Testimony of Richard M. Doerflinger

before the

House Health and Government Operations Committee
Maryland Legislature

In support of House Bill 481
"Human Cloning Prohibition Act of 2004"
and
In opposition to House Bill 1021
"Human Cloning Ban and Stem Cell Research Protection Act of 2004"

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I have been asked by the Maryland Catholic Conference to present testimony today on House Bills 481 and 1021. I am familiar with the approaches to human cloning taken by each bill, because each closely resembles a pending federal bill on which I have testified before Congress.

In support of HB 481

HB 481, a genuine and much-needed ban on human cloning, is similar to S. 245 in Congress, sponsored by Senators Sam Brownback (R-KS), Mary Landrieu (D-LA) and 27 others. This kind of cloning ban has been overwhelmingly approved twice by the U.S. House of Representatives, endorsed by President Bush, and enacted into law in five states.[1] It would ban the use in humans of the cloning procedure known as "somatic cell nuclear transfer" (SCNT), the technique used to make "Dolly" the sheep.

HB 481 should be supported by anyone who truly wants to prevent human cloning. It bans the human cloning procedure explicitly and precisely, without affecting any other area of stem cell research or any use of cloning techniques to make plants, animals, genes, or cells other than human embryos. Human cloning should be banned because it shows grave disrespect for human beings in the very act of creating them. It reduces human procreation to an assembly line, where fellow humans are manufactured to preset specifications and exploited for the sake of

1 Arkansas, Iowa, Michigan, North Dakota and South Dakota. Virginia's law may also be interpreted as a complete ban on human cloning. See USCCB Secretariat for Pro-Life Activities, "Current State Laws on Human Cloning," at www.usccb.org/prolife/issues/bioethic/statelaw.htm.

traits deemed useful by others.

While some have coined slogans to claim a difference between "reproductive" cloning (cloning for baby-making) and "therapeutic" cloning (cloning for research purposes), the cloning procedure is identical in both cases – the only difference lying in what is done with the cloned human embryo *after* the cloning procedure has been performed. The embryo can be placed in a womb for an attempt at live birth, or kept in the Petri dish and destroyed for stem cells or other research goals. But these later activities do not change the degree to which the embryo was "cloned."

In any case, as numerous *supporters* of "therapeutic" cloning now admit, the two uses cannot be separated in reality: If you allow and encourage cloning for research purposes, you will facilitate so-called "reproductive" cloning as well. In the words of Dr. Hwang of the South Korean team that has claimed success in cloning human embryos, "this technique cannot be separated from reproductive people cloning…"[2]

The professional association for our nation's fertility specialists agrees:

"Researchers have proposed using SCNT [somatic cell nuclear transfer] to generate embryonic stem cells for persons who need tissue or organ transplants... If undertaken, the development of SCNT for such therapeutic purposes, in which embryos are not transferred for pregnancy**, is likely to produce knowledge that could be used to achieve reproductive SCNT.**"[3]

Or in the words of researchers at Advanced Cell Technology in Massachusetts, pioneers in pursuing "therapeutic cloning": "It is true that the techniques developed in CRNT research can prepare the way scientifically and technically for efforts at reproductive cloning."[4]

In terms of disrespect for life, the difference between the two uses of cloning is this: Judging from animal trials, efforts to grow cloned humans in a womb will lead to their deaths 90 to 95% of the time, through "accidental" miscarriage and stillbirth; efforts to use them for research will lead to their deaths 100% of the time, through deliberate destruction.

In opposition to HB 1021

HB 1021, by contrast, can only be supported by someone who thinks everything about human cloning is fine, as long as government insists that the death rate be kept at 100%. It

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2 Quoted in Michael Vincent, "Korean Stem Cell Research Labeled Recipe for Cloning," ABC Online, February 13, 2004, http://www.abc.net.au/am/content/2004/s1044228.htm.

3 The Ethics Committee of the American Society for Reproductive Medicine, "Human Somatic Cell Nuclear Transfer (Cloning)," 74 *Fertility and Sterility* 873-6 (November 2000) at 873. This article's title also acknowledges "cloning" and "somatic cell nuclear transfer" to be one and the same thing – HB 1021's claim to ban one while allowing the other is scientific nonsense.

4 -R. Lanza, et al, "The Ethical Validity of Using Nuclear Transfer in Human Transplantation,"
284 *Journal of the American Medical Association* 3175-9 (December 2000) at 3178. (The authors use their own invented term, "cell replacement by means of nuclear transfer" or "CRNT," to describe the cloning procedure.)

allows human cloning, then tries to prevent the cloned human's survival by prohibiting pregnancy and live birth.

This bill is similar to S. 303 in Congress, sponsored by Senators Orrin Hatch (R-UT), Dianne Feinstein (D-CA) and 9 others. Its approach has never been approved by any chamber of Congress, or by any committee in either chamber. Similar laws have been enacted in two states, California and Rhode Island.[5]

HB 1021 is misnamed, because it does not prohibit the use of any cloning procedure in humans. Rather, it prohibits trying to implant a cloned human embryo in a uterus, or trying to let the embryo survive past 14 days of development. In effect, it would define a class of developing members of the human race that it is a crime *not* to destroy – a set of developing humans who are forbidden to *exist,* except as objects of research.

Comparing HB 1021 and last year's HB 482

A year ago I testified against this bill's predecessor, a broad proposal written to allow the use of human cloning to produce embryonic, fetal *and adult* stem cells for research (HB 482). It would have *allowed* researchers to develop cloned embryos to later stages and then exploit them for their stem cells. HB 1021's sponsors apparently think it is a more moderate proposal –but it actually creates new problems, and is in some ways *worse* than last year's bill:

1. Last year's bill *allowed* researchers to destroy cloned humans in research. HB 1021 effectively *requires* them to. To be specific:

- (a) HB 1021 prohibits implanting a cloned embryo in a uterus or "the functional equivalent of a uterus"; and

- (b) in any case where such implantation (which generally happens around the 6th day of embryonic development) has nonetheless occurred, HB 1021 prohibits "maintaining" the cloned embryo for more than 14 days after its first cell division – that is, it mandates that the pregnant woman have an abortion within a week after implantation, or face a civil penalty of up to $250,000.

Last year's pro-cloning bill had many flaws, but at least it did not allow cloning and then ban pregnancy and live birth. It did not try to institute a regimen of forced abortion, to implement a government policy that cloned humans deserve only to be manipulated and destroyed. It did not threaten the unethical -- and evidently unconstitutional -- coercion of

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5 Rhode Island, however, also has a separate law against harmful fetal research that may prohibit experimental use of cloned human embryos. A law recently enacted in New Jersey takes a different approach and is more similar to Maryland's HB 482, rejected by this committee last year: Rather than setting an upper time limit for the survival of cloned human embryos, this "fetus farming" law allows the implantation of cloned embryos in women's wombs and their survival to later fetal stages for the harvesting of more developed tissues, as long as the cloned human is not developed through the "fetal *and* newborn stages" to produce a liveborn cloned child.

pregnant women that HB 1021 seems to require.

2. This effort to have one's cake and eat it too – to allow human cloning, then ban the survival of cloned humans – is not only morally wrong and constitutionally suspect but also practically unworkable. HB 1021 will allow all the research in human cloning needed to develop and "perfect" the process. And once that technical progress is achieved and clonal "embryo farms" exist in laboratories throughout the state, how will anyone effectively stop a researcher from placing one of these embryos in a womb? Embryo transfer, the procedure HB 1021 tries to prohibit, takes place every day using embryos fertilized in the laboratory.[6] Indeed, once the embryos are created there is no reliable way to determine which were created by fertilization and which by cloning.[7]

Even if such a test were available, it is absurd to imagine that the state of Maryland will demand screening every embryo ready for implantation in a fertility clinic, to exclude those created by cloning. That absurdity is not remedied by HB 1021's provision seeking to ban performing the human cloning procedure in a reproductive technology clinic, because that provision simply begs the question posed above: Once cloned embryos and fertilized embryos have been created, through activities (somatic cell nuclear transfer and IVF, respectively) that would both remain perfectly legal under this bill, how would law enforcement authorities tell which embryos are which? And once the embryos are implanted, how will the state prevent "reproductive cloning" without forced abortion?

3. Last year's bill to allow "fetus farming" was a moral and legal horror, but its excesses were based on a scientific fact. HB 1021 simply ignores that fact. The fact is that "therapeutic cloning" using embryonic stem cells is not working well, even in animals, because these cells are too difficult to maintain, too uncontrollable, too genetically unstable, too likely to form lethal tumors in animals' bodies. A year ago there was strong evidence that cells derived from cloning will not be "therapeutic," *unless* cloned embryos are developed to at least the *fetal*

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6 Commenting on a similar federal bill, the U.S. Department of Justice notes that "the prohibited activity 'transfer of an embryo to a uterus' is an activity that is otherwise permitted now in all states and is performed thousands of times a year in fertility clinics. This legislation obviously is not intended to establish a broad prohibition on such lawful activity. However, the transfer of an embryo to initiate a clinical pregnancy is presumably the same regardless of whether the embryo involved was originally produced by cloning or fertilization. Hence, there is no visible difference between the prohibited activity and the permitted activity, both of which would presumably be conducted within the privacy of a hospital or medical office. Entrusted with enforcing such a limited ban, law enforcement would be in the unenviable position of having to impose new and unprecedented scrutiny over doctors in fertility clinics and/or research facilities to ensure that only fertilized embryos were being transferred to would-be mothers." Statement of U.S. assistant attorney general Daniel J. Bryant before the House Government Reform Committee, May 15, 2002, at www.cloninginformation.org/congressional_testimony/bryant_02-05-15.htm.

7 As the Department of Justice notes, "at the point when embryo transfer occurs, which is at the blastocyst stage (about 5-6 days after the embryo is produced), there does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo… Moreover, if a researcher mixed cloned and fertilized embryos in culture and then implanted only some of these embryos, there would simply be no way for a prosecutor to prove that the implanted embryos were the ones which arose from cloning. Even after the fact, it is not clear how one could determine that the fetus in utero was originally produced by cloning, unless one could demand a prenatal genetic profile and show that this profile is genetically virtually identical to a particular pre-existing individual." Id.

stage for cell harvesting. That evidence is twice as strong now. No one should recommend a return to the horrible excesses of HB 482; but HB 1021, while creating the moral and legal problems cited above, lacks even a utilitarian justification in terms of therapies.

Last year I cited two major studies in "therapeutic" cloning. In the first, designed to provide new kidney tissue, researchers found that they had to gestate cloned cow embryos in a uterus and then abort them for their *fetal* kidney tissue to achieve success.[8] The second study, designed to correct a genetically-based immune deficiency in mice, required taking the new mouse (produced by cloning and genetic modification) to the *newborn* stage and harvesting its *adult* stem cells to treat the original mouse.[9]

Now, a year later, we have two new studies. One, appearing this month in an online journal published by the American Heart Association, found again that cloned mice had to be grown to the fetal stage and then aborted to provide usable cells, this time for attempted repair of heart damage in mice.[10] The other study provides an explanation for such findings: The cloning process wreaks havoc with gene expression in the early embryo, because it tries to reprogram all the genes of a specialized body cell to become active again at one time, to make a new human being; this problem is worst at the embryonic stage, dimming the prospects for any safe or "therapeutic" use of embryonic cells. If the cloned embryo can be made to survive into the fetal stage, however, there is a second opportunity to complete this gene reprogramming and smooth out the gene expression errors.[11]

In plain English, this means that use of *embryonic* stem cells from cloning are likely to be incapable of safe and effective use in human patients. Even from a pragmatic point of view, then, this bill is a bad investment.

4. HB 1021 repeats the claim in HB 482's preamble that the bill's enactment could produce "unprecedented treatments and potential cures for diabetes, Parkinson's disease, Alzheimer's disease, cancer, and other diseases." Given what we now know, repeating these claims a year later is irresponsible, especially as applied to "therapeutic" cloning.

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8 R. Lanza et al., "Generation of histocompatible tissues using nuclear transplantation," 20 *Nature Biotechnology* 689-96 (July 2002). The authors wrote: "Because the cloned cells were derived from early-stage fetuses, this approach is not an example of therapeutic cloning and would not be undertaken in humans." Id. at 689.

9 W. Rideout et al., "Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy," 109 *Cell* 17-27 (April 5, 2002). For a critique see Americans to Ban Cloning, "Why the 'Successful' Mouse 'Therapeutic' Cloning Really Didn't Work," at www.cloninginformation.org/info/unsuccessful_mouse_therapy.htm.

10 The cloned mice had to be developed to the equivalent of *the fifth to sixth month* of human fetal development, then aborted for their cells. R. Lanza et al., "Regeneration of the Infarcted Heart With Stem Cells Derived by Nuclear Transplantation," *Circulation Research*, Published online before print February 5, 2004, http://circres.ahajournals.org/cgi/content/abstract/01.RES.0000120863.53562.DFv1.

11 See J. Fulka et al., "Do cloned mammals skip a reprogramming step?", in 22 *Nature Biotechnology* 25-26 (January 2004) (concluding that this finding poses serious problems for both "reproductive" and "therapeutic" cloning).

The claim that cloning is needed to treat three of the four diseases cited here – Parkinson's, Alzheimer's and juvenile diabetes – was dealt a serious blow this month by one of the world's leading experts on cloning, Dr. Ian Wilmut (leader of the Scottish team that cloned "Dolly" the sheep). He wrote in the *British Medical Journal*:

"In any treatment regime we must avoid immunological rejection of the transferred cells, but the immune response is likely to vary from one disease to another… [I]n the treatment of diseases within the central nervous system **cells from cloned embryos seem likely to offer less advantage as fetal cells in the central nervous system appear not to be subject to rejection.** Finally, several of the conditions that are mentioned as candidates for cell therapy are **autoimmune diseases, including type 1 diabetes. In such cases transfer of immunologically identical cells to a patient is expected to induce the same rejection.**"[12]

In other words, cloning is probably **unnecessary** for any condition involving the central nervous system such as Parkinson's and Alzheimer's, because that system does not have a strong immune response but will accept cells from genetically unmatched sources – and I would add that this is true not only for fetal cells but adult cells as well.[13] And cloning is **useless** for autoimmune diseases such as juvenile (Type I) diabetes, because the cells from a cloned embryo would have exactly the same genetic makeup that makes the diabetic patient's faulty immune system reject his or her cells in the first place.

In fact, after more than two decades of research using mouse embryonic stem cells, researchers have yet to find a reliable way to direct these cells to form pancreatic cells that can reverse juvenile diabetes in *mice*, let alone human beings. The most recent study on this issue has found that past attempts to differentiate these cells in the right direction failed to produce the "beta cells" needed for diabetes treatments. The cells did produce some insulin, but not in response to changes in surrounding glucose levels; and when placed in diabetic mice they did not reverse diabetes but only formed teratomas (tumors).[14]

This result also illustrates how misleading it is to claim that embryonic stem cells may cure cancer. These cells have a disturbing tendency to *cause* cancer.[15] In animal trials for

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12 I. Wilmut, "Human cells from cloned embryos in research and therapy," 328 *British Medical Journal* 415-6 (2004).

13 See: J. Hori et al., "Neural Progenitor Cells Lack Immunogenicity and Resist Destruction as Allografts," in 21 *Stem Cells* 405-16 (2003); S. Bhattacharya, "Immune 'invisibility' of brain stem cells proven," in *New Scientist*, 18 July 2003, at www.newscientist.com/news/print.jsp?id=ns99993953. This latter article notes that adult mesenchymal stem cells from bone marrow, with a versatility that may rival that of embryonic stem cells, are also "immune privileged" and are not rejected as foreign when placed in genetically unrelated recipients. For another recent advance in solving the immune rejection problem, using *adult* stem cells, see J. Down and M. White-Scharf, "Reprogramming Immune Responses: Enabling Cellular Therapies and Regenerative Medicine," in 21 *Stem Cells* 21-32 (2003).

14 S. Sipione et al., "Insulin expressing cells from differentiated embryonic stem cells are not beta cells," *Diabetologia,* published online 14 February 2004, doi: 10.1007/s00125-004-1349-z.

15 Says an ethicist who *supports* embryonic stem cell research: "The emerging truth in the lab is that pluripotent stem cells are hard to rein in. The potential that they would explode into a cancerous mass after a stem cell transplant might turn out to be the Pandora's box of stem cell research." Dr. Glenn McGee of the University of

Parkinson's disease as well, while half the animals seemed to derive some benefit from the cells, another 20% died from lethal tumor formation.[16] Even under controlled conditions in the laboratory, embryonic stem cells spontaneously acquire extra chromosomes – chromosomes closely associated with testicular cancer.[17] While critics have recently pointed out that the NIH-approved embryonic stem cell lines eligible for federal funding are becoming genetically abnormal, it turns out that the new cell lines these critics have now created are *themselves* already genetically abnormal – and the abnormal cells grow much more quickly than those which remain normal, in the same way that cancer cells do, with the implication that they will ultimately take over the cell lines entirely.[18]

Fortunately, advances in stem cell research *are* bringing us much closer to a cure for juvenile diabetes and spinal cord injury, and are already being used in clinical trials to reduce or cure Parkinson's disease, multiple sclerosis, leukemia, sickle-cell anemia, bone damage, heart damage, and dozens of other ailments – but these advances are coming from stem cells from adult tissue, umbilical cord blood, and other sources that create no moral problem.[19] Embryonic stem cells (whether from cloning or not) remain a very long way from any safe or effective use in humans – indeed, after more than two decades of research in *mouse* embryonic stem cells, we have yet to see a safe and effective treatment for any disease in *mice.*

Conclusion

There is one legally and morally responsible way to ban human cloning, and that is to ban the use of the cloning procedure to create humans in the first place. Iowa, Arkansas, North Dakota, South Dakota and Michigan have already enacted genuine laws against human cloning, and I urge Maryland to follow their lead by enacting HB 481. Such a ban is necessary to stop

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Pennsylvania, quoted in E. Jonietz, "Innovation: Sourcing Stem Cells," *Technology Review*, January/February 2001, http://209.58.177.220/articles/jan01/innovation_jonietz_printable.html. For a recent vivid example of this problem, see S. Wakitani et al., "Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint," in 42 *Rheumatology* (2003), 162-5.

16 "If large numbers of ES cells are transplanted into an organ like the brain, they grow into every cell type and form tumor-like masses called teratomas, eventually killing their host." C. Freed, "Will embryonic stem cells be a useful source of dopamine neurons for transplant into patients with Parkinson's disease?", 99 *Proceedings of the National Academy of Sciences* 1755-7 (Feb. 19, 2002) at 1755. Freed actually cites the 20% death rate from tumors as an improvement over earlier studies with an even higher death rate – an improvement achieved by transplanting a much smaller number of embryonic cells, but with the result that a large percentage of the animals received no benefit either. Freed drily admits that "the results were far from perfect." Id.

17 J. Draper et al., "Recurrent gain of chromosomes 17q and 12 in cultured human embryonic stem cells," in 22 *Nature Biotechnology*, advance online publication 7 December 2003, doi: 10.1038/nbt922.

18 C. Cowan et al., "Derivation of Embryonic Stem-Cell Lines from Human Blastocysts," 350 *New England Journal of Medicine* (March 25, 2004), advance publication, at Cowan-3.

19 For some of these advances see generally the web site of Do NoHarm: The Coalition of Americans for Research Ethics, at www.stemcellresearch.org; also see USCCB Secretariat for Pro-Life Activities, "Scientific Experts Agree: Embryonic Stem Cells are Unnecessary for Medical Progress," at www.usccb.org/prolife/issues/bioethic/fact401.htm.

irresponsible researchers from using cloning for unethical experimentation and for reproduction -- and it will not stop or interrupt medical progress toward the cure of devastating diseases. Rather, it will help direct the research enterprise toward promising therapies that all of us can live with.

If, on the other hand, this legislature enacts HB 1021, it will almost certainly have to revisit this issue at least two more times. First, almost immediately after enactment, the legislature will be told that this bill was merely a symbolic down payment which must be followed by a large infusion of dollars from the state's already overextended budget – for this is exactly what happened in New Jersey and in California after the passage of their bills to allow human cloning for research. The reality is that this research will not be pursued on a large scale without millions of dollars in state funding, because private investors are already aware of the scientific problems noted above and know this is a bad capital investment. Second, some time later, researchers will come back to the legislature and admit what I have recounted above -- that cells from cloning are unusable unless cloned embryos can be developed to later stages in "fetus farms." At that point the legislature will have been pushed, step by step, to the moral horror this legislature rightly rejected last year. I urge you to save human lives, save the taxpayers a bad investment of their money, and save yourself a good deal of time and trouble by simply saying "no" to human cloning now.