STEM CELL RESEARCH AND EMBRYO CLONING: INVOLVING LAYPERSONS IN THE PUBLIC DEBATES

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It is a pleasure to join all of you. I am Judy Norsigian, Executive Director of Our Bodies Ourselves, and as some of you know, we are now working on the eighth edition of our landmark text *Our Bodies, Ourselves*, which is coming out next spring on the book's thirty-fifth anniversary. We are including a short section on stem cell research and some of the biotechnology issues that are of particular concern to women. We also will be posting more extensive materials at the book's website companion.[1]

First, apropos of earlier presentations today, I would like to mention a new book, noted recently in the *New York Times*, called *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to do About It*, by Josh Lerner and Adam Jaffe.[2] Lerner told the *New York Times* that he felt that "the patent system, 20 years after the reforms, [is] mired in 'the land of unintended consequences.'"[3] Elsewhere, debates continue about whether the open-

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1. *See* Our Bodies, Ourselves, *at* http://www.ourbodiesourselves.org/ (last updated Feb. 1, 2005); BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, OUR BODIES, OURSELVES FOR THE NEW CENTURY (8th ed. forthcoming May 2005). I would also like to note three excellent websites that provide helpful information in this area: The Center for Genetics and Society, *at* http://www.genetics-and-society.org (last visited Feb. 21, 2005), the Institute on Biotechnology & the Human Future, *at* http://www.thehumanfuture.org (last visited Mar. 3, 2005), and the Council for Responsible Genetics, *at* http:// www.gene-watch.org (last visited Mar. 3, 2005).

2. ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS AND WHAT TO DO ABOUT IT (Princeton University Press 2004); Sabra Chartrand, *Patents; In a Forthcoming Book, Two Professors Make Suggestions on Reinventing the Patent System*, N.Y. TIMES, Sept. 27, 2004, at C8.

3. *Id*.

source biotechnology movement could be as successful as the open-source movement in software.[4] What is particularly relevant for our discussions today is whether there might be a way to control patents and profits so that needed therapies would ultimately be accessible to those who may need them.

Our organization became involved with the stem cell debates a few years ago, as we began to realize that there were aspects of embryonic stem cell research that posed unique and significant threats to women. We do support most embryonic stem cell research and do not agree with President Bush's August 2001 position that prohibited federal funds from destroying additional embryos to produce new stem cell lines.[5] In contrast, we support public and private funding of embryonic stem cell research using otherwise discarded embryos from IVF clinics. However, we have deep reservations about embryonic stem cell research that involves embryo cloning—also known as somatic cell nuclear transfer (SCNT), research cloning, or "therapeutic" cloning. Because of the substantial short term risks to women who would undergo multiple egg extraction to provide eggs for SCNT,[6] as well as the absence of data on long term risks, we support a moratorium on SCNT until certain regulatory frameworks are first put into place and the risks of multiple egg extraction are more clearly defined.

Many people are under the misimpression that there are no significant risks to egg extraction because it is practiced so widely—in several hundred IVF clinics across the country. This is not the case. In fact many of the drugs used in the process of egg extraction for IVF are not approved by the U.S. Food and Drug Administration (FDA) for that purpose, nor has the FDA ever performed a systematic review of these drugs for this purpose. Leuprolide acetate (Lupron) is one such drug. Often used to "shut down" the ovaries before hyperstimulation of the ovaries with different drugs, Lupron has adversely affected so many women that a number of them created the "Lupron Victims Network" in order to share their experiences as well as coping strategies. Their website, active for a number of years, posted numerous accounts of problems, including: Persistent and severe muscle joint and bone pain; loss of libido; memory loss; diminished concentration; depression; headaches; and insomnia.[7]

Lupron *is* approved for the treatment of prostate cancer in men, the

4. *See* Janet Hope, *Open Source Biotechnology*, GENEWATCH, Jan./Feb. 2005, at 6.

5. Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

6. *See generally* Annick Delvigne & Serge Rozenberg, *Epidemiology and Prevention of Ovarian Hyperstimulation Syndrome (OHSS): A Review*, 8 HUM. REPROD. UPDATE 559 (Nov./Dec. 2002), *available at* http://humupd.oupjournals.org/cgi/reprint/8/6/559.

7. The Lupron Victim's Network is no longer in service.

treatment of endometriosis in women, and for fibroid associated bleeding in women.[8] Thus, it is on the market and can be used "off-label" in IVF clinics, which vary in the adequacy of their informed consent procedures. Understandably, many women feel that even serious health risks are offset by the very real possibility that a baby may result from their efforts—whether it is a baby for themselves or for another person. Whether this level of risk-taking is appropriate solely for the purposes of SCNT research will hopefully be debated more carefully in the coming months. We do not believe that SCNT research with human eggs should go forward at this time, and our position is shared by a former Chief Medical Officer of the FDA.[9]

With respect to other concerns about stem cell research, our involvement with the ProChoice Alliance Against Proposition 71 (now the ProChoice Alliance for Responsible Research) led us to think more about the role of patents and profits in the development of therapies. If therapies are ultimately so expensive that most people would not have access to them, then we clearly have a problem. There is the additional problem of inappropriate restriction of researchers' access to important new knowledge about emerging technologies. The example of predictive breast cancer genetic testing[10] provides just one example of how research in the public interest can be undermined by inadequate controls over patents and profits. In California, the language of Proposition 71 basically guaranteed very little control over this issue by the State and its citizens.[11] Whether subsequent legislation can remedy this situation remains to be seen.

We have also been concerned about applications of SCNT that go beyond the realm of medical therapies to performance enhancement, to the selection of "desirable traits" for our offspring—so-called "designer babies." Unlike other embryonic stem cell research, SCNT is the gateway technology to these possibilities because it allows for germline genetic modifications, intended and unintended, that could be passed on to subsequent generations. Having such a capability could well produce a resurgence of the eugenics movement.

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8. *See* MEDICINENET, *at* http://www.medicinenet.com/leuprolide/article.htm (last updated Nov. 17, 2003) (explaining the approved uses of Lupron).

9. Letter from Suzanne Parisian, Former Chief Medical Officer of the FDA, to Our Bodies, Ourselves (Feb. 2005), *available at* http://www.ourbodiesourselves.org/parisian.htm.

10. *See generally* Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133 (2004).

11. *See* Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, 118 Stat. 3 (approved Jan. 23, 2004).

This type of discussion is not only about morals and ethics. It is also about where we as a society may want to set limits upon what scientists can do. It is about risk versus benefit, and even about preventing unforeseen consequences that might have drastic and permanent effects. Deciding where to draw the line will certainly not be easy, but this matter should not be left only in the hands of those with substantial financial interests in moving ahead.

My own personal experience with some members of the media has underscored how abortion politics continue to play a distorting role in these debates. Some articles cast me as a "strange bedfellow" with the Catholic Church[12] (which opposes all embryonic stem cell research) rather than as a supporter of most embryonic stem cell research with substantial concerns about SCNT. This latter, more accurate, representation reflects a deep disagreement with the Catholic Church—not a "bedfellow" relationship. And the position of "not now" towards SCNT, rather than "not ever" is a crucial distinction as well. What will always be unclear to me is whether the repeated conflation of all embryonic stem cell research with SCNT has been deliberate.

During the debates over Proposition 71 in California, we were able to engage some colleagues in thoughtful discussion and advocacy. After contacting the founder of Lotus Development Corporation, Mitch Kapor, we were pleased to see his subsequent "Dear Colleague" letter that underscored the ballot initiative's flaws. He said:

> As I've learned more about its details, I've concluded Proposition 71 represents the wrong way to do the right thing. While stem cell research holds major promise, it's not the shoo-in for guaranteed results its backers are implying and there are concerns about conflicts of interest, accountability, and ethical issues that warrant finding other ways to support stem cell research….
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> …
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> The language guarantees California only an "opportunity" to benefit from patents while also guaranteeing that the researchers are "not unreasonably hindered," suggesting continuing lack of precision in what happens to royalty and patent payments. Although this is being touted as a revenue generator for the state, payments could be siphoned to private interests, which would in turn surely be challenged in the courts. Similarly, sharing the risk through state funding that might entice the private sector to participate will be undermined by the lack of

12. *See* Sheryl Gay Stolberg, *Some for Abortion Rights Lean Right in Cloning Fight*, N.Y. TIMES, Jan. 24, 2002, at A25.

clarity.[13]

Interestingly, Senator Deborah Ortiz, who has been a major proponent of Proposition 71, is now appearing to be more critical of the measure:

> Proposition 71 requires appointees to refrain from voting on funding for their campuses or firms. But Sen. Deborah Ortiz, who was author of the state's original stem cell legislation and backed the initiative, said it doesn't go far enough to safeguard the taxpayers' money and interests.
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> The Sacramento Democrat said she plans to author legislation requiring financial disclosure from the working groups that will make the original recommendations on grants and loans.
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> She said she would also seek to open up more of the proceedings to the public as well as ensure the state recoups its investment and gets its share of profits from successful treatments and therapies.[14]

This ability to have closed meetings was one of our original objections as well. Proposition 71 also establishes a constitutional right to stem cell research, particularly focused on embryonic stem cell research and somatic cell nuclear transfer.

> In addition, Ortiz said she would try to strengthen patient protections and informed consent for those participating in the research or contributing embryos or eggs for the investigations.
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> Her ability to impose more restrictions may be limited. Proposition 71 says lawmakers must wait three years to make any changes in it, and 70 percent of both houses of the Legislature must approve those changes.[15]

One of the reasons Senator Ortiz originally supported Proposition 71 was because stem cell legislation that she had earlier introduced failed due to the requirement of a seventy percent favorable vote.[16] But one might argue that much more could have been done to build a constituency for a well-crafted bill and an outcome that could better serve the State and its

13. Posting of Mitch Kapor, to Of, By and For; The Future of the Republic (Oct. 25, 2004), *at* http://www.ofbyandfor.org/node/view/830.

14. Laura Mecoy, *Stem Cell Panel Gains Momentum*, SACRAMENTO BEE, Nov. 18, 2004, at A3, *available at* http://www.sacbee.com/content/politics/ca/election/v-print/story/11459
625p-12373723c.html.

15. *Id.*

16. *Id*. This is also why there are so many ballot initiatives in California—getting any bill through the state legislature is quite difficult.

residents. With a ballot initiative, those with the deepest pockets can conduct massive media campaigns to sway the vote, often with misleading messages that go unchallenged.[17] Senator Ortiz' ongoing efforts may yet prove to be worthwhile, but it will be difficult to undo many of the problems that Proposition 71 created:

> Ortiz said the legislative counsel believes she could make changes sooner. If not, she said, she still plans to use her legislation to try to force the oversight committee to adopt her reforms.
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> "The more transparency and less secrecy about this process, the greater the level of confidence and integrity we can provide to the voters," she said. "This is unprecedented and historic, and it has to be absolutely aboveboard."[18]

I believe that many of the Hollywood stars did not fully understand Proposition 71. Brad Pitt, who appeared on the *Today Show* in support of the measure was almost totally scripted with a prompter.[19] He was paired with a physician who also supported Proposition 71, while only one person was allowed to voice criticism on the same program—the President of the California Nurses Association.[20] And this happened even after a promise of a more level "playing field," where there supposedly would be the same number of proponents and opponents appearing on the show.[21]

The California Nurses Association, which represents about 58,000 nurses, thoroughly reviewed Proposition 71 before stating its opposition to the measure.[22] It wanted to support embryonic stem cell research but in a different way.[23] Many pro-choice groups did support Proposition 71, but some later questioned whether this was the right decision. One of the medical societies that had previously endorsed Proposition 71 reversed its decision about three weeks before the election, making many of the same

17. *See generally* KTVU.COM, *Proposition 71: Stem Cell Research Initiative, at* http://www.ktvu.com/politics/3736121/detail.html (Sept. 16, 2004). About $25 million was spent to pass Proposition 71. Most of this came from such wealthy individuals as Bob Klein, who was co-chair of the group seeking Proposition 71's passage. The founder of e-Bay, Bill Gates, and numerous movie stars also contributed substantial sums.

18. Mecoy, *supra* note 14.

19. *Today Show* (NBC television broadcast, Oct. 26, 2004) (interviewing Brad Pitt about his so-called views on stem cell research).

20. *Id.*

21. *Id.*

22. CAL. NURSES ASS'N, *California Nurses Assn. Calls for Added Public Protections as Proposition 71 Policy Board Convenes*, *at* http://www.calnurses.org (Dec. 17, 2004).

23. *Id*.

arguments made by the ProChoice Alliance against Proposition 71.[24]

Although a number of excellent critiques of Proposition 71 did appear in newspapers during October 2004,[25] these were not read by a sufficient number of voters to make a difference. The California Nurses Association not only developed an excellent written critique, but also produced a short, thirty second television advertisement which aired only once or twice as part of a news story portraying a "David and Goliath" situation. The other side had plenty of resources to air ads with Christopher Reeve or Michael J. Fox, but the California Nurses had a much smaller budget.

The smaller grassroots critics of Proposition 71 probably did have an impact on the final vote, reducing the anticipated seventy percent to thirty percent win to a fifty-nine to forty-one percent vote. Had the critics started sooner, there might have been an even smaller gap.

In closing, it is worth noting that embryonic stem cell research faces major technical problems. Therapies developed for animals have tended to produce tumors, and it is difficult to control embryonic stem cells so that they differentiate into the type of cell desired. John Gearhart at Johns Hopkins University has shown that the tumorigenicity problem can be resolved by growing a mouse embryo to the seven to nine week fetal stage (when germ line cells can be harvested to produce stem cells that do not have this problem), but this approach would not be feasible for human beings.[26]

Even if SCNT moves forward, there are safer ways than multiple egg extraction to obtain eggs for research. Eggs could be extracted at the time a woman is having an ovariectomy (when her ovaries are being removed) or when a woman is having a tubal ligation. Even natural cycling, where only one egg is extracted, is safer than procedures involving hormonal manipulations to produce multiple eggs. This type of approach will certainly not produce as many eggs, but it is far safer for the women willing to provide eggs for research.

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24. Carl T. Hall, *Foes Closing the Gap in Stem-Cell Measure*, Oct. 15, 2004, at B1, *available at* http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/10/15/BAGV099P6N1.DTL.

25. *See, e.g.*, Daniel Sarewitz, *Stepping Out of Line in Stem Cell Research; Proposition 71 Would Cut the Link Between Science and Democracy*, L.A. TIMES, Oct. 25, 2004, at B11; Daniel Callahan, *Combining Hope, Hype and Hucksterism*, SAN DIEGO TRIB., Oct. 22, 2004, *available at* http://www.signonsandiego.com/uniontrib/20041022/news_z1e22callaha.html; Ellen Goodman, *Stem Cells on the Ballot*, BOSTON GLOBE, Oct. 24, 2004, at E11; Dan Gillmor**,** *Some Thoughts on California's Propositions*, SAN JOSE MERCURY NEWS, Oct. 24, 2004, at 1F.

26. *See generally*, U.S. FOOD & DRUG ADMIN., *Twenty-Seventh Meeting of the Biological Response Modifiers Advisory Committee*, *available at* http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3629t2.rtf (July 14, 2000).

We are particularly concerned about the vulnerability of younger women and financially disadvantaged women for whom altruistic motives and the appeal of several thousand dollars (or more) would amount to inappropriate inducements. A number of college-age women, who responded to ads placed by IVF clinics for egg donors, and individual couples have approached us about what they see as misleading websites or counseling procedures that downplay or omit the risks of undergoing multiple egg extraction. Several who pursued the possibility of becoming egg donors have criticized the informed consent process as incomplete and imbalanced. Should SCNT research move forward, it is crucial that the recruitment and informed consent procedures for would-be egg donors be scrupulously crafted and implemented.

Thanks for your attention, and we look forward to further exchanges with some of you on these and other issues related to stem cell research.