Bob Levine on the Making of the Belmont Report

Interview by Mark Barnes

Robert J. Levine, MD, FACP, is Professor of Medicine and Chair of the Executive Committee of the Interdisciplinary Center for Bioethics at Yale University. He was co-author of the Belmont Report. He was also author of Ethics and Regulation of Clinical Research (2 editions), founding editor of IRB: A Review of Human Subjects Research (now named IRB: Ethics and Human Research) and, for 31 years, Chair of the IRB at Yale-New Haven Medical Center.

Mark Barnes interviewed Dr. Levine in a session at MAGI’s Clinical Research Conference – 2013 East.

Bob, how did you first get involved with the National Commission on Research and in what capacity?

In the early 1970s, I was doing a lot of writing critical of the then-proposed regulations for research involving human subjects. When they formed the National Commission, they asked me to join its staff. I said “No. If I understand the law correctly, if I work for the federal government, I can’t criticize it.” They came back with an offer that I could work 95% of the time for the government, and, in the other 5%, if I thought they were doing anything wrong, I could criticize that. I went to my Dean and he said, “Take it. You’ll do us a lot more good there than you do here.” I said, “Thank you for your high regard for my teaching.”

I became what they called a “special consultant.” They gave me the assignment to write what they called “background theoretical essays,” one on each of the general charges from Congress to the Commission. These papers had outlandish titles like “The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects,” “Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research,” and “The nature and definition of informed consent in various research settings.”

The first of these papers was “The boundaries between biomedical or behavioral research, and the accepted and routine practice of medicine or behavioral therapy.” Portions of this paper were adapted to become part of the Belmont Report. They sent each of the papers for criticism and comment to multiple experts, including philosophers, lawyers, ethicists, physicians, surgeons, other health care professionals, and others. Meanwhile, the Commission recruited many experts to write papers on various other topics, including ethical principles.

Then they recruited Tom Beauchamp, who subsequently became famous as the co-author with James Childress of Principles of Biomedical Ethics, the textbook for Ethics 101 all over the world, to join the staff. They asked him to write a brief report on the fundamental ethical principles that the National Commission was struggling to identify. Tom wrote that report. Then they asked him to include a definition of the distinctions between research and practice. He looked over all the papers that had been written on these topics and found that none of them really helped, except mine. He found my style of argument and writing to be very harmonious with his own. He took the central parts of my paper on the “Boundaries
between Research and Practice” and made them into the first half of the Belmont Report. That’s how I inadvertently became coauthor of the Report. Tom wrote the rest.

At the time, we thought we were writing a little document for in-house use by the members of the Commission and the staff. We had no idea that — to use a contemporary term that didn’t exist at that time — it would go viral. Within a couple of years, references to the Belmont Report were found in virtually every document on research ethics written in the world. We were astonished. That’s how I got involved.

Where did the three principles — respect for persons, beneficence and justice — come from?

The charge from Congress was to identify the ethical principles that should underlie the conduct of research. When it said “identify,” as we read it, it presupposed that the principles were already out there somewhere waiting to be identified. Many other commissions and committees seem to invent principles, but our task was to identify them.

We looked at the preceding documents on ethics of research, ethical codes. The primary one, of course, was the Nuremburg Code. The Nuremburg Code has, as its first principle: “The voluntary consent of the human subject is absolutely essential.” From that, we inferred the principle of respect for persons. We took the name of the principle, “respect for persons,” from the writings of Immanuel Kant, the 19th-century German philosopher. For this reason, many incorrectly believe the Commission’s principle is the same as Kant’s. Tom Beauchamp, in his subsequent writings, clarified the distinction by renaming the principle “autonomy.” The basic thrust of the principle is to recognize that each individual is of infinite value and not to be used as merely an instrument to serve the goals of others; this conception of the person has been recognized in Judeo-Christian doctrine for millennia. Kant’s contribution was to explain this principle in secular philosophical terms so you didn’t have to be part of a religious tradition to accept the validity of its grounding. As Kant put it, each person is to be regarded as an end and never as only as a means to the ends of others.

The Nuremburg Code contains three other statements that suggest the principle of beneficence: “The experiment should be such as to yield fruitful results for the good of society...,” “...avoid all unnecessary physical and mental suffering and injury,” and “The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved...”

They also suggested the principle of non-maleficence, do no harm. The Commission said, “Beneficence is not a fundamental ethical principle. People don’t have the obligation to go around doing good for people.” It accepted Beneficence as sort of a conditional principle, so that if you are accepting public or private money to fulfill a certain objective in your research, which is almost always doing good in the sense of developing new benefits for people or at least developing beneficial new knowledge, then it became a principle. Also, if you are putting people at risk in research, then this should be justified in terms of the anticipated benefits.

The other question was, “Should we have two separate principles: beneficence and non-maleficence?” The Commission considered “do good” and “do no harm” as mirror images of a single principle and named it beneficence. But Beauchamp and Childress later separated them into two separate principles — beneficence and non-maleficence.

What about the third principle, justice? One commissioner, Karen Lebacqz, argued forcefully that justice ought to be one of the principles. She has since written major books on the principle of justice. Everyone knew that justice had to be considered in the distribution of burdens and benefits of research, but, until she made her argument, it had not been
elevated to the level of a fundamental ethical principle. Much as we tried, we couldn’t find any statements in the preceding ethical codes that set forth the principle of justice, even implicitly. The closest thing we found was in the preamble to the Nuremburg Code, which states that the research on trial at Nuremburg was done on “asocial persons,” implying unjust recruitment of such people for research.

**Who else had a big role in writing the Belmont Report?**

Tom and I were the only ones who put pen to paper, fingers to typewriter, actually. We drafted the report in connection with, and in response to, discussions that took place at the Belmont Conference Center in Elkridge, Maryland. That’s why it’s called The Belmont Report. I spent four days there with the National Commission. It was the middle of February and ice-cold outside. But we were in a lovely building with a big roaring fire.

Tom and I were certainly not the only major contributors to the Belmont Report. I mentioned Karen’s advocacy of the principle of justice. Joe Brady, another member of the Commission, argued forcefully for the principle of beneficence, a very important feature of Roman Catholic moral philosophy. Joe had a Jesuit education and looked exactly like a priest. If you were making a movie and called central casting and said, “I want a guy who looks like a priest,” they would send Joe. In fact, Joe and I worked together later on the lecture circuit. When we went into stores, the people behind the counter almost always said, “Yes, Father.” He was actually a behavioral psychologist (a radical behaviorist). One of the tenets of radical behaviorism is the utter rejection of religion, and they said, “Yes, Father.”

In my initial draft of the definition of research, I said research refers to a class of activities intended to do certain things, to develop knowledge. Joe Brady argued that there is no such thing as intent. One of the tenets of behavioral psychology is that the only things that count are what you can observe and measure; Joe insisted that one could not observe intent. He and I had a friendly and collegial, but very forceful argument. I argued that, before you write a protocol, you should know what people intend to do.

At the next meeting, Joe brought in reinforcements — Israel Goldiamond, a psychologist from Chicago, to help explain why intent should not be used because you could never measure intent. We compromised on the term, “design.” You can measure the design. You can look at it. It’s written out in a protocol. I said the protocol represents intent, but I lost the argument. I was a pretty good loser. “Design” is not all that bad.

**Who was the chair of the Commission?**

Kenneth Ryan. I knew Ken from my residency, when he was my attending physician for a month. It was a marvelous experience. At the time, Ken was President of the Boston Women’s Hospital. He was a most learned man.

When the Commission met, after getting to know each other for about an hour, one of the first actions was to elect a chair. The Commission, by design, consisted of five people in either medicine or science and six other people. Everyone assumed that the majority would select somebody other than a physician or a scientist as chairman. But on the first ballot, I think he got eight out of the 11 votes. Wow. He was a true leader, a splendid leader. Somehow, the Commission discerned that in the first hour of our being together.
Didn’t Ryan go on later to also chair the committee that wrote the principles that ultimately became the regulations on research misconduct, falsification and fabrication of data?

He did. Ken played a lot of very important leadership roles in developing the early regulations. What we now call misconduct was totally omitted from the Belmont Report and totally omitted from the regulations that were written in its aftermath. The Belmont Report focused on the direct interactions between researchers and subjects because this is what Congress emphasized in its mandate. This is also what most interested the National Institutes of Health.

In 1966, the Surgeon General of the United States Public Health Service issued a memorandum saying that anybody who wanted a grant or contract from that agency for research involving human subjects had to include a “statement of assurance” that their proposal had been reviewed by a committee of “institutional associates.” This committee was charged to assure an independent determination of the rights and welfare of the research subjects, the methods of informed consent, and the balance of risks and potential medical benefits. Responsibility for collecting and reviewing these statements of assurance was assigned to the Institutional Relations Branch of the NIH Division of Research Grants. Donald Chalkley, an extraordinary man, was in charge. He was an embryologist and widely learned. In conversation on almost any topic he would quote from the book, 1066 and All That. He personally reviewed all the statements of assurance.

Chalkley issued the famous “Yellow Book” of guidelines for the committees of institutional associates. Leonardo da Vinci’s picture of the Vitruvian man was on the front cover. Chalkley’s assistant, Bonnie Lee, designed the yellow cover. She drew it the way da Vinci did and it showed his genitals. When the draft came out, the NIH said you can’t show genitals, so they moved the title so it would discreetly cover that part of the picture...early censorship at the NIH.

In any event, Don Chalkley was in charge of the NIH office. Five or six years later, they renamed his "Institutional Relations Branch" as the "Office for Protection from Research Risks.” That’s a whole different tone.

Were any mistakes made in drafting the Belmont Report?

In my opinion, we should have done a careful study of social and behavioral research. Congress caused this mistake when it told the Commission to distinguish research from the routine and accepted practice of medicine or behavioral therapy. You don’t have to go very far to distinguish sociology from routine practice. Sociologists don’t have “practices.” Sociology, anthropology, education and other vast areas of research were left out. The Commission made some passing statements that have been interpreted as being relevant to social and behavioral research, but they did not look into it thoroughly.

Many people do not know that the Commission also wrote other reports. The Belmont Report is only about as thick as an issue of the New England Journal of Medicine. The rest of the Commission’s publications are much larger. I think of the Commission’s entire corpus as “the 5-foot shelf of books,” the name given earlier to the complete set of the Harvard Classics.

The Commission’s report on research involving children has an interesting and illustrative story. Congress had charged the Department of Health, Education and Welfare to write regulations based upon the Commission’s recommendations, but DHEW had its own agenda. The draft regulations they wrote (protections for children involved as subjects in research) in response to the Commission’s recommendations were outlandish. On receipt of their draft, the Commission wrote a very stern letter to the Department, basically saying, "Come
on, you guys, get it right.” The regulation writers were then directed to follow the Commission’s recommendations. They came close but still put in those inane classifications in the subtitles, for example, “Research...presenting the prospect of direct benefit to individual subjects.” That’s not what the Commission said — they were talking about interventions or procedures that were either beneficial or not. Many people, to this day, talk about research that is going to benefit people. The subtitles were written after the Commission had signed off on the document and therefore were not reviewed by the Commission.

The Commission subsequently issued a report on research involving what they called, “those institutionalized as mentally infirm.” The title of the report reflected the Commission’s attitude that many people institutionalized as mentally infirm were not, in fact, mentally infirm. The regulation writers did just as bad a job on this as they had on the children. By this point, the Commission had successfully pleaded to be allowed to disband. It had been appointed for a term of two years and had by now been in business for about three and a half years. So, the Commission never had an opportunity to respond to DHEW’s draft regulations. I’ve been told that public response to the draft regulations on those with mental infirmity produced more commentary than any other proposed regulations in the history of the department. The commentary was so negative that DHEW withdrew the regulations and, to this day, we have no regulations for this category of people. Subsequent commissions, such as the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, have said, in effect, “Hey, you have to have regulations for people with mental incapacity,” and the DHEW, now DHHS, response has been, “We can get by with the general regulations. They will give us sufficient guidance.” But, of course, they don’t.

**How did the Belmont Report get transmuted into regulations?**

The Belmont Report itself never got translated directly into regulations. The recommendations that led to the regulations can be found in the Commission’s other publications, including the report on children, on the fetus and in vitro fertilization, on prisoners, on IRBs, and so on. The one on IRBs became the main substance of what we now call Subpart A, the general regulations for research involving human subjects. Subpart B is about research on the fetus, IVF and so on. Subpart C is prisoners. Subpart D is children. Subpart E might have been institutionalized mentally infirm. That is where the regulations come from.

The Belmont Report provides the basis for distinguishing research from health practices and specifies the fundamental ethical principles. It informs the regulations and provides guidance for those who work to assure compliance with them. But, except for the definition of research, it is not directly incorporated into the regulations.

**Would you like to mention any other contributions the Commission made?**

Yes, the Commission rejected the distinction between therapeutic and non-therapeutic research and redirected the focus to distinguishing beneficial from non-beneficial interventions and procedures, based on a paper I wrote arguing that the Declaration of Helsinki had confounded thinking in the field. Among the several errors of Helsinki that I pointed out were that it precluded development of new therapies for conditions or diseases for which there were existing therapies. The Commission straightened this out, primarily in its report on children, published in 1977 or 1978. The World Medical Association didn’t get around to disposing of the distinction between therapeutic and non-therapeutic research until the year 2000.
**Interviewer**

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