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Response - Jay Katz: From Harms to Risks

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Response

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Jay Katz's towering presence in the scholarship on human experimentation has been a source of personal and professional inspiration. As I noted over thirty years ago in my review essay about his classic work, *Experimentation with Human Beings*,[1] Jay's scholarship asks tough and penetrating questions about a truth we modern professionals hold to be sacred.[2] We have always assumed that growth in scientific knowledge and social progress are linked. Yet as Alex Capron discusses in his paper,[3] scientific knowledge has sometimes been produced by means we would *not* consider socially progressive. Jay's analysis of the history of experimentation with human beings before, during, and after the Nazi era dispels the comforting notion that the Nazi investigators were individuals working outside the moral ethos of modern medicine and science (i.e., that they were merely racists and sadists). Instead, Jay reveals that they were physician-investigators searching aggressively (albeit blindly) for even better ways of making science socially useful and relevant.[4]

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1. JAY KATZ ET AL., EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSIONS, AND STATE IN THE HUMAN EXPERIMENTATION PROCESS (1972).

2. Larry I. Palmer, Commentary, *The High Priests Questioned or at Least Cross-Examined*, 5 RUTGERS-CAM. L.J. 237 (1973-1974).

3. Alex Capron, *Experimentation with Human Beings: Light or Only Shadows?*, 6 YALE J. HEALTH POL'Y L. & ETHICS 431 (2006).

4. *See, e.g.*, Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 227 (George J. Annas & Michael A. Grodin eds., 1992) (observing that the Nuremberg Code's relentless and uncompromising commitment to the psychological integrity of research subjects has not been matched either prior to its promulgation or since); Jay Katz, *The Nuremberg Code and the Nuremberg Trial: A Reappraisal*, 276 JAMA 1662, 1663 (1996) (noting that, in the history of medical science, harms, including death, have always been associated with

In this response, I illustrate Jay's broad influence on the entire field of bioethics by beginning with a personal tribute that honors Jay as a scholar and teacher. As one of his former students, I can attest that his method of combining scholarship and teaching deserves the label "inspirational." Second, I discuss how my own scholarship and teaching have been shaped by Jay's courageous insistence that to protect human subjects we must develop new types of institutional arrangements.[5] Jay used his position on bioethics commissions (starting with the panel to review the Tuskegee Study of Untreated Syphilis in the Negro Male)[6] and his writings to advocate for institutional change of the manner in which we regulate research. Finally, I argue that Jay Katz's scholarship and career provide a warning to those of us who call ourselves "bioethicists" in what I have called the "human genome era."[7] Bioethics is now in some senses a new "profession," with all of the accompanying risks and benefits of that societal recognition. We may need to return to Jay's work to uncover the reflective skills for analyzing our own role in promoting, or perhaps impeding, "social progress."

I. JAY'S INFLUENCE: A PERSONAL REFLECTION

I was one of approximately thirty students in Jay's Family Law class in the spring of 1968. At a certain point in the course, Jay invited Anna Freud to participate in our class for several weeks. On those occasions, the classroom was also packed with a large number of law school faculty members, including Joe Goldstein.

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medical research, but death had not been part of the research design before the Nazi doctors); Jay Katz, *The Regulation of Human Experimentation in the United States—A Personal Odyssey*, 9 IRB: REV. OF HUM. SUBJECTS RES. 1, 2 (1987) [hereinafter Katz, *Regulation*] (arguing that Nazi studies had antecedents and recounting some earlier examples of investigators discounting the dignity of human beings); Jay Katz, Human Sacrifice and Human Experimentation: Reflections at Nuremberg, Address at the Conference Commemorating the Fiftieth Anniversary of the Nazi Doctors' Trial at Nuremberg Convened by International Physicians for the Prevention of Nuclear War and Physicians for Social Responsibility (Oct. 27, 1996) (transcript available at http://www.law.yale.edu/outside/html/Publications/pub-katz.htm) (reviewing other examples of research involving human subjects where human dignity was not maintained and observing that in medicine's quest to become a respected science, "doctors lost sight of the fact that it is one thing to experiment with atoms and molecules and quite another to do so with human beings").

5. Larry I. Palmer, *Paying for Suffering: The Problem of Human Experimentation*, 56 MD. L. REV. 604 (1997).

6. *See* PUB. HEALTH SERV., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, FINAL REPORT OF THE TUSKEGEE SYPHILIS STUDY AD HOC ADVISORY PANEL (1973) [hereinafter TUSKEGEE ADVISORY PANEL REPORT], *available at* http://biotech.law.lsu.edu/cphl/history/reports/tuskegee/tuskegee.htm.

7. Larry I Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1 (2002).

The presence of Joe Goldstein and others signaled to me that our discourse with Anna Freud was part of a much wider conversation about the relationship between psychoanalysis and law, a topic Robert Burt elegantly addresses in his paper for this symposium.[8] More important, it signaled to me Jay's generosity and openness to ideas and colleagues. In the classroom discussion of *Painter v. Bannister*,[9] Anna Freud outlined her rationale for defending the court's disposition of the child custody dispute in favor of the grandparents, i.e., the "psychological parent," over the child's biological father. As it turned out, what was going on during Anna Freud's visits to our class was the outlining of themes that she, Joe Goldstein, and Albert Solnit subsequently pursued in their *Beyond the Best Interests of the Child*.[10] Experiencing something rare and wonderful during that course stimulated me to work with my own students in such a way that the larger context of my scholarship could in turn inspire each student to find his or her light.[11] Thus, my first tribute to Jay is a personal note of gratitude: He has the ability to inspire those of us exposed to his light to take risks when we speak as citizens and as scholars.[12]

II. JAY'S INFLUENCE: TEACHING ETHICS

When Alex Capron was editor of a special edition of the American Society of Law, Medicine and Ethics' journal honoring Jay's work, he asked me to contribute a piece, and I chose to write about how Jay's approach to human research could be a model for revitalizing interdisciplinary teaching.[13] At the time I was co-teaching a seminar for undergraduates on "Institutions and Social Responsibility"[14] in Cornell University's Biology and Society Program that used some materials from Jay's casebook on human experimentation.[15] In the course

8. Robert Burt, *The Uses of Psychoanalysis in Law: The Force of Jay Katz's Example*, 6 YALE J. HEALTH POL'Y L. & ETHICS 401 (2006).

9. 140 N.W.2d 152 (Iowa 1966).

10. JOSEPH GOLDSTEIN ET AL., BEYOND THE BEST INTERESTS OF THE CHILD (2d ed. 1979); *see also* JOSEPH GOLDSTEIN ET AL., IN THE BEST INTERESTS OF THE CHILD (1986).

11. Larry I. Palmer, *Research with Human Subjects as a Paradigm in Teaching*, 16 L. MED. & HEALTH CARE 183 (1988).

12. Joe Goldstein's warning to psychoanalysts to distinguish between their roles as scientists and their roles as mere citizens should be heeded by bioethicists today, who regularly are called upon to provide normative answers to whether a particular line of research—for instance, stem cell research on cloned embryos—should proceed. *See* Joseph Goldstein, *Psychoanalysis and Jurisprudence*, 77 YALE L.J. 1053, 1059-60 (1968).

13. Palmer, *supra* note 11.

14. *Id.* at 183.

15. KATZ ET AL., *supra* note 1, at 9-65.

of writing my article during the summer of 1989, I took a morning away from my duties as a vice president at Cornell to go to the library. There I encountered David Feldshuh, the author of the play, *Miss Evers' Boys*,[16] a fictionalized account of the Tuskegee Study.

As we stood in the library lobby conversing, David, a physician by training with a Ph.D. in theater arts, asked me: "Do you know anything about the Tuskegee Syphilis Study?" Inspired, perhaps, by the generosity toward the perspectives of other scholars I remembered from Jay's class, I tried to hear the anxiety or the silence behind David's question and recognized the invitation to conversation. I told him about the paper I was writing, about Jay's role on the Tuskegee Syphilis Study panel, and about how I had followed the developments regarding the Tuskegee Study since 1972.[17] That conversation led David to ask me to read a draft of what would become *Miss Evers' Boys* before he took the play to the Sundance Festival. David was not concerned, as some critics were, with the politics of race and gender that might overshadow his attempts, as a white, male, Jewish physician-playwright, to portray the fictitious heroine of his play—an African-American public health nurse. Rather, he was concerned with his portrayal of the African-American physician. The implication—albeit a fictitious one—that Dr. Brodus, a black physician, was somehow involved in a study condemned as unethical and racist would raise some special issues.[18] The litigation on behalf of the survivors of the Tuskegee Study against the United States Government and the State of Alabama had alleged that the men were placed in the study without their consent solely because they were African-Americans.[19]

That conversation sparked several collaborations, including presentations of excerpts from the play before various audiences followed by interdisciplinary panel discussions about the issues of race, gender, and research raised by *Miss Evers' Boys*. The moving response of a large Cornell alumni audience to one of our panels convinced me to bring *Miss Evers' Boys* to Cornell as a way of engaging the entire campus in a conversation about research ethics, race, and gender. The 1991 theater production of *Miss Evers' Boys* at Cornell was a focal point of freshman orientation and became part of the eventual production of the prize-winning educational video, *Susceptible to Kindness: 'Miss Evers' Boys' and the Tuskegee Syphilis Study*.[20]

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16. DAVID FELDSHUH, MISS EVERS' BOYS (1995).

17. Palmer, *supra* note 2, at 245.

18. Palmer, *supra* note 5, at 614-16.

19. *Id.* at 609.

20. Videotape: Susceptible to Kindness: 'Miss Evers' Boys' and the Tuskegee Syphilis Study (Cornell Univ. 1994).

In writing the study guide to accompany the video, I was inspired again by Jay's approach to teaching and scholarship, in which framing the question is the key to analysis. Recall that each part of Jay's casebook starts with a narrative introduction that ends with four to six overarching questions.[21] These questions help both the teacher and the student organize the process of reflection and engaging discussion provoked by the 200 to 300 pages that follow each introduction. I thought our forty-two minute video, which included vignettes from the play, comments by "experts," interviews with survivors from the Tuskegee Study, and documentary material about the conditions in rural Alabama, needed a set of questions that would help teacher-leaders guide a reflective discussion of the issues raised by the various vignettes from the play.[22] I organized the study guide around a major question for each of the six vignettes from the play. For instance, given Jay's analysis of the role of the Hippocratic Oath in the success or failure of physician-scientists in securing consent,[23] I encouraged discussion leaders to ask, in relation to the nurse-scientist, Miss Evers, "[i]n a religiously diverse society, before whom should modern professionals take their oath?"[24] While that question related to the first of the six vignettes, the same question is discussed by the expert commentators on the video. Furthermore, in designing the questions, I had to keep in mind that the leaders and students considering my questions would come from a variety of disciplines.

Building from this interdisciplinary and collaborative work on the Tuskegee project, I began to develop a research agenda around two issues that are pervasive in research on human subjects. First, in my own writing about the issues of race and genetics, I have been inspired by Jay to develop a framework that will help us question some common assumptions about how to deal with increasingly diverse research subjects. Second, I have been drawn to consider what it means to be a "professional" in the field of bioethics.

III. PROFESSIONALISM, RACE, AND HUMAN SUBJECTS RESEARCH

The Institute of Medicine and others have called for greater training in "cultural competency"[25] on the part of health professionals in response to

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21. KATZ, *supra* note 1, at 7, 8.

22. *See* Larry I. Palmer, *Writing Law*, *in* WRITING AND REVISING THE DISCIPLINES 113, 121-23 (Jonathan Monroe ed., 2002).

23. JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 93-94 (Johns Hopkins Univ. Press 2002) (1984).

24. LARRY I. PALMER, SUSCEPTIBLE TO KINDNESS: *MISS EVERS' BOYS* AND THE TUSKEGEE SYPHILIS STUDY: STUDY GUIDE FOR DISCUSSION LEADERS 9, 11 (1994).

25. INST. OF MED., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN

granting agencies' insistence that racial and ethnic minorities have "an equal opportunity" to participate in clinical trials. My concern is that we assume too easily that minority medical students, minority physicians, or minority outreach workers will not experience a cultural divide in seeking to recruit minority research subjects. Discussions of this topic often ignore the possibility that minority professionals may, in some cases, be committed primarily to the modern biomedical definition of "professional," thereby sharing with their non-minority colleagues tendencies toward silence in terms of sharing risks.[26] To put it another way, why should we believe that minority physicians will not concentrate as much as their majority counterparts on minimizing physical harm during interventions, while largely ignoring risks to the subject's sense of human dignity? Why do we assume that minority professionals will necessarily show greater respect for the authority of subjects to say "no" to participation in research?[27]

When I listen to current discussions about the need to recruit minority members as organ donors, donors of tissue samples for genetic tests, or participants in clinical trials for diseases that disproportionately affect African-Americans such as sickle-cell anemia, I often think back to the conflicted role of Dr. Brodus in *Miss Evers' Boys*. Dr. Brodus is the same race as the men involved in the Tuskegee study, but he is culturally different from them. He does not, for instance, understand much about the form of folk dance in which one of the men is deeply involved.[28] He, like the white doctor in the play, Dr. Douglas, needs the black public health nurse, Miss Evers, to translate his medical terminology.[29] Dr. Brodus questions Dr. Douglas's decision to start the study of untreated syphilis in the Negro male, but eventually acquiesces when Dr. Douglas suggests that a scientific study might prove that both races are biologically the same.[30] Dr. Brodus's fictionalized struggle illustrates that employing racially diverse medical professionals is not a quick fix for the problems raised by the vulnerability of minority subjects. What we need, rather, is for bioethicists of all racial and ethnic backgrounds to find a forum for having open discussions about racial and ethnic differences in the genomic era.[31] Issues of race and ethnic status cannot be resolved by a procedural approach built on avoiding physical harms. Thinking about race in the post-Tuskegee world, where *de jure* segregation no longer

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HEALTHCARE 199-214 (2002) (encouraging medical educators to increase physician skills in cultural competence as a means of eliminating health disparities).

26. KATZ, *supra* note 23, at 1-29.

27. *See* Palmer, *supra* note 5, at 611-13.

28. FELDSHUH, *supra* note 16, at 72-73.

29. *Id.* at 72, 75-77.

30. *Id.* at 39-44.

31. Ari Patrinos, *'Race' and the Human Genome*, 36 NATURE GENETICS S1 (2004).

exists, requires us to embrace Jay's call for more attention to risks to human dignity in human research.

IV. BIOETHICS AS A PROFESSION

The second challenge we must face is that of the professionalization of bioethics itself.[32] When Jay, the insider and the outsider, worked with Alex Capron and Eleanor Glass on their classic book on human experimentation,[33] they challenged scientists of all kinds, including social scientists, to examine the ethics of their work. Since the outset of the Human Genome Project, the ethical, legal, and social implications (ELSI) of genetic developments have become part of the federal research agenda. But the allocation of three to five percent of genetic research funds to ELSI work[34] may be both a curse and a blessing.

We, the bioethicists, now have a potential source of funding that equips us to convince university administrators to build centers for bioethics within universities. This institutionalization within the federal research funding structure may be seen as a positive sign that we can carry on the process of providing the critical analysis of research development. On the other hand, given the failures that Alex Capron outlines in his paper,[35] we ought to pay attention to the possible downsides of our marriage to federal funding. Given this dilemma, how do we avoid becoming captive to the ethos that scientific knowledge automatically leads to social progress? How many of us will have the courage that Jay demonstrated to dissent?[36] Will we be able to challenge federal funding officials when the funding of our centers or programs is partially dependent upon our maintaining a certain kind of favorable visibility among program officers?

I am not suggesting that any of these dangers has been realized in any particular ELSI project of which I am aware. I am, however, suggesting that it is our responsibility to start asking questions about our own role in relationship to the funding for our work, and to develop a research agenda that reflectively assesses and challenges our own relatively new profession. We should not make

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32. In *Grimes v. Kennedy Krieger*, 782 A.2d 807 (Md. 2001), the court relied upon bioethics literature to hold that researchers could be civilly liable for an impaired informed consent process where parents were asked to consent, on behalf of their children, to participation in a lead-abatement study involving low-income housing. *See* Larry I. Palmer, *Genetic Health and Eugenics Precedents: A Voice of Caution*, 30 FLA. ST. U. L. REV. 237, 244-53 (2001).

33. KATZ ET AL., *supra* note 1.

34. Human Genome Program, U.S. Dep't of Energy Office of Sci., Human Genome Project Information: Ethical, Legal, and Social Issues, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml (last visited Apr. 11, 2006).

35. Capron, *supra* note 3.

36. Katz, *Regulation*, *supra* note 4.

the fatal error of presuming that our own good intentions and so-called "expertise" in bioethics provide sufficient insurance against our participating in or enabling affronts to human dignity within the research process.

Let me use an illustration from my own recent work as the principal investigator on a grant for teaching cultural competency in medical schools. My proposal involved a disease-based model for training in cultural competency and built on some work dealing with sickle cell anemia already being done at my current institution.[37] When I was filling out the human subjects protection section of the grant proposal, I was tempted to state that there were minimal risks to the students and faculty involved in my "teaching experiment" because the *physical* risks were minimal. I was further tempted to admit only a risk of loss of confidentiality during the evaluation required by the request for proposals. Perhaps it was working on this paper that pushed me to venture beyond such boilerplate statements. Instead, I felt compelled to outline for the peer-review group the true risks to human dignity I could foresee even at this research design stage of the study. I proposed including in the consent form, in addition to the standard language about possible physical harms, some language about the risks of stigma and dignitary harms to both individuals and communities that might result from participation in a project that attempts to deal with race.

For example, in the context of a training program meant to increase the "cultural competency" of future physicians, it is possible that some of the materials used, such as the educational video on the Tuskegee Syphilis Study, could provoke teachers and leaders to make statements that would make some individuals feel stereotyped and disrespected. This risk applies to both minority and non-minority students. Being labeled a "racist" has professional implications for a future physician of any race or ethnicity. On the other hand, a racial or ethnic minority student's learning might be hindered by provocative and insensitive statements by white students about supposed customs of Jews, Muslims, African immigrants, "Hispanics," or African-Americans. These risks are real and worthy of mention in the context of a training project because training *is* human experimentation. We should be aware of the dignitary risks involved in education, in attempting to shape people's minds as educators in a value-laden field such as ethics. Jay's approach to research with human subjects, as I observed above, provides an excellent framework for analyzing the nature of teaching and education. If knowledge changes people, then those of us involved

37. Kathy Keadle, *Bridging the Gap*, MEDICINE (Univ. of Louisville, Louisville, KY), Fall/Winter 2002, at 8, *available at* http://www.louisville.edu/hsc/medmag/fw02/sickle.html; Tiffani Humphrey et al., The Medical Student Sickle Cell Project: Innovation, Outreach, Opportunities, Oral Presentation at the 32nd Annual Convention of the Sickle Cell Disease Association of America, Inc. (Sept. 30, 2004) (on file with author).

in the transmission of knowledge to others are constantly involved in human experimentation.

V. LESSONS FOR THE GENOMIC ERA

I have shown how Katz's analysis of human experimentation has influenced my own thinking with respect to issues of race, ethics, and education. I would like to close with some thoughts about how his insights should influence *all* of our thinking in the near future. Specifically, I want to caution that Katz's fundamental insight—that we must always consider carefully the potential implications of our work for the dignity of human persons—will be crucial as we enter the genomic era. Genomic science has conclusively shown that we are biologically one race.[38] With such worldwide scientific consensus and the growth of the research enterprise, we should be careful not to overlook the persistent and growing risks associated with social, ethnic, and religious differences. Put another way, as scholars and citizens, we are at risk of failing to respect "the dignity of difference."[39] Jonathan Sacks, a theologian, philosopher, and rabbi, insightfully describes the challenge of thinking about ethical discourse in a pluralistic society: "Plato's assertion of the universality of truth is valid when applied to science and a description of what is. It is invalid when applied to ethics, spirituality, and our sense of what ought to be."[40]

Jay challenges us—particularly those of us trained as lawyers—to move beyond law's traditional focus on physical harms to subjects, to consider how risk-taking on the part of both subjects and investigators enhances or diminishes human dignity.[41] I would propose that in dealing with the issue of race in the genomic era, we must combine Jay's quest for *individual* human dignity within the research process with a new *systemic or institutionalist* perspective towards the dignity of racial, ethnic, and religious differences. Those of us mentored by Jay, as a teacher, scholar, and friend, are aware that the challenge to be faced involves not only protecting individuals, but also respecting—without stigmatizing—groups and developing analyses of the research process that facilitate that respect.

Genomics, informational technology, and a global economy have dramatically changed our human environment since the publication of Jay's pioneering book on human experimentation. Alex Capron's work at the World

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38. Patrinos, *supra* note 31, at S1.

39. JONATHAN SACKS, THE DIGNITY OF DIFFERENCE: HOW TO AVOID THE CLASH OF CIVILIZATIONS (2d ed. 2003).

40. *Id.* at 54.

41. Jay Katz, *Statement of Committee Member Jay Katz*, *in* ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, THE HUMAN RADIATION EXPERIMENTS 543 (1996).

Health Organization demonstrates that the scope of our concern as bioethicists has expanded to encompass the globe and its varied peoples. What has not changed—and, in my view, should not—is our continuous effort to emulate the respect for every human being Jay modeled in his teaching, scholarship, and everyday encounters.