SUBMISSION
TO
THE JOINT OIREACHTAS
ALL PARTY COMMITTEE

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Pro-Life Campaign
104 Lower Baggot Street
Dublin 2

Phone: 01-6629275
Fax: 01-6629302
Email: prolife@indigo.ie
Website: www.prolifecampaign.ie

FOREWORD

The Pro-Life Campaign views all assisted human reproduction from the viewpoint of the inviolability of human life that cannot be deliberately destroyed at any stage of development. There are strong arguments against forms of assisted reproduction such as ovum donation and sperm donation which, although they do not put unborn human life at risk, confuse biological relationships, create legal problems and leave children ignorant of their antecedents, something which disturbs some of those conceived by such methods. There are certainly strong health arguments for the woman against induced ovary stimulation to harvest ova.

The Pro-Life Campaign's main concerns, however, are procedures which explicitly cause the deliberate destruction of human embryos in IVF, screening, experimentation, storage and that euphemistic term *disposal*.

In procreation, it is accepted that couples have a right to the means by which children are produced. There is no *right* to a child per se. If pregnancy occurs, in the natural course of events, it comes as a gift. Internationally, the assisted human reproduction industry seems to work on the assumption that every couple has a right to a child, and almost by any possible means and at any cost in terms of human lives lost. They see themselves justified by a consumer demand for their services. Furthermore, they find it philosophically difficult to deny anyone regardless of age, marital status or sexual orientation. They seem blind also to the nature of methodologies that treat embryonic human life as a consumer item with quality controls designed to reject defectives, like consumer products on the factory assembly line. Where freezing of embryos is accepted, after a stated period of shelf life, these "surplus" human beings are discarded. Overall, the industry destroys far more life than it brings to birth.

Article 40.3.3 of the Constitution protects unborn human life at all stages of gestation. Although it has never been defined, it can be reasonably assumed that it protects life from the time of fertilisation, and all assisted human reproductive procedures should

be regulated with that in mind – i.e. that they cannot "create" life that is not then given a reasonable chance of survival. Certainly such life should never be deliberately destroyed or abandoned in situations where it is intended that it will die.

P.L.C. Submission to the Joint Oireachtas All Party Committee

INTRODUCTION

The Pro-Life Campaign is a non-denominational single-issue lobby group whose members share a commitment to unborn life. The Campaign recognises the dignity of all human beings and promotes pro-life education and research into every stage of human life from conception to natural death.

The Pro-Life Campaign suggests to the Committee that the Commissions recommendations be approached from the following standpoint:

1. The recognition that all human life, born or unborn, is, from the moment of conception, of special value and worthy of protection.
2. The acknowledgement of the fact that in pregnancy the doctor has a duty of care towards two patients, the mother and the unborn child.

Embryo Freezing and Storage

Since IVF is at present under-regulated and its control is left to the vagaries of the individual practitioners whose activities cannot be monitored or controlled, the Committee should insist that:

1. Recommend that IVF in Ireland be regulated along the lines of the Italian model.

2. A prohibition on embryo storage or freezing, accompanied by notice of appropriate powers of inspection and realistic sanctions.

3. A prohibition on the placing of embryos in a part of the woman's body where it is anticipated that they will not survive

4. .The Committee should also assess, from an ethical perspective, whether or not practices associated with IVF represent a disproportionate response to the treatment of infertility by medical practitioners.

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IVF IN IRELAND

History of IVF in Ireland

On the 31st May 1985, it was reported in the medical press that three women had been successfully implanted in Ireland with ova that had been fertilised *in vitro*. The work, carried out by Prof. Robert Harrison, Consultant Gynaecologist, in St. James's Hospital and Sir Patrick Dun's Hospital involved two campuses as equipment in each location was essential for his purposes Permission was not sought by him from either institution..

In late July 1985, the then Minister for Health, Barry Desmond, announced in the Dáil that his Department would examine the issue with a view to legislation. One month later, in August 1985, a conference on the ethical and legal issues in IVF was held in Maynooth. The Board of St. James's Hospital imposed a moratorium on further IVF work in St. James's pending the outcome of an inquiry by a Board sub-committee into the matter. The Medical Council, by a majority decision in December 1985 approved the guidelines on IVF promulgated by the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland.[1] This effectively delayed the re-introduction of IVF in St. James's until January 1986 at which point, however, the IVF debate in Ireland, what little there was, was effectively completed.

At no point in the brief debate were the public, and even informed members of it, aware that IVF procedures were anything more than helping infertile couples. They did not know then the attack on life and nature which many procedures entail. It is time now to have a national debate and explain to the Irish public just what it involves.

The Medical Council subsequently approved the therapeutic application to married couples of the revised guidelines on IVF of the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland.[2]

[1] *A Guide to Ethical Conduct and Behaviour and to Fitness to Practise* (Third Edition) approved by the Medical Council at its meeting on 7th October 1988 and published in March 1989.
[2] *A Guide to Ethical Conduct and Behaviour and to Fitness to Practise* (Fourth Edition) approved by

Later, there were demands for embryo freezing and storage as desirable from a clinical and patient standpoint and some IVF clinics such as the HARI unit at the Rotunda, decided to force the pace by unilateral action, of very questionable validity. Furthermore, a sub-committee of the Institute of Obstetricians and Gynaecologists of the Royal College of Physicians of Ireland examined the matter in 1999, wrote a confidential report but reached no consensus. Media comments purporting to set out the conclusions reached by the sub-committee – although subsequently denied – indicated that proposals in relation to embryo storage were being considered. Arising therefrom, it was anticipated by some that the revised 1998 IVF Medical Council guidelines would cover embryo storage or freezing. This in fact did not happen. The 1998 Guidelines forbade deliberate destruction of a human embryo and while they did not forbid freezing explicitly, that would naturally follow from the latter prohibition

Are There Particular Issues To Be Addressed By The Committee?

A detailed enquiry into the history of IVF in Ireland clearly indicates that there was no effective public debate at the time of its introduction. The reality was that it was presented as a *fait accomplait*. St. James's Hospital initially prevaricated, then imposed a moratorium and awaited the view of the then Medical Council. The Council's view, in turn, was published with great rapidity. From this sequence of events, it could reasonably be concluded that the medical profession, and its regulatory bodies - whether intentionally or otherwise - had arrogated to themselves the right to decide the issue. It might further be reasonable to conclude that with the Medical Council's effective approval, the application of IVF in Ireland continued relatively unhindered and initial concerns essentially receded from the public consciousness until recent times. Indeed, over the years, numerous media articles expounding the successes of the application of the technology were commonplace, often associated with the names of individual medical practitioners and their units (some of which were or are

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the Medical Council at its meeting on 1st October 1993 and published in January 1994

commercial enterprises). Thus, IVF in Ireland, to the minimal extent that it is regulated, is regulated solely by the self-regulating medical profession, a situation which might or might not be satisfactory.

Is the Control Of IVF By The Medical Council Adequate In All Of The Circumstances?

General Considerations

The extent of self-regulation in relation to IVF in Ireland may not be sufficiently comprehensive to allay community fears about excesses which can arise from its effectively unfettered practice. Especially where there are vested interests, the *bona fides* of those involved in IVF can be called into question, particularly with the formation of limited companies and other commercially oriented enterprises to promote use of the methodologies – as is the case with some IVF units operating in this jurisdiction. Although not necessarily a criticism that could be levelled at medical practitioners working in the field of IVF in Ireland, it is arguable that the secrecy which normally surrounds scientific work might be further reinforced by commercial secrecy. This could lead to legitimate concerns that IVF practitioners might not reveal what they are doing, and even, might do anything that seems necessary in pursuit of career or commercial viability.

There must be concern about the adequacy of any professional guidelines in a commercial – or even quasi-commercial – environment. This is particularly true in the absence of any inspectorate function on the part of the Medical Council, and by the absence of clear enforcement measures, in relation to the regulation of IVF in Ireland. Accordingly, it is difficult to imagine what controls are used by the medical practitioners working in the field of IVF to prevent them engaging in ethically impermissible – not to say outrageous – procedures or practices. Some have said that they follow British law which is almost no control at all.

Medical Council Guidelines

In this regard, it is of concern that past guidelines promulgated by the Institute of Obstetricians and Gynaecologists and approved by the Medical Council were merely exhortatory in nature. The language, being couched in subjunctives and in terms of

proposed and recommended best practice, seemed devoid of any imperative force and apparently relied on a benign self-regulatory environment for adherence. There are significant changes between the guidelines in the 1989 and 1994 editions of the Medical Council's *Guide to Ethical Conduct and Behaviour and to Fitness to Practise*. For example, guideline number 2 in the 1994 edition provided as follows:

> "All fertilised embryos produced by IVF should be replaced, optimally this should be three in any treatment cycle"

whereas the previous guideline required that

> "All fertilised embryos produced by IVF should be replaced in the potential mother's uterus."

Leaving to one side the slightly difficult concept of who constitutes a "potential mother" in this context, the fact along with the deletion of the phrase concerning the 'mother's uterus' cannot be wholly without effect. The 1998 Medical Council Guidelines were more directive and insisted that no fertilised ovum would be deliberately destroyed.

This was continued in the present 2004 Guidelines which class ***the "the creation of new forms of life for experimental purposes or the deliberate and intentional destruction of in vitro human life already formed is professional misconduct."***

The 2004 (present) Medical Council Guidelines are clearly opposed to CAHR recommendations

The Treatment Of Certain Embryos

The practice of medical practitioners engaged in IVF in Ireland, previously only hinted at in articles and letters to the medical and national press, was confirmed in interviews with these practitioners, carried out by RTÉ's *Prime Time* programme in November 1996. It was made clear that 'surplus' or 'low grade' embryos are not implanted in the mother's uterus, but are rather placed in the cervix or vagina in the clear anticipation, and with the intention that they will perish.

Such practices are gravely violative of the unborn child's human and constitutional rights, the whole thrust of the Medical Council's ethical guidelines, the long standing tradition in medicine of respect for all human life and the medical profession's

prohibition on killing. The principle violated is identical to that violated by deliberate abortion – a practice that the Medical Council regards as unethical.

Lest it be considered that IVF embryos are not appropriate subjects of constitutional rights, it may be pointed out that in the intense debates on the right to life of the unborn carried on in this jurisdiction for over twenty years, no distinction was ever made between different stages of unborn life. Recently, it has been reported that Ireland has not signed the Council of Europe's Bioethics Convention because it allows for experiments on human embryos **– clearly showing that this is understood as a practice which violates the constitutional protection given to the unborn.**[3]

Accordingly, it is important that the Committee and the Medical Council take steps to prevent the practice of placing 'surplus' or 'low grade' or any embryos in the vagina or *cervix uteri* with the intention that they will perish there.

Should Embryo Storage Or Freezing Be Permissible?

It is disingenuous to justify the storage or freezing of human embryos on the basis that it is either 'pro-life' or represents a 'pro-life strategy'. Apart from the very dramatic lessons that can be learned from the British experience in this regard, the storage of a human embryo is not 'pro-life'. Rather it merely tolerates the existence of the unborn human involved without respecting its right to life, with no guarantee that its right to life will ever be respected.

In the circumstances, the storage of human embryos is fundamentally violative of the constitutionally protected right to life of the unborn enshrined in the Eighth Amendment of the Constitution. The Committee might consider adopting, as a statement of ethical principle, the affirmation of the April 1996 Annual General

[3] *Sunday Tribune*, 18-1-98

Meeting of the Irish Medical Organisation that the freezing of embryos is inconsistent with the medical profession's long-held tradition of respect for human life at all stages of development.

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Some might attempt to resolve the constitutional or legal problems associated with embryo storage or freezing by proposals which suggest freezing of the embryonic development process prior to syngamy. Such an approach fails to take account of the true nature of the developing embryo and represents an entirely arbitrary and unacceptable determination of the time at which rights should vest in an unborn.

The Establishment of CAHR

Of the 24 Committee Members, at least 7 were directly associated with the IVF Industry and 6 were civil servants. There were no obvious members to represent the view that the human embryo has rights and needs protection. This was communicated to Deputy Miceal Martin, Minister for Health, at the time of their appointment. From the makeup of the Committee of CAHR, one could have accurately forecast, even then, just what the recommendations would be. It was an inward looking elitist group which did not represent the views of the people at large.

If there were any doubts on that matter, the extremely one sided Seminar in Dublin Castle (which CAHR ran in early 2003), would have quickly dispelled. The CAHR Committee, from the very start wanted the British model which has no regard whatsoever for the human embryo and did not want the German, Austrian or Italian models which respect the humanity of the human embryo to varying degrees. The type of speakers they invited to talk at this "educational seminar" was also very revealing of the Commission's intentions. Basically, they wanted the human embryo outside the womb to be declared a non-person so that consideration for the embryos right to life would never arise.

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PLC's Submission to CAHR

PLC made a detailed submission to CAHR in October 2002. CAHR claims to have received 1,700 submissions. WE know that we never received an acknowledgement for our submission and none of the 1,700 received were even listed in the publication nor summaries of what they contained, nor as far as we are aware were people asked to discuss their submissions with the Commission. CAHR missed an opportunity for openness, transparency and real consultation. Presumably, their minds were already made up, and they did not want to waste time with obscurantist viewso

PLC Recommendations to CAHR In October 2002

The following recommendations were made and argued:

1. All embryos created by means of fertilisation outside the body of a woman, and all stages of the subsequent life of that embryo, must be individually and clearly recorded. These records must be inspected by an independent regulatory body to ensure that full respect has been accorded the embryo at all stages and optimum conditions for birth have been maintained. At no stage can embryos be 'lost', 'discarded' 'stored' or otherwise treated in a manner that contravenes the respect due to all human life. Any failure in this area should lead to a revoking of the licence to engage in Assisted Reproduction.

2. The regulatory body must issue a publicly accessible report each year on all assisted reproduction units which, *inter alia,* must include the following information:

- number of couples treated
- breakdown as to causes of infertility
- number of embryos and method of their creation
- origin of gametes, whether from gestational parents or donors
- details of the fate of all embryos
- inspectors report on records of each unit including details of any transgressions and sanctions.

3. All possible therapeutic measures must be shown to have been explored before a couple can be considered for any procedure that involves fertilisation outside the body of the woman.

4. Every child has the right to full information about its biological parents. If the Commission were to allow gamete donation it should require assisted reproduction units to keep full and adequate records for this purpose and require gamete donors to sign a contract agreeing to this before being accepted as donors.

5. Where a child would otherwise be left destitute it must, if it has been conceived from donor gametes, have the right to apply for support from its biological parents. In the event of this being impossible e.g. because the biological parents have died or emigrated, the clinic wherein they were conceived must set up a fund for their support.

Postscript: Since then, the Italian law on IVF, *Regulations related to Assisted Reproductive Technologies (*published in Gazzetta UfficialeNo.45 on 24/2/2004 has

passed and withstood a referendum. This type of legislation respects human life and would be very suitable for Ireland.

Popular Support For CAHR's proposals?
This ss something that would be of interest to legislators. It is difficult to measure as most ordinary people in a random sample would not know what is involved in what CAHR proposes. Its survey of complicated issues was by telephone and had four category of answers instead of the usual three. According to their findings of December 2002

68% agreed with the use of AHR and another 3% in some cases
45% agreed with Third Party Donors and 16% in some cases
45% felt surrogacy should be allowed with 34% opposed
45% opposed the production of surplus embryos
48% opposed the freezing of embryos
27% only felt surplus embryos should be disposed of
23% felt they should be donated to another couple

Imagine a person being tackled on the phone without advance warning and given 17 abstruse questions to answer and the results will be anything bit clear. As a matter of fact, CAHR did not publish all the answers received. The opposition even in CAHR's own poll to the production of suprlus embryos and to to embryo freezing is very significant.

PLC Poll
In February 2005, the Pro Life Campaign commissioned a poll from Millward Brown IMS.

To the question : *"Currently. experimentation involving the destruction of human embryos does not take place in Ireland. Do you think the Dail should enshrine the protection of the human embryo in law or not"?*
48% said Yes, 15% said No and there were 30% Don't Knows/no opinion. Of those who expressed an opinion, 78% agreed that the Dail should legislate to protrect the human embryo. After distribution of Don't Knows there was an overall majority in every social class, age group and geographic region.

This is a more realistic appraisal of respect for the human embryo than CAHR's 2002 survey as there was an intense national debate on the status of the human embryo in December 2003.
A Eurobarometer poll commissioned by the EU Commission published in June 2005, though the questions were indirect and sometimes leading, as regards Ireland, showed stronger respect for the rights of the human embryo than in most other countries..

CAHR's Recommendations

The CAHR Report made 40 recommendations. They are mostlyl inspired by a utilitarian viewpoint and are unacceptable. We will comment on each in turn.

CAHR Proposals 1, 2,3,4,5,7,8,12,13,14,18, 21,23,24.25,28,29,35,36,37,38,39 and are reasonably OK taken on their own..

CAHR Proposals 6,9,10,11,15,16,17.19,20,22,26,27,30,31,32,33,34 and 40 are unacceptable

Comments On CAHR's Unacceptable Proposals
CAHR Proposal No 6: To produce surplus embryos at all is an abuse. As in Italy and Germany all embryos fertilised should be implanted.

CAHR Proposal No 9: No freezing or surplus embryos should be allowed as mosty of the abuses of IVF stem from this as the Italian legislators realised.

CAHR Proposal No 10; This proposal is completely unethical, unconstitutional and we would say inhuman. The principle as contained in the medical council guidelines is that a human embryo should not be deliberately killed. If all freezing is stopped by law, all frozen embryos, as in Italy, should be brought to one central location and be available for the original couples to use themselves or for adoption. When the last embryo is disposed of in this way, all freezing ceases.

CAHR Proposal No 11: This could be acceptable if it means deciding to let embryos out for adoption and the parents cannot agree.
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CAHR Proposal No 15: The storage of embryos should not be allowed.

CAHR Proposal No 16: This recommendation is totally unacceptable. The human embryo is entitled to protection under the Constitution.

CAHR Proposal No 17: This is an extremely perverse recommendation. The best interests of the child is married heterosexual parents.

CAHR Proposal No 19: Certainly embryos should not be donated and the prohibition on freezing would rule them out anyhow.

CAHR Proposal No 20: The word "embryos" should be deleted.

CAHR Proposal No 22: Delete word "donated embryo".

CAHR Proposal No 26: Delete words "embryo donation". There is a big legal problem her and trying to use the law to have non-biological parents classed as legal parents where there is no such relationship is dishonest and perverse.

CAHR Proposal No 27: Why not? If children can find out who they are why can they not establish any children they may be related to?

CAHR Proposal No 30: Surrogacy should not be permitted

CAHR Proposal No 31: Surrogacy should not be permitted. Regardless of that, limiting recompense to out of pocket expenses is unenforceable and hypocritical as if the proposers are trying to establish that they too have ethical principles.

CAHR Proposal No 32: Surrogacy should not be allowed**.** Accessing the identities of donors of gametes should be by consent.

CAHR Proposal No 33: Surrogacy should not be allowed and classifying the baby as the child of the commissioning parents, whether ot not they have any biological connection with the child is wrong.

CA**HR Proposal No 34:** This proposal is totally unacceptable using human embryos "surplus" from IVF requirements for destructive research. Again there is the hypocritical consition that enbryos should not be produced solely for research!

CAHR Proposal No 40: Pre-implantation diagnosis is unacceptable. What happens to the embryo if it fails the quality control tests?

Comment: The CAHR Committee having such an over-representation of people directly involved in the IVF Industry, thanks to the then Minister for Health, proceeded, naturally enough, to tailor the recommendations as to what suited themselves and the IVF industry best. They had no feelings whatsoever about the rights of the human embryo and proceeded to treat it as inanimate raw material with no rights whatsoever. Apart from the dissenting report of Professor Gerry Whyte, there is nothing in this report that represents what we believe to be the feelings of the majority of the people and their human values. Putting people with so much vested interests on a Committee to regulate themselves and their own industry is ludicrous. They should have been free to give evidence to an impartial committee but not to be in a position to decide the outcome by their votes.

While not quite comparable, such vested interests deciding how they should be regulated is somewhat like a Government setting up a Commission of drug-barons to decide how the narcotics problem should be tackled or criminals deciding how the Gardai should be organised. We are not comparing, any members of the Commission to drug barons or criminals but their own interests and ethics are far removed from the public interest and their virtual unanimity on a wide range of proposals reflect a sense of ethics that is far from the public's sense of ethics.

They want to be free to reject human embryos at any stage for imperfections, store them in freezers, knowing that freezing itself is an endangerment, throw them down the sink if considered surplus and finally sell them off to researchers for experimentation which will lead to their deaths. They have no inhibitions about surrogate motherhood, donated embryos. Their only purported inhibitions appear to be not paying too much for donated gametes, embryos or anything else. This is the New Morality. Not the immorality of the action itself but the indecency of paying for it!

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REVISED PROPOSALS FROM PRO LIFE CAMPAIGN

In light of the CAHR report, we would recommend a law like the Italian law *Regulations related to Assisted Reproductive Technologies* (Published in the Gazzetta Ufficiale No.45, 24th February 2004). This is more compatible with Irish culture and ethical sense than the CAHR proposal which seems to have been exclusively inspired by the British Human Fertilisation and Embryology Authority.

There were many abuses in IVF in Italy over he years and the Government reacted. It established a good Bio-Ethical Commission, manned by people who understood ethics. Proposals were discussed over many years and eventually began to wend their way through the Italian Legislature.

The legislation passed the Senate on 11th December 2003 by 169 votes to 90 and passed the Chamber of Deputies on 10th February 2004 by 277 votes to 222. It was a free vote in both Houses and attracted significant leftwing and opposition support.

What The Italian Law Does

- A maximum of three embryos to be crated per attempt and all embryos created must be implanted in the womb.
- Pre-implantation eugenic screening, cloning or experimentation on human embryos forbidden.
- Freezing of embryos forbidden.
- Couples availing of IVF must be heterosexual and married or provide evidence of a stable relationship.
- Surrogate motherhood, sperm or egg donation forbidden.
- Health Minister, Girolamo Sirchia, arranged to gather all frozen embryos into the Polyclinic in Milan.. These can be used by their parents or given for adoption and when the last embryo is gone all embryo freezing in Italy comes to an end. From the time the law comes into force, no new embryos will be frozen.
- Infringements of the law, attract heavy fines of imprisonment or both.

Comment: The fact that something can be done does not mean it is acceptable to do it. The Italian law banned multi-fertilization and freezing which is the practice from which most abuses spring. It further banned the donation of sperm, ova and, of course, embryos and surrogacy all of which lead to ambiguous relationships, almost impossible to put on a legal rational footing.

For the good of the child, it allows IVF only in stable heterosexual relationships and is concerned about the right to life of the embryo, in a country which has legal abortion up to 12 weeks of pregnancy.

The Radical Party and some extreme leftwing groups organised a referendum to try to overturn the law. The referendum was held in June 2005. It attracted a 26% turnout where 50% + is necessary for the poll to be valid. The referendum failed and the law remains in force.

It is a good model for Ireland in so much as it eliminates most of the abuses concerning the right to life and dignity of human life and also many of the legal problems regarding relationships and inheritance created by surrogacy, donated gametes *et cetera*

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Regulations related to Assisted Reproductive Technologies

(Published in the Gazzetta Ufficiale no 45 February 24 2004

CHAPTER 1
GENERAL PRINCIPLES

ARTICLE 1
(Aims)

1. With the aim of promoting a solution to reproductive problems as a result of sterility or infertility, assisted reproductive technologies are consented to under the conditions and according to the terms allowed in this law that shall ensure the rights of all the people involved including the conceptus.

2. Recourse to assisted reproductive technologies is consented to whenever there are no other efficient therapeutic methods of removing the causes of infertility or sterility.

ARTICLE 2
(Interventions to counter sterility and infertility)

1. The Minister of Health having consulted with The Minister for Education, Universities and Research can promote research on the pathological, psychological, environmental and social causes of sterility and infertility and favour the necessary interventions to remove them and also to reduce the incidence of them and can also give incentives for the study and research on sex cells and the techniques of cryopreservation and can also promote information and prevention campaigns on sterility and infertility.

2. To achieve the aims which are outlined in Section 1, a funding of 2 million euro shall be authorized from 2004.

3. In order to put into effect Section 2 a certain proportion of the allocation shall be provided at the end of the triennial budget of 2004-2006 within the range of the total estimated as part of the state's current special fund to be estimated by the Minster for Finance and the Economy for the year 2004 with the balance coming from some of the allocation available to the Minister of Health. The Minister for Finance and the Economy is authorized as he decrees to carry out the necessary balance adjustments.

ARTICLE 3
(Modification to the law July 29 1975, n. 405)

1. To the first Section of the law of July 29 1975, n.- 405 the following is added:

Information and assistance regarding the problems of human sterility, infertility and techniques of assisted reproductive technologies.

Information on adoption and foster family procedures.

2. From the enactment of this Article no other onus must be put on the public finances deriving from it.

CHAPTER II
ACCESS TO THE TECHNIQUES

ARTICLE 4
(Access to the techniques)

1. Recourse to the techniques of assisted reproductive technologies shall be permitted only when the impossibility of otherwise removing the causes impeding reproduction is assured and shall be permitted in cases of sterility and infertility the cases of which are verified and certified by a doctor and also in cases of unexplained sterility and infertility supported by a doctor.

2. The techniques of assisted reproductive technologies are applied on the basis of the following principles:

a) graduality, with the aim of evading recourse to interventions that have a more dangerous technical and psychological level of intrusion for the people, and aspiring to the principle of the least intrusion possible.

b) informed consent, to be realized in accordance with Article 6.

3. Recourse to techniques of assisted reproductive technologies of the xenograft type shall be forbidden.

ARTICLE 5
(Subject requirements)

1. Having fulfilled the requirements established by Article 4, Section 1, couples over 18 of different sex, married or cohabitating and of a potentially fertile age, both still living, can have access to techniques of assisted reproductive technologies.

ARTICLE 6
(Informed consent)

1. To achieve the aims indicated in Section 3 the doctor, before the recourse to and in every phase of the practice of assisted reproductive technologies, shall inform in a detailed manner the people indicated in Article 5, of the methods, bioethical problems and of the possible collateral effects and psychological consequences of the same practice. He shall inform them of the probability of success and of the associated risks and also of the relative judicial consequences for the woman, man and the future child. The couple must be presented with the possibility of recourse to adoption and fostering procedures in accordance with the Law of May 4 1983 no.184 and subsequent amendments as an alternative to assisted reproductive technologies. The information including that of the present Section and that concerning the degree of intrusion of the techniques relating to the woman and the man must be supplied for each of the applied techniques and in such a way as to guarantee the forming of a clear choice that is willingly expressed.

2. The couple must be made clearly aware of the economic cost of the complete procedure whenever a private service is involved.

3. The willingness of both parties to agree to the practices of assisted reproductive technologies shall be expressed in writing jointly to the leading consultant of the clinic according to the terms defined and decreed by the Ministers of Justice and Health adopted according to Article 17, Section 3 of Law No. 400, August 23 1988, within three months from the date that this law will come into force. A period of not less than seven days must pass between the declaration of agreement and the

commencement of the practice. The agreement of either person (indicated by the present Section) can be revoked up to the point of fertilization of the ovum.

4. Apart from the necessary requirements of the current Law, the head consultant of the clinic can decide not to proceed with assisted reproductive technologies solely for medical health reasons. In that case he must furnish the couple with a written reason for any such decision.

5. The applicants must be made clearly aware of the judicial consequences of the terms referred to in Article 8 and 9 of this law at the moment of agreeing to the practice of assisted reproductive technologies. A document shall be signed to that effect.

ARTICLE 7
(Guidelines)

1. The Minister of Health availing of the Higher Health Institute and having consulted with the Higher Health Council will define by decree the guidelines including the procedures and the techniques of assisted reproductive technologies.

2. The guidelines in Section 1 are binding for all the authorized organisations.

3. The guidelines will be updated periodically at least every three years, in conjunction with technical-scientific developments of the same procedures in
Section 1.

CHAPER III
ARRANGEMENT REGARDING THE PROTECTION OF THE CHILD

ARTICLE 8
(Judicial Status of the Newborn)

1. Children born as a result of the techniques of assisted reproductive technologies have the status of legitimate children or of children recognised by the couple who have expressed the willingness to avail of the aforementioned practise according to Article 6.

ARTICLE 9
(The Prohibition of Non-Recognition by Parents and of the Anonymity of the Mother)

1. Whenever someone chooses the practice of assisted reproductive technologies of the xenograft type in violation of the prohibition of Article 4, Section 3 the spouse or the cohabitant whose consent can be withdrawn due to concluding acts cannot exercise non recognition of parentage/paternity in cases covered by Article 255, first Section No. 1) and 2) of the Civil Code or appeal under Article 263 of the same code.

2. The mother of a child born as a result of assisted reproductive technologies cannot declare the wish not to be named in accordance with Article 30, Section 1, or Regulation No. 396 decreed by the President of the Republic, November 3 2000.

3. In the case of application of practices of the xenograft type in violation of the prohibition of Article 4, Section 3, the donor of the cells does not acquire any judicial family relationship with the child and under the law has no rights in relation to the child and has no rights to hold any duties/responsibilities in relation to it.

CHAPTER IV
REGULATIONS FOR THE AUTHORIZED ORGANISATIONS USING THE PRACTICE OF ASSISTED REPRODUCTIVE TECHNOLOGIES

ARTICLE 10
(Authorized Clinics)

1. Operations of assisted reproductive technologies shall be carried out by authorized public and private clinics of the regions and entered in a register mentioned in Article 11.

2. The Autonomous Regions and Provinces of Trento and Bolzano, within three months of the date of this law coming into force, shall define with their own law:
a) The technical-scientific and organizational requirements of the clinics
b) The personnel and organization specification
c) The criteria for determining the duration of authorization and revoking of same.
d) The criteria for developing checks in relation to this law and making permanent the organizational and technical-scientific requirements of the organisations.

ARTICLE 11
(Register)

1. The National Register of Authorized Clinics for the practice of assisted reproductive technologies of formed embryos and of children born as a result of the said practice shall be established by decree of the Minster for Health.

2. Joining the register mentioned in Section 1 is compulsory

3. The Higher Institute of Health, in collaboration with regional epidemiological observers shall collect and make available the necessary information with the aim of permitting publicity and transparency of the practices of assisted reproductive technologies adopted and the results achieved.

4. The Higher Institute of Health shall gather the requests, information, suggestions and proposals of the scientific organisations and the users of assisted reproductive technologies.

5. The organisations mentioned in the Article shall supply the regional epidemiological observers and the Higher Institute of Health with the necessary data for the aims outlined in Article 15 and also the other necessary information for developing the functions, checks and inspections of the relevant Authorities.

6. In order to put into effect this Article a sum of 154,937 euro shall be provided from the year 2004. A certain proportion of the allocation shall be provided at the end of the triennial budget of 2004-2006 within the range of the total estimated as part of the state's current "special fund" to be estimated by the Minster for Finance and the Economy for the year 2004 with the balance coming from some of the allocation available to the Minister of Health. The Minister for Finance and the Economy is authorized as he decrees to carry out the necessary balance adjustments.

CHAPTER V
PROHIBITIONS AND PENALTIES

ARTICLE 12
(General Prohibitions and Penalties)

1. Whoever uses for the means of procreation, cells from people outside the couple which is in violation of Article 4, Section 3 shall be punished with a financial penalty of between 300,000 and 600,000 euro.

2. Whoever in violation of Article 5 uses the practice of assisted reproductive technologies on couples where one of the couple is not of legal age or, where both of the couple are of the same sex, or where they are not married or cohabitating, shall be punished with a financial penalty of between 200,000 and 400,000 euro.

3. For verification of requirements referred to in Section 2 the doctor shall use a declaration signed by the couple. In the case of a false declaration Article 76, Section 1 and 2 shall be applied, it being the only legislative text available pertaining to administrative documents, which was decreed by the President of the Republic December 28 2000 No. 445.

4. Whoever uses the practice of assisted reproductive technologies without having received consent according to the terms referred to in Article 6 shall be punished with a financial penalty of between 5,000 and 10,000 euro.

5. Whoever uses the practice of assisted reproductive technologies in clinics different to those referred to in Article 10 shall be punished with a financial penalty of between 100,000 and 300,000 euro.

6. Whoever, in whatever form, implements, organises or advertises the trade of cells, embryos or surrogate motherhood shall be punished by incarceration from three months to two years and a fine of between 600,000 and one million euro.

7. Whoever carries out a process towards obtaining a human being, descended from a single starting cell, in the end identical as regards genetic and nuclear inheritance to another human being alive or dead shall be punished by way of incarceration from ten to twenty years and a fine of between 600,000 and one million euro. The Doctor shall be punished by lifelong expulsion from the profession.

8. The man and woman to whom the practice is applied in the cases referred to in Sections 1, 2, 4 and 5 shall not be punished.

9. A suspension of practising the profession, of one to three years, shall be given to a practitioner convicted for one of the crimes referred to in this article except for that mentioned in Section 7.

10. If one of the forbidden practices referred to in this Article occurs in a clinic that has been granted authorization in accordance with Article 10, that authorization shall be rescinded for one year. In the event of more violations referred to in this Article or in the event of a relapse the authorization can be revoked.

CHAPTER VI
MEASURES TO PROTECT THE EMBRYO

ARTICLE 13
(Experimentation on Human Embryos)

1. Any type of experimentation on any human embryo is forbidden.

2. Clinical and experimental research on each human embryo shall be permitted on condition that the final aims are exclusively therapeutic and diagnostic and are connected to the protection of health and the development of the embryo and when alternative methods are not available.

3. The following are prohibited:

a) The production of human embryos for research or experimental purposes or for purposes different to those allowed for in this law.

b) All forms of selection of embryos and cells for eugenic purposes and interventions that through selection techniques, manipulation or through artificial processes are directed at altering the genetic patrimony of the embryo or sex cell or at pre-determining the genetic characteristics of it, with the exception of interventions for diagnostic or therapeutic purposes, referred to in Section 2 of this Article.
c) Cloning interventions through transfer of the nucleus, splitting of the embryo or of Ectogenics both for procreative and research aims.
d) The fertilization of a human cell with a cell of a different species and the production of hybrids or chimeras.

4. Violation of the terms referred to in Section 1 shall be punished with a jail term of between two and six years and with a fine of between 50,000 and 150,000 euro. Violating one of the terms referred to in Section 3 shall be punished with a longer sentence.

5. A suspension of one to three years from practising the profession shall be given to a practitioner convicted of one of the crimes referred to in the Article.

ARTICLE 14
(Limits to practising on embryos)

1. The cryopreservation and destruction of embryos is forbidden.

2. The practice of producing embryos taking into account the technical-scientific developments and that provided for in Article 7 section 3 must not create a number of embryos more than strictly necessary in one implant at one given time, that is not greater than three.

3. In the case that the transfer of the embryos to the uterus is not possible because of serious risk to the woman's health, that could not be predicted at the moment of fertilization, the cryopreservation of the embryo shall be permitted up to the new date of transfer which shall be as soon as possible.

4. Under the aims of this law on assisted reproductive technologies the use of embryos for multiple pregnancies is forbidden except in cases provided for in the law of May 22 1978 no. 194.

5. Every person referred to in Article 5 shall be informed of the number and, at their request, the state of health of the embryos produced to be transferred to the uterus.

6. The violation of any of the prohibited terms or obligations referred to in the previous Sections shall be punished with a jail term of up to three years and with a fine of between 50,000 and 150,000 euro.

7. A suspension of not more than a year from practising the profession shall be given to a practitioner convicted of one of the crimes referred to in this Article.

8. The cryopreservation of male and female sex cells shall be permitted with written consent.

9. Violation of Article 8 shall be punished with a fine of between 5,000 and 50,000 euro.

CHAPTER VII
TEMPORARY AND FINAL ARRANGEMENTS

ARTICLE 15
(Report to Parliament)

1. Before February 28th of every year, the Higher Institute of Health shall prepare an annual report for the Minister for Health on the activities of the authorized clinics on the basis of data collected under Article 11, Section 5 with a particular emphasis on the epidemiological evaluation of techniques and interventions made.

2. Before June 30th of every year, the Minister for Health, on the basis of the data referred to in Section 1, shall present a report to Parliament on the effectiveness of this law.

ARTICLE 16

(Conscientious Objection)

1 It is not compulsory for conscientious objectors employed in the public health sector and employees in the auxiliary health services to take part in procedures that use assisted reproductive technologies under this law when they make a declaration to object on a conscientious level. Not later than three months after the date that this law comes into force, the declaration must be made to the director of the local head service or hospital, in the case of public employees or to the manager in the case of personnel employed by the authorized accredited private clinics.

2 The objection can always be revoked or proposed outside the terms under Section 1 but in that case the declaration shall come into effect one month from its presentation to those referred to in Section 1.

3 The conscientious objection shall release public health personnel and employees in the auxiliary health services from carrying out procedures and activities specifically directed at bringing about the practice of assisted reproductive technologies but not from assisting before and after the practice.

ARTICLE 17

(Temporary arrangements)

1 The centres and clinics registered in the list at the Higher Institute for Health under the rule of the Minister for Health of March 5 1997 and published in the "Gazzetta Ufficiale" no. 55 March 1977, shall be authorized to practice assisted reproductive technologies as outlined in this law, up to nine months after the date that this law comes into force.

2 Within thirty days from the date that this Law comes into force the centres and clinics referred to in Section 1 shall give the health ministry a list containing the number of embryos produced as a result of practising assisted reproductive technologies, for the period before the date that this law is enacted, as well as, respecting the arrangements in force protecting personal data, the names of every person that used the same technologies the result of which being that embryos were formed. Every person who violates the contents of this Section shall be liable to a fine of between 25,000 and 50,000 euro.

3 Not later than three months after the date of this law coming into force the Minister for Health, consulting with the Higher Institute of Health shall define by decree the terms and ways of preserving the embryos referred to in Section 2.

ARTICLE 18

(Funds for the techniques of assisted reproductive technologies)

1. The Ministry for Health shall place funds for the techniques /practice of assisted reproductive technologies with the aim of providing access to the techniques of assisted reproductive technologies to the people mentioned in Article 5. The funds shall be issued firstly in the Autonomous Regions and Provinces of Trento and Bolzano on the basis of criteria decided by decree of the Minister for Health, and shall be issued not later than sixty days after this law comes into force, having consulted the Conference for Relations between the State and the Autonomous Provinces and Regions of Trento and Bolzano.

2. For the benefit of the fund referred to in Section 1, a sum of 6.8 million euro shall be allocated from 2004.

3. In order to put into effect this Article a certain proportion of the allocation shall be provided at the end of the triennial budget of 2004-2006 within the range of the total estimated as part of the state's current "special fund" to be estimated by the Minster for Finance and the Economy for the year 2004 with the balance coming from some of the allocation available to the same minister. The Minister for Finance and the Economy is authorized as he decrees to carry out the necessary balance adjustmen

BRIEFING DOCUMENT TO OIREACHTAS MEMBERS (2003)

Preventing Destruction of Embryos in Assisted Human Reproduction

Assisted human reproduction (AHR)

Infertility affects up to 10% of couples. They need our understanding and support. AHR refers to ways of addressing infertility problems, including:

(1) Treating causes of infertility

Medical Council *Guidelines* require thorough investigations "to identify and explore treatable causes of infertility before IVF and similar techniques are considered." Treatments include diet, exercise, availing of times most suited for conception, surgery to correct physical defects, or replacing hormones the body lacks. Such treatments are non-controversial and are a more satisfactory response to the problem of infertility as they treat the underlying causes.

(2) Use of donor ova, sperm, or embryos

Sometimes AHR techniques use sperm or ova, or even embryos, from persons other than those trying to conceive. This does not correct the underlying causes of infertility. The use of donors means the children are not genetically related to one or both "parents". They do not know who their biological parent or parents are. They should be legally entitled to establish the identity of their biological parents for reasons of personal identity and health. This is generally not the case in AHR, as practised in Ireland, where donors are involved..

(3) IVF (in vitro fertilisation)

In techniques like IVF, fertilisation occurs outside the body of the woman trying to conceive. In its most common form, she is given fertility drugs causing multiple ovulation. This does not correct the underlying causes of infertility. Resulting ova are collected and mixed with sperm. Up to one dozen human embryos may be created at a time. When living human embryos form, some are placed in the woman's womb. Some are deliberately destroyed because they are "low quality". Usually two or three are placed in the woman's womb in the hope that at least one will develop to birth. In up to 25% of cases, the treatment leads to a birth. Remaining embryos are frozen and stored for possible future use. If not wanted they are placed in the woman's cervix where it is intended they will die, or poured down the sink.

Medical Council *Guidelines*, however, state: "Any fertilised ovum must be used for normal implantation and must not be deliberately destroyed." (See note A)

Freezing human embryos should not be permitted

Embryos are frozen so the couple may try for another baby. But if the first attempt is successful or they are discouraged by the difficulties involved in IVF, or for other reasons, they decide they do not want the remaining embryos, then, sooner or later, most of them will be deliberately destroyed or used in embryo research which kills them. Likewise, the freezing and thawing process itself kills many.

Freezing is incompatible with human dignity and leads to large numbers of embryos in storage.(See note C) What happens when couples do not want them? Is it right to keep tiny human beings frozen indefinitely? There are an estimated 400,000 frozen embryos in the United States, 60,000 in the UK and 71,000 in Australia. The existence of numbers of "surplus" embryos inevitably leads to demands that they be used in experimentation.

IVF *can* be performed without deliberate destruction of human embryos

German and Italian IVF regulations forbid deliberate destruction of human embryos. Invited speakers at the Commission for Assisted Human Reproduction seminar in Dublin Castle, 6th February last, examined only the British and French approach to regulating AHR, suggesting IVF cannot be performed without deliberate destruction of human embryos, giving a grossly misleading message that this was the only possible approach.

Present Chairman of the Institute of Obstetricians and Gynaecologists, Professor John Bonner, and a past Chairman, Dr Conor Carr, however, have made it clear that IVF *can* be performed without the destruction of human embryos. Professor Martin Clynes agrees. (See note B)

RECOMMENDATIONS

From its beginning at conception/fertilisation every human life is entitled to respect and protection as an equal member of the human family. In IVF and such procedures, the presence of human embryos is not speculative but can be observed with certainty. From the viewpoint of the protection of human life, we make the following recommendations:

1. Clinics practising AHR should be required to keep a record of each human embryo produced by fertilisation outside the body of a woman, with details of the biological parents and, where different, the couple for whom the embryo was produced. Any procedure to which it was subjected should be recorded. These records should be inspected annually by an independent regulatory body to ensure that the life of the embryo is fully respected at all stages and optimum conditions for birth are maintained.

2. The German regulatory model, rather than the British, should be followed, where only the number of human embryos are produced that are intended to be placed in the woman in one treatment. This makes it unnecessary to store embryos, leading to inevitable "disposal" problems involving destruction of human embryos couples do not want.

3. To respect and protect the unborn, it should be clear public policy that human embryos cannot be deliberately destroyed at any stage by any means whether by placing them in the cervix where they are intended to die, by pouring them down the sink, by handing over surplus embryos for research, or by simply "leaving them to die".

4. The regulatory body should publish an annual report on all AHR units. It should include information on: number of couples treated, details of investigations to identify treatable causes of infertility, number of human embryos produced, methods employed to produce them, whether the sperm and ova were from gestational parents or donors, details of the fate of all embryos; where a clinic is found to breach the regulations, details of breaches should be included and sanctions imposed.

5. Every child has the right to information about its biological parents. If the Government allows sperm and ovum donation it should require AHR units to keep full records for this purpose. Donors should sign a contract agreeing.

6. Where a child conceived from donor sperm ova or embryo and would otherwise be left destitute, it should have the right to seek support from the biological parents. This might not be feasible where the biological parents have died, emigrated, or are untraceable, so the AHR clinic should set up a fund for their support.

Notes

A. Medical Council *Guidelines* state:

26.1 The creation of new forms of life for experimental purposes or the deliberate intentional destruction of human life already formed is professional misconduct.

26.2 However, if the intention is the creation of embryos for experimental purposes it would be professional misconduct.

26.6 Any fertilised ovum must be used for normal implantation and must not be deliberately destroyed

B. IVF *can* be performed without deliberate destruction of human embryos

Chairman of Institute of Obs. & Gyns., Professor John Bonnar

…we have heard today a fairly overwhelming case for regulation and legislation. We have also heard some comments which I found quite worrying, some statements made that IVF is not possible without destroying embryos. This is not in fact true. We may need to change some of our activities but I can assure people at this conference that there is every respect for human life by the gynaecologists working in this country. (*Commission On Assisted Human Reproduction Public Conference Transcript*, p. 66)

Former Chairman of Institute of Obs. & Gyns., Dr. Conor J. Carr FRCOG FRCPI

"… in Germany … it is prohibited to fertilise an egg for any purpose other than to create a pregnancy in the woman who produced it. It is illegal to fertilise more eggs than are required for replacement in a given cycle, and a maximum of three embryos may be replaced in any one cycle. Storage, freezing and donation of embryos are therefore, by implication also proscribed.

Such regulations reduce the chance of success in that less than three fertilised eggs may be available for implantation, and there are no spare embryos for further attempts at pregnancy. Against this must be set the fact that there are no "wasted" embryos and no frozen embryos which have to be destroyed, like the 4,000 in the UK recently.

As a correspondent wrote in *The Lancet* recently, it is time that both those who create human life and those on whose behalf this life is created took responsibility for their creation. Being cavalier with created human life is the thin end of a very dangerous wedge." (*Irish Medical Times*, 18th October 1996)

Dr Martin Clynes, Professor of Biotechnology, Dublin City University:

"…The practice in countries such as the UK is to fertilise 10-12 ova, of which usually only three are implanted. The rest are frozen for future use. If they are not required at a later date by the parents, they are either destroyed or used for research. Should the UK be the headline for Irish legislation? That depends on your view of the early embryo

….

> Despite assertions at the conference, IVF does not at all need to involve embryo destruction, for three reasons. First, only the number of ova needed for implantation could be fertilised. If embryos are to be frozen, regulations can ensure use by parents or availability for adoption, but not destruction.
>
> And finally, technology for freezing ova is improving, reducing the need for freezing embryos for later use…..
> ….I hope that CAHR and the Minister, Mr. Martin will have the courage to draft legislation which gives Irish patients access to new treatments, but without allowing violence to individual citizens at the most vulnerable point in their existence." (*Irish Times*, 7th March 2003)

C. Respect for the human embryo 'foolish', British speaker admits

Baroness Mary Warnock, leading speaker at the AHR Commission Seminar in Dublin Castle on 6th February last, chaired the UK report that led to the approval of destructive experimentation on human embryos up to 14 days yet still hypocritically expressing respect for the human embryos destroyed. She since accepted this was "foolish"

> "You cannot respectfully pour something down the sink, which is the fate of the embryo after it has been used for research, or if it is not going to be used for research or anything else. I think what we meant by the rather foolish expression "respect" was that the early embryo should never be used frivolously for research purposes." (*House of Lords Select Committee* 5th December 2002)

D. A Government View

In a written reply (dated 3rd April 2003) to a Dáil question, Minister for Health and Children, Mícheál Martin stated:

> "There are no plans to introduce legislation which would permit the deliberate destruction of human embryos. In relation to assisted human reproduction services generally, while there is no legislation regulating this area at present, medical practice is governed by guidelines issued by the Medical Council. These state that the creation of new forms of life for experimental purposes or the deliberate and intentional destruction of human life already formed is professional misconduct. I am conscious of concerns about the absence of a statutory framework to regulate this area. "

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Tel: 01-8748090 Fax:01- 8748094 e-mail: prolife@indigo.ie
website: www.prolifecampaign.ie www.prolifecampaign.ie