

News and Views

Using Mentally Incompetent Adults as Living Organ Donors: Widely Diverging Regulations in Europe

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Abstract

With the current situation in Belgium as its initial focus, this article will examine the regulatory framework that governs the use of mentally incompetent adults as living organ donors in Europe. Our survey of the national regulation of 22 countries will reveal widely diverging viewpoints, ranging from an absolute prohibition on organ procurement to a barely restricted authorisation to retrieve even non-regenerable organs. We also have a look at the way in which American and English court decisions have applied the best interests standard in an attempt to define the contours of acceptable organ removal from mentally incompetent donors. Taking the best interests of the mentally incompetent person as a yardstick, we suggest that legally prohibiting organ removal from mentally incompetents may be problematic, even if it concerns only non-regenerable organs, and that regulations should be refined accordingly.

Keywords

organ donation; mentally incompetent adults; legislation; bioethics

1. Introduction: The Legal Situation in Belgium

On 12 February 2010, the Belgian Advisory Committee on Bioethics¹ was approached with an unusual request by the federal government. Laurette Onkelinx, Federal Minister for Social Affairs and Public Health, decided to consult the Committee about, inter alia, the moral acceptability of the provisions of the Belgian organ transplantation law regarding organ procurement from mentally incompetents.² Asked for the first time in its history to give advice on an existing rather than a draft law, the Committee set out to assess whether these provisions might be ethically problematic. The law under consideration was the

¹) Two of the authors are members of the Belgian Advisory Committee on Bioethics. Opinions expressed in this article represent the personal views of the authors and do not necessarily reflect the views of the other Committee members.

²) Letters from the Minister to the Committee, 12 February 2010 and 22 March 2010.

Law on the Removal and Transplantation of Organs, enacted on 13 June 1986 and partially modified on 25 February 2007.³

The Law on the Removal and Transplantation of Organs originally did not mention living donation by mentally incompetents but concerned only competent adults and minors. According to the general applicable provisions, that remain unchanged and are contained in Articles 5 and 8, organ removal from a living donor may be carried out only on competent adults who have given free, informed and prior consent, put in writing and signed both by the person involved and an adult witness. Article 6 states that, in case the organ retrieval could have severe⁴ consequences or concerns organs that cannot regenerate, it may be carried out only if the recipient's life is in imminent danger and the transplantation of organs from a deceased person would not produce as satisfactory a result. In the original version of the law, living donation by incompetent adults was not addressed. Considering Articles 5 and 8 in conjunction, this type of donation simply was not allowed at all.

However, the law of 25 February 2007 introduced a new provision, explicitly allowing organ removal from adults who are unable to express their will due to their mental state. Curiously, the amendment was made to Article 6 and, consequently, only pertains directly to organ removal with possible severe consequences to the donor or concerning organs that cannot regenerate. Under these circumstances, organ procurement may take place if the recipient's life is in imminent danger, the transplantation of organs from a deceased person would not produce as satisfactory a result, and consent has been given by the legal or personally appointed representative (or, in case such a person is not available or does not want to act, a representative appointed in accordance with the provisions of the Belgian Act on Patients' Rights of 22 August 2002). By implication, if these three conditions are met, organ removal from adults who are unable to express their will due to their mental state is also allowed if it concerns organs that can regenerate (even if this normally could have severe consequences for the 'donor').

On 9 May 2011, the Belgian Advisory Committee issued its Opinion, which unanimously considered the provisions on organ procurement from mentally incompetents in the Belgian transplantation law to be ethically unacceptable.⁵ The Committee argued that the facts that not even a criterion of last resort is upheld, the intended recipient may be totally unrelated, no approval by an inde-

³) Wet betreffende het wegnemen en transplanteren van organen/Loi sur le prélèvement et la transplantation d'organes, available at http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1986061337&table_name=wet (Dutch) and http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1986061337&table_name=loi (French).

⁴) The French and Dutch versions of the law differ slightly, in that the former only speaks about 'consequences' (des conséquences) whereas the latter mentions 'severe consequences' (ernstige gevolgen).

⁵) Belgian Advisory Committee on Bioethics, Opinion No. 50, 9 May 2011. Accessible via <http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Committees/Bioethics/Opinions/index.htm> (in Dutch and French).

pendent supervising body is needed, and transplantation may proceed even when the prospective donor faces severe health risks and indicates refusal, leave the door wide open for exploitation. At least in theory, the Belgian law currently allows an organ that does not regenerate to be procured from a mentally incompetent person and to be transplanted into a total stranger or, worse, into the person's own proxy, even if an organ from a competent donor is available, the incompetent donor would suffer severe injury, and clear indications of his refusal are available. The Committee made recommendations for revision, with some members favouring a total ban on procurement of organs that cannot regenerate from adults who are unable to express their will due to their mental state and other members opting for the introduction of additional substantive and procedural safeguards.

Somewhat surprisingly, the publication of the Opinion was soon followed by the introduction of two separate bills in Parliament, one calling for a ban on the procurement of non-regenerable organs and one calling for a ban on the procurement of non-regenerable *and* regenerable organs from mentally incompetents.⁶ By their own account, these parliamentary initiatives aim to bring the Belgian transplantation law into line with international guidelines and, more specifically, with EU Directive 2010/45/EU. If passed, the Belgian regulation on living donation by mentally incompetents could swing to the opposite side of the regulatory spectrum, from the most permissive approach to possibly a categorical prohibition.

With the current situation in Belgium as its initial focus, this article will examine the regulatory framework that governs the use of mentally incompetent adults as living organ donors in Europe.⁷ In our survey, we will concentrate on 21 additional countries: Austria, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland, and the United Kingdom. In Section 2, we analyse the standards provided by *international guidelines*. We first consider the recommendations for the protection of mentally incompetent adults that pertain to the medical context in general and next turn our attention to the recommendations that more specifically concern

⁶ C. Fonck. Wetsvoorstel betreffende het wegnemen van organen bij wilsonbekwame levende personen/Proposition de loi concernant le prélèvement d'organes sur des personnes vivantes qui ne sont pas en mesure de manifester leur volonté, 5 October 2011, available at <http://www.lachambre.be/FLWB/PDF/53/1780/53K1780001.pdf>; J. Brotschi et al. Wetsvoorstel tot wijziging van artikel 6, § 2, van de wet van 13 juni 1986 betreffende het wegnemen en transplanteren van organen/Proposition de loi modifiant l'article 6, § 2, de la loi du 13 juin 1986 sur le prélèvement et la transplantation d'organes, 11 May 2011, available at www.senate.be/www/?MIval=/dossier&LEG=5&NR=1024&LANG=nl (Dutch) and www.senate.be/www/?MIval=/dossier&LEG=5&NR=1024&LANG=fr (French).

⁷ This article will focus only on mentally incompetent adults who have not been competent before. The situation of mentally incompetent adults who have been competent before (i.e., Alzheimer patients) is more complex, since in this case regulation will not only need to be based on the best interests standard but also on the substituted judgment standard. These standards may sometimes come into conflict with each other.

organ procurement. In Section 3, we explore *national regulations* regarding the use of mentally incompetent adults as living organ donors. Our survey will reveal widely diverging viewpoints. Half of the countries under consideration have opted for a ban on the harvest of both non-regenerable and regenerable organs from mentally incompetents. The other half allow removal of regenerable organs from mentally incompetents under strict conditions. Of the latter countries, only four also authorise removal of a non-regenerable organ from mentally incompetents. In contrast to current Belgian legislation, very strict requirements are imposed in the three other countries at issue. Subsequently, in Section 4, we have a look at the way in which US and English court decisions have applied the best interests standard in an attempt to define the contours of acceptable organ removal from mentally incompetent donors. In Section 5, taking the best interests of the mentally incompetent person as a yardstick, we suggest that legally prohibiting organ removal from mentally incompetents may be problematic, even if it concerns only non-regenerable organs, and that regulations should be refined accordingly. We conclude that, while the current Belgian legislation is far too permissive, the total prohibition that is now on the table would be overly restrictive.

2. Living Organ Procurement from Mentally Incompetents in International Guidelines

Before analysing national regulations regarding living organ removal from mentally incompetent adults, we will focus on how mentally incompetents are protected in international human rights instruments and international transplantation guidelines.

2.1. International Standards for the Protection of Mentally Incompetent Adults

International standards for the protection of mentally incompetents have been developed in the *Convention on the Rights of Persons with Disabilities*, which was adopted by the United Nations General Assembly in December 2006 and entered into force in May 2008.⁸ The Convention invites the contracting parties to take all appropriate legislative measures to guarantee persons with disabilities effective legal protection against discrimination and exploitation, to promote respect for their inherent dignity and physical and mental integrity, and to give them the opportunity to be actively involved in decision-making processes on issues directly concerning them. Similar objectives have been put forward in a draft proposal for an *EU Directive on Implementing the Principle of Equal Treatment Between Persons*

⁸) United Nations, Convention on the Rights of Persons with Disabilities, available at <http://www.un.org/disabilities/convention/conventionfull.shtml>.

Irrespective of Religion or Belief, Disability, Age or Sexual Orientation, which has been under discussion since 2008.⁹

More specific propositions can be found in the Recommendation *Rec(99)4E on Principles Concerning the Legal Protection of Incapable Adults*, adopted by the Committee of Ministers of the Council of Europe in February 1999.¹⁰ Apart from calling on Member States to develop a system of representation sufficient to guarantee adequate protection of mentally incompetent persons, the Recommendation sets out general principles which are to be taken into account. Most importantly, it emphasizes that ‘in establishing or implementing a measure of protection for an incapable adult the interests and welfare of that person should be the paramount consideration.’ In addition, measures of protection should be proportional to the mental capacity of the individuals concerned and tailored to their individual circumstances and needs. This implies that, with regard to every major decision affecting them, their wishes and feelings should be determined as far as possible, the information provided should be appropriate to their level of cognitive development, and their opinion should be given due respect. The Recommendation explicitly states that, when their capacity permits them to do so, mentally incompetents should not automatically be deprived of the right to consent or refuse consent to any intervention in the health field. Although these principles are considered to be of vital importance, it remains rather unclear what they would amount to in practice in the context of organ procurement.

2.2. *International Transplantation Guidelines*

2.2.1. *Non-binding International Instruments*

Numerous international organisations have enacted guidelines for living organ donation. In May 1991, the World Health Assembly endorsed several *Guiding Principles on Human Tissue, Cell, and Organ Transplantation*, which were last revised in May 2010.¹¹ Guiding Principle 3 sets forth some basic conditions for living donation. This procedure is acceptable only when the donor has given free and informed consent after having been presented with complete and understandable information on the probable risks, benefits, and consequences of donation. The donor must be legally competent, capable of weighing up the information, and under no undue influence. As a rule, donors should only donate to recipients to whom they are genetically, legally or emotionally related. Guiding

⁹ The proposal may be consulted at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0426:FIN:EN:PDF>.

¹⁰ Committee of Ministers of the Council of Europe, *Rec(99)4E on Principles Concerning the Legal Protection of Incapable Adults*, available at http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec%2899%294E.pdf.

¹¹ World Health Assembly, *WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation*, available at http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf.

Principle 4 explicitly considers the use of mentally incompetents as organ donors. It stipulates that, just as is the case for minors, no tissues or organs should be removed from a legally incompetent person for the purpose of transplantation. However, narrow exceptions may still be allowed under national law. In this regard, the commentary to the Guiding Principle hints at the possibility of donation of regenerable organs when no other suitable donor is available. Where national legislation would indeed allow organ removal from a mentally incompetent person, specific protective measures should be put in place and the person's own opinion should be given appropriate consideration.

The World Medical Association's *Statement on Human Organ Donation and Transplantation*, adopted in October 2000 and revised in October 2006, underlines the need to ensure that the choice to donate is informed and free of coercion.¹² Prospective living donors should be provided with all relevant information, including information about the risks and benefits of transplantation. In addition, special efforts should be made to prevent undue pressure, for instance by guaranteeing that the donor's consent is obtained by a physician who is not part of the recipient's transplant team. The Statement emphasises that individuals incapable of making informed decisions, such as minors or mentally incompetent persons, should not be considered as potential living donors 'except in extraordinary circumstances and in accordance with ethics committee review or established protocols.'

In 2004 and 2006 respectively, the Ethics Committee of the Transplantation Society issued its *Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor* and its *Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor*.¹³ These Statements recommend that the potential donor of a non-regenerable organ be provided with detailed information regarding the health, psychological, economic, and social risks of the surgical procedure, the expected transplant outcomes for the intended recipient, and the alternative therapies available. In addition, all potential donors should undergo prior psychosocial screening and the consent procedure should incorporate mechanisms to evaluate whether the donor understands the information and decides voluntarily. Efforts should be made to ensure that the information is provided and the assessments are made by health care professionals who are not involved in the care of the recipient. Finally, safeguards should be implemented to enhance autonomous decision-making and after consent has been given, absolute

¹² <http://www.wma.net/en/30publications/10policies/t7/index.html>. See also the October 2007 World Medical Association's Statement on human tissue for transplantation, available at <http://www.wma.net/en/30publications/10policies/t6/index.html>.

¹³ The Ethics Committee of the Transplantation Society, "The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor", *Transplantation* 78(4) (2004) 491-492; The Ethics Committee of the Transplantation Society, "The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor", *Transplantation* 81(10) (2006) 1386-1387.

freedom to withdraw at any time prior to removal should be guaranteed. The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor implicitly recommends that mentally incompetents not be used as living kidney donors, since they are incapable of giving true informed consent. Rather surprisingly, the Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor leaves the door open for the removal of non-regenerable organs that may cause more severe health risks to the donor. According to the Statement, mentally incompetents should not be used as living lung, liver, pancreas or intestine donors, but in rare instances this might still be considered.

In May 2008, the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* was adopted under the aegis of the Transplantation Society and the International Society of Nephrology.¹⁴ Apart from suggesting strategies to increase the donor pool, to optimise transplantation programmes, and to prevent organ trafficking, transplant commercialism, and transplant tourism, the Declaration calls for universal implementation of the recommendations of the Amsterdam and Vancouver Forums. The Declaration makes only broad suggestions and has no immediate bearing on the position of mentally incompetent living donors.

2.2.2. *Binding International Instruments*

Although the guidelines, statements, and declarations have considerably influenced national legislation, professional codes, and transplantation policies, they are not directly binding on those to whom they are addressed. By contrast, the European Union and the Council of Europe have adopted instruments that are legally binding on the contracting states.

The *Directive 2010/45/EU on Standards of Quality and Safety of Human Organs Intended for Transplantation*, approved by the European Parliament on 7 July 2010, contains some general principles regarding living organ donation, although its primary objective is to establish an effective framework for quality and safety of human organs. It calls on European Union Member States to take all necessary measures to guarantee the highest possible protection of living donors, to ensure that living donation is voluntary and unpaid, and to allow living organ procurement only after all national requirements relating to consent and authorization have been met. More specifically, the Directive, in its (non-binding) preamble, requires that the potential living donor should be informed in advance about the purpose and nature of the donation, the consequences, and the risks, and that she has to be able to make an independent decision on the basis of this information. Moreover, living donations have to be performed in a manner that minimises the health, psychological and social risks to the donor and also does not jeopardise

¹⁴) “The Declaration of Istanbul on Organ Trafficking and Transplant Tourism”, *Nephrology Dialysis and Transplantation* 23 (2008) 3375–3380.

the public's trust in the healthcare community.¹⁵ As usual, the implementation of these general principles is left to the discretion of the individual Member States. The Directive offers no specific guidance on the topic of living donation by mentally incompetent.

A more detailed framework is sketched in the *Convention on Human Rights and Biomedicine*, which was adopted by the Council of Europe on 4 April 1997 and entered into force on 1 December 1999.¹⁶ As a general rule, Article 19, paragraph 1 states that the removal of organs or tissue from living donors for transplantation purposes 'may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.' Article 19, paragraph 2 requires prior consent by the potential living donor, given both free and informed, expressly and specifically, either in writing or before an official body. In accordance with Article 5, this consent must be preceded by disclosure of appropriate information about the purpose, nature, consequences, and risks of the intervention, and may be freely withdrawn at any time.

In January 2002, the Convention on Human Rights and Biomedicine was complemented with an *Additional Protocol on Transplantation of Organs and Tissues of Human Origin*.¹⁷ Apart from reiterating the basic principles already laid down in the Convention, the Additional Protocol contains detailed provisions on living organ donation that are considered additional articles to the Convention. Article 10 restricts living organ donation to persons who have a close personal relationship with the recipient as defined by law or, in the absence of such a relationship, only to donations under the conditions defined by law and with the approval of an appropriate independent body. In addition, Article 11 explicitly calls for an *a priori* assessment of the physical and psychological risks to the donor and prohibits organ or tissue removal if a serious risk to the life or health of the donor is indeed likely. With regard to the information to be presented to the donor, Article 12 specifies that the donor shall also be informed of the rights and safeguards prescribed by law for her protection and, more specifically, of the right to have access to independent advice by experienced health professionals not involved in the transplantation procedure.

In addition to the Convention and its Additional Protocol, a range of motions have been adopted by the Committee of Ministers of the Council of Europe with

¹⁵ Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, preamble para. 23 and Art. 15(1), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF>.

¹⁶ The text of the Convention is available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

¹⁷ The Additional Protocol was adopted on 24 January 2002 and entered into force on 1 May 2006 (after its ratification by 5 parties). The text is available at <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>.

a view to regulating living organ donation. Most important of these are *Resolution CM/Res(2008)6 on Transplantation of Kidneys from Living Donors Who Are Not Genetically Related to the Recipient* and *Resolution CM/Res(2008)4 on Adult-to-Adult Living Donor Liver Transplantation*, both reaffirming the main principles of the Convention and Additional Protocol.¹⁸

The Convention on Human Rights and Biomedicine and the Additional Protocol on Transplantation of Organs and Tissues of Human Origin are the only international instruments containing detailed provisions on organ procurement from mentally incompetents. As a general rule, Article 6, paragraph 1 of the Convention, stipulates that medical interventions on a person who lacks the capacity to consent may only be carried for her 'direct benefit'. Consequently, as a cardinal principle, Article 20, paragraph 1 of the Convention imposes a general prohibition on organ or tissue removal from persons who lack the legal ability to consent. However, Article 20, paragraph 2 permits removal of regenerable tissue, provided that — in addition to the general provisions concerning living donation set forth in Article 19 — six cumulative requirements are met: (1) no compatible donor is available who has the capacity to consent, (2) the recipient is a sibling of the donor, (3) the recipient is terminally ill and the donation has the potential to be life-saving, (4) the representative or authority, person or body provided for by law has given free and informed, specific and written authorisation, in accordance with the law, (5) this authorisation has been approved by a competent body (a court, professionally qualified body or ethics committee),¹⁹ and (6) the potential donor does not object. Furthermore, in keeping with Article 6, paragraph 3, the incompetent individual should as far as possible take part in the authorisation procedure. Finally, Article 6, paragraph 5, provides that the authorisation may be withdrawn at any time in the best interests of the person who lacks the legal ability to consent. This stipulation indicates that the best interests of the person concerned are of crucial importance when deciding whether or not to authorise organ or tissue removal. All these provisions are reiterated in the Additional Protocol. All in all, the Convention and the Additional Protocol allow organ or tissue procurement from adults who lack the capacity to consent, but only if it involves organs or tissues that can regenerate and if seven substantive and four procedural requirements are met.

¹⁸ Available at <https://wcd.coe.int/ViewDoc.jsp?Ref=CM/Res%282008%296> and <https://wcd.coe.int/ViewDoc.jsp?Ref=CM/Res%282008%294>.

¹⁹ Explanatory Report to the Convention on Human Rights and Biomedicine, para. 129, available at <http://conventions.coe.int/treaty/en/Reports/Html/164.htm>.

3. Living Organ Procurement from Mentally Incompetents in National Regulations

3.1. General Considerations

We will now take a closer look at the way living organ removal from mentally incompetents is regulated in the countries under consideration. Before proceeding, it is important to note that a wide variety of legal and non-statutory instruments pertaining to living organ donation may exist at the national level. As a rule, living donation is regulated by parliamentary acts, often supplemented by executive decrees. Across national regulations, considerable differences may be observed regarding the level of detail of the legal dispositions, with some countries having enacted only minimal standards while others have opted for comprehensive and detailed provisions. Especially in the former case, living organ donation may also be governed by binding or non-binding guidelines elaborated by national health or transplant authorities or by codes of practice or ethical guidelines developed within the context of a professional association or an ethics committee on the national, regional or hospital level. In Austria and Ireland, no legal instruments regarding living organ donation have been adopted.²⁰ In all other countries under consideration, living organ donation is regulated in a transplantation law.²¹

Moreover, any analysis of the national regulatory framework is also complicated by the uneven ratification of the Convention on Human Rights and Biomedicine and its Additional Protocol. To this day, the Convention has only been ratified by 29 of the 47 Member States of the Council of Europe.²² Of the countries under consideration here, 11 have ratified the Convention.²³ The ratification rate of the Additional Protocol is even considerably lower, with only 12 of the aforementioned 29 Member States having taken such an initiative.²⁴ Of the countries that we will examine, only four have ratified the Additional Protocol.²⁵

²⁰ With regard to Austria, procedural requirements are listed in a position paper on living donation issued in 2005 by the Advisory Committee on Transplantation of the *Österreichisches Bundesinstitut für Gesundheitswesen*. See *Lebendspende: Positionspapier des am ÖBIG eingerichteten Transplantationsbeirates*, available at http://www.goeg.at/cxdata/media/download/berichte/Positionspapier_zur_Lebendspende2005.pdf. In Ireland, they are clearly spelled out in the ethical guidelines drafted for the Irish *Living Donation Programme*, pending the adoption of the Human Tissue Bill.

²¹ See the listing of relevant national legal instruments at the end of this article.

²² An up-to-date list of ratifications can be consulted at <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.aspx?NT=164&CM=8&DF=18/02/2012&CL=ENG>.

²³ Bulgaria, Czech Republic, Denmark, Finland, France, Greece, Hungary, Norway, Portugal, Romania, Spain, and Switzerland.

²⁴ An up-to-date list of ratifications can be consulted at <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.aspx?NT=186&CM=8&DF=18/02/2012&CL=ENG>.

²⁵ Bulgaria, Finland, Hungary, and Switzerland.

In countries that have ratified, the provisions of the Convention (and, as the case may be, those of the Additional Protocol) are to be given effect as national regulation.²⁶ Domestic law and practices may comply with the Convention by adapting existing legislation or enacting new legislation. However, even in the absence of any formal way of implementation, it should be noted that a number of provisions would, under the constitutional law of the ratifying Member States, qualify as directly applicable, namely those conferring individual rights that are unconditional, sufficiently clear and precise, and do not call for additional measures.²⁷ In this respect, the restrictions on organ and tissue removal from mentally incompetents may be considered as directly binding. However, the direct applicability of these provisions does not imply that, in all ratifying Member States, this type of organ and tissue removal is subject to exactly the same conditions as those set forth in the Convention. Indeed, by virtue of Article 27, parties to the Convention may always grant their citizens a wider scope of protection.²⁸

Concern for the personal integrity and dignity of mentally incompetents has resulted in the formulation of a range of different proposals at the level of national regulation. Some impose a total ban on all organ harvests from mentally incompetents. Equally moved by a sense of obligation to help people in desperate medical need, other national regulations allow organ procurement when the foreseeable risks to the mentally incompetent organ source are very limited and the potential benefits to the intended recipient are huge. A few allow organ removal from a mentally incompetent person even if it could entail more than minimal risk, if the psychosocial benefits she would likely receive from providing an organ can reasonably be expected to significantly outweigh the risks, and if several additional threshold requirements are satisfied. In sum, in the countries under consideration here, living organ donation by incompetent adults is regulated in very heterogeneous ways, ranging from an absolute prohibition on organ procurement to a barely restricted authorisation to retrieve even non-regenerable organs. We will examine this continuum by proceeding from the most restrictive to the most permissive approach.

3.2. Countries that Prohibit Procurement of Both Regenerable and Non-regenerable Organs

In ten of the 21 countries that we have analysed, procurement of both regenerable and non-regenerable organs from mentally incompetent adults is prohibited. This

²⁶ See the Convention on Human Rights and Biomedicine, Art. 1 and the Explanatory Report to the Convention on Human Rights and Biomedicine, para. 20.

²⁷ See the Explanatory Report to the Convention on Human Rights and Biomedicine, para. 20. See also the legal doctrine on the effect of European law on domestic law as, elaborated in the judgments of the Court of Justice with respect to European Union law.

²⁸ See the Explanatory Report to the Convention on Human Rights and Biomedicine, paras. 161–162.

is the case for Austria, Bulgaria, Denmark, Germany, Greece, Italy, Luxembourg, Poland, Romania, and Spain, and may also be the future solution favoured by the Belgian legislator. In Austria, Denmark, and Germany, the legal prohibition is implicit, in that mentally incompetents are not capable of fulfilling the necessary requirement of informed consent. In Italy, Luxembourg, and Poland, the ban is more explicit, in that a living donor has to be in full possession of her mental faculties. In Bulgaria, Greece, Romania, and Spain, the law contains a specific provision prohibiting the use of mentally incompetents as living organ donors. It is interesting to note that Bulgaria, Denmark, Greece, Romania, and Spain have all ratified the Convention on Human Rights and Biomedicine but have opted for much stricter regulation, prohibiting even the procurement of regenerable organs from mentally incompetents.

3.3. *Countries that Allow Procurement of Regenerable Organs Only*

Eight of the 21 countries under consideration only allow removal of regenerable organs from mentally incompetent adults. This is the case for the Czech Republic, Finland, France, Hungary, The Netherlands, Norway, Portugal, and Switzerland. With the exception of The Netherlands, all of these countries have ratified the Convention on Human Rights and Biomedicine. Finland, Hungary, and Switzerland have also ratified the Additional Protocol on Transplantation of Organs and Tissues of Human Origin. Although few of these ratifying states have amended their transplantation laws accordingly, possible additional requirements listed in the Convention and the Additional Protocol are applicable. Because the Dutch transplantation law coincidentally also seems to closely resemble the Convention in this regard, the provisions on the procurement of regenerable organs from mentally incompetents are very similar in all eight countries.

Several substantive requirements apply to living donation in general. Accordingly, removal of a regenerable organ from a mentally incompetent adult is allowed only for the *therapeutic benefit* of an intended recipient, if *no suitable cadaveric organ* is available, and if *no alternative therapeutic treatment of comparable effectiveness* exists. In the case of mentally incompetent organ donors, the criterion of last resort is supplemented with the additional requirement that *no compatible competent living donor* is available.

The next two requirements aim at guaranteeing a reasonable benefit-to-risk ratio, considering that mentally incompetents do not have the ability to autonomously accept a low benefit-to-risk balance. First, mentally incompetents may only be considered as donors if the *intended recipient is in mortal danger* and the transplantation has the *potential to be life-saving*. Exposing a vulnerable person to such an intrusive medical procedure merely to improve the quality of life of a third party is clearly deemed unacceptable. *Second*, organ harvest from mentally incompetents is only allowed if the *health risks to the donor are reasonable*. Although

this requirement also applies to competent donors, the acceptable maximum threshold of anticipated risk will have to be considerably lower in case of incompetent donors. In the eight countries under consideration, this line of reasoning helps to explain why removal of a non-regenerable organ may be carried out on competent but not on incompetent donors.

As an additional requirement, procurement of a regenerable organ may only be carried out if the mentally incompetent person herself will *psychologically benefit* from the intervention. This condition is explicitly mentioned in the Dutch transplantation law, where it is stated that the mentally incompetent person must have a personal and keen interest in the continued survival of the intended recipient. Although the legislations of the seven other countries do not contain a similar provision, the requirement that the transplant procedure should be of psychological benefit to the mentally incompetent donor may be inferred from Article 6, paragraph 5 of the Convention on Human Rights and Biomedicine.²⁹

The need for psychological benefit is also implied by the condition that mentally incompetents may only donate to a recipient with whom they are closely related, on the assumption that the interests of the mentally incompetents would be severely compromised by the death of a person with whom they presumably have a high degree of emotional intimacy. As to the nature of acceptable relationships between recipients and mentally incompetent donors, some variation exists. All countries allow organ removal from a mentally incompetent person *for the benefit of her sibling*. In The Netherlands and Switzerland, donation to a parent or a child is also allowed. The transplantation law of Norway exceptionally even allows more distant relatives to be considered as recipients. In France, donation to a cousin, uncle or aunt, nephew or niece is envisaged but, surprisingly, parents and children are not explicitly mentioned. However, the Convention on Human Rights and Biomedicine only mentions siblings as an acceptable category of recipients. Although parents and children may possibly also be considered permissible, since they are relatives of a closer degree of consanguinity, this probably will not be the case for more distant relatives.

In addition, the transplant legislation in the countries under consideration also contains procedural requirements intended to protect the mentally incompetent organ donor. First, the *guardian* of the mentally incompetent person has to give *free and informed authorisation*. Second, the potential *donor* should as far as possible be *consulted*. It will thus be necessary to explain to her the significance and

²⁹) A medical intervention involving mentally incompetents should only be allowed if this is in their interests. In case of organ removal, this deliberation will be central to the authorisation process where the fulfilment of all substantive requirements is evaluated. Since organ removal cannot be to the therapeutic benefit of the mentally incompetent person, her interests will only be served if she will likely gain psychological benefit from saving the intended recipient. See Explanatory Report to the Convention on Human Rights and Biomedicine, para. 48, available at <http://conventions.coe.int/treaty/en/Reports/Html/164.htm>.

circumstances of the organ removal and subsequently to obtain her opinion. If there is an indication of refusal, organ removal must not be carried out. Third, an *independent competent body* has to give *final authorisation*. In the Czech Republic and Hungary, this decision is taken by the pluridisciplinary living donor commissions. In Norway, additional permission by a County Medical Officer has to be obtained. In France and The Netherlands final decision-making authority is delegated to a judge, in Finland and Portugal a professionally qualified body at the national level is petitioned, and in Switzerland an independent authority, that may be either a court or a Guardianship Supervisory Authority,³⁰ has to grant final approval.

3.4. *Countries that Allow Procurement of Both Regenerable and Non-regenerable Organs*

Removal of a non-regenerable organ from a mentally incompetent person is allowed in four European countries only. Apart from Belgium, where the current regulation is extremely permissive, as noted earlier, this is the case for Ireland, Sweden, and the United Kingdom.

In *Ireland*, organ procurement from mentally incompetents is currently governed by a set of ethical guidelines drafted for the Irish *Living Donation Programme*.³¹ The principles embodied in these guidelines have greatly inspired the legal provisions envisaged in the draft Human Tissue Bill and the draft Mental Capacity Bill, which are pending adoption.³² Both the guidelines and the draft Bills allow procurement of regenerable and non-regenerable organs from mentally incompetents but subject this to severe restrictions.

Several of these restrictions also apply to living donation in general. For instance, it is required that the proposed organ removal solely aims at the therapeutic benefit of an intended recipient and that no cadaveric organs or therapeutic alternatives of comparable effectiveness are available. Other criteria focus on the need for adequate substitute decision-making in the absence of the donor's ability to provide informed consent. In this case, free, informed, and written proxy consent has to be provided by the incompetent's personal guardian or a person conferred with enduring power of attorney. These decision-makers should

³⁰ The Swiss transplantation law stipulates that it is up to each canton to establish the independent body and regulate the procedure. The explanatory report to the Swiss transplantation law clarifies that the function of the independent body could be performed by either a civil court or a Guardianship Supervisory Authority. In practice, a wide range of bodies have been selected, varying from one canton to another. We would like to thank Dr. Bianka Dörr (Senior lecturer in Private Law at the University of Zurich) for providing this information.

³¹ We would like to thank Dr. Sióbhán O'Sullivan (Lecturer in Healthcare Ethics and Law at the Royal College of Surgeons of Ireland, Dublin) for providing this information.

³² See Draft Proposals for General Scheme of the Human Tissue Bill 2009, available at http://www.dohc.ie/consultations/closed/human_tissue_bill/draft_proposals.pdf?direct=1; Scheme of Mental Capacity Bill 2008, available at http://www.inis.gov.ie/en/JELR/Pages/Scheme_of_Mental_Capacity_Bill_2008.

seek the active assent of the person concerned to the greatest extent possible and may not authorise organ removal if she is unwilling. After proxy consent has been given and assent has been secured, authorisation from the High Court has to be obtained. Both the decision-makers and the High Court may only approve organ removal if they are convinced that this procedure would be in the incompetent donor's overall best interests. In addition, several requirements are introduced that are more strict than those regarding organ donation by competent persons. For instance, the ethical guidelines stipulate that organ removal from a mentally incompetent person may be allowed only if there is no competent donor available and if the proposed transplant will be of great benefit to the recipient and would entail only minimal risk and discomfort to the donor. With regard to the nature of the permissible relationship between the donor and the recipient, it is made clear that organ removal is only acceptable for the benefit of a recipient with whom the mentally incompetent donor has an intimate relationship (i.e., a sibling or a parent), whereas in case of living donation by competent adults there is only a preference for a recipient with whom the donor has a close personal relationship.

Both the guidelines and draft Bills in Ireland leave the door open for kidney removal from mentally incompetents. Although, as of now, such a case has yet to arise, it is deemed that even this kind of organ harvest may under exceptional circumstances be in the best interests of the incapacitated adult and that this is a matter for the High Court to decide on a case-by-case basis.

In *Sweden*, organ removal from mentally incompetents is regulated by the Transplantation Law of 1995. This Law allows the removal of both regenerable and non-regenerable organs if several requirements are met. Like all other types of living donation, the procedure is not allowed if it can be expected to cause serious danger to the donor's health. In contrast to living donation by competent adults — which is allowed if the donor has given informed consent and, in case of non-regenerable organs, stands in a particularly close relationship with the prospected recipient or provides convincing reasons to allow living unrelated donation — much stricter provisions apply when the intended donor is mentally incompetent. This kind of organ procurement is allowed only if no suitable organ from another person is available, if the mentally incompetent person is related to the proposed recipient, if her legal guardian gives free and informed proxy consent, and if there is no indication that the intervention would be against her will. The Law also requires prior permission from the National Board of Health and Welfare. This authorization may be granted only if the donor's transplant surgeon agrees and, in the case of removal of non-regenerable organs, if exceptional reasons make it appropriate.³³ Guidelines issued by the National Board of Health and Welfare stipulate that serious danger to the recipient's life or health may be

³³) Lag om transplantation m.m. 8 juni 1995, §§ 5-8.

considered an exceptional reason.³⁴ Although the Law gives no indication as to how the National Board should reach its decision, it may be presumed that due to its specific purpose and the general obligation to act on behalf of the mentally incompetent person, the Board will only permit organ removal to proceed if it is convinced that this would be in her best interests.

In the *United Kingdom*, with the exception of Scotland,³⁵ organ removal from mentally incompetents is regulated in the Mental Capacity Act 2005, the Human Tissue Act 2004, and the Human Tissue Act Regulations 2006/1659. In accordance with the Human Tissue Act and its Regulations 2006/1659, a strict procedure must be followed when organ removal from a mentally incompetent person is being considered. First, the case must be referred to the Court of Protection³⁶ for a declaration that the removal would be lawful.³⁷ If court approval has been obtained, the case must be referred to the Human Tissue Authority for additional approval. In order to assist the Authority's deliberations, a written recommendation has to be submitted by an independent Assessor, a professional attached to a hospital transplant unit with the responsibility to assess whether the requirements of the Human Tissue Act and Regulations have been met.³⁸ The Assessor has to ensure that proxy consent has been given freely and on the basis of complete and intelligible information. The Human Tissue Act stipulates that, if all requirements have indeed been fulfilled, the mentally incompetent donor herself may be deemed to consent to the organ removal.³⁹ Following consideration of the Asses-

³⁴ SOSFS 2009:30 Socialstyrelsens föreskrifter om donation och tillvaratagande av organ, vävnader och celler, 6 Kap, §§1–2, available at http://www.socialstyrelsen.se/sosfs/2009-30#anchor_5.

³⁵ In Scotland, organ removal from mentally incompetents is regulated in the Adults with Incapacity (Scotland) Act 2000, the Human Tissue (Scotland) Act 2006, and the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. According to these instruments, removal of regenerable organs is allowed if there is no other adult who could act as a donor, the removal involves at most a minimal foreseeable risk and discomfort, and the person concerned has not indicated an unwillingness to be a 'donor'. Where these requirements have been fulfilled, the mentally incompetent person needs to be referred to an independent Assessor and final decision-making authority is delegated to the Human Tissue Authority. Removal of a non-regenerable organ from a mentally incompetent person is allowed only as part of a domino organ transplant operation (i.e., a transplant procedure during which an organ is removed from the recipient which in turn may prove suitable for transplantation into another person). Since this form of donation is not regulated by the Human Tissue Act, the procedure is not subject to approval by the Human Tissue Authority but is instead covered by the common law.

³⁶ The Court of Protection is a specialised court established by the Mental Capacity Act for all issues relating to people who lack capacity to make specific decisions. It has the same powers and authority as the High Court, which dealt with these matters before the Act came into force in October 2007.

³⁷ See Human Tissue Authority Code of Practice 6 — Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation, para. 93, available at <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code6donationofbonemarrow.cfm>; Human Tissue Authority Code of Practice 2 — Donation of Solid Organs for Transplantation, para. 50, available at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>.

³⁸ Human Tissue Authority Code of Practice 6 — Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation, paras. 55 and 57; Human Tissue Authority Code of Practice 2 — Donation of Solid Organs for Transplantation, paras. 62 and 64.

³⁹ Human Tissue Act 2004, Sect. 6.

sor's report and the requirements laid down in the Act and Regulations, the Authority has to decide whether to approve organ removal or not. Permission is required from one of the Human Tissue Authority transplant approval teams in the case of regenerable organs and from a panel of no fewer than three members of the Human Tissue Authority in the case of non-regenerable organs.⁴⁰

According to the Mental Capacity Act, all decisions involving an adult⁴¹ who lacks capacity must be made in that person's best interests.⁴² Consequently, both the Court of Protection and, in cases approved by this Court, the independent Assessor and the Human Tissue Authority should make their decision as to whether to proceed with organ removal from a mentally incompetent adult on the basis of a *test of best interests*. Although the Act does not actually define best interests, it contains a set of key principles and a checklist that is expanded upon in the Mental Capacity Act Code of Practice.⁴³ Decision-makers are instructed to take into account all relevant factors that it would be reasonable to consider. They should try to find out the values and wishes of the incompetent person and, wherever possible, involve her in the decision-making process. Apart from the best interests standard, no specific substantive requirements are imposed — e.g. the absence of alternatives, minimal health risks to the donor, huge health benefits to the recipient, close relationship with the recipient. However, it can be readily assumed that all these factors are given due consideration as elements that jointly determine whether organ removal may be in the mentally incompetent's best interests.

4. The Best Interests Standard

In countries where organ removal from mentally incompetents is not prohibited, the decision on whether or not to authorise such a procedure should depend on a moral deliberation that focuses on their best interests. As we have seen, the best interests standard is not explicitly mentioned in the transplant legislation of countries that allow removal of regenerable organs only. However, an evaluation of the foreseeable risks and benefits of the intervention to the incompetent is the purpose of several substantive requirements (e.g. health risks to the donor are reasonable, recipient has to be a sibling, and there is no indication of refusal). Moreover, Article 6, paragraph 5 of the Convention on Human Rights and

⁴⁰ Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, R. 12(1) and (3).

⁴¹ It may be important to note that adults are defined in the Mental Capacity Act as 16 or over, whereas the Human Tissue Act defines adults as 18 or over.

⁴² See Mental Capacity Act 2005, Sect. 1(5), available at http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf.

⁴³ See Mental Capacity Act 2005, Sect. 4; Mental Capacity Act 2005 Code of Practice, Chapt. 5, available at <http://www.justice.gov.uk/downloads/protecting-the-vulnerable/mca/mca-code-practice-0509.pdf>.

Biomedicine, to which seven of these countries are parties, indicates that in cases where all substantive criteria are satisfied, the final decision should give due weight to the best interests of the mentally incompetent person.

To aid reflection upon the circumstances under which organ removal from a mentally incompetent person may be deemed to be in her best interests, it is useful to examine some decisions from English and US courts, where the best interests requirement is more explicitly invoked and courts have been petitioned to authorise this kind of intervention.

The best interests standard has been applied in two famous cases regarding removal of a *regenerable* organ from a mentally incompetent. In *Re Y*, a case from 1996, the Family Division of the High Court of England and Wales was petitioned with a request to authorise bone marrow procurement from 25-year-old, severely mentally incapacitated Y for the benefit of her 36-year-old sister P.⁴⁴ Similarly, in *Matter of Doe*, a case that was decided in 1984, the Appellate Division of the New York Supreme Court was presented with a request to grant permission for bone marrow procurement from a 43-year-old, severely mentally retarded man for transplantation in his critically ill 36-year-old brother.⁴⁵ In both cases, bone marrow procurement was authorised after it was established that the procedure would be of only minimal risk to the incompetent person, that it was the only reasonable medical option to save the sibling's life, and that it would be in the incompetent's best interests. The Courts argued that the survival of the recipient would plausibly result in important emotional, psychological, and social benefits. As to *Re Y*, the High Court was convinced that the death of P would adversely affect the level of care Y would receive from her mother. Moreover, in case of successful transplantation, the relationship with her mother and her sister would be improved due to their gratitude. With regard to *Matter of Doe*, the intended recipient was the incompetent's sole sibling and the only family member truly involved in the placement and treatment decisions for the incompetent. Consequently, the Appellate Court agreed that 'the benefits to him of his brother's future company and advocacy outweigh any physical and psychological risks.'

Although to date no request to authorise *kidney* removal from a mentally incompetent person has been filed before the Family Division of the High Court of England and Wales, or its successor, the Court of Protection, it might be argued that on similar facts and following the same reasoning, this may be judged to be in the incompetent's best interests under the Mental Capacity Act.⁴⁶ By contrast, US courts have on several occasions been petitioned to permit kidney removal from a mentally incompetent person and have in their judgment invariably

⁴⁴ *Re Y* [1996] 2 FLR 787 (Fam Div).

⁴⁵ *Matter of John Doe* [1984] 481 N.Y.S.2d 932 (App Div).

⁴⁶ See J. Herring, *Medical Law and Ethics*, (Oxford: Oxford University Press, 2010) p. 424; S.D. Pat-
tinson, *Medical Law and Ethics*, (London: Sweet & Maxwell, 2009) p. 478.

resorted to the best interests standard.⁴⁷ In *Strunk v. Strunk*, a path-breaking case from 1969, kidney removal from 27-year-old mentally incompetent Jerry Strunk for the benefit of his 28-year-old brother Tommy was authorised by the Court of Appeals of Kentucky.⁴⁸ Similarly, in *Little v. Little*, a case from 1979, kidney removal from 14-year-old Anne, suffering from Down's syndrome, for the benefit of her brother Stephen, was authorised by the Court of Civil Appeals of Texas.⁴⁹ Both Courts listed similar reasons to support their ruling. It was pointed out that there were no medically preferable alternatives to the transplant, that the chances of obtaining a suitable cadaveric kidney were extremely remote, that the incompetent sibling was the only family member who was an acceptable match, that the estimated success rate of the transplant was very high, that parents and guardian consented to the donation, and that the incompetent donor had not been subjected to family pressure when stating her willingness to donate.

However, what really persuaded the Courts was the assessment that the benefits that the mentally incompetents would gain from the donation would far outweigh the risks they would likely face. The dangers of the operation were deemed to be only minimal and no psychological harm was said to be expected. By contrast, in view of the close relationship between the siblings, their concern for each other's well-being, and the incompetents' awareness that they were in a position to help their ailing sibling, according to the Court a refusal to donate would result in severe psychological distress.

Preventing the negative psychological and social effects of the recipient's death on the donor was the main focus in *Strunk v. Strunk*. The Court established that Jerry identified very much with Tommy, who was his primary tie to his family and one of only a few people who could understand his defective speech. In view of the fact that Tommy was Jerry's only sibling, it was feared that in case of Tommy's untimely demise and their parents' eventual death, Jerry would be totally deprived of the intimate communication that was so crucial to his mental stability. Taking all these aspects in consideration, the Court reasoned that the transplantation would serve Jerry's best interests, because 'his well-being would be jeopardized more severely by the loss of his brother than by the removal of a kidney.'

In *Little v. Little*, the Court was of the opinion that, apart from the prevention of the detrimental effects that would occur if the recipient eventually were to die, allowing transplantation would also significantly increase Anne's happiness. Citing studies of the psychological effects on competent kidney donors, revealing 'heightened self-esteem, enhanced status in the family, renewed meaning in life, and other positive feelings including transcendental or peak experiences', the

⁴⁷ In some cases courts also relied on the substituted judgment doctrine but only to substantiate their equity powers.

⁴⁸ *Strunk v. Strunk* [1969] 445 S.W. 2d 145 (Ky Ct App).

⁴⁹ *Little v. Little* [1979] 576 S.W. 2d 493 (Tex Ct App).

Court stated that Anne would likely receive considerable psychological and emotional benefits.

Both Courts emphasised that the best interests test should encompass all factors that could influence the mentally incompetent's general well-being. Moreover, in reaching the verdict, they had considered a whole set of substantive requirements.

Subsequently, in two other cases, kidney removal from a mentally incompetent person was denied because these requirements had not been fulfilled and it was assessed that, under the particular circumstances, the procedure would not be beneficial to the incompetent donor herself. In *In re Richardson*, a case from 1973, the Court of Appeals of Louisiana declined a request to permit kidney removal from 17-year-old mentally retarded Roy for the benefit of his adult sister Beverly.⁵⁰ It turned out that not all other siblings had been tested and that Roy was the closest but not the only match. Furthermore, considerable uncertainty existed about the immediate medical necessity of a kidney transplant and the recipient's medical prospects if she would receive a kidney. In 1975, in *In re guardianship of Pescinski*, a request to allow kidney removal from 39-year-old mentally incompetent Richard for the benefit of his 38-year-old sister Elaine was declined by the Supreme Court of Wisconsin.⁵¹ The Court noted that another brother who was competent, in good health, and not too old, had refused to consider donation because as a farmer and father of ten children he felt that the obligation to his own family prevailed. In addition, it found no indication that Richard had in any way agreed to the whole procedure.

In both cases, the Courts also relied on the best interests standard, but denied the claim that donation would be beneficial to the mentally incompetents. In *In re Richardson*, the assertion that Beverly might well become Roy's primary caretaker after the death of their parents was brushed aside as speculative and even highly unlikely. Consequently, the Court concluded that 'surgical intrusion and loss of a kidney clearly would be against Roy's best interests' and that the transplant could not be approved. In *In re guardianship of Pescinski*, the Court emphasised that no evidence had come to light showing that the transplantation would serve any interests of the mentally incompetent person, let alone that it would be in his best interests. With this line of reasoning, and explicitly recalling that an incompetent should have his own interests protected and that certainly no advantage should be taken of him, the Court determined that it had no power to approve the transplantation.⁵²

⁵⁰ *In re Richardson* [1973] 284 So. 2d 185 (La Ct App).

⁵¹ *In re guardianship of Pescinski* [1975] 226 N.W. 2d 180 (Wis Sup Ct).

⁵² See, however, the vigorous dissenting opinion by Justice Day, who concluded that kidney retrieval from Richard should indeed have been authorised.

5. Refining Regulations

US court decisions suggest that *non-regenerable* organ removal from a mentally incompetent person may, in exceptional circumstances, be in her best interests. As we have argued in detail elsewhere,⁵³ contrary to what legislators in most European countries take for granted, a total ban on the removal of non-regenerable and — *a fortiori* — regenerable organs may not necessarily protect the interests of mentally incompetents. There may thus be good reasons to amend the regulatory framework in European countries so as to allow this kind of procedure in cases where specific substantive as well as procedural conditions are met.

In accordance with the general principle that organ removal should not be allowed if a serious risk to the life or health of the donor is likely, only an extension to kidney donation would be permissible. Contrary to the interpretation in the US court cases, the risk of mortality and morbidity from kidney donation appears to be too significant to fit the label of ‘minimal risk’.⁵⁴ Nevertheless, in contrast to partial liver donation, which, in view of the medical risks involved,⁵⁵ ought to be totally rejected in the case of mentally incompetents, kidney removal does not seem to entail serious medical risks.

Second, the best interests standard should be clearly reflected in any regulation on this issue. Indeed, from a moral point of view, severely intruding upon the physical integrity of a mentally incompetent person for the benefit of another person could only be justified if this would be the last resort to save the life of that person *and* if the dignity of the mentally incompetent person would not be compromised. The prohibition of pure instrumentalisation entails that, after the urgent medical need of the intended recipient has indeed been established, final authorisation may only be granted if the intervention would *also* be in the interests of the mentally incompetent person. Since organ removal cannot have any therapeutic benefit for the mentally incompetent person, it should only be

⁵³ K. Van Assche, G. Ginicot and S. Sterckx, “Living Organ Procurement from Mentally Incompetents: The Need for More Appropriate Guidelines”, *Bioethics* 5 July 2012, doi: 10.1111/j.1467-8519.2012.01982x.

⁵⁴ Segev et al. report a mortality risk of 0.031 %. See D.L. Segev et al., “Perioperative Mortality and Long-term Survival Following Live Kidney Donation”, *Journal of the American Medical Association* 303(10) (2010) 959–966. As to morbidity, some reports estimate that the complication rate of donor nephrectomy is as high as 35 % with up to 7 % major injuries. See J.D. Kallich and J.F. Merz, “The Transplant Imperative: Protecting Living Donors from the Pressure to Donate”, *Journal of Corporation Law* 20 (1995) 148; G. Mjøen et al., “Morbidity and Mortality in 1022 Consecutive Living Donor Nephrectomies: Benefits of a Living Donor Registry”, *Transplantation* 88(11) (2009) 1278; A. Spital, “Ethical Issues in Living Related Donors”, in: W. Shelton and J. Balint (eds.) *The Ethics of Organ Transplantation* (Oxford: Elsevier Science, 2001) p. 103.

⁵⁵ Merion reports a mortality risk of 0.2 to 0.5 %. See R. Merion, “Current Status and Future of Liver Transplantation”, *Seminars in Liver Disease* 30(4) (2010) 417. A recent review article reports a mortality risk of 0.2 to 2 %. See Y. Yuan and G. Mitsukazu, “Biliary Complications in Living Liver Donors”, *Surgery Today* 40(5) (2010) 411–417. As to morbidity, Yuan and Mitsukazu report a morbidity rate of 0 to 78,3 %, depending on the criteria that are used.

allowed if there is a significant likelihood that she will accrue important psychological benefits.

Third, the requirement that organ removal may only be carried out if it would be in the best interests of the mentally incompetent donor should be made more specific in order to preclude that surrogate decision-makers may let their assessment of the incompetent's likely benefit be guided by their own opinions and judgments. In this regard, it has been argued that US courts allowing organ harvests from mentally incompetents have all too often applied the best interests standard as loosely as necessary in order to support their decision to help the recipient.⁵⁶ In an evolution that was foreshadowed in the reasoning behind *In re Richardson* and *In re guardianship of Pescinski*, several critics have forcefully advocated the incorporation of a clear and convincing evidentiary burden of proof.⁵⁷ Inspiration can be found in the *clear benefit standard*, which has been elaborated and promoted by the Council on Ethical and Judicial Affairs of the American Medical Association.⁵⁸ Like the more general best interests standard, the clear benefit standard holds that probable positive psychological effects and potentially hazardous side-effects may be characterised as important benefits and unacceptable risks that may tip the balance as to whether organ harvest should be allowed. In addition, however, by prompting decision-makers to choose what *clearly* would provide the mentally incompetent individual with the most benefit, the clear benefit doctrine is explicitly intended to prevent their own subjective preferences from clouding their judgment. Therefore, the preferences of the mentally incompetent person need to be reckoned with, commensurate to her level of maturity. As the case may be, the incompetent's ability to appreciate the medical condition of the intended recipient as well as any indications of a possible desire to help, are important factors to be taken into consideration. Most importantly, the continued survival of the intended recipient must be deemed essential to the mentally incompetent person's general well-being. After all, only under these circumstances can the psychological benefits that mentally incompetents would likely receive from providing an organ reasonably be expected to significantly outweigh the risks. Thus, only in such cases could organ harvest from mentally incompetents be considered to be in their best interests.

Fourth and finally, if the highly beneficial effect of the continued companionship of the intended recipient is the main criterion for authorising organ removal, limiting organ donation to a recipient who is the mentally incompetent's sibling

⁵⁶ C. Cheyette, "Organ Harvests from the Legally Incompetent: An Argument against Compelled Altruism", *Boston College Law Review* 41 (2000) 465-515.

⁵⁷ See for example L.E. Lebit, "Compelled Medical Procedures Involving Minors and Incompetents and Misapplication of the Substituted Judgment Doctrine", *Journal of Law and Health* 7(1) (1992) 128; R.W. Griner, "Live Organ Donations Between Siblings and the Best Interest Standard: Time for Stricter Judicial Intervention", *Georgia State University Law Review* 10(3) (1994) 610.

⁵⁸ In its Report on The Use of Minors as Organ and Tissue Donors. See http://www.ama-assn.org/resources/doc/ethics/ceja_3i93.pdf.

may be too restrictive. Since the interests of a mentally incompetent person could, in exceptional cases, be severely compromised by the death of a non-relative with whom she has a high degree of emotional intimacy, the range of acceptable recipients may need to be extended.

6. Conclusion

Across Europe, organ removal from mentally incompetent adults is regulated in very heterogeneous ways. However, with ten of the 22 countries analysed opting for a total ban, and a further eight only allowing procurement of regenerable organs, it is fair to say that the general approach is clearly restrictive. However, this restrictive approach may not always be in the best interests of the mentally incompetents. We have argued that regulations should be modified so as to include the possibility of non-regenerable organ removal from mentally incompetents in extraordinary circumstances. At the same time, robust safeguards should be put in place to prevent sacrificing the integrity of mentally incompetents if compatible competent donors are unwilling or hesitant to donate. Several substantive and procedural threshold requirements would have to be satisfied, in the event of which final authorisation should only be granted, preferably by a pluridisciplinary independent body, if the psychological benefits that the mentally incompetent person is likely to receive from the continued personal companionship of the intended recipient could reasonably be expected to significantly outweigh the risks she will be facing. At all times, legal regulation should guarantee that the best interests of the mentally incompetent person are the ultimate yardstick.

Appendix: List of Relevant National Legal Instruments

Belgium: Wet betreffende het wegnemen en transplanteren van organen/Loi sur le prélèvement et la transplantation d'organes, Art. 6, available at http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1986061337&table_name=wet (Dutch) and http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1986061337&table_name=loi (French).

Bulgaria: Закон за трансплантация на органи, тъкани и клетки, 19 септември 2003, Чл. 24, available at http://www.zdrave.net/document/institute/e-library/BG_Health_Acts/Transplantations_Act.htm.

Czech Republic: Zákon ze dne 30. května 2002 o darování, odběrech a transplantacích tkání a orgánů a o změně některých zákonů, § 4, available at <http://aplikace.mvcr.cz/archiv2008/sbirka/2002/sb103-02.pdf>.

Finland: Laki ihmisen elimien, kudoksien ja solujen lääketieteellisestä käytöstä 2.2.2001/101, § 3 & § 5, available at <http://www.finlex.fi/fi/laki/ajantasa/2001/20010101>.

France: Code de la santé publique, L 1231-1 to L 1231-4 and L 1241-4, available at <http://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006171033&cidTexte=LEGITEXT000006072665&dateTexte=20110516>.

Germany: Gesetz über die Spende, Entnahme und Übertragung von Organen (Transplantationsgesetz) vom 5. November 1997, § 8, available at <http://www.gesetze-im-internet.de/bundesrecht/tpg/gesamt.pdf>.

Greece: Νόμος Υπ' αριθμ. 3984/2011 Δωρεά και μεταμόσχευση οργάνων και άλλες διατάξεις, Άρθρο 8, available at <http://www.hellenicparliament.gr/User-Files/bcc26661-143b-4f2d-8916-0e0e66ba4c50/d-orgam-pap.pdf>.

Hungary: 1997. évi CLIV. törvény az egészségügyről, 206, available at http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV.

Italy: Legge 26 giugno 1967 n. 458. Trapianto del rene tra persone viventi, Art. 2, available at <http://www.airt.it/pdf/Lex458.pdf>.

Luxembourg: Loi du 25 novembre 1982 réglant le prélèvement de substances d'origine humaine, Art. 2, available at <http://www.dondorganes.public.lu/fr/que-dit-loi/memorial.pdf>.

Netherlands: Wet van 24 mei 1996, houdende regelen omtrent het ter beschikking stellen van organen (Wet op de orgaandonatie), Artikel 4, available at <http://www.ieb-eib.org/fr/pdf/wet-op-de-orgaandonatie-nl.pdf>.

Norway: Lov 1973-02-09 nr 06 om transplantasjon, sykehusobduksjon og avgivelse av lik m.m., § 1, available at <http://www.lovdato.no/all/tl-19730209-006-001.html#1>.

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