Statement

by Professor Maria Böhmer, MdB,

at the

Catholic University of America, Washington D.C.

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Ladies and gentlemen,

The lectures which we have just heard defined the legal framework in which German politics must respond to current biopolicy issues.

In my statement, I would like:

1. to outline the basic concept that informs biopolicy in Germany, with specific reference to cloning; and
2. to draw attention to developments at international level, i.e. within the European Union and the wider international community.

1. In Germany, cloning is banned. This applies to both reproductive cloning and therapeutic cloning, which should rightfully be called "research cloning".
The ban on cloning is the outcome of a chain of logic which begins with the fundamental question: When and how is human life to be protected? The answer is as follows:

- The development of the person begins at the moment of fertilization and is a continuous process. As is the case after birth too, the unborn person is dependent on specific conditions which enable him or her to thrive. If these conditions are in place, development occurs without further intervention. Once fertilization of the egg cell has taken place, the act of creating a person is complete. From this point onwards, what occurs is not his or her development INTO a person, but the development OF the person. That is why it is absolutely imperative, in my view, to ensure that life is fully protected from the start. I believe that taking any other point in time as the beginning of life and decoupling the start of the embryo's life from its full right to life and human dignity would be arbitrary, constituting a violation of the human dignity which Article 1 of Germany's Basic Law calls upon us to respect and protect.
- As cloning by means of cell nuclear transfer produces an identical outcome to fertilization, the embryo created through cloning also has a right to protection of his or her life and human dignity from the outset. Logically, this means that the embryo may not be destroyed. Of course, in ethical terms, developing a potential treatment for serious illnesses is a very noble objective. But it does not justify the use of every possible means. We must justify and be accountable not only for our objectives but also for the outcomes and the methods we deploy. Destroying human life is not a permissible method. There is another argument against research cloning as well: to produce human embryonic stem cells through research cloning or "therapeutic" cloning, egg cells have to be harvested from women who are used as "egg cell suppliers"[1]. This threatens to create a new form of "egg cell prostitution".

The opinion which I have just put forward is shared by most Germans and the overwhelming majority of Members of the German Bundestag. Let me sum up our basic supposition as a simple equation: embryo equals person, and person equals human

[1] But see also the article "*Spermien aus Stammzellen*" [Sperm from Stem Cells] in *DIE WELT*, 17.9.2003.

dignity and the protection of life. This is reflected in the two laws which we have adopted on genetic engineering issues. In 1991, the Embryo Protection Act came into force – I have supplied you with a translation. It was followed in 2002 by the Stem Cell Act, which establishes restrictions on the basic research that is permissible using imported embryonic stem cells.

2.

Let me now turn to the international level. In my view, it is here that the future of biopolicy will be mapped out in the coming years.

I shall start with the European Union. European Union directives must be transposed into national law by the German Parliament. In other words, EU directives are not directly applicable. Nonetheless, their importance, especially in the field of biotechnology and genetic engineering, has increased substantially in recent years. One example is the Directive on the legal protection of biotechnological inventions, which we are currently debating in the Bundestag. Whereas the EU is in favour of wide-ranging opportunities to patent human genes, in Germany, we would prefer – for both economic and ethical reasons – to restrict patenting to the specific function of individual genes. However, we need to find a solution that is compatible with European law. As this example shows, the scope available to the Member States' national Parliaments, even on biotech issues, is substantially constrained by EU law.

Let me cite the European Union's Sixth Research Framework Programme, which runs until 2006, as my second example. Germany's contribution to the EU budget – 19.8% – reflects its economic weight (this figure applies to the period before enlargement). The European Commission wants some of this taxpayers' money to be used to fund destructive embryo research which is banned on constitutional grounds in Germany. Germany, together with a number of other EU countries, has protested about this use of the EU's budgetary resources and has been successful in ensuring that no destructive embryo research is currently being funded. However, the legal position is unclear and can change very quickly in the EU.

Since the European Union's enlargement in May this year, it has been difficult to reach agreement on common biopolicy objectives and bioethical standards.

The German Bundestag's demand is quite clear: research which would be banned in some EU Member States on constitutional grounds cannot be a stated objective of European biopolicy, and nor should it be funded from the European Union budget.

Negotiating biopolicy at the level of the United Nations is, without doubt, an even more complex challenge. The talks on an anti-cloning convention, which were broken off a year ago, have now been resumed in New York. The UN negotiations have revealed very substantial differences in the political, legal and ethical evaluation of cloning.

Since last year, news has reached us about developments in South Korea and Great Britain. In Seoul, research cloning has been successful for the first time. And in Newcastle, cloning experiments are now being carried out. Other countries are bound to follow suit. Cloning is no longer science fiction. Time is running out. If we want to try and control this development using the instruments available in international law, we really do need to get started right away.

As a politician, I believe that there are three lessons to be learned from these international trends:

1. **We urgently need an intensive intercultural and interdenominational discourse about the opportunities and risks associated with biotechnology and genetic engineering.** The aim is to reach out to countries which, until now, have attached little importance to biopolicy and bioethics, and win them over to our way of thinking. I am thinking in particular of countries where the debate is being conducted not by the general public but, at best, by an elite. After all, the far-reaching impacts of this technology will affect humankind as a whole. **We need to conduct this dialogue at all levels, and especially among parliaments.**
2. **UNESCO (Universal Declaration on the Human Genome and Human Rights, 1997), the WHO (Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services, 1997) and the Council of Europe have launched important initiatives on bioethics, but many question marks still hang over them. When issues of human dignity and human rights are at stake, the texts remain non-binding – a fact which has often been criticized. But I believe we should now shift our attention away from these shortcomings and focus instead on promoting the international agreements and filling them with life.**
3. **As regards the United Nations, I endorse the German Bundestag's position and call for a ban on all forms of cloning, i.e. reproductive and research cloning.** Many scientists believe that research cloning is the wrong route for us to take. In fact, there is no need to go down that road at all, for there are better options available which we should focus on, namely research using adult stem cells and umbilical cord blood stem cells. I realise that at present, a ban on cloning would probably only be supported by around half the member states. Nonetheless, a total ban would send out an important signal to the international community, making it clear that countries should not be vying with each other to achieve the lowest ethical standards. I would have liked to see Germany working more closely with countries such as Costa Rica and the United States a year ago. That would have given fresh impetus to the international negotiations. A good model to follow is the Non-Proliferation Treaty, which started off in the mid 1960s as an initiative involving 18 countries but has since been ratified by some 180 states. In other words, negotiating is worthwhile.

2nd Statement by

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Ladies and gentlemen,

This session deals with stem cell legislation. In Germany, the Stem Cell Act has been in force since 1 July 2002. Unusually for the German Bundestag, this law was not only adopted by parliamentarians but was also drafted by them in detail on a cross-party basis. The Federal Government was not involved. I mention this unusual scenario because it explains why the large majority of Members of the German Bundestag identify with the Stem Cell Act.

The Stem Cell Act was the culmination of a discussion process which was certainly conducted with particular intensity in Germany. I would like to start by outlining this process briefly (1), before going on to explain the core elements of the Act (2).

1.

The German Bundestag first set up a Study Commission on Chances and Risks of Genetic Engineering in the 10th electoral term (1983-1987). From a current perspective, its approach was very far-sighted: it explored issues such as genetic analysis (a topic which we are currently dealing with again in the German Bundestag) and genetic interventions. In the early 1990s, the German Bundestag adopted the Embryo Protection Act, which prohibits the improper use of embryos. In particular, it imposes penalties on anyone who attempts to fertilize an egg cell for any purpose other than bringing about a pregnancy. In addition, no more than three egg cells may be fertilized within one treatment cycle. That is why no so-called "surplus" embryos exist in Germany and why research is only possible with stem cells produced in foreign countries.

Since 2000, the German Bundestag has appointed Study Commissions on the Law and Ethics of Modern Medicine.

In summer 2000, two of Germany's leading scientists submitted applications to the German Research Foundation with the intention of importing and carrying out research on human embryonic stem cells.

Let me say a few words about the German Research Foundation. The German Research Foundation is the central, self-governing research organization that promotes research at universities and other publicly financed research institutions in Germany. It is funded from taxpayers' money.

The two scientists' applications showed that there was a need to clarify, in legal terms, whether importing and conducting research on human embryonic stem cells should be permissible or not. The scientists and research funding organizations in Germany agreed to uphold a moratorium pending a decision by the German Bundestag.

The need for legislation arises from the German constitution, the Basic Law, which attaches great importance to the principle of freedom of research. Article 5 (3) of the Basic Law states: "Art and scholarship, research, and teaching shall be free." Restrictions on this freedom must be regulated by law.

At the start of the parliamentary procedure, we debated three motions. The first aimed to permit stem cell research. The second was aimed at a total ban on stem cell research. And the third sought to ban stem cell research while allowing a number of very restrictively formulated exemptions. This third motion also introduced a cut-off date. I was responsible for drafting the third motion together with two parliamentary colleagues, both women – one a Social Democrat, the other from the Greens. In essence, Members were asked to choose between two fundamentally opposing positions: should the destruction of human embryos for research purposes be permissible in Germany or not?

After an emotional debate in Parliament, our motion was adopted. It later formed the basis for the drafting of the Stem Cell Act. Unlike the usual situation in Parliament, each of the three motions was supported by Members from all the parliamentary groups. There was no dividing line between the governing majority and the opposition. Every Member voted in accordance with their own profound convictions. This also meant that each Member had to form an opinion of their own. Today, all the Members of the Bundestag have at least a basic knowledge of genetic engineering. As early as summer 2001, the CDU/CSU parliamentary group in the Bundestag set up a scientific advisory committee on biotechnology and genetic engineering, consisting of scientists, jurists and ethics experts, who provide us with state-of-the-art information in line with the highest standards.

Since the parliamentary debate, at the latest, the issue of stem cell research has attracted a considerable amount of public interest. This continues to have a positive impact on the quality of our biopolitical debate. In Germany, controversies over biotechnology and genetic engineering are reported on the front page of the newspapers.

2. What are the core elements of the Stem Cell Act?

The importation and utilization of human embryonic stem cells are banned as a matter of principle; they are permissible only in exceptional cases and solely for basic research projects under the following stipulated conditions:

1. The most important condition is that **the stem cells must have been derived before the cut-off date, i.e. 1 January 2002.** Why do we have this cut-off date? It ensures that no embryos are destroyed in other countries for German research projects. In Germany itself, the destruction of embryos was already banned under the Embryo Protection Act. You are familiar with cut-off dates in the United States as well, but in Germany, it applies to all research, whether publicly or privately funded.
2. The second condition is that alternative research options, especially animal experiments, do not offer the same prospect of success.
3. Thirdly, the embryos from which the stem cells are derived must have been produced by in vitro fertilization with the original aim of inducing pregnancy.
4. No compensation or other monetary benefit may have been granted for the purpose of stem cell derivation.
5. Scientific reasons must be given to show that the research serves eminent objectives.
6. The ethical acceptability of the research project must be determined by a high-level interdisciplinary Central Ethics Commission.

The Federal Government, which is required to submit a report on the Stem Cell Act every two years, noted only a few weeks ago that the Act is fulfilling its purpose. To date, five research applications have been approved on the basis of the Stem Cell Act, and a further three are currently being considered. In the Federal Government's view, there is no need for any reform of the Act's provisions.

The Stem Cell Act is thus meeting the expectations which we, as parliamentarians, had:

We are enabling basic comparative stem cell research to take place in Germany. However, we only permit research on human embryonic stem cells within a very narrow framework, which is important for the acquisition of knowledge in the ethically unproblematical field of research using adult stem cells and umbilical cord blood stem cells.

It is quite clear: Germany is not investing its hopes in embryonic stem cell research but in the ethically unproblematical alternatives.

So what is required is far more funding for research using adult stem cells or umbilical cord blood stem cells. The German Government currently contributes just € 109 million in funding for biotechnology as a whole. That is a tiny amount compared with the volume of funding available in the United States. Of course, more money – as we know – is no guarantee of success, but it can pave the way for this success.