Memorandum

To: The Council
Cana Movement

From: Dr. Robert Tufigno

Date: 12 September, 2012

Subject: Critical analysis of the Embryo Protection Bill ("Bill")

Introduction

In this Memo the undersigned has attempted a critical analysis of the Bill.

The Memo does not intend to enter into the ethical and moral issues of the Bill. These have in principle already been dealt with in the Pastoral Letter of the Bishops of Malta and Gozo entitled *Celebrating Human Life* published on the 26 July, 2012. The teaching of the Catholic Church on this matter may also be found in the Encyclical Letters *Humanae Vitae* and *Evangelium Vitae* and in the instructions of the Congregation for the Doctrine of the Faith, *Donum Vitae* and *Dignitas Personae.*

In the Memo the legal and cultural implications of the Bill will be highlighted.

This Memo does not enter into the technical (such as biological and medical) implications of the Bill. Nor is it intended to be a comprehensive analysis of the Bill. It is an attempt to shed light on the Bill's implications.

The exercise certainly merits further reflection and studying both from a legal perspective as well as from the medical, technical and ethical aspects.

Scopes of Bill

The declared scope of the Bill is to "regulate the procedure relating to medically assisted procreation and to protect human embryos".

The term "medically assisted procreation" ("MAP") is nowhere defined in the Bill. However, going through the bill one can infer that it refers to the process of fertilisation of a human egg by a human sperm cell by any means other than through sexual intercourse. This would include artificial insemination and in vitro fertilisation ("IVF"). In this Memo the terms MAP and IVF are used interchangeably.

MAP: a ray of hope?

In the period leading to the publication of the Bill government Minsters have publicly underlined that the reason for justifying the legality of MAP is that it provides a solution ("a ray of hope") to those suffering couples who, having desired a child, cannot achieve the much desired pregnancy and child. This reason is nowhere stated in the text of the Bill. However, IVF has been publicly presented as the solution for such couples' desire, and therefore, according to the proponents of the Bill, should be allowed under the Maltese legal system.

Such an approach might imply that the satisfaction of the desire to have a child, which is indeed a noble desire, whether achieved as a natural process or through MAP, would satisfy the couple's ultimate desire for happiness. One cannot give the impression that the "child project" is indeed the answer to the desire for happiness: like any other particular project or desire that are met, it does not. The complete correspondence to such a need and desire for happiness lies elsewhere, precisely in an Other. Reducing one's quest for happiness to the desire of the child project is a reduction of man's ultimate desires and humanity.

Moreover, the excessive emphasis on IVF as providing infertile couples a "ray of hope" is also misleading. For whilst IVF does assist unfertile couples to have a child, this is subject to the small success rate of the procedure and to the risks involved. One has also to consider the possible psychological effects, the complications that may arise to both mother and offspring, the cost involved, and this without mentioning the intrusive and artificial nature of the process itself[1].

The declared objects and reasons of the Bill

The declared scopes of the Bill are (i) to regulate MAP and (ii) to protect human embryos.

This would be in the spirit of the Oviedo Convention[2] which sought to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine ".

Efficacy of regulating MAP

With regards to the regulation of MAP, the most obvious comment that comes to mind is whether this scope can realistically be effectively reached. After more than twenty years of complacency of various legislatures, who whilst being aware of the practice of

[1] This is acknowledged by article 18 (2) of the Bill.

[2] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 4 April, 1997, and additional protocols.

MAP opted to be conspicuous by their absence, government has now decided to intervene though the enactment of legislation in an attempt to halt abuses and regulate the practice.

Regulation is mainly sought through the intervention of the "Embryo Protection Authority" ("Authority") and the provision of criminal responsibility in the case of breach of the provisions of the law.

The functions of the Authority as contained in the Bill are somewhat generic, and much is left to regulations, that still have to be issued. This means that the public discussion would be postponed after that the regulations would have been promulgated and not before, unless the Minister responsible and/or the Authority opt for a public consultation prior to the issuing of any regulations. It would be augured that any consultation process on any proposed regulations would be as wide as possible and undertaken during normal times of the year when people are not in vacation.

The effectiveness of the Authority "to regulate" MAP depends on two main factors. One is the functions and powers that the law itself would vest in the Authority. The other would consist in the resources made available to the Authority.

Role of the Authority

Regulation of MAP

The functions and powers of the Authority are mainly listed in article 4 of the Bill, and then in articles 4 (2), 7, 18 and 22 of the Bill. Broadly speaking the Authority's functions, as listed by the law, fall very short of effectively ensuring regulation and the proper observance of the law. The general impression given is that the Authority is mainly an agency of moral value, but with no real power to regulate MAP and protect the embryo.

Article 4 refers to the role of the Authority as being: that of ensuring the maintenance by all personnel involved in MAP of high standards of ethics (and not law, also erroneously referred to as "codes of practice")[3]; the issue of licences to clinics and the imposition of conditions relating to hygiene, equipment, implements, structure, space and accommodation[4]; keeping under review information about embryos and subsequent development of embryos and about the provision of treatment services[5]; the maintenance of a statement of the general principles that it should follow in carrying out its activities and functions.[6] The Bill then contemplates that the Authority

[3] Article 4 (1) (a) and (g) (ii).
[4] Article 4 (1) (b) and article 22.
[5] Article 4 (1) (d).
[6] Article 4 (1) (f).

may issue "certificates of eligibility" to prospective parents, without the need for such certificates as a requirement for eligibility.[7]

The Bill contemplates that the Authority should have a function, (i) in respect of activities under the law, to ensure "compliance" with the law and obligations arising thereunder and with codes of practice[8] and (ii) to carry out regular inspections in order to ensure the respect and implementation of standards of best practice.[9] However, most of the "norms" to be complied with are not in the nature of law but rather in the nature of "standards of ethics" or "standards of best practice" or "codes of practice". This normally implies that such "norms" are not enforceable as rules of law.

Moreover, nowhere does the Bill vest the Authority with the power of entry into premises or with the power to appoint inspectors with powers of entry into premises and the power to take possession of anything that might be used both for ensuring compliance with the law as well as for probatory purposes in any court of law. Nor does the Bill vest the Authority with the power to suspend or revoke any licence in the case of breach of law, or to suspend or withdraw any professional licence or warrant to any professional who is in breach of the law.

If one were to source any model provisions with regards to the functions, powers, and effect of codes of practice reference may be made to the UK Human Fertilisation and Embryology Act 1990 as amended.

It would appear that it is being assumed that the enforcement of the law is by default vested in the Police, as in the case of normal criminal activities. In such cases the Authority does not even have any *locus standi* in criminal proceedings.

Thus the practice on non-intervention obtaining prior to the enactment of the law would now be replaced by inadequate means to ensure the enforcement of the law. The only real difference that the new law would introduce is that under the pretence of regulation of MAP and of the protection of the embryo it has legitimated MAP.

The effectiveness of the Authority depends also on its resources. The Bill is completely silent on such matters as human resources and funding. Other laws that contemplate the setting up of a corporate body or authority normally employ "template" provisions to this effect. Moreover, the Bill does not contemplate any initial funding for the Authority.

The main thrust of the Bill in providing protection to the "embryo" lies in the resort to criminalising certain practices that would not be ethically acceptable, such as improper use of embryos, unauthorised fertilisation, embryo transfer and artificial fertilisation

[7] Article 4 (1) (c).
[8] Article 4 (1) (g).
[9] Article 4 (1) (b).

after death, sex selection, cloning, formation of chimaerae and hybrids, etc. In this sense the Bill follows the German model.[10] Resort only to criminal liability as a manner of regulating MAP and as a manner of protecting the "embryo" has three generic consequences: one is that what would not be prohibited is allowed; the second is that the laws would, in case of lack of clarity, be interpreted restrictively; and thirdly that in the case of any criminal proceedings the normally applicable principle of "in dubio pro reo" would be applicable. On the other hand rendering unlawful practices as criminal offences (that is the opposite of the decriminalisation of abortion) is significant, and more so if the punishments are really proportionate to the nature of the offence. In this respect one can only compare the punishments contemplated by the Bill to those contemplated by the German model, the UK Human Fertilisation and Embryology Act 1990 and the Italian law number 40 of 2004 entitled "Norme in material di procreazione medicalmente assistita".

The status of the embryo

When the Oviedo Convention was promulgated in 1997, it was then very difficult for agreement to be reached on the nature or status of the embryo. Indeed, various acceding states had laws that permitted abortion and therefore the Oviedo Convention could not tackle the issue as to whether the embryo is a person or subject according to law. However, all acceding states acknowledged that some regulation has to be made to ensure proper conditions for the application of procedures involving the creation and use of embryos in vitro. Accordingly domestic laws aimed at implementing the convention, of course to the extent each national state deemed appropriate, did not prejudice the applicability of their domestic laws permitting abortion.

The Bill is therefore an occasion for the Maltese State to expressly recognise and acknowledge the status of the embryo as a human person, vested with all rights proper to a person, such as the right to life. Since in Malta abortion is illegal, and the government proposing the Bill is adamant in not formally legalising (or decriminalising) abortion, then one would have expected that the Bill should have included a provision that acknowledges the embryo's status of a human person or subject from the moment of fertilisation.

The Bill is however very careful in not recognising or granting to the "fertilised" female egg any status of a "subject" or "person". Although the embryo is "human", the Bill does not afford it the rights of a "person" nor the full "dignity" of the human person. In this context the following comment seems quite pertinent: "The attempts to deny the subjectivity of the embryo, to which we are witness in our times, in medical and scientific fields, have consequent repercussions on the entire society, determining a disparagement or disregard of the human individual, especially in those moments in which he/she is more fragile and defenceless: if man cannot be

[10] See Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG) [The |Embryo Protection Act] adopted by the Bundestag on the 13 December, 1990.

guaranteed adequate protection, especially in situations in which he is at his weakest, how can every human being be always protected, in every circumstance?"[11]

Indeed the Bill defines "embryo" as a process (i.e., "fertilisation") and not as a subject. In other words what is being protected, when protection is afforded to an "embryo", is the process of fertilisation (of a human egg cell by a human sperm which is capable of developing (that is if the human egg that is fertilised is not capable of development then it would not fall in the definition of "embryo" (even though a process). The embryo itself is excluded from the definition of embryo. One would have thought that this is a matter of bad drafting. However, in other parts of the bill one finds that the "embryo" is considered as a "product"[12].

There is no definition of "fertilisation". Reference is always made to "embryo" and not to "zygotes". The definition of embryo then seems to include within the term "embryo" the fertilisation of "each totipotent cell removed from an embryo or otherwise produced", that is assumed [in the Maltese text which normally prevails the word used "prezunt" is stronger] to (i) be able to divide and (ii) develop as a human being, (iii) in appropriate circumstances.

The Bill moreover makes a distinction between "child" and "embryo". In article 5 which provides when resort to MAP may be had, one of the criteria applicable is that the procedures "do not entail any known undue risk to the health of the woman or the child". In other words the health of the embryo is not relevant at all; the only criterion is that the health of the child, which is eventually born, is not prejudiced. On the other hand clinical interventions on a human embryo are allowed if they pursue an exclusively diagnostic or therapeutic purpose related to the embryo and are in the interests of the health and development of the embryo itself.[13] Hopefully such practices should not lead to eugenic practices which are considered unlawful.[14]

One also notices that the Bill is not consistent when referring to "human embryos": sometimes the simple term "embryo" is used, at other times it uses the term "human embryo" and exceptionally "fertilised embryo" or "fertilised eggs".

Of concern are the provisions that render the commission of a criminal offence linked to "completion of implantation" of an embryo in the woman's womb. This occurs in two contexts in the Bill, namely article 6 (d) and article 8 (1). The former renders it a criminal offence to remove "an embryo from a woman before the completion of implantation in the womb in order to transfer the embryo to another woman". The latter also provides for criminal liability if one "removes such embryo from a woman

[11] Synthesis on the theme discussed during the Congress entitled, "The human embryo in the Phase prior to Implantation" organised by the Pontifical Academy for Life on the 27th and 28th of February, 2006 (8 June, 2006).
[12] See articles 6 (c) and 8 (1).
[13] See for example article 15 (3).
[14] Article 6 (e).

before the completion of implantation in the womb." Interesting is the omission in such context (hopefully not deliberate) of the adjective "human" in the qualification of the word "embryo", as if endorsing the theory that prior to implantation there is no human person. The words "completion of implantation" presuppose that implantation has commenced: any process cannot be completed unless it has commenced. The implications of such wording is that once implantation in the womb has not commenced, there is no legal or criminal responsibility for removing the "embryo" from the woman in whom it has been placed, unless such removal constitutes the "wilful destruction" of the embryo, which constitutes a separate offence.[15]

On the other hand once implantation has been complete, the removal of the embryo from the woman's womb would normally constitute abortion (procurement of miscarriage) punishable under articles 241 et sequitur of the Criminal Code.

One cannot not comment that the Bill itself, other than in its title and in the explanatory rider at its end, does not expressly contain in its text any declaration (that would have the effect of law) that the law is intended to safeguard and protect the dignity and life of the fertilised human female egg at all stages of its development from fertilisation.

The right of "any prospective parent" to MAP

The Bill also provides that "any prospective parent shall have access to medically assisted procreation procedures" . The implications of such a statement are far reaching. It is really implying that the prospective parent has a right to have a child. There is indeed no reason to resort to IVF if not for the purpose of having a child. This is a *liet motif* of a number of articles of the Bill. Accepting the principle that "couples have a right to a child" diminishes the value of love as being the gift of self without the expectation of a tangible result. The expectation of a result implies that the gift of self is not gratuitous and the result is not desired for its own sake, but as the satisfaction of a need, however noble. A corollary of such an approach would be that if a child is not desired, or if a "parental project" ceases to exist, then there should be no reason why it should not be destroyed or abandoned. This type of reasoning has in various jurisdictions justified resort to abortion.

Moreover, if such a principle is accepted, there is no logical reason why such a right is not extended to any "couple", for so long as there is such a desire for a child, then there should be a right that would provide a solution.

This implication could easily be avoided if the text of the Bill, instead of granting a right to MAP, would be drafted in a way so as to "permit" recourse to MAP in particular circumstances. This is for example the option chosen by the Italian legislator.[16] The

[15] Article 16 (1). The Maltese text needs to be corrected as "wilfully" is translated as "b'mod volontarju" rather than as "xjentement".
[16] See article 1 of the Italian law.

German law is completely silent as it only provides for criminal liability, and does not grant any rights.

MAP as an alternative method of procreation

IVF is conceived by the Bill as a method for achieving procreation. It is not considered as an exceptional method, that may be resorted to in cases of unsolved cases of sterility or impotence and after that resort to therapeutic measures proved unsuccessful[17]. By not restricting resort to IVF to such exceptional cases, the Bill would be elevating artificial fertilisation to the status of the normal generative conjugal act. In other words the natural and the technological are put on the same level. This goes beyond what has been publicly stated by various politicians that IVF should be permitted (and then regulated to avoid abuse) as it provides a solution to suffering married couples who cannot achieve a much desired pregnancy and child. Indeed the Bill itself does not make any reference to the plight of such couples to justify or excuse resort to IVF.

With social changes contributing to postponing pregnancies to older parental ages, the demand for IVF will likely continue to rise, but the fertility rate need not. In such circumstances policy makers should consider family policies that encourage and help young couples start a family earlier in life and thus contribute to a demographic balance and intergenerational solidarity. The Bill does not indicate any policy in this direction. IVF is not a solution. Rather it is counter-productive as it provides a ray of hope to those who postponed conception to a later age, thus making the postponement of a first pregnancy to older age a favoured option.

By not restricting resort to IVF to cases of sterility or impotence in married couples and widening the procedure of IVF to all heterosexual couples in all circumstances the idea that is being given by the Bill is that the wanted child is a commodity that may be procured, albeit at a high cost – emotional, financial and relational - from a clinic. The most natural and noble desire of a married couple, that to have a child, is being reduced to a need for something which may be satisfied through a technological process. This approach implies that the "embryo" is a product of technology using human sources, and as any product may be disposed of at any time.

A product, as any other object, may be disposed of and utilised as one wishes. The Bill, without going as far as considering the "embryo" as a human being, then aims at prohibiting the abuse of "embryos" through regulating of how many "embryos" may be produced, their destiny and what may be done with them. These will be dealt with later on in this Memo.

[17] This is the approach taken by the Italian legislator. See article 4 of the Italian law.

A treatment but not therapeutic

. Although MAP involves a "treatment" this is not really so, (see Articles 4 and 18). The Bill nowhere states that resort to IVF does not constitute a therapeutic intervention leading to a cure. The terminology adopted is therefore misleading to lay persons, as indeed IVF is not therapeutic at all.

Who may resort to IVF: the "prospective parent" and the undermining of marriage

The Bill allows any prospective parent to resort to IVF. Resort to IVF is not given to the couple as a couple[18], but to each prospective parent individually. In other words the prospective parents who resort to IVF, who must be either married or in a stable relationship, need not be married to each other or in a stable relationship between them.[19] It is therefore not surprising that the Bill nowhere prohibits heterologous artificial insemination.

In other words "prospective parent" is defined as meaning one of two persons of opposite sex who are united in marriage / who have attained the age of 18 and are in a stable relationship with each other[20]. The right to MAP procedures is given to "any prospective parent".[21] There is no requirement that the prospective parents must be married to each other or are in a stable relationship with each other. It does not necessarily follow that the egg and sperm must come from the two persons who are united in marriage, or for all that matters who are in a stable relationship with each other. What is necessary is that either of the prospective parents be married or in a stable relationship.

This is further complemented by the Bill's treatment of the civil status of the child born as a result of MAP procedures.[22] The Bill provides that such a child "shall be considered to be the child of the prospective parents who have expressed their consent in writing[23] …….. and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parents without the intervention of the procedure as aforesaid." So as to make it more clear that the normal rules of paternity contained in the Civil Code are not applicable (including the presumption that the husband is the father of the wife's child), the Bill further continues as follows: "and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status as the direct descendant of such prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child." Of

[18] As the Italian law clearly states in article 5.
[19] See definition of "prospective parent" in article 2, and article 5.
[20] Article 2.
[21] Article 5 provides: "Any prospective parent shall have access to medically assisted procreation procedures".
[22] Article 19.
[23] Article 18 provides that prior to access to MAP procedures each prospective parent must express their consent jointly in writing.

course probably this would not exclude recourse to the action of disavowal of paternity by any husband.

The recognition of "couples who are in a stable relationship" at par with married couples, is significantly undermining marriage as the socially preferred basis for stable families.

In the definition of "prospective parent", the Bill refers to "either of two persons of the opposite sex who are united in marriage". This seems to imply that there are at least two types of marriages: those between persons of the opposite sex, and those of the same sex.

If marriage between transgender persons would be allowed, we may be faced with a situation where the wife of husband (a transgendered female who became a male) be entitled in terms of article 5 to request to become pregnant through IVF.

By allowing individuals who are in a stable relationship with an individual to qualify as "prospective parent", and once having accepted the principle that the conjugal act is not necessary for procreation, the Bill is introducing an argument in favour of same sex couples to claim discrimination. Moreover, one may not but notice that whilst marriage is prohibited between persons who are closely related, this does not apply to stable relationships.

No criteria are given to determine what constitutes a stable relationship. It is therefore a matter of fact to be established in each particular case. Perhaps reference can in this context be made to the Rights and Obligations of Cohabitants Act, 2012. If this were the case then two years (if there are other children) or five years would be the norm. As already stated, in case of doubt one may always require an "eligibility certificate" from the Authority, unless the medical practitioner carrying out the MAP procedure took reasonable care to determine the eligibility of the user of the MAP procedure[24].

If there is a doubt as to whether two individuals would each qualify as prospective parents, they may resort to the Authority to obtain a certificate regarding their eligibility for treatments relating to medically assisted procreation – see article 4 (1) (c).

In the absence of a certificate issued by the Authority, a medical practitioner who took reasonable care to determine that the individual involved was a prospective parent and violates the law by providing services that can only be provided to prospective parents has a defence to be exempt from criminal liability – see article 5 (2) and article 9.

[24] Article 5 (2).

The protection of the rights of "prospective parents"

Some comments have already been made in this regard. In this section it is intended to comment further.

The general principle is that certain rights of the "prospective parents" are to be protected. These rights might also protect the dignity of the "embryo", but may also be independent of such a consideration. In some cases, as already highlighted above, the rights of the prospective parents might not tally with the rights or dignity of the married couple or of marriage as a social institution.

Certainly access to MAP cannot be resorted to if (i) there is no reasonable chance of success, or (ii) the procedure entails any known undue risk to the health of the woman or the child (as distinct from embryo). Of course what constitutes "reasonable chance" is a term of art, as it is quite well known that the success rate of IVF is for example low. What constitutes "undue risk to the health of the woman" is also debatable, as this might be of a physical or psychological nature, but then what is "undue" ("bla bzonn") besides being a matter of degree would not normally arise as any risk undergone in MAP procedures would indeed be necessary for that procedure. Therefore, these restrictions to the use of MAP procedures seem only to be cosmetic, but with no practical application. The same applies to health risks to the child, as it is quite well known that children born from certain types of IVF procedures (e.g. ICSI treatments) might have a propensity for certain abnormalities (not necessarily of a serious nature). The deletion of the word "undue" ("bla bzonn") would alter the meaning and effective application of the legal text.

Certain prohibited practices are intended to protect the rights of the "prospective parent"[25], namely,

(i) The artificial fertilisation of any egg cell without the consent of the woman whose egg cell is to be fertilised, or without the consent of the man whose sperm cell will be used for fertilisation;
(ii) The transfer of an embryo into a woman without her consent;
(iii) The artificial fertilisation of an egg cell or of a sperm cell after the death of the relevant contributor.

For the same reason any consent given a prospective parent who will be availing himself/herself of MAP procedures may be withdrawn so long as fertilisation of the relevant egg cell or sperm cell has not commenced.

It is interesting to note that the above unlawful acts are punishable by a fine of not less than €10,000 and not more than €25,000. If one were to equiparate "the transfer of any embryo into a woman without her consent" to rape (punishable under article 198 of the Criminal Code) then the punishment contemplated for the latter is

[25] Article 12.

imprisonment for a term from three to nine years imprisonment. On the other hand the crime of indecent assault (contemplated by article 207 of the Criminal Code) is punishable with imprisonment for a term from three months to one year.

Under German Law such offences attract a punishment of up to three years imprisonment and to a fine. Under Italian law the punishment for (iii) is imprisonment up to three years and/or with a fine from €50,000 to €150,000[26].

One may also notice that the transfer into a woman (recipient) of an unfertilised egg of another woman (donor) is not unlawful.

The protection of the "dignity" of the "embryo"

The protection of the embryo is then protected by a number of specific provisions. In this part I will deal with those that may normally arise in connection with the practice of MAP procedures.

As mentioned above the procedure of MAP is afforded to any "prospective parent,"[27] and heterologous MAP is not prohibited. Any such prospective parent may, through MAP, bring to life a child who would eventually be born out of wedlock. Whilst one cannot intervene in the privacy of the lives of persons to preclude non married couples from conceiving a child naturally, one would have expected that as a matter of policy the state would not legislate to facilitate this practice through MAP procedures. In such a case not only the institution of marriage is undermined, but the right of the child is also ignored in preference to the private individualistic choice of two adults.

Moreover, the law is then silent regarding the status of a child conceived with the sperm cell of a person who is not the "prospective parent" who gave his consent for the MAP procedure. One way how to tackle this circumstance would be that adopted by Italian law, which provides that the "prospective parent" giving his consent in writing cannot exercise the action of disavowal of the paternity of the child and the donor cannot claim any parental rights on the child nor be liable for any obligations arising from being the natural father of the child.[28] In the absence of such a specific provision the normal rules of the Civil Code regarding the action of disavowal would apply.

What is considered unlawful by the bill is not heterologous MAP but the provision of MAP procedures to persons who do not qualify as a "prospective parent". In such a case the service provider, or whoever assists, would be liable to a fine from €10,000 to €23,000 and/or to imprisonment up to five years. Under Italian law the punishment contemplated is a fine from €200,000 to €400,000[29]. As already stated heterologous

[26] Article 24 of legge n. 4 of 2004.
[27] Article 5.
[28] Article 9 of legge n. 40 of 2004.
[29] Article 12 of legge n. 4 of 2004.

practices are not unlawful. The persons themselves who benefit from the MAP procedure are likewise not criminally liable. In such cases the rights of the adults supersede those of the child.

In the interest of the "embryo" the Bill provides for the following unlawful procedures:

(i) The artificial fertilisation of any egg cell for any purpose other than that of bringing about the pregnancy of the woman from whom the egg cell originated;
(ii) The intentional fertilisation of more than two egg cells from one woman within one treatment cycle;
(iii) The failure to transfer all embryos "produced" into a woman within one treatment cycle;
(iv) The removal of an of an embryo from a woman before completion of implantation in the womb in order to transfer the embryo into another woman;
(v) The selection or disposal of an embryo for eugenic purposes;
(vi) The fertilisation of, or the transfer of a human embryo into, a woman who is prepared to give up her child permanently after birth (surrogate mother).

Such acts are punishable by a fine from €5,000 to €15,000 and /or to imprisonment for a term not exceeding three years. Under Italian law the "production" of more embryos than is permitted by law is punishable by imprisonment up to three years and/or with a fine from €50,000 to €150,000[30].

It is to be noted that whilst the fertilisation of more than two eggs from one woman in one treatment cycle is unlawful if "intentional", it would not otherwise be unlawful. The text of the German law does not require the "intentionality" on the part of the service provider, but then renders the attempt to fertilisation also unlawful[31].

Whilst the artificial fertilisation of an egg cell for a purpose other than bringing about the pregnancy of the woman provider is illegal, the fertilisation of an egg of a woman by an egg provided by a man, who though a prospective parent, is not married to her, is not illegal. It is a matter of consent. Similarly the acquisition and transfer of an egg from one woman donated to be implanted in another woman after fertilisation is not of itself illegal. This donation and consequent transfer can also be effected after that the fertilisation of the egg has been effected (that is, the fertilisation would have been effected for the purpose of making the donor woman pregnant).

On the other hand surrogate motherhood is illegal.

As already stated eugenic practices are illegal. However, clinical interventions on a human embryo are allowed if they pursue an exclusively diagnostic or therapeutic

[30] Article 14 (6) of legge n. 4 of 2004.
[31] Se section 1 of the German law.

purpose related to the embryo and are in the interests of the health and development of the embryo itself.[32] However, in such cases such interventions may be resorted to only if there is no other medical method or procedure available, and there is no undue risk to the embryo and to the mother. In any case the consent in writing of the prospective parents must be obtained. Whilst sex selection is prohibited, the selection of a sperm cell in order to preserve the child (that is when born) from falling ill with a sex-linked genetic illness is permitted[33].

Whilst the preservation of human egg cells and human sperm cells is permissible, the preservation of embryos, including cryo-preservation is generally speaking prohibited. The breach of such a rule is punishable with a fine from €5,000 to €15,000 and/or to imprisonment up to three years[34]. Under Italian law the preservation of more embryos than is permitted by law is punishable by imprisonment up to three years and/or with a fine from €50,000 to €150,000.[35]

There are circumstances where cryo-preservation is permissible. These are the following:-

(i) Where the transfer of the fertilised embryos into the womb is not possible owing to a grave and certified *force majeure* not predictable at the moment of fertilisation;
(ii) Where there has been a breach of any provisions of the law.

In the first case, the service provider may preserve the fertilised embryo up to such date when transfer into the womb is possible, and such transfer should be effected as soon as possible. In these circumstances the Authority has no role at all. It is not even required that it be informed. It is suggested that in such a case notification to the Authority should be compulsory as the Authority has the power to give such embryos (referred to as "fertilised eggs") for adoption.[36]

Where there has been a breach of the law, the Authority has the power of order the freezing of any embryo to preserve its life. In such a case, there is no requirement regarding the length of time during which the life of the embryo is to be preserved. Such "life" in limbo is indefinite or indeterminate. The embryo will be kept in what Jerome Lejeune had termed a "concentration can".

In such cases of breach of law it is pertinent to note that the Authority has no power to give the embryo for adoption, as this power is only exercisable where implantation cannot take place due to the death of the mother, or where for any other reason the implantation of the "fertilised embryo into the womb cannot take place". Perhaps the

[32] Article 15 (3).
[33] Article 10.
[34] Article 7.
[35] Article 14 (6) of legge n. 4 of 2004.
[36] Article 4 (2).

replacement of the words “cannot take place” with the words “cannot or did not take place in accordance with the provisions of tis Act” might widen the power of the Authority to cover all cases of breach of the law. The hurdle to overcome would then be how to apply the requirement of informed consent[37] in such circumstances, as article 4 (2) that provides for the Authority’s power to give embryos for adoption is subject to the provisions of article 18 regarding informed consent. Moreover, the provisions of the Civil Code regarding Adoption have to be streamlined to cover the circumstances contemplated by the Bill.

The main problem regarding preserved embryos is that keeping the life of a human person suspended in limbo indefinitely is certainly not compatible with human dignity. Neither is it compatible with the right to life, which implies that it must follow a natural course. But then neither is the immediate (or eventual, and perhaps inevitable) destruction of the embryo, who is entitled to life, compatible with the rights of the embryo.

Perhaps another remedy, to be available cumulatively, could be that of extending the provisions of the Children and Young Persons (Care Orders) Act (Cap. 285) to embryos, with such modifications as are warranted.

The preservation of the embryo, especially if indefinitively or for a long time, would also have legal implications under the current provision of the Civil Code and more so if the subjectivity of the embryo is acknowledged as argued earlier. The Civil Code currently provides that those who at the time of the testator’s death were not yet conceived are incapable of receiving by will[38], meaning that once at the moment of death of a testator an unborn child was already conceived it will then inherit when it is born. Similarly “Persons who are not yet conceived at the time of the creation of a foundation may be named as beneficiaries or form part of a class of beneficiaries but their rights arise only once they are born viable”[39]. This would mean that if an embryo exists and is being preserved, the putting into full effect of testamentary provisions or of donations or foundations is suspended. This will be more so once the subjectivity of an embryo is recognised by law.

In accordance with generally acknowledged legal principles adopted in furtherance of the Oviedo convention, the following are also considered unlawful and are punishable through criminal sanctions:

(i) the disposal or, or handing over or acquisition of a human embryo “produced outside of the body”, or the removal thereof before completion of implantation in the womb[40];

[37] Article 18.
[38] Article 600 (1) of the Civil Code.
[39] Article 33 (5) of the second Schedule of the Civil Code.
[40] Article 8 (1).

(ii) causing an embryo to develop further outside the body for any purpose other than to bring about a pregnancy[41];
(iii) the use, transfer or fertilisation of germ line cells not originating from the prospective parent[42];
(iv) sex selection when fertilising a human egg cell[43];
(v) cloning[44];
(vi) the artificial alteration of human germ line cells[45];
(vii) the formation of chimera and hybrids[46];
(viii) the experimentation on human embryos and of human embryos for the purpose of research or experimentation[47].

In such cases the criminal punishments contemplated by the Bill are the following:

(i), (ii):	Fine of €5,000 to €15,000 and imprisonment up to three years
(iii):	Fine of €10,000 to €23,000 and imprisonment up to five years
(iv):	Fine of €4,000 to €10,000
(v), (vi):	Fine of €10,000 to €23,000 and imprisonment up to five years
(vii):	Fine of €10,000 to €70,000 and imprisonment up to seven years
(viii):	Fine up to €70,000 and imprisonment up to seven years

General comments on criminal responsibility

There is criminal responsibility of "any person who provides, or assists in, any medically assisted procreation procedure" or who carries out a prohibited act.

However, in the case of MAP procedures if the person providing the procedure is a medical practitioner, he is not criminally responsible if he "shows that he took reasonable care to determine that the person on whom the procedure was performed or attempted was entitled to access to such procedure". In the opinion of the undersigned this "immunity" might be a dangerous back door to the de facto carrying out of unlawful assistance to persons who should not qualify to access to such procedures.

[41] Article 8 (2).
[42] Article 9.
[43] Article 10.
[44] Article 11.
[45] Article 13.
[46] Article 14.
[47] Article 15.

Where the Bill provides for the punishment of imprisonment, it only specifies the maximum imprisonment. The minimum term of imprisonment is not indicated and is left to the discretion of the court.

One may notice that the person who avails himself/herself of the procedure does not have any criminal responsibility. This follows the practice adopted in other jurisdictions, where abortion is de-penalised. In Malta in the case of procured abortion the woman involved is liable to the same punishment.

The Bill provides that where the offender is a medical practitioner or health care professional, the Court who delivers judgment will order that a copy of the judgement be served upon the competent council under the Health Care Professions Act (Cap. 464). This Act provides that the relevant council may, in the case of conviction for as term exceeding one year or in the case of professional or ethical misconduct or in the case of failure to abide by any professional and ethical standards applicable to him, direct any one or more of the following measures, that is:

> (i) his name be erased from the appropriate register and, where appropriate, recommend to the President of Malta that the professional's licence be withdrawn; or
>
> (ii) his name be taken off such register for such period of time as the relevant Council may determine and, where appropriate, recommend to the President of Malta that the professional's licence be also so suspended; or
>
> (iii) a penalty, not exceeding such amount as may be prescribed, is inflicted on the health care professional concerned; or
>
> (iv) the health care professional concerned is cautioned; or
>
> (v) order that the health care professional undergoes such period of training or practice of the profession under supervision for such period as the relevant Council may determine[48].

It is submitted that in the case of breaches of the provisions of the Bill, the Court, and/or the Authority should have the power to suspend or withdraw the professional licence (in the case of procured miscarriage, perpetual interdiction from the exercise of the profession may be ordered by the Court) or warrant of the professional involved.

Moreover, the suspension of any licences relating to the clinic involved and to the forfeiture of any premises and equipment may also be contemplated as a deterrent.

[48] Article 32 of the Health Care Professions Act.

Licensing of clinics

Licences to carry out any activity relating to medically assisted procreation are not issued to any organisation (company, association of persons, group practice, or other legal entity). According to article 22 licenses are issued in respect of "premises". Article 4 (1) (b) then provides that the Authority issues licences to "clinics" that apply for registration. On the other hand registration or the holding of a specialised licence by any professional is not a requirement for such "clinics" to house procedures of medically assisted procreation.

It is submitted that in such cases, the provision of any medically assisted procreation procedures / services should be subject to the holding of a licence from the Authority. Licenses should be issued to physical or legal persons ("operator") of a hospital or a clinic and in respect of the premises where the clinic or hospital is sited. The Authority issuing the licence should ensure not only that the premises and equipment are adequate, but that the clinic as an organisation is adequate and that all individual professionals involved are highly specialised in the field, if need be by having a specialised registers for the various professional and technicians involved in the provision of IVF procedures.

Moreover, in the best interest of the embryo and the child yet to be born, sufficient assurance or security should be provided by the operator of the clinic/hospital that the procedures and services to be provided will be according to best practice standards as may be applicable in the specific Maltese context and that the professionals and technical persons who would be involved in the procedures will be specialised in the field and entered in the appropriate specialised registers.

It would also be desirable as a matter of law to give certain powers to the Authority in the case of licenses issued by it to suspend and revoke them in cases specified by law, this without the need of waiting for a court judgment on the matter.

There would obviously also be the need to extend the jurisdiction of the Administrative Review Tribunal to review the administrative acts of the Authority. Alternatively, in view of issues that might be of a sensitive personal nature a specific tribunal might be set up for the purpose. The Bill is silent on this matter.

In addition to the penalties contemplated by the Bill, I would also add that the organisations that are involved in the activities in violation of the law would be civilly liable for the fines contemplated by the law and the premises be subject to forfeiture. This is what happens in the case of dealing in Dangerous Drugs. In this case premises would include the whole building complex of property where the premises is situated and all equipment and movables used by the organisation within the building complex. Key officials of the operator should also be responsible for the observance of the law.

Directors and administrators of such organisations would also be personally responsible through the application of the provisions of the Interpretation Act.

Conscientious objection

Article 20 of the Bill provides for the right of health care professionals to be exempted from participating in any MAP procedure if they consider such participation objectionable as a matter of conscience. The source of such an article is article 16 of the Italian law.

This provision is lacking in the following respects:

(i) It does not prohibit discrimination for having exercised the right of conscientious objection.

(ii) It does not extend to all assistance required prior to the provision of MAP procedures, when such assistance is necessary prior to the commencement of such procedure.

(iii) With regards to assistance after the procedure, the assistance that the medical professional should be required to give is that required by the Hippocratic Oath or is otherwise necessary to safeguard the health of the mother and child.

Dr. Robert Tufigno