1999, at A10.

90. *Id.*

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overwhelming noncompliance in reporting adverse events in gene therapy trials, especially to the "public" RAC, has resulted from the RAC's refusal to keep these reports confidential.

The ethical challenges here are clear. The best attempts to use public regulatory power to protect the autonomy of experimental subjects through informed consent, risk/benefit disclosure, and adverse event reporting requirements, must fight against political and economic pressure from the results-driven biotechnology industry that is funding much of the research. In such an environment, researchers revert to paternalistic attitudes toward research subjects and are learning to streamline and make more "efficient" the execution of the research protocols. Informed consent and allied measures are messy. They are time-consuming. They are expensive. Thus, the real social and legal challenge has become to protect the autonomy of experimental subjects—truly seeing the ethical face of each subject as person—by preserving and enhancing the social safeguards against the powerful systemic pressures to do otherwise.

The long and painful story that precedes the brief legal case of Jesse Gelsinger provides one important example of the ongoing problems with providing for strong protection of the autonomy of experimental subjects. The rapidity with which the suit was settled may indicate the increasing sensitivity to this problem in both the law and public opinion. While that sensitivity grows, especially as more and more problematic cases come to light, the question of the treatment of the Other—in Jesse Gelsinger's case as well as in the case of other research subjects, present and future—remains a vital issue.

IV.
CONCLUSION

The South African poet Breyten Breytenbach has written about the core issues of ethical Otherness in a recent notebook entry, inspired by reflections on a visit to Weimar, later distributed to his students. Breytenbach experienced Weimar as doubleness, both in the "historical" re-creations for tourists found in the town itself and in the cold, interlocutory silences he found just outside of Weimar, at Buchenwald. Breytenbach told his students: "The recognition and the acceptance of the Other's humanity (or humanness) is a maiming of the self. You have to wound the self, cut it into strips, in order to know that you are similar and of the same substance of shadows."[91]

When he actually visits Buchenwald, he finds the evidence of inhumanity overwhelming. Unlike Brandt's reaction to the deeds committed in the name of biomedicine in the same camp, Breytenbach finds the "desperate" cold of the silences there almost impossible to bear: "But this I cannot

91. Breyten Breytenbach, *Note 3 Nov. (Write and Wrong)*, HARPER'S, Mar. 2000, at 21.

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look at. This then is the Other. This is Me. This is what we do. This is what we're like. Vietnam. Rwanda. Kosovo."[92]

How can sensitivity to the demands of heteronomic alterity, grounded in Kant and Levinas, found in Breytenbach's reflections, and absent in Karl Brandt, help us understand the double facelessness of Nazi biomedicine? How can it help us understand contemporary challenges in biomedicine and law? The first principle of the Nuremberg Code, arising out of the judgment in the Nazi Doctors Trial, can be understood and expanded upon on the basis of this conception of the Other. That first principle states that "[t]he voluntary consent of the human subject is absolutely essential."[93] The text elaborating on this principle stresses the necessity of the *independence* of the subject as an autonomous agent capable of exercising both the narrowly legal capacity for choice (free of force, fraud, or coercion) and the broader social capacity for choice that requires freedom from more subtle constraints, including the constraint caused by a lack of information about the proposed experiment or by an incapacity to comprehend that information. The court in the Doctors Trial held that the determination of such agency is the personal affirmative duty of each person involved in organizing or carrying out the experiment. Each person who would experiment on another is called upon to recognize—not just passively but actively—the ethical presence of the subject as Other. As chief prosecutor James McHaney stated in his closing argument for the prosecution in 1947, "it is the most fundamental tenet of medical ethics and human decency that the subjects volunteer for the experiment after being informed of its nature and hazards."[94]

It is possible to see in the ongoing recognition of the significance of the Nuremberg Code and of the Doctors Trial a concomitant recognition of the essential requirement of respect for the face of the Other. In August 1997 the Swedish public acknowledged its native version of the untidy and poorly-kept "secret" of most Western countries: for much of this century, Sweden—as well as France, Great Britain, Switzerland, the United States, and many others—sterilized people without their consent for eugenic reasons, for reasons often little more pressing than concerns about racial hygiene. In Sweden the practice continued until 1976; in the United States it ended in 1973. Condemned in the abstract as "socially undesirable" or lacking racial "purity," many of these victims of forced sterilization were also victims of biomedical practice that from the early years of this century and lasting at least through the 1970s has too often played the willing assistant to malignant social theory. In the United States, criticism of Gulf War vaccine trials,[95] the revelations and condemnation of Cold War Radiation

92. *Id.* at 22.

93. Nuremberg Code, *supra* note 12, at 181.

94. Grodin, *supra* note 14, at 175.

95. *See* COMMITTEE ON HEALTH EFFECTS ASSOCIATED WITH EXPOSURES DURING THE GULF WAR, DIVISION OF HEALTH PROMOTION AND DISEASE PREVENTION, GULF WAR

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Experiments on civilian and military populations,[96] the official apology by the U.S. President to the victims of the Tuskegee Syphilis Study,[97] and the expansion of public dialogue about biomedical research ethics all indicate progress. Elie Wiesel sees the "spark of a lesson" for us, in that "we must not see *any* person as an abstraction. Instead we must see in every person a universe with its own secrets, with its own treasures, with its own sources of anguish, and with some measure of triumph."[98] In this way we can end the interlocutory silences created by treating the Other as useful object or even refuse, as we show our face to the other as another Other, as you, as my friend, as me.

AND HEALTH: VOLUME 1. DEPLETED URANIUM, PYRIDOSTIGMINE BROMIDE, SARIN, AND VACCINES 267–324 (Carolyn E. Fulco, Catharyn T. Liverman & Harold C. Sox eds., 2000).

96. *See supra* note 24.

97. *See* William J. Clinton, Remarks by the President in Apology for Study Done in Tuskegee (May 16, 1997), *at* http://clinton4.nara.gov/New/Remarks/Fri/19970516-898.html.

98. Wiesel, *supra* note 1, at ix.

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