I want to thank you all for the opportunity to speak here this morning and to particularly thank the symposium organizers for their attention to detail in putting this conference together. We did a similar conference at Santa Clara University in October. The advantage that we all have this morning is that there actually is a public report from the California State Advisory Committee on Human Cloning, which there wasn't in October. When people at Santa Clara's conference asked what the Advisory Committee had recommended, all we could say was, "Well, we might say this," or "we might say, kinda maybe that," or "maybe you should consider this or that." So, I'm feeling somewhat unfettered this morning by the fact that our report is out there, the recommendations have been made, and we are now free to talk about it.

It does seem as though we have been thinking about cloning forever. The idea of human cloning has come into our vocabulary and our thinking as Professor Silver described, and it has really taken up residence there in its short life span. It was only a few years ago, in 1997, that we heard about the birth of Dolly. One of the reasons that Dolly came to our attention was that the story was picked up by the New York Times, appearing on the front page of the paper. That article came out, in fact, well after Dolly's original birthday. That's why the pictures of Dolly are always of a full-grown sheep. She had actually been born on July 5th in 1996 and kept under wraps, as it were, until the story appeared in 1997. Dolly's story first appeared stateside in the New York Times, and was published as a subsequent scientific article in the journal, Nature. What was remarkable about Dolly was that this was the first instance—the first reported instance—of the successful use of nuclear transfer cloning with an adult mammalian cell nucleus. Genetic material was taken from an already existing sheep and put into an enucleated egg in order to produce a lamb genetically identical to the donor sheep. So, this was
the first reported instance of using the nucleus of an adult mammalian somatic cell in order to create an offspring.

What was exciting to the public, and to the media, was that "Dolly cloning" technology allows the creation of a temporally displaced genetic twin. For example, using this technology we could possibly create a genetic twin of me this morning. But if we created such a being, she would be a number of years younger than I am, a baby born 9 months from now who would be a temporally displaced genetic twin. But what fired the biologists up about this was that it blew one of the fundamental concepts that we all held about cellular biology right out of the water. That concept was that once DNA had differentiated so as to express a particular set of genes that made a cell an eye cell, or an ear cell, or a stomach cell, for example, then it couldn’t go backwards, couldn’t "dedifferentiate." And what this experiment showed was that you actually could reverse the genetic clock. You could make cellular differentiation go backwards.

Well, people in general were not so astounded by cellular differentiation going backwards, or being able to dedifferentiate DNA. Scientists were interested in that. People started thinking, "Oh my gosh, we have a cloned lamb—what if we decided to clone people?" We were not so much concerned about cloning sheep. It's hard to tell one sheep from another anyway. But we were very concerned about the application of this technology to people. The ensuing contentious regulatory debates have been fueled, to some extent, by this fear—the fear of what is called the technological imperative, our all too human tendency to think that because something can be done, it will be done. Or, put more strongly, because something can be done, it must be done. This is a fairly typical response to change, especially to change in science or medicine. The default position quickly becomes that we consider what we can do the template for what we will or what we must do. It seems like such a tiny step from can to will, but I would argue strongly that "if we can, we will," or that "if we can, we should," is much too simple a motto for lives as complex as ours. How we use biotechnology in general, and cloning technology in particular, is a choice for us, a choice in which we ought actively and enthusiastically to engage. Despite the magnitude of the technological imperative, it will do nothing to absolve us from the responsibility; we have to decide consciously and reflectively about cloning, which was the task those of us who served on the California State Advisory Committee on Human Cloning engaged in from 1999 to January 10, 2002.

In a technological environment riddled with change and surprises such as Dolly, we find ourselves struggling not only privately, but also publicly, with questions of ethics. Questions about what is right making and wrong making about our actions, about our motives, and
about our intentions. Questions about what is right making or wrong making about human cloning.

It is ethics which asks us to justify our decisions and our actions. Not just to do something, but to describe why we do what we do. Ethics asks us to search for particular traits of character, such as integrity, courage, and compassion. And ethics asks us to imaginatively perceive possibilities for acting in a particular situation. Not just to do what we do, but to think outside the box. Ethics is basically about questions. About who asks, what they ask for, and how we as individuals and communities respond. It is in thinking about our possible responses to troubling issues, such as human cloning, that ethics and law often overlap. I think this quote from physician-ethicist Linda Emanuel sums up the context in which we find ourselves: “Much of the challenge of our era is bringing our ethical—and we could add legal—compass up to date to match our technical expertise.”

Many days, our technical expertise seems to be running away with us. The possibility of human cloning really fires our imagination. It is the stuff of conferences and coffee table conversations. Everybody wants to talk about this. But, along with the kind of “wow” and the conversational buzz come many probing and difficult questions. The basic questions of why clone, for whom, and at what cost? What is the social impact of employing cloning technology on human beings? What are the potential impacts of cloning on our values, our virtues, and our relationships? What are the risks, harms, and benefits? On whom do they fall? How are the benefits and burdens to be distributed? And, what is an acceptable way to achieve a given benefit? May we do anything, as long as the outcome is good on balance? Or are there limits on what we do, even in the name of human health and well-being?

And more ethics questions. Does a particular application of cloning technology protect or endanger human or personal rights? Are the benefits and burdens distributed fairly? Does cloning technology advance or impede the common good? And, perhaps most importantly to our task of “conceiving a code for creation,” a careful consideration is warranted on who should answer these questions—individuals, voters, experts, senators, congress people...?

We ask and answer these ethics questions from behind a cultural scrim. First, we live in an American context which privileges, both ethically and legally, individualism and self-determination, my right to make my own decisions, and on balance, your duty not to interfere with them. Second, we live in a pluralistic society. As Americans, we always have. It’s just that now we seek to acknowledge the different voices. However, we are painfully aware that there are disagreements and there is conflict. But just because we don’t agree on everything
does not mean that we don't agree on anything. Our task is to
discover what we hold in common. Third, despite the dot com
debacle, we live in a technology savvy and dependent culture. How
many of us have a cell phone or a pager with us this morning? It's
striking to realize that while we tote around these gadgets on our
waistbands, less than 50% of people in the world have ever made a
phone call. Not own a phone. Made a phone call. And lastly, we
consider questions of cloning in the context of the American health
care system. It is a system focused on cure, but financially
inaccessible to over 15% of the population. And in the current
economic climate, that number is increasing daily. It's against this
backdrop that we are asked to respond to the challenges raised by
human cloning.

In updating our ethical compass, we need to begin with the facts.
The scientific facts of cloning are quite complex. And the language
we use in our cloning talk is quite fuzzy; for example, the ambiguity of
terms like "therapeutic cloning," the increasing imprecision in the use
of the term "embryo," and the distinction between stem cell research
in general and research on human nonreproductive cloning in
particular. We have to get the facts straight because our ability to do
ethics well, and our ability to craft legislation well, depends on our
having the correct fact set to begin with. We also need to
discriminate between two uses or purposes in applying cloning
technology to humans. The first is "reproductive," that is using
cloning technology to produce a child for rearing, the context in
which Dr. Silver made his remarks this morning. There is also "non-
reproductive cloning," which includes the use of cloning technology
to produce immunologically compatible tissues for transplant. The
State Senate gave the California Advisory Committee a definition of
reproductive cloning. SB 1344 defined cloning as "the practice of
creating or attempting to create a human being by transferring the
nucleus from a human cell, from whatever source, into a human egg
cell from which the nucleus has been removed for the purpose of, or
to implant, the resulting product to initiate a pregnancy that could
result in the birth of a human being." That is the legislative definition
of human reproductive cloning. That is the definition that the
California State Advisory Committee took with them into their
deliberations. But the Committee extended the legislative mandate
and decided to look not only at the reproductive context, but also at
the context known as "nonreproductive human cloning." We
developed our own definition for nonreproductive human cloning—
that is, "the transfer of human cell nuclei into enucleated oocytes
(eggs) to produce human pre-embryos, without implanting the pre-
embryos to produce a human child." The distinction here is that in
reproductive cloning, the intent is to produce a child. In
nonreproductive cloning, there is no intent to produce a child. And, as Professor Rao mentioned earlier today, one of the caveats the Committee followed was that in thinking about nonreproductive cloning, we confined our consideration to those embryos that have not reached the primitive streak stage, embryos less than 14 to 18 days old.

All of this verbiage is quite confusing. It might be helpful to illustrate these two applications of cloning technology. And this is a modest illustration, showing a human egg from which the nucleus has been removed. Then nuclear material from an already existing (or previously existing) person is put into that egg so that you have the entire genetic compliment from an already existing person in the egg. You do some manipulation of the egg in the laboratory and, lo and behold, that egg starts to behave as if a sperm had just fertilized it. It hadn’t, but it behaves as if it had. And so, it goes into cell division. Normal progression of egg cell division leads to the formulation of a blastocyst about five days later. Here is where the distinction between reproductive and nonreproductive cloning comes in. In reproductive cloning, the ball of cells is implanted in a woman’s uterus to be brought to term to produce a child. In nonreproductive cloning, the cells from the inner cell mass are isolated and then put into tissue culture and used in research on so-called “therapeutic cloning,” better termed “nonreproductive human cloning.” So, we have two different applications of the same basic technology.

The scientific facts of human cloning are very, very complicated. So, if you find yourself scratching your head, we all do. It’s okay. Once we understand the facts, which honestly took some of us on the State Committee a year or more, we can move to a fundamental ethical consideration of the application of any technology to human beings, and that is the consideration of safety. Respect for each other and protection of human beings requires that the basic standard of safety always be met. In fact, it is the lack of information regarding safety and efficacy that led the National Academy of Scientists to recommend a ban on human reproductive cloning, a recommendation which they made last week. It is the lack of demonstrable safety in the use of cloning technology to produce a child that led the State Advisory Board to reach the same conclusion; although most members of the State Advisory Committee voiced other ethical or regulatory concerns as well. And although most of the safety concerns have been brought up regarding reproductive human cloning, it is important to remember that there are also safety concerns with developing transplantable tissues through nonreproductive cloning. There is the concern that the transplantable tissues developed in this way may, in fact, be tumorogenic, for example. So, when thinking ethically about either application of
cloning, either in the reproductive sphere or in the nonreproductive sphere, one must think about safety first.

Focusing on reproductive cloning for a minute, there are some specific safety concerns, a number of which have been referred to earlier this morning, usually grouped under a general concern for potential physical and psychological harms to the baby and/or the gestational mother. There have been profound concerns for the physical safety of a baby produced by cloning. Animal studies show a live birth rate of 5% or less and things seem to go wrong later in the lives of animals produced by cloning technology as well. In addition, cloned fetuses seem to grow unusually large in utero, posing potential harm to the gestational mother.

The ethical parameters that I am presenting to you at this point are those areas of ethics that the State Advisory Committee addressed in its deliberations over the last few years. So, in case you're wondering why these issues and not those, these concerns are ones that floated to the surface of the State Advisory Committee's deliberations. So, first, there are concerns for physical harms. Second, there are potential psychological harms to the child produced through nuclear transfer cloning. Among those mentioned most often are: first, a diminished sense of individuality; and, second, the heightened pressure of parental expectations.

One is left to wrestle with what counts as ethically relevant harm. Certainly, the physical dangers recounted by the National Academy of Sciences panel last week rise to the occasion. But there is room to wonder whether speculative psychological harms warrant the same consideration. After all, don't all parents have "unrealistic expectations" of their children?

In addition to the set of safety concerns focused on child and mother, there is a second collection of issues related to potential harm to society. First, human reproductive cloning might result in a confusion of family and generational structures. Would the human clone be the child or the sibling of the human DNA donor? And does it matter ethically as long as the law is clear regarding parentage and responsibility? One might argue that the blurring of family and generational boundaries, in and of itself, is ethically questionable since the family unit forms the basis of human community and societal structure. Second, there are questions of distributive justice. Unless one argues that human reproductive cloning is a positive right, which no one has argued to my knowledge, then questions of just distribution of resources naturally arise. Will human reproductive cloning further divide the medical "haves" and "have nots"? Or, more importantly in my view, might the resources—money, time, effort, expertise—be better applied to leveling the health care playing field or boosting the public health care system? Third, there is a
concern for the commodification of children. This is voiced as a
danger that children might become to be seen as manufactured and
fungible goods, rather than unique, priceless human beings. Even if
"cloning commerce" was banned, there would be a danger of the
lessening of human dignity by the very nature of a process which
requires access to human eggs and promises a "precise product"—a
child of your choosing with known genetic qualities and a living
example to follow. And, finally, there is concern for the protection of
procreative liberty and the freedom of choice, especially in this
intimate area of reproduction. On this view, reproduction is an act of
profound significance to the individual and the community. Hence,
individuals ought to have complete autonomy in this area, absent
substantial harm to ethically relevant others. The Advisory
Committee was persuaded that the child born of cloning technology,
as it exists now, would be so harmed, and that such harm was
significant enough to trump the general predilection towards
procreative liberty.

Now, we'll switch gears to human nonreproductive cloning,
which I think to many people, is a more ethically ambiguous area of
thinking. Basically, one is asked to weigh the benefits of human
health and well being against creating human embryos for research
purposes. So, fundamental questions to ask are the following: What
ethical weight should the anticipated medical benefits of stem cell
therapies developed through nonreproductive human cloning carry in
assessing the ethical valence of this research? How does one weigh
the potential benefits to human health against the creation of
embryos for research or for use in developing tissue based therapies?
Additional concerns in the nonreproductive human cloning sphere
include: (1) the fear of sliding down the slippery slope to human
reproductive cloning; (2) the potential exploitation of women who
donate eggs; and (3) the concern for distributive justice. But the
crux—and it is a painful crux—of the ethical matter in
nonreproductive human cloning is the question of the moral status of
the pre-embryo. It is the question of when protectable human
personhood begins. And, you know, I wish I had an answer but I
don't. We, as a society, do not and perhaps never will.

At the edges of the moral status spectrum lie "weak moral
status" and "strong moral status." "Strong moral status" argues that
a pre-embryo is entitled to the same respect due an infant or an adult
human and, hence, cannot be used as a means, even to a good end.
We don't take the life of Uncle Ned so that others may live; and,
therefore, we should not destroy human pre-embryos just as we ought
not to destroy Uncle Ned, even if hundreds or thousands of others
would benefit. On the other end of the spectrum is "weak moral
status" of the pre-embryo. This is a developmental view which claims
that an individual acquires interests and rights incrementally. Based
on the developmental continuum from pre-embryo to adult, the
human embryo deserves "minimal, but real, respect," but not the
protections associated with full human personhood. One ought not
treat human pre-embryos as property, for example. On this view, the
potential substantial benefit to thousands of ill people on balance
justifies the creation of pre-embryos through cloning technology for
research purposes.

As I conclude, I want to acknowledge a trait of ethicists. We
usually leave you with more questions than answers. But that's our
job. Our job is to point to things we ought to worry about and to
offer ways to help you worry about them. Cloning is a tough issue.
Every one of the issues I've contoured for you this morning can be
painful for us, can put us on the knife edge. If you take nothing else
away from my talk this morning, take this: That we would do well to
consider regulation of human reproductive and non-productive
cloning separately. Indeed, there is some overlap, but there are
profound differences which need to be taken into account in
developing ethically sound public policy. This is what troubles me
about the activity in Washington, that everything is lumped together
under "cloning" and the relevant differences—scientific, medical,
ethical, and even political—are not taken into account. Here, once
again, California is one up on the Feds. There are two separate bills
in the state Senate now—one dealing explicitly with reproductive
cloning, the other dealing explicitly with embryo research.

This is complicated and high voltage stuff. We need our very
best thinking as we go about seeing double and conceiving a
responsible "code for creation." Thank you.