Università degli Studi di Pavia

2012 Law & Science Young Scholars Informal Symposium

Book of papers

University of Pavia, May 14th 2012

Alessandra Malerba – Laura Massocchi – Amedeo Santosuosso (eds.)

2012 law & science young scholars informal symposium : book of papers : University of Pavia, May 14. 2012 / edited by Alessandra Malerba, Laura Massocchi, Amedeo Santosuosso. - Pavia : Pavia university press, 2013. - VIII, 157 p. ; 24 cm. - (Atti)

ISBN 9788896764411

In testa al frontespizio: Università degli studi di Pavia, Centro di ricerca interdipartimentale dell'Università di Pavia European Centre for Law, Science and New Technology.

1. Scienza e diritto - Innovazione tecnologica - Congressi

I. Malerba, Alessandra II. Massocchi, Laura III. Santosuosso, Amedeo

IV. European Centre for Law, Science and New Technology <Pavia>

344.095 CDD-22 Diritto in materia di scienza e tecnologia

ISBN: 978-88-96764-41-1

Texts published by Pavia University Press in the series "Editoria scientifica" have been peer-reviewed prior to acceptance by the Editorial Board.

The cover shows: University of Pavia, "Aula Scarpa".

Virtual URL <http://purl.oclc.org/paviauniversitypress/atti/YS-2012>

Published by Pavia University Press – Edizioni dell'Università degli Studi di Pavia
Via Luino, 12 – 27100 Pavia (PV) Italy
<http://www.paviauniversitypress.it>

Printed by Digitalandcopy S.a.s., Segrate (MI)

Contents

Introduction

This volume collects the materials of the "2012 Law & Science Young Scholars Informal Symposium". The event, that is still the only one of its kind, was promoted by the Interdepartmental Research Centre "European Centre for Law, Science and New Technology" (ECLT) in collaboration with the Collegio Ghislieri (Pavia) and the Institute for Advanced Study (IUSS, Pavia). Already at its fourth edition in 2013, the Symposium has established itself as a steady reference point in ensuring that the focus on young researchers may be maintained within the scientific and academic communities.

The ECLT, instituted by the University of Pavia in 2004 under its previous name of "European Centre for Life Sciences Health and the Courts" (ECLSC), studies the evolution of legal systems according to the scientific and technological progress from an international perspective. Moreover, the Centre pays particular attention to those young people who are just starting off in the world of academic research.

The idea of organizing one single day completely dedicated to young researchers came about in 2010 and was then followed, within a few weeks, by the first edition of the Symposium, aimed at Italian researchers. Right from the beginning, the initiative aroused great enthusiasm and papers of an extremely high standard were submitted.

In 2011 the event was expression of the same idea and was enriched by the precious collaboration of the Collegio Ghislieri, Istituto Universitario di Studi Superiori (IUSS) of Pavia and the Fondazione Maugeri of Pavia (which funded the "Fondazione Maugeri Prize"). The 2011 Symposium also took on an international dimension (with the decision to have English as the sole working language) so that young scholars would have the chance to work directly with colleagues from around the world. The "2012 Law & Science Young Scholars Informal Symposium" has therefore become both an institutional and an informal forum within which young researchers (post-graduate researchers, Ph.D. students, post-doc students or early-career researchers in general) in the field of Law & Science can discuss their research results, meet other young scholars in the sector, enjoy the experience of participating in a conference and publish their papers.

The third edition has developed along these previous successful experiences. Special attention was paid to the participant selection procedure. An international commission of legal and scientific experts examined candidate proposals by double crossed revision. Two referees (not of the same nationality as the candidate) evaluated each abstract. This preliminary judgment led to select eight candidates. These eight young scholars were then requested to write a full paper, which was assessed by two other members of the Evaluation Panel.

At both stages each candidate received the referees' observations on the strong points of his/her work and some advice on how to improve weak areas, thus obtaining precious and authoritative feedback. The names of the referees and the details of the selection procedure were published on the ECLT website page on the event along with a short report (<http://www.unipv-lawtech.eu/lang1/2012-law---science-young-scholars-informal-symposium-and-prize---pavia--i-,-14-may-2012.html>).

The 2012 round of the Symposium confirmed the success of the initiative: among the 34 abstracts, which have been submitted from all over the world, 8 were selected. The successful candidates had the chance to present and discuss their work at the final event of the Symposium, which was held on May 14, 2012, in the 18th Century "Aula Scarpa" of the University of Pavia, already a symbol of the event: the historical setting in which the event takes place at first sight clashes with the contents of the presentations, all dealing with the most advanced technologies and scientific discoveries. On the contrary, it marks a continuity between the century long tradition of the University of Pavia and the new boundaries of knowledge which were discussed during the conference.

The morning and afternoon sessions opened with a Keynote Lecture from an eminent scholar. The morning session was opened by Carlo Casonato, professor of Constitutional Law and Biolaw at the University of Trento, who gave a lecture on *Hot issues in comparative constitutional biolaw*, a hymn to mutual understanding between law and science. The scientific Keynote Lecture, given by Gabriella Bottini, Professor of Physiological Psychology at the University of Pavia and coordinator of the laboratory of Neuropsychology at the Neurological Science Department of the Niguarda Hospital, addressed the most hotly-debated issues in current neurolaw research. Her lecture, with a voluntarily provocative title, *Neuroscience and law: any relationship?*, was an exhaustive reflection on all the possible contributions of neuroscience in the determination of legal responsibility.

The two best papers (as selected by the International Evaluation Panel) were awarded the "Fondazione Maugeri Prize", sponsored by Fondazione Salvatore Maugeri of Pavia, while two other papers received a special mention from the jury.

The four best papers constitute the first four chapters of the volume, whereas the other contributions are presented in the alphabetical order of the authors' names.

We would like to thank the academic institutions of Pavia and everyone who made this event possible. We wish that this work would boost the interest of other young scholars in participating to the next edition of the Young Scholars Informal Symposium.

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Courts as Academies: Balancing of Scientific Arguments in Regulation of Uncertainties[1]

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Abstract: Regulation of new technologies involves high uncertainty which allows broad epistemic discretion to usually unelected regulators. The common response to this challenge is the turn to "science-based regulation" however this approach in practice makes authorities defer to the advice of obscure and even less legitimate scientific bodies. Worse still, the courts are considered incompetent to review the scientific basis of such decisions and they fail in their duties in their own turn. This paper interprets the well-known Pfizer case of the General Court of the EU as a way out of the problem. On this reading, the Court reviewed the validity (but not the soundness) of the reasoning of the EU institutions in order to determine whether they could reasonable stray away from the received expert advice. This rigorous review gave the authorities the flexibility necessary in cases of uncertainty yet it held them to a very strict standard of reasoning not to allow them to act arbitrary. Beyond the particular issue, the case shows that the traditional duty to give reasons, if taken seriously, can constrain epistemic discretion and on the other hand can allow the courts to review complex scientific issues without second-guessing the political authorities.

Keywords: precautionary principle; Pfizer; non-arbitrariness; regulation; reasoning; argumentation

Contents: 1. Introduction - 2. Containing discretion - 3. Why reasons matter - 4. Enforcing discipline of reason - 4.1. Precautionary principle as empowering principle - 4.2. Precautionary principle as bright-line rule - 4.3. The Precautionary principle as balancing formula - 5. Conclusion - References

[1] Earlier versions of this paper were presented at the Conference "Quantitative Aspects of Justice and Fairness", European University Institute, Florence, 2011, at the International Graduate Legal Research Conference, King's College, London, 2012 and at the Law&Science Young Scholars Informal Symposium, University of Pavia, 2012. The author wishes to express his gratitude to the anonymous reviewers at the latter symposium for assessing my work so high and to the Fondazione Maugeri for awarding it. Special thanks to all of the participants of these events for the helpful comments. Certainly the responsibility for any mistakes is my own. An earlier version of the paper was made available as a Working paper at the EUI website.

> The High Court of Justice of England and Wales asks the Court what is to be understood by the term "monomer substance". At first sight the reference for a preliminary ruling appears peculiar. One might have expected the question to be addressed to a chemist. However, a closer examination shows that the question can and must be answered with the tools of Community law.
>
> Advocate General Kokott[2]

1. Introduction

David Hume noted that "A wise man proportions his beliefs to the evidence" and chooses what is supported by the greater number of experiences[3]. Respectively a wise society would base its fiats on balance of the available competing expertise. Yet it is surprising how the need for balancing of evidence by the public authorities is neglected in legal theory. It is so preoccupied to make political process responsive to citizens (to their will or to their interest), that the need to make it responsive to arguments was ignored. This is explainable with the legacy of the Enlightenment: we still live with the implicit assumption of scientific certainty and progress even as it is becoming increasingly untenable today[4]. On the contrary, on the account adopted in this article, the conclusions of scientific inquiry are matter of judgement on the balance of different competing pieces of evidence. However, having abandoned the vain hope for one undisputable Truth, we have to acknowledge also that balancing is not an "objective" formula or a bright-line rule which will yield The Ultimate Answer. As Thomas Kuhn[5] has thought us, science cannot sustain any pretence for universal correctness and validity, and the works of Bruno Latour[6] and Sheila Jasanoff[7] amply demonstrate that science is neither neutral nor independent of society, politics and culture. Instead, we have to cope with "reasonable pluralism"[8]. This applies not only to scientific discovery, but to any other forms of thinking, including balancing, rule-following and even computation. Yet this is not to say that we should abandon them; on the contrary – we should employ formal methods to add rigour to our reasoning and decision-making, to uncover our hidden assumptions and to make our conclusions sensitive to argumentative challenges. We only should accept that the state of persistent controversy (or in the area discussed here persistent uncertainty) is not exception or pathology, but the norm. The acknowledgment that decision-making (and even science-based regulation) is inevitably value-laden requires us to take into account those values: if we know it is futile to

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[2] Opinion in Case C 558/07 *S.P.C.M. SA, C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs,* (ECJ) ECR I-05783.

[3] Hume D. (2008), *Enquiry Concerning Human Understanding*. Peter Millican (ed.), Oxford University Press, p. 80.

[4] For a concise summary of the "Enlightenment view" and discussion of its obsolescence see Gaus G.F. (2003), *Contemporary Theories of Liberalism: Public Reason as a Post-Enlightenment Project*, SAGE Publications.

[5] Kuhn T.S. (1970), *The structure of scientific revolutions*, University of Chicago Press.

[6] Latour B. (1993), *We have never been modern*, Harvester Wheatsheaf.

[7] Jasanoff S. (2005), *Designs on nature: science and democracy in Europe and the United States*, Princeton University Press.

[8] Gaus G.F. (2003), p. 14.

straighten our scales, we can instead deliberately tilt them according to the societal goals and values which are at stake.

This may appear too bold claim. Similarly the title "Courts as academies" may be taken by scientist as direct affront to their authority. Yet such claims are warranted by the circumstances of contemporary adjudication – the quotation by AG Kokott in the beginning is a telling example what kind of questions courts are asked to decide. Confronted with such cases[9] scientists are rightly dismayed and wonder is the judge the right person to answer such questions. This paper can be seen as an answer to this question, and the answer is a nutshell is "both 'no' and 'yes.'" My claim is that contemporary governance raises hard questions which have both epistemic and practical dimensions[10]. While the epistemic side of the coin may and ought to be left to scientists only, on the practical side we face a complex mixture facts, uncertainties and affected values, which ought to be decided by laypersons. However they should be made responsible to engage with all of the available scientific expertise into account and justify their choice with reasons which both scientists and laypersons could accept[11].

The present paper will discuss the system of risk regulation in EU as one which functions in a state of irredeemable uncertainty yet which is sensitive to arguments. The system is heavily dependent on science, which is the common response to complexity and uncertainty[12]. As science fails to yield the hard and fast evidence needed to resolve controversies, the stakeholders have to "fight science with science"[13]; thus the decision-making authority is provided with abundant evidence favouring each of the sides which is not conclusive for either position. This leaves the decision-makers in the position to pick and choose. On the other hand, the common good, general will, the election results etc underdetermine the actual measures which are adopted by the various branches on a daily basis. This allows discretion on a scale which renders the principal-agent theory meaningless. The complexity of governance seems to open space for arbitrary choices, where decision-maker can act as it pleases and justify its choice *ex post*.

In the first part of the present paper I suggest that this situation can be remedied if the well-known requirement for the administration to give reasons is taken seriously.

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[9] Another case in point is C 34/10 Brüstle v. Greenpeace where ECJ claimed authority to determine what a "human embryo" is and invalidated a patent for material extracted from it. Special thanks to prof. Carlo Casonato to bringing the case to my attention.

[10] Resnik disentangles the practical and epistemic dimensions of a question and notes that in case of uncertainty the decision on each of them may be guided by different rationales, see Resnik D.B. (2003), "Is the Precautionary principle unscientific?", *Studies in History and Philosophy of Biological and Biomedical Sciences*, 34, pp. 329-344.

[11] It should be clear that I hold the decision-makers responsible to conform to Habermas's discourse principle ("Just those action norms are valid to which all possibly affected persons could agree as participants in rational discourses", see Habermas J. (1996), *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy*, The MIT Press, p. 107. This is not to say that participants must actually agree – this will hardly ever happen – but that the decision authorities take must be justified with reasons which are *acceptable* for the affected side (even if they are not actually *accepted*).

[12] It is somewhat paradoxical that facing recognizable *scientific* uncertainty we choose to rely on *science* to resolve it. See Asselt M.B.A. van, Vos E. (2006), "The Precautionary Principle and the Uncertainty Paradox", *Journal of Risk Research*, 9, pp. 313-336. My guess is that we turn to science because it is an argument-sensitive discipline.

[13] Holder J., Lee M., Elworthy S. (2007), *Environmental protection, law and policy: text and materials*, 2nd ed., Cambridge University Press.

Whatever its choice, it should be required to make explicit the whole chain of reasoning, from the most fundamental implicit assumptions to the furthest reaching conclusions. Thus the stakeholders and the critical public will evaluate whether the reasoning that lead to the decision is empirically sound and logically valid. My suggestion is that "adding a method to their choices" would make the decision-making critically dependent on the new information which is made available. On the other hand, it will constrain the decision-makers and prevent arbitrary or strategic decisions. However this will happen only under rigorous watch of the reasoning process. In the second part I discuss how the European Commission adopted a method to its reasoning and how the court enforced it in the *Pfizer* case[14]. This was one primer how the General Court[15] (formerly the Court of First Instance) of the EU required the rigor necessary to assure non-arbitrary argument-sensitive decisions. Although the judges were no experts on the substance of the issue, they reviewed the substantive justification of the decision without second-guessing. Thus, it promoted what I shall call argumentative rationality.

2. Containing discretion

This irreducible pluralism even in cases of science-based regulation raises obvious concerns for the legitimacy of authoritative action yet the complexity of the contemporary governance necessitates flexibility of the authority to deal with the arising novel challenges. The normative requirement for non-arbitrariness clashes with the pragmatic requirement for flexibility in the face of uncertainty. The most serious attempt to face this challenge in my view is made by Elisabeth Fisher. She suggested that the traditional responses of administrative scholarship are doomed to fail and developed a new paradigm for administrative constitutionalism[16]. The traditional paradigm – rational-instrumental (RI) in her terms – assumes that public administration is an instrument to the legislature to achieve certain pre-ordained democratic will, and to do so it only needs capacity to act effectively and efficiently. This approach has the virtue of being (or appearing to be) democratic as the unelected administration merely implements the laws adopted by elected legislature. However it is growing increasingly inadequate: if an agency has to deal with the volcanic ash crisis of 2010 where an unexpected eruption of an Icelandic volcano led to closure of European airspace for about a week, it cannot find any substantive clue how to proceed in any piece of legislation. As administrations worldwide have to deal with such challenges on a daily basis a new type of response is increasingly needed. In several case studies Fisher identifies another pattern of dealing with unorthodox challenges which she calls deliberative-constitutive (DC). On this ac-

[14] Case T-13/99 Pfizer Animal Health v. Council. Hereinafter all references to paragraphs will be to this case, unless otherwise indicated.

[15] Hereinafter "the Court" will stand for the General Court while the European Court of Justice will be always referred to with its abbreviation "ECJ".

[16] In her phrase administrative constitutionalism is a theory what is the legitimate role of public administration; Fisher E. (2007), *Risk regulation and administrative constitutionalism*, Hart. Such language is warranted because in contemporary governance what may appear as merely technical issue usually has far-reaching normative repercussions, so "disputes over how to govern technological risks will merge into disputes over the legal validity of public administration" (p. 26).

count "legislation is less a set of strict commands and more akin to a constitution that sets out a series of general principles and the 'broad parameters' for the exercise of discretion"[17]. Instead of looking for cues in the statute, the administration is to find it by deliberation: "Deliberation is the means by which the issues for standard setters can be defined, the relevance of information and expertise established, and the risk ultimately evaluated"[18]. While the RI approach relies on the objectivity, the DC approach relies on "the human capacity for civic virtue and public reason[19]. Although I agree that DC is the adequate response to the inherent uncertainty in contemporary governance I am still uneasy with the broad and unchecked discretion and potential arbitrariness which is allowed by it. Being republican myself I would also put my trust on civic virtue and public reason, however I think we need to develop a more precise account of these ideals to make them applicable to administrative governance. The simplest way to put my proposal is to contain discretion by taking the reasons by which authoritative decisions are justified really seriously. I claim that a strict reasons-giving requirement would allow the necessary flexibility while avoiding arbitrariness.

So far the reason-giving requirement is rarely taken in earnest neither by the decision-makers, nor by the deciding courts. In the jurisprudence of the ECJ for example the EU authorities are required to state motives, however the court is satisfied with "very thin reasoning"[20]. Reasons matter in everyday talk and decision-making as everyone of us knows from experience. Reasons matter also in science, esp. in the form of assertions of experimental results. Reasons matter in legal proceedings as well. But in order to matter in administrative or political process they must be enforced by methods for discipline of reason, i.e. certain procedures like the impact assessments and the ultimate weapon is the reviewing court. In the following I show how reasons *could* bind, and then how they can be *made to* bind.

3. Why reasons matter

In the previous sections of this paper I have argued that contemporary governance requires both expertise and flexibility, which in practice grants broad discretion to obscure expert bodies which raises legitimacy concerns. I have also argued that reliance on "objective science" cannot reduce discretion and therefore the responsibility for the ultimate choice should remain with the legitimate authority. I further suggested that when reasons are made central to the decision-making discretion can be controlled. In this section I shall argue why reasons are more than "cheap talk" and how can we built on the established western tradition which requires that political authority is not only democratically responsive but also rational and reasonable. This translates into Pettit's requirement for non-arbitrariness of the acts of authority, and they are such to the ex-

[17] Fisher E. (2007), p. 30.
[18] Fisher E. (2007), p. 31.
[19] Fisher E. (2007), p. 35.
[20] See Chalmers and colleagues who lament that the duty to give reasons does "little more than [provide] a context for understanding the decision." See Chalmers D., Davies G., Monti G. (2010), *European Union Law: Cases and Materials*, 4th ed., CUP, p. 377.

tent that they are forced to track the relevant interests and *ideas* of citizens according to their own judgement[21]. Legitimate authorities must be able "to give democratically persuasive reasons for their decisions"[22]. A valid reason would be one that is believed to true by most members of the society, otherwise *for the society* it is not a reason at all. This is a demanding condition, because it places on the authorities the burden to take not only the right decisions but to take them for the right reasons (where both decisions and their premises are substantively contestable). The non-arbitrariness condition is applicable also to the "technical" decisions; they also have to be supported by a chain of propositions which are empirically sound and logically valid. Citizens and stakeholders participate in the democratic process by either contesting such chains or by offering alternative decisions premised on chains of their own construction.

Apart from conferring legitimacy the non-arbitrariness requirement can make the argumentation matter in the decision-making[23]. Even a single individual would act for certain reasons; if acting reasonably means to act for reasons, then a reasonable individual would be able to state her reasons for taking certain action[24]. Thus far, this is a minor constraint on her actions; having reasons need not (though it may) imply conformity to an external normative standard; even a whimsical choice has its reasons – if I eat strawberries with champagne my reason for doing so may be that I like them together and not necessarily because I want to impress someone with my cultured palate or my riches. Only in some cases reasons for actions are based on science or morals – I eat fruits because they are good for my health, or I do not eat strawberries in February because I do not like to damage the environment by having them shipped from the Southern hemisphere. In all cases however, reasonableness implies at least (1) availability of reasons (which the agent can articulate if asked), and (2) some degree of coherence among them[25]. But I will strike you as unreasonable, if I state that I have eaten the first strawberry I was offered because "I like strawberries" yet I deny the second one because "I don't like strawberries". Yet, I can still reasonably deny the second strawberry because "I do not want to appear gluttonous" which does not contradict the reason already stated ("I like strawberries)".

The same applies for public authorities: for example they cannot arbitrarily subsidise one strawberry farmer and not the other. Once a regulator has announced a policy to support strawberry producers it binds itself to apply it according to its stated terms. In administrative law this is well-known as the principles of legitimate expectations and of non-discrimination. What is less discussed is that authorities may find themselves constrained also by the reasons for the adoption of the policy. Suppose that the regulator has stated that it would support strawberry farmers because it is committed to promote public health. If later becomes known that strawberries are actually bad for health, the authority may find itself bound to reverse the policy. This would not be the case if

[21] Pettit P. (1997), *Republicanism: a theory of freedom and government*, Clarendon, p. 55.
[22] Pettit P. (2004), "Depoliticizing Democracy", *Ratio Juris*, 17, p. 53.
[23] Elsewhere I shall demonstrate by formal models that there is more than semantic link between reason (as capacity) and reason (as premise for action).
[24] Reasons for action are the beliefs on the premises one may consider relevant in deciding whether to take the action.
[25] Coherence is not a normative requirement, yet a reason that is cancelled by another reason is no reason at all.

the stated reason for the policy was not public health but rural development – the new evidence would have no bearings on the policy at all. To generalise, the authoritative decisions are path-dependent, and the path is being set not only by the earlier decisions, but also by the reasons they were premised on.

A telling example how such innocuous statements can matter was provided by a recent authorisation of a genetically modified potato for cultivation in Europe[26]. There was vigorous controversy on all aspects of the issue, but eventually it boiled down to debate on two relevant premises – whether the potato may confer resistance to certain antibiotics to consumers through the food chain *and* whether these antibiotics are actually (or potentially) used in human medicine. According to the statement of the European Food Safety Authority (EFSA) it was very unlikely that the cultivation of the potato may confer antibiotic resistance to humans and the antibiotics affected (kanamycin and neomycin) were not important for human and veterinary medicine anyway. Thus both premises were cumulatively satisfied and the potato was in train for authorisation. In the meantime however the World Health Organisation (WHO) published a report identifying these antibiotics as very important. Thus EFSA came under pressure to reverse its opinion. It actually did not; instead it tried to reshape the initial decisional framework stating that the premises should not be cumulatively but alternatively available. But this move took a big toll on its credibility, EFSA was severely criticised by the EU authorities and citizens. More importantly, on this ground the authorisation decision is now being challenged by five member states in the General Court. Should the Court rule for the applicants it will made a huge step toward making the Union non-arbitrary authority. In any event, this example illustrates how the stated decisional method may constrain its author and how the new evidence may become factor for the decision, outside of decision-maker's control. Note how the non-arbitrariness requirement has two sides: first, statements of reasons are commitments affecting future acts, and second, the use of reasons makes process sensitive to arguments.

But if we want any of this to be more than a theoretical construction, we must seek institutions for epistemic vigilance – they are to make the decisions sensitive to arguments, i.e. they have to identify the commitments, to expose the ignoring of evidence and to punish violations. This is done by the adoption of rigorous reasoning methods and opening the process to argumentative challenges on the substance. Many of the established institutions and principles of public law can be interpreted as methods to enforce discipline of reason[27]. Beyond the very duty to give reasons such function is performed by judicial review, ministerial oversight, the principles of transparency and accountability, public inquiries, impact assessments, cost-benefit analysis and generally, any criticism in the public sphere. Most of the institutions of contemporary democracy, intently or not, make the decision-making more sensitive to arguments and thus less arbitrary.

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[26] For a detailed study of the case see Paskalev V. (2012), "Can Science Tame Politics: The Collapse of the New GMO Regime in the EU", *European Journal of Risk Regulation*, 4.

[27] Pettit's classic model is that of premise-wise voting, see Pettit P. (2001), "Deliberative Democracy and the Discursive Dilemma", *Noûs*, 35, pp. 268-299. Elsewhere he has suggested also use of straw-poll and sequential voting but none of this is actually implemented anywhere. His practical proposals are various "contestatory" institutions allowing citizens to subject the authoritative decisions to public valuations see Pettit P. (2004), (n. 22).

My claim it that this argument holds for all public authorities including the administrative regulators even though they usually are agencies which are (or at least are perceived) as a singular decision-maker. Indeed, they always have very broad margin both to identify the set of premises relevant for the decision and to assess them with regard to the available evidence. However, once this is done in a policy paper, guidance or another "soft law" instrument, the regulator is constrained by its own statement. It is under pressure to stick to its words. Certainly, this constraint is effective only when it is costly for the decision-maker to foreswear its earlier public statements of reasons[28]. When it needs to interact with the surrounding environment this would often be the case; it is the vigilance of the others that makes the statements of reasons matter. This is especially the case with the EU institutions, when no institution possesses full legal authority on any issue and even if it does it constantly seeks the cooperation of the others.

Thus far I have argued that reasons ought and sometimes do matter in public decision-making. When this is so, rational actors would have a special interest to use reasons in order to influence the decisions. For the purposes of this paper I shall call the use of arguments to influence the decision-making process argumentative rationality[29]. Argumentative rationality is a subspecies of instrumental rationality, where the means are arguments and the end is persuading the other actors in order to secure certain preferred collective decision. Argumentative rationality is not always an effective means to this end but in two cases it is: either when other agents are open to be persuaded or in cases where the decision-making process is deliberately designed to be sensitive to arguments so that participants are *forced* to acknowledge the reasons of the others. The former corresponds to what deliberative democrats call ideal speech situation and the present paper is not concerned with it. It will be concerned only with the latter case where the decision-making itself is geared in such a way that the arguments brought forward make difference, despite the stubbornness or selfishness of the agents. My claim is that public exchange of arguments, i.e. discourse in the public sphere, may be an independent factor for the behaviour of the rational agents. I haste to note that the present paper does not take side in the current debate whether arguing or bargaining prevails in international negotiations and especially in the EU[30]. It takes the modest position that arguments matter at least *ceteribus paribus*, and is interested how they can be made to matter more. This is the perspective of "discursive institutionalism" whose leading proponent cautiously warns that discourse does not preclude power and we should not assume that deliberation can trump manipulation[31]. That the relationship between reasons and

[28] It may loose credibility, be publicly censured by the overseeing authority, its directors fired or loose bonuses or promotions; its decisions may be contested by stakeholders or even reversed by administrative or judicial review.

[29] The paradigmatic example here is the jury trial where the parties use argument to secure the outcome that suits them best. It may appear that the second case depends on the availability of at least minimal number of persuadable participants but this is not necessarily so.

[30] For this debate see for example Risse T. (2000), "*Let's Argue!*: Communicative Action in World Politics". *International Organization*, 54, pp. 1-39; Ulbert C., Risse T., Müller H. (2004), "Arguing and Bargaining in Multilateral Negotiations", *Center for Transnational Relations, Foreign and Security Policy (ATASP)*. For the futility of the debate see Deitelhoff N., Müller H. (2005), "Theoretical paradise – empirically lost? Arguing with Habermas", *Review of International Studies*, 31, pp. 167-179.

[31] Schmidt V.A. (2010), "Taking ideas and discourse seriously: explaining change through discursive institutionalism as the fourth *new institutionalism*", *European Political Science Review*, 2, p. 21.

power is complex and multidimensional was neatly exemplified in the example with GMO authorization above. It showed both how reasons do matter and yet how they did not make a difference. Apparently for the reason(s) to be taken seriously in the real world something more is necessary.

4. Enforcing discipline of reason

In the previous sections I have postulated the non-arbitrariness as condition for legitimacy of the acts of public authority. I argued that this condition can be satisfied if reasons are made to matter, and that the reliance on reasons constrains the authority and limits discretion. For this to happen in practice however, I suggested that first authorities must have stated methods for reasoning, and second, the others must be vigilant whether they act consistently with their statements of reason. Now I show how soft law is such method and how the court can enforce it. In the well-known *Pfizer* case the Court reviewed the reasoning of the EU institutions with regard to the method announced in a Communication of the European Commission. In particular, it assessed whether certain array of available evidence could justify certain the conclusion of the Council. Thus, it reviewed the quality of epistemic base of the decision and the validity of the conclusions drawn from it.

The controversy concerned the application of the precautionary principle. It was interpreted in three ways – as empowering principle in the beginning, as a "bright-line rule" by the Commission and as a balancing method by the Court. The first interpretation mandated deliberative-constitutive mode of administrative action, it provided the flexibility necessary to deal with uncertainty, however it allowed arbitrariness. The second required rational-instrumental approach, which tries to deal with arbitrariness but runs afoul of the uncertainty paradox. The third engages with the available reasons and shows a middle way: controlling discretion while eventually sustaining the adopted solution.

4.1. Precautionary principle as empowering principle

The precautionary principle as understood by the European Commission provides an instructive example for a rigorous method for discipline of reason. Originating in environmental law now it is understood to be a general principle of Union law[32]. On its face, this is a broad principle which *empowers* the decision-makers to take measures for protection even if the actuality of the danger is uncertain[33]. Such seemingly was its initial understanding by the European Court of Justice (ECJ) which used to be deferential to the Union institutions. In the previous landmark case – *FEDESA* – ECJ reviewed only "whether the measure in question is vitiated by a manifest error or misuse of powers, or whether

[32] In Pfizer see par. 114 and par. 183 and the list of cases referred to in par. 115.
[33] See Principle 15, UN Declaration on Environment and Development (Rio Declaration), [online], URL: <http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163>, accessed on 12 February 2011.

the authority in question has manifestly exceeded the limits of its discretion"[34] and it applied this test with a "light touch"[35].

From the fact that the countries were unable to agree on the assessment of evidence the Court assumed that evidence was inconclusive and this had unleashed the Council to do as it pleased. Thus, in the parlance adopted here, the ECJ did not impose any reasoning methodology to the authorities. Many commentators commended this approach; interestingly for Fisher claimed that instead of being controlled by the political principal, the decision-maker should be "insulated from the mainstream political process, which is over-responsive to particular political interests"[36]. Thus, *in lieu* of trust in objectivity, the trust in such deliberative decision-making process should be derived "from human capacity for civic virtue and public reason"[37]. This claim, in principle, agrees with the argument developed in the previous section. Fisher's argument from practical reasoning finds normative support in the republican theory. The call for deliberation and insulation of the decision-maker apparently corresponds to Pettit's call for depoliticization[38] and to his argument that decisions should embody collective reason rather than public opinion[39]. Fisher's argument is not based on the republican theory and does not discuss how public reason is to be achieved. On the contrary, she explicitly contrasts the suggested "deliberative" approach to the application of stricter methodology which she associates only with the principal-agent paradigm[40]. This is unfortunate, because if the argument elaborated above is correct non-arbitrary decisions can be attained only through use of some method imposing discipline of reason.

4.2. Precautionary principle as bright-line rule

Feeling the need to deal with the precautionary discretion the Commission published a *Communication from the Commission on the Precautionary Principle*[41]. The Communication is not a binding instrument, nevertheless it represents a commitment by the Commission to abide to it itself[42].

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[34] C 331/88 *FEDESA and Others v. Council,* (ECJ), par. 8.
[35] Craig P.P., De Búrca G. (2008), *EU law: text, cases, and materials*, Oxford University Press, p. 570.
[36] Fisher E. (2007), *Risk regulation and administrative constitutionalism* (n. 16), p. 31.
[37] Fisher E. (2007), p. 35.
[38] Pettit P. (2004), (n. 22).
[39] See especially Pettit, P. (2001), (n. 27).
[40] See Fisher E. (2007), *Risk regulation and administrative constitutionalism* (n. 16), p. 221. The view advocated here is that strict separation of risk assessment and risk management is just one possible methodology and while it is too dependent on quantification and therefore often unattainable and counterproductive, other methods of discipline of reason are not only possible but necessary.
[41] Communication from the Commission on the Precautionary Principle, COM (2000) 1, 02.02.2000, [online], URL: <http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf> hereinafter "the Communication".
[42] "The aim of this Communication is to inform all interested parties […] of the manner in which the Commission applies or intends to apply the precautionary principle when faced with taking decisions relating to the containment of risk", COM (2000), p. 9. It is worth noting that as the Commission has monopoly in proposing legislation in the EU and therefore constraining itself would in effect constrain all institutions. Further, the ECJ tends to apply the constraining principles of EU even more stringently when reviewing actions by MS so the Communication would potentially have much broader impact.

According to the Communication risk regulation consists of three elements – risk assessment, risk management, and communication of risk[43]. Risk assessment is considered to be a matter of scientific expertise, while risk management is a matter of political choice.

In the parlance adopted here this would allegedly provide a method for discipline of reason and should be welcomed. However the method appears to be too rigid and its core is the mechanical division of risk assessment and risk management. The Communication is very clear that precautionary principle guides risk management only[44]. One reason to circumscribe it in this way was the pursuit of scientific legitimacy by reliance on an objective and independent source of knowledge. Note that scientific objectivity is understood as firm exclusion of social and political factors which are supposed to be taken into account by the political authority in the distinctively different phase of risk management. Ideally, this division into discrete tasks should still allow the administration free choice to act or not to act in the face of risks, yet it should not allow the adoption of arbitrary decisions as the discretion phase is reached only after certain triggering conditions are satisfied according to the "independent science".

Thus, only after satisfying itself that there is "a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question" the public authority is unleashed to choose whether to take precautious action[45]. The action itself should be subject to cost-benefit analysis as well as the other applicable principles of EU law as proportionality, non-discrimination, etc.[46] Public health should have greater weight than economic considerations (but only in this stage)[47]. If the conditions of what we may call precautionary discretion are met, the precautionary action is expected to be judicially reviewed only for manifest error, misuse of power or exceeding the scope of discretion, which used to be a low-intensity test until 2002 when *Pfizer* was decided.

The risk analysis framework established by the Communication ignored what Weimer calls the "social embedment of scientific reasoning" and its usual uncertainty in the areas of risk. Apparently the Commission called the Enlightenment view to provide scientific legitimacy to its regulatory power. There are three palpable problems with such objectivist view. First, the application of norms reliant on conclusive assessments is thwarted when science fails to deliver them. Science often cannot provide any probability of the risk assessed yet some probability estimate is needed to trigger the more flexible risk management. Nor is science always able to estimate the degree of its

[43] This division is not novel, it is common practice worldwide.
[44] However the Communication distinguished precaution from prudence, with the former being part of risk management while "the prudential approach is part of risk assessment policy which is determined before any risk assessment takes place […] it is therefore an integral part of the scientific opinion delivered by the risk evaluators", COM (2000), p. 13. This seems to be completely ignored in practice.
[45] Note that according to the Communication, even when the triggering conditions are met the precautionary principle does not oblige the institutions to take action on the safe side, but is only allowed to do so if it so chooses.
[46] COM (2000), p. 18.
[47] COM (2000), p. 20.

uncertainty about the results. Second, if the risk assessment and risk management phases remain truly discrete, the allegedly political risk management decisions will be often pre-determined by obscure expert risk assessors. The seemingly functional division of labour actually brings about an enormous shift of decision-making power. Thus, the employment of independent expertise fails to confer scientific legitimacy to regulatory decisions yet it deprives political actors from choice. Finally, while the objectivist view explicitly excludes legitimate considerations from the assessment, many implicit value-laden assumptions still pervade them[48]. Certainly "if science is perceived as objective and neutral, then all the 'extra-scientific' considerations will necessarily appear as secondary, because they are interest guided or arbitrary or simply not 'fact'"[49]. If some premises are granted the status of "hard and fast" then it is inevitable that the others will be "softened" and easier to ignore[50]. The last problem seemingly was noticed by the European Council which agreed with the Communication but called for greater role of deliberation and values[51]. As it will be seen below, the Court got the message.

There is one further reason why risk assessment cannot be left to science only: the principle of scientific parsimony. It is generally considered that in case of doubt a diligent scientist should apply Occam's Razor[52] i.e. she should presume non-existence of certain causal effect or untoward consequences. She would certainly state the limitations of current knowledge, yet if she is to draw a conclusion it is likely to contain only what is certain or at least probable and the variety of effects that are merely possible (as well as the disclaimers) are likely to be left out[53]. Thus science and regulation are guided by different decisional principles and the principle of the one may lead to inadequate conclusions if applied to the other[54]. When the two are rigidly separated and compartmentalised to the

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[48] Even Cass Sunstein, notorious as a critic of precautionary principle, see Sunstein C.R. (2002), *Risk and reason: safety, law, and the environment*, Cambridge University Press.

[49] Weimer M. (2008), "Legitimacy through Precaution in European Regulation of GMOs? From the Standpoint of Governance as Analytical Perspective" in Joerge C., Kjaer P.F. (eds.), *Transnational Standards of Social Protection: Contrasting European and International Governance*, vol. 5 (ARENA Report No 5/08, RECON Report No 4 2008), p. 160.

[50] This is a common problem of all partial quantifications. M. Livermore recently emphasised the strenuous relationship of quantification and values: emphasis on non-quantified factors undermines consistency, transparency of analysis and increases discretion but failing to take these factors into account unduly ignores potentially important consequences merely because of our epistemological limitations. See: Livermore M.A. (2011), "A Brief Comment on *Humanizing Cost-Benefit Analysis*", *European Journal of Risk Regulation*, 3, p. 15.

[51] Fisher E. (2007), p. 228.

[52] This is the popular name of the methodological principle, initially formulated by Duns Scotus in 13c AD also known as law of Parsimony, "which prohibits, without a proven necessity, the multiplication of entities, powers, principles or causes", Hamilton W. (1856), *Discussions on philosophy and literature, education, and university reform*, Harper & Brothers, p. 580. It is still dominating scientific reasoning today: "nature may or may not favour simplicity, but we should certainly do so – simply as a matter of rational procedure. […] [this is] a methodological tool of inquiry." Rescher N. (1990), *Aesthetic factors in natural science*, University Press of America, pp. 3-4.

[53] Fisher gives a very pertinent example of the Southwood Working Party, which was an advisory group that gave early assessment of the risk related to the BSE. It stated that they were operating in uncharted waters and *at that time* the disease was not known to be transferable to humans and that was way further research was necessary. This was taken by the risk managers as a conclusion that probability of the risk is low; Fisher E., (2007), p. 80.

[54] In different context Fred Schauer noted that "Slight support (or weak evidence) ought not to be good enough for scientists, but is often sufficient for law". Schauer F. (2010), "Can Bad Science Be Good Evidence: Lie

respective epistemic community there will often be negative collisions: scientific parsimony will often prevent political precaution from coming into play at all.

The problems would be avoided is two distinct conclusions from the *same evidence* can be drawn; if it is insufficient we may have to suspend our epistemic judgment, nevertheless we still can make a practical judgment if we must decide on a policy[55]. Apparently the job of the scientists is to make only epistemic judgments and of the regulators to make practical ones. Both judgments are to be premised on the same evidential basis, while the reasoning methodology may be different. The trouble with the Communication's approach is that the compartmentalisation of the two judgments into risk assessment and risk management makes the practical judgment premised on the epistemic one. On the view advocated here, the risk managers are to engage with the factual premises themselves, i.e. to balance the evidence and this seemingly is what the Court in *Pfizer* allowed them to do.

In the preceding section I have argued that non-arbitrariness requires public authorities to be constrained by the arguments and evidence and this may appear to contradict to the argument here that they should have the liberty to assess the evidence differently. Yet the contradiction is only *prima facie*. Precisely because decision-makers can be constrained by the evidence placed in the public domain they are to remain responsible to draw the practical conclusions from it. But if scientific evidence is central for regulation of certain issue then it should be subjected to the usual mechanisms of accountability and criticism in the public sphere and not black-boxed into obscure expert bodies. In turn courts must review the evidence the public authorities relied upon.

4.3. The Precautionary principle as balancing formula

The issue in *Pfizer* was a Council decision to prohibit the use of virginamicin, an antibiotic used as growth promoter in pig and poultry farming throughout Europe for the past 30 years. Yet a concern was growing that excessive antibiotic use promotes development of antibiotic resistance which might be transferred from animals to humans. Virginamicin is not used in human medicine, but it belongs to the group of streptogramins, and there are several other antibiotics in this group, which are or may be used; it is their efficacy that would be endangered if virginamicin-resistance is transferred to humans. However, there was no conclusive evidence that the continuous use of virginamicin as growth promoter in farming presents *actual* risk of transfer of such resistance and respectively that there is any risk for human health. Pfizer which had been dully authorised to produce virginamicin, claimed that the available evidence did not justify its prohibition, and that the precautionary principle does not warrant adoption of a zero-risk policy. The EU institutions claimed that there is enough evidence that potential risk exists, even though they agreed that there is no evidence for actual danger for the time being and also that precautionary principle does not justify zero-risk policy.

Detection, Neuroscience, and the Mistaken Conflation of Legal and Scientific Norms", *Cornell Law Review*, 95, p. 1208.

[55] See Resnik D.B. (2003), p. 341, emphasis added.

The process which lead to the ban was initiated by Denmark, which decided to prohibit virginamicin use in farming on its territory. It invoked a safeguard clause in the applicable directive, which allowed it to take such action if there is "new information" or "reassessment of existing information" that an EU-authorised product constitutes danger to animal or human health[56]. The Commission referred the information supporting the Danish ban to the Scientific Committee on Animal Nutrition (SCAN), a permanent advisory body. Pfizer also submitted its observations to SCAN and had discussions with the Commission officials. On 10 July 1998 SCAN issued its opinion where it considered the information provided and concluded that "there was no new evidence […] to substantiate the transfer of [antibiotic] resistance [to] compromise the future use of therapeutics in human medicine" and also that "the data provided do not justify the immediate action taken by Denmark to preserve streptogramins as therapeutic agents of last resort in humans"[57]. Nevertheless, the Commission proposed to ban the use of virginamicin and three other antibiotics as growth promoters[58]. The draft was considered by a comitology committee (Standing Committee for Feedingstuffs) which failed to reach a decision. Thus, the regulation was referred to the Council which adopted it (17 December 1998). Pfizer filed an application for its annulment.

The central controversy was on the fact that the EU institutions had disregarded the opinion of the scientific advisory body – SCAN – and relying on the precautionary principle adopted the ban on the ground of what was acknowledged to be inconclusive scientific evidence. There was some evidence for potential risk and abundant evidence from the long harmless practice, so that the institutions had to balance between arguments for and against the ban, while the Court reviewed if that balancing was done correctly with surprising rigour. In effect it "peer-reviewed" the assessments of the institutions in order to decide whether they had proper evidential basis to draw a conclusion that they can take precautionary action.

What provoked this new rigour were, in my view, the special circumstances of the case: there was well-established practice to use antibiotics as growth promoters and no case of actual harm to animal or human health. Thus, the unrestrained discretion of institutions to act as they choose which was allowed by Even though the precautionary principle on its generous interpretation as per *FEDESA* would sustain a ban, public authorities should not destroy so well-established economic activity and abolish the predominant farming practices[59] without sufficiently substantiated argumentation. It would be unpredictable, populist, capricious, superstitious and most importantly it would violate the non-arbitrariness principle.

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[56] Article 11 of Council Directive 70/524/EEC concerning additives in feeding-stuffs, OJ L 270 from 14.12.1970.

[57] *Opinion of the Scientific Committee for Animal Nutrition on the immediate and longer-term risk to the value of Streptogramins in Human Medicine posed by the use of Virginamicin as an animal growth promoter (produced at the request of the Commission in response to the action taken by Denmark under a safeguard clause to ban virginamicin as feed additive)* (10 July 1998), [online], URL: <http://ec.europa.eu/food/fs/sc/scan/out14_en.html>, last accessed 15 February 2011.

[58] Another banned antibiotic was bacitracin zinc. This was the reason for another appeal against this regulation, in *Alpharma Inc. v. Council*, T 70/99 (General Court) [2002], II-03495. The judgment in this case was delivered on the same day as Pfizer and most of the reasoning in the two opinions was identical.

[59] The Court recognised them to be "legally protected positions", see below.

Apparently the other thing that brought about change in the jurisprudence was that the Commission itself had moved to constrain itself with the Communication. Even though the ban was adopted (and the appeal was lodged) before the Communication was issued, the case was decided after it, and the Court relied on it in its reasoning. It explicitly noted that the Communication "may be taken as a codification of the law as it stood at the time"[60]. In the phrase adopted here, with the Communication the Commission adopted a method for collective reasoning, and subsequently the Court controlled whether its decisions were up to its own method.

The first striking thing in this judgement is its sheer length – it is 519 paragraphs long, well above the 50 paragraphs of *FEDESA*[61]. The second and more important thing is that the Court reviewed the scientific information that was presented by the parties in the run up to the ban in terms of availability and comprehensiveness of evidence and of validity of the inferences drawn from it. The Court did not shy away from this task, but plunged in what seems to be quality control of scientific reasoning[62]. As the dispute was on what the proper *assessment* of the risk was, the Court explicitly announced that it will examine whether "the Council was wrong on conclusion of a risk assessment that was not properly conducted"[63] before evaluation of its management of that risk. The third important thing in this judgement is the elevated role that the Court awarded to the scientific advisory bodies. It is impressive that the Court dismissed Council's defence that SCAN was Commission's advisor and the Council was in no way bound by its opinion[64]. The Court held that EU institutions *must* seek advice from independent advisors, which is not new[65], but also that they will be held responsible to justify their deviations from that advice. Finally, it is not immediately obvious, but the Court abandoned the clear distinction between facts and value that the Communication was at pains to establish, and allowed the assessment of the facts to be tinted by the values at stake.

This was the first deviation from the Communication. In Court's understanding of the method, values could be taken into account in risk *assessment.* However, it provided guarantees against arbitrariness – institutions were required to collect all evidence and to take advice from independent experts. Yet this expertise should not prejudice the practical judgement of the political authorities. In order to preserve responsibility to whom it belongs the Court allowed them to diverge from the recommendations on the condition that they can justify it on "sufficiently reliable and cogent"[66] alternative information. To maintain the latter guarantee meaningful the Court itself would engage in rigorous review of the available epistemic base and the conclusions drawn from it.

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[60] Par. 149.
[61] See note 34.
[62] This is not uncharacteristic for the EU judicature; speaking about the pre-Pfizer cases Fisher notes that "the concern of both courts was on the quality of reasoning rather than on the accuracy of factual analysis" (Fisher E. 2007, p. 223). *Pfizer* fits in this process-perfecting tradition well, the only difference was that here the Court took its quality control mission seriously.
[63] Par. 110.
[64] Par. 193-195.
[65] There is a number of cases where courts held that decision-makers are obliged to seek advice, including to seek scientific advice when expertise is needed – see *Angelopharm GmbH v Freie Hansestadt Hamburg,* Case C-212/91 (ECJ) ECR I-00171 for one.
[66] Par. 162.

By allowing values at stake to affect the assessment of evidence the Court turned Communication's bright-line rule into open-ended balancing[67]. Even though it formally maintained the distinction between risk assessment and risk management, it emphasised that the non-scientific factors at stake should be taken into account when the level of unacceptable risk is being determined:

> the authority may take account, *inter alia*, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge[68].

The Court was aware that in cases of risk regulation evidence will be often inconclusive, that is why it held that, having collected the best available expertise,

> the competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society[69].

In turn when reviewing the weighing by the institutions the Court should take account "first of the seriousness of the repercussions […] and second, of the results of the scientific research". Figuratively speaking they have to balance the evidence with scales tilted according to values at stake.

Yet by reinterpreting the precautionary principle as open-ended formula the Court did not issue a blank check to the EU institutions to make arbitrary risk assessments. On the contrary, it placed on them heavy burden to justify their decision with scientific reasoning of highest quality[70]. The Court went a long way to make authorities engage with assessment of the evidence and thus to remain fully responsible for the decision. It was well aware of the danger of allowing the "other" factors to undermine the scientific legitimacy and that is why it emphasised that when the institutions are granted broad discretion to affect legally protected positions[71] "the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental im-

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[67] Balancing as judicial technique usually refers to weighing and choice between two conflicting and incommensurate values which are equally important so that the outcome cannot be given in advance (in rules) but is to be decided with regard to the particularities of the case. Notwithstanding this, it is essential for balancing that the choice is to be made in non-arbitrary way, i.e. following some formula, structure or any other relatively autonomous criteria for correctness. In this case the balancing was done by the Union institutions, but the Court reviewed it to ensure non-arbitrariness.

[68] See paragraphs 152-154.

[69] Par. 161

[70] Par. 154.

[71] Par. 170.

portance"[72]. With its lengthy judgement the Court was struggling to re-establish these guarantees and enforce a method to institutions' reason.

The first guarantee was that the "competent public authority *must* […] entrust a scientific risk assessment to experts who […] will provide it with scientific advice"[73] and they must obtain scientific advice even if the secondary legislation has not specifically provided so. The rationale of this requirement is apparently the information provided by the advisors, once in the public domain, would make a difference. The Court went on to hold that the institutions "must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research"[74] and also that "the institutions were in a position to examine carefully and impartially *all* relevant evidence in a particular case"[75]. The Court sought to perfect not only the decision-making process but the epistemic base of the decision and to enforce methodology for rigorous reasoning.

It is worth to consider the role of scientific advisors which is accorded by this test. Even though SCAN was advisory body *of the Commission*, the Court found that "the Council was wrong to maintain […] that the assessment made in the SCAN opinion could not have any influence on its own position [because it] did not ask for an alternative risk assessment to that carried out by SCAN but that it endorsed the position adopted by the Commission […] and did so on the basis, *inter alia*, of the SCAN opinion [therefore] the risk assessment carried out in this case by the Commission on the basis, *inter alia*, of the SCAN opinion also binds the Council"[76]. Thus the fact that Council's decision was justified in part by the information from the advisor's opinion was taken to mean that Council is constrained by that opinion. In other words, the Court held the Council to abide to the reasons made available in the public domain. The Council would not be able to justify different conclusions if it did not rely also on other scientific information (which in this case it did):

> To the extent to which the Community institution opts to disregard the opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question[77].

Yet in the same time the Court was at pains not to make Council's decision predetermined by SCAN's opinion, because "the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority"[78]. What the Court was struggling to promote was to make the public authorities, layper-

[72] Par. 171.
[73] Par. 157, emphasis added. This claim was following from well established case law.
[74] Par. 159.
[75] Par. 268, emphasis added.
[76] Par. 195.
[77] Par. 199.
[78] Par. 201.

sons as they are, make choices informed by the best scientific evidence yet not predetermined by this evidence:

> risk management […] can be properly performed by a public authority only if it acquires from the various bodies and departments working on its behalf […] sufficient technical knowledge to grasp the full significance of the scientific analysis performed by the independent experts and to decide, in full knowledge of the facts, whether a preventive measure should be taken and, if so, which.

Taking into account the different principles which should guide epistemic and practical judgements discussed above, this should come as no surprise. The legitimate way to respond to uncertainty is to allow public authorities to draw different conclusions from the same evidence. This rationale explains the almost baroque holding that the Council may "rely on certain aspects of the scientific analysis"[79]. By allowing the political authorities to rely only *partly* on scientific opinions, the Court intended to encourage them[80] not to treat "The Science" as a black-box but to engage with the scientific arguments and if need be, to balance them differently with regard to the values they are called to protect. On other accounts this partial reliance would appear as allowing the authorities to cherry-pick the scientific advice. The only way for the Court to ensure that the new freedom to take different view on the same evidence will not violate the principle of non-arbitrariness was to engage itself in rigorous judicial review.

As for the review itself, the Court did not discuss much the intensity of review, nor its own role in imposing discipline of reason; it only reiterated the mantra that it is a case of discretion and it will review the decision only for manifest error, misuse of powers or excess. However the judgement itself was a striking departure from the lenient earlier jurisprudence of both the General Court and the ECJ. The review consisted of two parts. In the first the Court scrutinised whether Council had distorted SCAN's findings, i.e. whether the same evidence could be assessed differently. In the second part, the Court reviewed whether from these factual assessment the Council could logically draw the conclusions it did (i.e. if he had made any "errors in conclusion").

Thus, the Court satisfied itself that the institutions reasoning was sufficiently substantiated by with the available information, they did not distort the SCAN findings but only weighed the evidence differently, did not made manifest error in drawing conclusions on the basis of it, and narrowly upheld the contested regulation.

The rigorous scrutiny of the justification of the decision taken by the political authority in *Pfizer* may appear similar to that of the infamous *Lochner* case of the US Supreme Court[81]. *Lochner* is criticised as allowing the courts to second-guess the legislature on the substance of the adopted rules. There the Supreme Court reviewed a statute limiting the working hours of bakers on the ground of health concerns. The Supreme Court substantively re-evaluated the arguments for protection of public health and decided that the measure was "unreasonable, unnecessary and arbitrary interference" in

[79] Par. 200.
[80] According to many observers, Chalmers in particular, this effort backfired and made the community institutions surround themselves with the best available expertise only to defer to it.
[81] *Lochner vs. New York,* 198 US 45 (US Supreme Court).

contractual freedom. Even though the *Pfizer* court seems to do that as well, in my view it is quite different. What the Court was doing was rigorous evaluation of the quality of evidence, and also review of validity of conclusions. As the evidence was inconclusive, i.e. allowed more than one logical conclusion, the Court allowed the public authorities to make the ultimate choice. The judicial approach in *Pfizer* should rather be called legislative due care review and the more appropriate analogy is with the *Waterpenny* case of the German Constitutional Court[82]. There the court reviewed the constitutionality of legislative act which was justified with economic arguments. It required from the legislature, "when introducing social science evidence into their considerations […] to take due care in not glossing over the evidence and being circumspect in gathering enough of it. […] to engage in an extensive procedure of fact finding and hearings prior to legislating, just in order to make sure that the act under controversy will survive before the constitutional court"[83]. Similarly, *Pfizer* established a tight standard for due legislative care. It may be debatable whether the *Pfizer* Court was too lenient or too rigorous, yet it did open space for value judgements and political sensitivities which the *Lochner* court did not, and that is why it ruled for the administration in the end of the day.

It is debated whether this new test was stringent or lenient. On one side, Corkin claims that *Pfizer* put the "evidential bar so low that the community institutions should, in most cases, be able to make their regulations review-proof in spite of any "inconvenient" scientific advice"[84]. Others think the test was too stringent and placed unbearable evidential burden on the institutions (Chalmers) and impeded their ability to react to the unexpected (Fisher). According to Chalmers the Court allowed to the authorities to stray from SCAN's opinion only because two conditions were fulfilled: "the Council relied upon other scientific evidence of equivalent probative value and gave reasons for why it departed from SCAN's opinion"[85].

If we distinguish the scope of discretion from the reasoning rigour that may be required in exercising it both sides are correct[86]. Institutions may have wide array of options for possible action yet be subjected to a stringent requirement to derive their choice from persuasive evidence. Even though *Pfizer* was apparently departure from earlier cases like *FEDESA* or *Angelopharm*[87] Corkin correctly notes that it "fit[s] comfortably into the same process-perfecting tradition"[88]. If Fisher was right to say that the Court limited the scope of discretion in applying the precautionary principle the ban would be overturned. On what she calls rationalist-instrumentalist approach the EU institutions would not be allowed to deviate from SCAN's opinion.

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[82] *BVerfG Entscheidung, Gen. 413/88 and 1300/93* (BVerfG).
[83] Backhaus J.G. (1998), "Harmonization of Law in the European Union", in Newman, P.K. (ed.), *The New Palgrave Dictionary of Economics and the Law*, Macmillan Reference, Stockton Press.
[84] Corkin J. (2002), "Regulating Risk Regulation: How the Court of Justice ensures the European Community responds to both popular and scientific voices", *SCARR: Social Contexts and Responses to Risk*, p. 20.
[85] Chalmers D. (2003), "*Food for Thought*: Reconciling European Risks and Traditional Ways of Life", *Modern Law Review*, 66, p. 541.
[86] Fisher apparently contrasts the breadth of discretion with the use of rigorous methodology, and this is why she is very critical of *Pfizer* and its progeny.
[87] See note 65.
[88] Corkin J. (2002), "Regulating Risk Regulation: How the Court of Justice ensures the European Community responds to both popular and scientific voices" (note 84), p. 15.

Chalmers is more to the point, because in his view the discretion was not limited, but only its exercise was made more difficult by the additional burden for justification. Indeed, even though the Court upheld the ban, the review was rigorous and if the judgement is juxtaposed to *FEDESA* it becomes obvious that this was not a limited review as Corkin believes. Yet is correct to note that *Pfizer* opened space for political judgement (in the face of the Communication). Yet again, with regard to the aftermath of the case, Chalmers and Fisher are rightly concerned that the Court placed so heavy justificatory burden to the institutions who wish to deviate from advisors, that they effectively never did it again.

Alberto Alemanno suggested that peer-review should be practiced in risk assessments, where "it involves an in-depth assessment of the assumptions, calculations, alternative interpretations, methodology and conclusions. In particular, by taking the form of a deliberation, it involves an exchange of judgements about the appropriateness of methods and the strength of the author's inferences"[89]. In my opinion the *Pfizer* court was very close to doing that. Its review, just like the peer reviews aimed to ascertain transparency and consistency of reasoning and inclusion of all relevant argumentation. To generalise beyond the particular case, both the peer editing an academic article and the reviewing court have to engage substantively with the argumentation, while abstaining from second guessing the assessments and the conclusions under review. Currently Pfizer is the leading authority on the precautionary principle in the EU. However, for the ten years since it was decided its rigour remains unmatched[90] so my claim for the potential of courts to exercise epistemic vigilance may be overblown.

In the recent *Gowan* case[91], the Commission had deviated from the received expert advice to restrict the use of certain substance for plant protection. On its surface the ECJ followed the earlier reasoning of the General Court in Pfizer and confirmed that the Commission could not adopt unjustified restrictions without scientific justification[92], and claimed to have verified whether the facts it relied on were accurately stated and supported the conclusions reached. But it did so perfunctorily and failed to control the steps of the reasoning process which lead to the decision as was done in *Pfizer*; remarkably it failed to review whether the Commission could modify its own position without stating reasons or having new justification. In view of one commentator it reduced the reason giving requirement to a duty of production and not a duty of persuasion; it surrendered its role as gatekeeper of precautionary action thus undermining the legitimacy of the decision-making process in cases of uncertainty[93].

On the account suggested here, a more rigorous review leading to occasional strokes of arbitrary actions of the EU institutions would strengthen their legitimacy. Unfortunately, this time is yet to come.

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[89] Alemanno A. (2008), "EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review", in Vos E. (ed.), *European Risk Governance, Its Science, Its Inclusiveness And Its Effectiveness*, vol. 6 (Connex Rep. CONNEX 2008), p. 66.

[90] In Fisher's view "neither the court[s], nor the AGs engage in a particularly careful analysis of the scientific uncertainties involved" Fisher E. (2007), (n. 16), p. 238.

[91] Case C-79/09, *Gowan v. Ministero della Salute*, Judgment of 22 December 2010.

[92] Par. 53.

[93] Case note, Alemanno A. (2011a), "Gowan (C-79/09)", *Common Market Law Review*, 48, pp. 1329-1348, 14.

5. Conclusion

The Commission of the European Union felt the need to increase its legitimacy by imposing some method for discipline of reason when applying the precautionary principle. For that purpose it adopted a Communication which turned what was thus far broad and empowering principle into a clear-cut formula or bright-line rule, which would function ideally with quantifiable scientific conclusions untainted with political considerations. It is arguable whether the nature of the regulated matter, marred by uncertainty even when the best available science is employed, could be subject to such framework at all. Without explicitly departing from this interpretation, in *Pfizer* the Court allowed for more flexible balancing of evidence with regard to the values at stake and made best efforts to put the EU institutions back in charge of doing that. It had clear intent both to keep political authorities responsible for the choices, and in the same time make their decisions informed by the scientific expertise. This was delicate task, as the line between mandating the institutions to defer to experts on life and death issues, and allowing them free sway to disregard science is thin. On the question whether and how much the authorities are constrained by the opinion of their expert advisors hangs the balance between scientific and political legitimacy of the Union regulation. Holding that SCAN's opinion is not binding would risk arbitrariness of decisions and stripping the independent risk assessment of any meaning. Holding that it is binding would shift all decision-making power to obscure expert bodies. By allowing the Union institutions to rely on the provided scientific advice but to draw different conclusions, the Court stroke a middle ground. In the parlance adopted here, it enforced a modified version of Commission's own formula for discipline of reason and argument-sensitive decision-making.

The way the Court seemingly squared the circle was by rigorous review of the quality of information and of the validity of conclusions, and deferring to the outcome of the balancing. This was its attempt to ensure that in conditions of uncertainty the choice will be open to the Union institutions but that they will remain responsive to scientific argumentation albeit the balance will be conditioned by the values at stake.

Yet the rigour of Court's approach may have backfired. The burden to justify deviation from expert advice encouraged the Union institutions to defer to the received expertise rather than critically engage with it. *Pfizer* judgement was followed by proliferation of expert advisory agencies in the EU, which are likely to provide highest quality of expertise, thus promoting scientific legitimacy, however this very excellence of the available epistemic base makes all but impossible for the Commission to find alternative source of knowledge if it were to make an independent choice.

With regard to the account developed in the beginning of the paper, in *Pfizer* the General Court demonstrated that judiciary is able to evaluate how evidence was used or misused by political authorities. It also showed the ability of courts to hold the authorities up to their own standards for argumentation. Finally, if we can generalise the analysis of precautionary principle as a formal method for republican governance, it shows that formulas add rigor to decision-making, reduce its arbitrariness, make it sensitive to arguments, new evidence and changes of belief. Procedurally, this makes hidden assumptions and value judgements explicit, provides for transparency and allows quality control, by judges or crit-

ical public. The limits of the formula are also made obvious – formulas may bring about consistency and thus fairness, but cannot provide The One Right solution, the use of independent scientific expertise does not prevent political contestation, it only shifts it into different domain. That is why instead of searching for what is unattainable, the authorities and reviewing courts should rather gear the decisional framework to integrate competing evidence and diverging interests, thus merging scientific and political legitimacy rather than segregating them.

It is often suggested that guidances like the Communication and soft law in general structure discretion[94]; on the suggested account that is to say that they facilitate the argumentative rationality and make the decision making reasoned and non-arbitrary. The soft instruments are methods for discipline of reason, which ideally would constrain the decision-maker to act non-arbitrarily yet would not deny it the necessary flexibility of judgement and would not relieve it from the flexibility for that judgement. While the soft instruments themselves would often suffice as a method, I hope to have showed how courts can enforce (and reshape!) it.

Note that although the courts can control the rigour of reasoning of just about any authoritative decision, they rarely do. The oft-cited reason is lack of resources, but my guess is that courts willingness to take a hard look also depends on the availabilities of alternative reasons and narratives in the public sphere. Such is the argument of Alberto Alemanno who claims that impact assessments, which are increasingly used in US and EU, may become important source of reasons in the subsequent judicial review[95]. Similarly Wyatt suggests that the most important difference that the so called yellow card mechanism would make is that national parliaments would place in the public sphere new arguments which would facilitate rigorous judicial review[96]. The placement of reasons and arguments in the public sphere can enable judicial rigour, which in turn would increase the role of the reasons. This is a virtuous circle which is needed to implement the republican ideal of non-arbitrary governance.

[94] For the classic argument see Scott J., Sturm S.P. (2007), "Courts as Catalysts: Rethinking the Judicial Role in New Governance", *Columbia Journal of European Law*, 13.

[95] Alemanno A. (2011b), "A Meeting of Minds on Impact Assessment: When ex ante Evaluation meets ex post Judicial Control", *European Public Law*, 17, pp. 1-20.

[96] Wyatt D. (2006), "Could a *yellow card* for national parliaments strengthen judicial as well as political policing of subsidiarity?", *Croatian Yearbook of International Law and Policy*, 2, pp. 1-17. He sees reason giving as important procedural guarantee for substantive correctness of the application of the subsidiarity principle and laments that currently the explanatory memoranda of legislative drafts have only brief and self-serving references to subsidiarity and the arguments against do not enter public domain at all. With the opinions of national parliaments this situation may change dramatically (but a chicken and egg problem, to take off them must see their opinions matter).

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Direct to Consumer Genetic Testing: Steps on the Path towards a Personalised Healthcare?

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Abstract: Genetic tests are sold (mainly online) by direct to consumer (DTC) genetic test companies straight to an individual. Simple as it may seem, this kind of activity raises ethical and legal issues which need to be faced in order to avoid unintended consequences and possible abuses. Main concerns regard the absence of involvement of a healthcare provider into the process and privacy issues. Both of these aspects should be taken into account in order to understand how to shape a proper regulatory framework without hampering individuals' autonomy and market development. As this paper suggests, the development of new technologies, determining an increased degree of choice and control over health, requires to reason about the role of law in establishing how far this wish to "take control" over health related issues could go.

Keywords: direct to consumer (DTC) genetic testing; personalised medicine; informed consent; biomedical research; privacy

1. The raise of DTC genetic tests: widening the information society

> We are at the beginning of a personal-genomics revolution that will transform not only how we take care of ourselves but also what we mean by personal information. In the past, only elite researchers had access to their genetic fingerprints, but now personal genotyping is available to anyone who orders the service online and mails in a spit sample[1].

With this statement the so called "Retail DNA Test", more commonly referred to as direct-to-consumer (DTC) genetic test – was introduced by TIME magazine.

Genetic tests – analysing human DNA, RNA, chromosomes, or proteins in order to detect mutations involving specific diseases, identifying risks, predicting responses to drugs, or simply highlighting ancestral relationships – are sold (mainly online) by DTC genetic test companies straight to an individual: the process develops through a customer purchasing DTC genetic tests over the Internet, receiving a kit by mail, providing a sample (buccal swab or saliva), shipping it back to the laboratory and receiving results. Companies are basically offering an alternative way to obtain personal genetic information, moving around the conventional route provided by the health service[2].

Simple as it may seem, this kind of activity raises crucial ethical and legal issues which need to be faced in order to avoid unintended consequences and possible abuses.

Main concerns regard, on the one side, the absence of involvement of a healthcare provider into any of the steps of the described process and, on the other hand, privacy issues which have to be given relevance, considering that companies are going to have in their hands samples and related information.

Both of these aspects should be taken into account in order to understand how to shape a proper regulatory framework without hampering individuals' self-determination and market development.

The phenomenon of DTC genetic testing perfectly fits into the modern society, more and more shaped as a society of information: in this sense, genetics developments in the last decade gave a powerful contribution in making available a huge mass of information, which need to be managed and interpreted. The possibility of being provided with information about most intrinsic features of one's constitution made the way for a different attitude towards clinical practices, health related matters and decision-making processes in that field. The panorama of last decades' healthcare has been marked by a process of increased patients' participation in areas that were once exclusive domain of physicians.

How far this process went can be highlighted by giving a glance to the language used in discussion: patients are more and more referred to as consumers and the widespread defensive attitude showed by physicians proves that the perceived aim of medical care underwent a controversial shift from care to satisfaction.

The aim of empowering individuals over matters of health is pursued through different strategies which involve not only direct to consumer genetic testing, but different as-

[1] Hamilton A. (2008), "Best Inventions of 2008: The Retail DNA Test", *Time*, 29 October, [online], URL: <http://www.time.com.ezp.biblio.unitn.it/time/specials/packages/article/0,28804,1852747_1854493,00.html>
[2] Kaiser J. (2007), "It's all about me", *Science*, 318, p. 1843.

pects of healthcare, such as seeking health information, accessing data about health history and status, obtaining medication, imaging directly online, as well.

All of these new possibilities, which determine an increased degree of choice and control over health, are claimed, by some, to herald a new era of personalised healthcare, embodied not only by personalised medicine, but by online medicine and medical profiling, as well. Appreciation for an increased degree of involvement and choice must not leave in the background the fact that these innovations challenge traditional medical professionalism and the doctor-patient relationship. The call for autonomy has to be properly balanced with the public interests in avoiding harm and protecting personal information. If the past paternalistic approach was characterised by a lack of information, patients have nowadays to face an overflow of information which often appear to be of doubtful clinical validity and utility. It is therefore necessary to reason on the role law shall play in establishing how far this wish to "take control" over health related issues could go.

2. The nature of supplied services and provided information

First thorny point to be considered is that of the nature of the activities carried out by DTC genetic test companies. At the very beginning tests addressed only dietary issues and people received indications about what kind of food they should eat. Business went on and nowadays main companies (such as 23andMe, deCODEme, Navigenics, Lumigenix, Knome…) offer a wide array of tests of different nature: ancestry tests, aimed at reporting on familial relationships among individuals go together with predictive genetic information and diagnostic testing which allow to identify carrier status of genetic diseases or to detect a condition or a predisposition towards it and, lastly, pharmacogenetic testing linked to genetic variations that may imply an adverse response to drug treatments. Practical relevance of information obtained by these kinds of tests is obviously characterised by different degrees of sensitivity.

Regulatory interventions need to take into consideration the manifold nature of the object they should address: what customer is going to receive is actually the result of a combination of tests, carrying information which can alternatively be qualified as health related – and in this case stronger safeguards should be required – or not. Another consideration that affects results' reliability is that European DTC companies perform testing on a gene-by-gene basis, involving a smaller number of SNPs (single nucleotide polymorphisms)[3] and thereby weakening disease risk prediction. However, even in the U.S., where DTC genetic testing mostly involves a genome-wide SNP analysis, it has to be noted that technology is currently just a surrogate for whole-genome sequencing[4].

All of these aspects make evident that qualification of activities carried out by DTC companies is strictly related to the very nature of information provided. Companies themselves are perfectly aware about consequences which might derive from the determination of this qualification and about the substantial difference about regulation implied.

[3] SNPs are variations of a DNA sequence given by the difference of a single nucleotide.
[4] Kricka L.J. *et al.* (2011), "Direct-Access Genetic Testing: The View From Europe", *Nature Reviews Genetics,* 12, 670, October.

It is not by chance that almost each of the most active companies in this field require customers to read an online form which not only aims at informing buyers, but to serve the specific purpose of protecting companies from liability, as well. In this sense, for instance, 23andMe explains customers that information they learn from the company "is not designed to diagnose, prevent or treat any condition or disease or to ascertain the state of [...] health" and that "23andMe's services are intended for educational, informational and research purpose only"[5]. Similarly, Navigenics states that offered information is "not intended to substitute for professional medical advice, diagnosis or treatment"[6]. Likewise, Pathway Genomics' Terms of Service inform customers that "information on the website is for informational and educational purposes and is not intended to be used for medical advice or diagnosis or treatment"[7]. All of these statements cannot be considered as mere formal disclaimers and have to be regarded as highly relevant, even from a legal standing point: this is even more true if we consider that U.S. FDA – which, as we will see, is involved in the regulation of these issues – indicates that the basis for determining whether a genetic test is clinical, is the requirement of the "intended use"[8], and not that of its actual or potential clinical significance.

Another crucial point is strictly related to genetic data's own features: raw data obtained by performing a test have by themselves no concrete informative relevance. In order to obtain meaningful information, in fact, data have to be properly interpreted and translated into practical conclusions. This aspect adds more confusion to the discussion: Lumigenix, for instance, decided to exclude from its services certain information – specifically connected to very serious conditions[9].

Nevertheless, excluding information does not necessarily mean excluding the data: it might well be that raw data returned to consumers could contain variants about the "excluded" traits, which end up to be traits about which no specific report or interpretation is given. The point is made even trickier by the recent appearance of online tools for analysing personal genomic data[10].

In this respect, it has to be highlighted that one company offers a genetic counselling service[11] and most of others recommend buyers to consult with a physician before making

[5] [Online], URL: <https://www.23andme.com/about/consent/?version=1.3>.
[6] [Online], URL: <http://www.navigenics.com/visitor/what_we_offer/our_policies/terms_conditions/>.
[7] [Online], URL: <https://www.pathway.com/about-us/terms-and-conditions>.
[8] This approach is consistent with §201(h) of the Food, Drug, and Cosmetic Act (FDCA) under whose provisions a medical device (subject to the FDA's authority) is defined as "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease…". It would also appear to logically require an FDA policy whereby DTC genetic tests clearly limited to research, educational or informational intended uses would not be subject to FDA regulation. Moreover, according to the Supreme Court, "[v]iewing the FDCA (food drug and cosmetic act) as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use", *United States v. Rutherford*, 442 U.S. 544, 556 (1979).
[9] The company doesn't currently test for BRCA1/2 markers, Cystic Fibrosis and Tay-Sachs disease, genomic testing for an individual's response to certain medications.
[10] For instance, Promethease, SNPTips and Interpretome.
[11] Navigenics is the only company which offers a "team of board-certified Genetic Counselors on staff", available to answer questions.

health related choices on the basis of the obtained data[12]: the onus, nonetheless, is on the customer.

Answering the question about how to qualify services provided by DTC genetic test companies is a necessary prerequisite in order to understand which is the best regulatory framework to be adopted. In this field, the blurring power of genetics, which blended the dividing line between health and illness, talking in terms of possibilities and probabilities rather than knowledge and certainty, shows all its challenging strength.

It has to be acknowledged that DTC testing is basically a business selling a product or a service to individuals, which play the role of independent consumers, making their own decisions and therefore exercising their right to self-determination. Even if companies advice customers to talk to a physician, their service is, nonetheless, sold out of the context of traditional healthcare relationships. Which rules have to be applied? The basic business relationship existing between consumer and test providers intuitively has to follow a path which is different from that guiding physicians' actions. In this case, a principle like that of beneficence, which – together with others – informs modern clinical practice, makes few sense and is overrode by that of autonomy, strengthened by market's logic: there is a strong call for finding a convenient balance between strict interventions, which would hinder progress and welfare, and a short-sighted vision which, underestimating the potential of these new practices and leaving them unlimited, would cause DTC genetic testing to harm rather than benefiting public.

In order to get this achievement it could be useful to focus attention on the main risks involved in DTC genetic testing practices.

2.1. The limping knowledge

As outlined before, one of the main issues is related to the possibility of interpreting the information received by the company, especially when it could be possible to base on them specific health-related decisions. This aspect, moreover, can well be divided into different more specific concerns.

The first one is based on the circumstance that consumers could be misled by results: in this sense, in the U.S. two reports from Government Accountability Office (GAO) can be cited[13]. After recognising that "genetic testing is becoming an integral part of health care with great potential for future test development and use", GAO undertook an investigation about nutrigenetic tests offered by different companies, purchasing tests from four web sites and creating "fictitious consumers". Results, according to GAO's opinion,

[12] See, to make an example, Pathway Genomics Terms and Conditions, cited above: "[t]he individuals should always consult with their physician or other qualified healthcare provider about questions concerning a medical condition, and before starting, stopping or modifying any treatment or medication".

[13] [Online], URL: <http://www.gao.gov/new.items/d0754.pdf>. Very similar conclusions were recently reached by the European Academy Science Advisory Council and the Federation of the European Academies of Medicine in their report *Direct-to-consumer genetic testing for health-related purposes in the European Union*, [online], URL: <http://www.easac.eu/fileadmin/Reports/EASAC_Genetic_Testing_Web_complete.pdf>), in which the two institutions do not "wish to encourage EU citizens to use DTC GT" because it "has little clinical value at present and, on occasion, has potential to be harmful".

proved to be ambiguous, presented in a way that renders them meaningless, alarming or misleading. GAO's representatives testified that these companies made medically unproven disease predictions, concluding the report affirming that

> companies that sell nutrigenetic tests like the ones we purchased may mislead consumers by promising results they cannot deliver. Further, the unproven medical predictions these companies can include in their test results may needlessly alarm consumers into thinking that they have an illness or that they need to buy a costly supplement in order to prevent an illness. Perhaps even more troubling, the test results may falsely assure consumers that they are healthy when this may not be the case.

In short, there is a strong evidence for both overestimation and underestimation of risks.

Four years later, in 2010[14], GAO was asked to investigate DTC genetic tests at the time on the market and the advertising methods used to sell them. This time GAO purchased 10 tests, each from four companies, selected five donors and sent two DNA samples from each donor to each company. After the donors received their results GAO compared risk predictions for 15 diseases, made calls to the companies in order to seek health advice, consulted with genetics experts, interviewed representatives from each company and similarly as years earlier concluded that "test results are misleading and of little or no practical use. For example, GAO's donors often received disease risk predictions that varied across the four companies, indicating that identical DNA samples yield contradictory results". GAO reported that one of the donors received DNA-based disease predictions that conflicted with their actual medical conditions and, further, that some companies even failed to provide the expert advice they promised. GAO has eventually referred all the investigated companies to the Food and Drug Administration and Federal Trade Commission for appropriate action.

The report contains also consulted experts' opinion: "the fact that different companies, using the same samples, predict different directions of risk is telling and is important. It shows that we are nowhere near really being able to interpret [such tests]".

Part of the problem outlined by GAO is pathological and is probably linked to ill technical practices, but other part of it – and here comes the second concern – is deeply rooted into the nature of provided results, which – as said before – need to be interpreted in order to become meaningful. The interpreting activity is inherently influenced by many factors, which have to be taken into account when evaluating different responses coming from different companies.

In this sense, some studies try to single out reasons underlying differences in the obtained responses. Thus, for instance, while Navigenics distinguishes population disease risk between men and women (for example, men are more likely to have heart attacks than women), 23andMe primarily considers age (for example, incidence of rheumatoid arthritis increases with age)[15]. Risk assessment, in particular with reference to polygenic conditions is a complicated endeavour, determined by the discretional relevance given to some key factors: main differences are due to three reasons:

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[14] [Online], URL: <http://www.gao.gov/new.items/d10847t.pdf>.
[15] Ng P.C. *et al*. (2009), "An agenda for personalized medicine", *Nature*, 461, 8 October, pp. 724-726.

> [f]irst, different average lifetime risks for the same underlying populations are used. Second, different criteria are used in the selection of research studies, which leads to the use of different SNPs and loci by each company. Third, different quantitative risk assignment methodologies are used[16].

The physiological degree of variability which comes together with any kind of interpreting activity has to be rigorously distinguished by any kind of distortion: this can be done by means of establishing clear and harmonised standards in order to evaluate two main measures of accuracy of tests together with a measure of their quality. These are analytical validity (which refers to how well the test predicts the presence or absence of a particular gene or genetic change) and clinical validity (which refers to how well the genetic variant being analysed is related to the presence, absence, or risk of a specific disease), one the one side, and clinical utility (referred to whether the test can provide information about diagnosis, treatment, management, or prevention of a disease that will be helpful to a consumer) on the other.

The outlined concerns, centred on the lack of knowledge on the part of the individual consumer, who not necessarily has the means to interpret the results of a genetic test – assuming that the validity of the carried out tests could be taken for granted – is exactly the same as that which induced the adoption in many countries of pieces of legislation aimed at guaranteeing and focusing on the phase of counselling, which happens to be one of the distinctive traits on genetic data processing rules. Art. 11 of the UNESCO Declaration on Human Genetic Data[17] calls for a "non directive, culturally adapted and consistent with the best interest of the person concerned". To make another example, art. 12 of the so called Oviedo Convention[18] and, more specifically, art. 8 of the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes[19], requires "appropriate genetic counselling" to be available for the person who is undergoing tests predictive of a monogenic disease, tests serving to detect a genetic predisposition or genetic susceptibility to a disease, tests serving to identify the subject as a healthy carrier of a gene responsible for a disease. Moreover the same article states that the form and extent of this genetic counselling shall be tailored according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices. Similar provisions are introduced by national sources of law: for instance, §10 of the German *Gendiagnostikgesetz* (GenDG) of 2010 provides that counselling shall take place – for both diagnostic and predictive genetic testing – in a manner that is generally comprehendible and non-directive. In particular, it shall include an explanation of possible medical, psychological and social issues which might arise in relation to conducting or not conducting the subject genetic examination and as regards any given or potential examination results, alongside the possibilities of

[16] Swan M. (2010), "Multigenic condition risk assessment in direct-to-consumer genomic services", *Genetics in Medicine,* 12, pp. 279-288.
[17] UNESCO, *International Declaration on Human Genetic Data*, 16 October 2003.
[18] Council of Europe, *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*, opened for the signature by Council of Europe's member states on 4 April 1997.
[19] The Protocol was opened to subscription in Strasbourg, on the 27 November 2008.

supporting the subject person in the context of any physical or psychological difficulties which have or may occur as a result of such genetic examination or its results[20]. Similar provisions can be found in legislations of many European countries: this is the case, among others, for Austria[21], France[22], Italy[23], Portugal[24] and Switzerland[25].

The main issue concerning all of these provisions is that – how the Title of the Additional Protocol to the Oviedo Convention clearly shows – they formally apply only to genetic testing *for health purposes*.

A connected concern, raised by some, is that the essential separation between giving information and providing interpretation could cause people to turn to traditional health services in order to obtain clarifications, and putting on physicians the duty to deal with analytical validity, clinical validity and utility[26].

2.2. The privacy concern

A further concern is that of privacy. As in many other fields of genetics, privacy policies play a key role in DTC genomics. With regard to this specific point it has firstly to be considered the fact that companies receive a biological sample from the consumer and, by means of sequencing activities, they obtain related information: the intimate relationship between the material dimension and the informational one, is one of the most disputed into the legal genetic discourse.

Two ontologically different entities have to be considered together, given the recent new relevance gained by biological samples as privileged sources of data. As we are going to explain in a while, also seen in this angle, activities carried out by DTC companies seem to be attracted from the mere realm of business towards more sensitive disciplines, like that of scientific research.

And once again, difficulties in establishing which nature has to be attributed to information derived by samples come to be of the utmost importance: according to their degree of sensitivity different standards of protection will be required. Genetics, as said before, is more and more blurring boundaries and even traditional categories – like that of health-related information – seem to start crackling.

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[20] In the original language: "Die genetische Beratung erfolgt in allgemein verständlicher Form und ergebnisoffen. Sie umfasst insbesondere die eingehende Erörterung der möglichen medizinischen, psychischen und sozialen Fragen im Zusammenhang mit einer Vornahme oder Nichtvornahme der genetischen Untersuchung und ihren vorliegenden oder möglichen Untersuchungsergebnissen sowie der Möglichkeiten zur Unterstützung bei physischen und psychischen Belastungen der betroffenen Person durch die Untersuchung und ihr Ergebnis".

[21] § 69 of the Gentichinkgestetz – Einwilligung und Beratung.

[22] Article L1131-1-3 introduced into the *Code de la Santé Publique* by art. 2 of *Loi* n. 2011-814 in July 2011.

[23] Point 5.1. of the General Authorization for Genetic Data Processing, 24 June 2011.

[24] Law 12/2005, January 26.

[25] Art. 14 of the Loi fédérale sur l'analyse génétique humaine(LAGH), 8 October 2004.

[26] Hunter D.J., Khoury M.J., Drazen J.M. (2008), "Letting the Genome out of the Bottle. Will We Get Our Wish?", *New England Journal of Medicine*, 358, 10 January, pp. 105-107. According to some Authors "a primary role of health care professionals in the future may be to interpret their patients' DTC genetic test results and advise them about appropriate follow-up", see: Evans J.P., Dale D.C, Fomous C. (2010), "Preparing for a Consumer-Driven Genomic Age", *New England Journal of Medicine*, 363, pp. 1099-1103).

Generally speaking, however, the specific branch of genetic research is making its way through other kinds of scientific research and is catalysing not only the attention of the scientific community but huge amounts of resources and investments as well.

A quick glance to privacy policies by some DTC companies will suffice in understanding how DTC genetic testing and genetic research could touch each other and sometimes overlap and which are the risks for rights and interests involved.

To make some examples, we can consider TruGenetics' Privacy Policy and Terms of Use which contain a promise of confidentiality and anonymity, but no promise that data will not be distributed.

The Privacy policy's statement assessing that "genetic information will be kept in a secured protected database" and that users can "authorize the release of […] genetic information" has to be read under the light of Terms of Use, which clarify that "genetic information will be used for genetic research" and that TruGenetics may "conduct this research, or may partner with another organization, including non-profit and commercial entities, to conduct research".

Moreover, it is openly stated that TruGenetics may charge a fee for conducting research using the database, that research may lead to publications that reveal the finding (but they won't contain any information that can be used to identify users) and to the development of a commercial product; in this case users will not receive any payments if this occurs.

Even mechanisms of protection that usually guard participants' rights in genetic research come into question: for example TruGenetics provides that withdrawal is allowed anytime and information will not be included in any future research. Nonetheless, if that information "was included in research conducted or initiated prior to receiving this documentation, that research will not be altered".

It is quite evident that the purpose of data collection is for it to be used also by third parties for research, and the policy seems to provide no kind of assurance that the data will not be used for other reasons and no indications about how data will be transferred in the ordinary course of business or bankruptcy are provided. Relevant and more specific provisions are contained, as well, in the three policies established by 23andMe: Privacy statement, Consent and Legal Agreement and Terms of Service.

Terms of Service distinguish between "23andWe Research" – which is a scientific research that 23andMe performs with the intent to publish in a scientific journal carried out by using "only […] Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document" – and "R&D", explicitly excluded by 23andWe Research activities, which are research and development activities performed by 23andMe on users' data, which may include "conducting data analysis that may lead to and/or include commercialization with a third party". The distinction does not appear so well defined.

Anyway, to start using the 23andMe services it is necessary to accept the Terms of Service, which can be done by simply start "actually using the Services"[27], while

[27] According to Terms of Service, "[i]n this case, you acknowledge and agree that 23andMe will treat your use of the Services as acceptance of the TOS from that point onwards".

participation in 23andMe Research is "voluntary and based upon an IRB-approved consent document" and the research "only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document".

The opening of this document is absolutely clear in affirming that "participating in this study, you are agreeing to allow us to use your genetic data, survey responses and any other non-identifying data for research on genetic markers associated with traits, disease and other physical conditions". This statement seems to be very far from the logics intuitively connected to those underlying DTC genetic testing and shifts the focus from obtaining information for personal purposes towards a proper participation into a research program.

Beyond the clearness of this first statement, it is openly said that the "research project is open-ended": this kind of perspective is barely compatible with a requisite of truly specific and informed consent, considering that it is absolutely not limpid which kind of research is going to be performed, in this bringing the proposed model to be very close to forms of blanket consent[28]. The approach is clearly an all-or-nothing approach, since the only alternative possibility offered by the online Consent Document is "not to participate in the 23andWe research study".

The vagueness of research purposes can be inferred also from the fact that once user have chosen to have his/her saliva stored, the company "may also use the results of further analysis" of the sample in research. In this case, resulting data may or may not be returned to the customer.

As to 23andMe activities, (which are supposed to be different from those of 23andMe Research) very careful provisions such as that which states that unless customer decides to biobank or store saliva sample or DNA at company's laboratory, after analysis, the "remaining DNA and saliva samples will be destroyed", go together which less transparent statements. For example it is said[29] that "[b]y obtaining 23andMe's services, you are agreeing to contribute your genetic information to our research efforts as described below. These efforts could translate into meaningful information about your genetics" and that 23andMe Sponsored Research "will analyze your genetic and other voluntarily contributed personal information as part of our scientific research with the purpose of advancing the field of genetics and human health".

Section 5 of the Consent document clarifies that "[i]f 23andMe develops intellectual property and/or commercializes products or services, directly or indirectly, based on the results of this study, you will not receive any compensation": attention was driv-

[28] A model of consent covering "all forms of research". See Rumball S., Mccall Smith A. (2002), *Report Human Genetic Data: Preliminary Study by the IBC on its Collection, Processing, Storage and Use,* UNESCO, Paris, 15 May. Similarly, the WHO somehow supported this kind of model stating that "[a] blanket informed consent that would allow use of sample for genetic research in general, including future as yet unspecified projects appears to be the most efficient and economical approach, avoiding costly re-contact before each new research project" (WHO, *Proposed international guidelines on ethical issues in medical genetics and genetic services*, report of a WHO meeting on ethical issues in medical genetics, Geneva, 15-16 December 1997, p. 13).

[29] [Online], URL: <https://www.23andme.com/about/consent/?version=1.3>.

en on this statement when, in May 2012, the company was awarded its first patent, entitled "Polymorphisms associated with Parkinson's disease" [30].

As to Collaborative research, 23andMe will only provide individual level data to external researchers upon individual consent from each customer.

Sharing with third parties, however, cannot be tout court excluded considered that under Terms of Service "23andMe will never release […] individual-level Genetic Information and/or Self-Reported Information to any third party without asking for and receiving your explicit consent to do so". It is not clear how the phrase "individual-level" has to be interpreted and which degree of anonymization would do in order to avoid the application of this provision.

Some concerns, moreover, could arise from the Business Transitions section of the Privacy Policy, according to which in the event of "a business transition such as a merger, acquisition by another company, or sale of all or a portion of its assets, your Personal Information will likely be among the assets transferred": even if the consumer is assured that "[i]n such a case, […] information would remain subject to the promises made in any pre-existing Privacy Statement", it has nonetheless to be highlighted the absence of any provision about requiring a prior consent or giving notice.

Turning to deCODEme, privacy rules appear stricter: the company will send email to customers to inform them about, for instance, opportunities to participate in studies or other research activities, giving space to forms of reconsent in case of secondary uses of data.

deCODE binds itself not to intentionally share personal information with third parties without the express consent of the interested person except "(ii) in connection with the sale, assignment, or other transfer of the business of this Website to which the information relates, in which case deCODE will require any such buyer to agree to treat such information in accordance with this Privacy Policy".

In spite of attention given to privacy, some lacunas can nonetheless be found: in giving users the open possibility to have their account cancelled, which implies elimination of all data, Service Agreement specifies that "[i]f you cancel your account after the Genetic Scan is finished, deCODE will discard the scan and all other data. However, it is possible that all your data may remain stored in deCODE's archival and backup media and systems for an indefinite time, and deCODE will not be obligated to delete this data".

Even when strongly built and reliable, provided privacy safeguards prove to yield in front of the guarantee of an anonymization of data. In the legal discourse about the privileged locus of genetic research, that of biobanks, this mechanism has been sharply criticised: the first criticism towards it is related to its technical impracticality[31] due to involvement of biological samples, which allow to obtain DNA sequence, referred to as the "the most accurate individual identifier"[32]. Moreover, this technique would jeopardise research quality standards in asking it to renounce to personal information, related to cus-

[30] Vorhaus D. (2012), "Patenting and Personal Genomics: 23andMe Receives its First Patent, and Plenty of Questions", *Genomics Law Report*, 1 June, [online], URL: <http://www.genomicslawreport.com/index.php/2012/06/01/patenting-and-personal-genomics-23andme-receives-its-first-patent-and-plenty-of-questions/>.

[31] Lunshof J.E. *et al.* (2008), "absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver any longer", "From Genetic Privacy to Open Consent", *Nature Reviews. Genetics*, Vol. 9, May, 406-11.

[32] The American Society Of Human Genetics, *ASHG Response to NIH on Genome-Wide Association Studies*, 2006.

tomers' health history and development which could be of high relevance[33]. Lastly, anonymization proves to be an ill substitute for informed consent: the latter is deprived of its moral nature and replaced by a method which should serve an ideal of privacy as a right to be let alone, rather than the possibility of controlling information and realising an ideal of self-determination (for instance, by not agreeing with some kinds of research).

3. Current regulatory framework

It has to be acknowledged that, sensitive as the topic is, there are by now few regulatory controls in place at the national, European or global levels. One of the reasons is that many non specifically dedicated regulations can well be applied to DTC: for example, rules regarding data protection, electronic commerce, in vitro diagnostic medical devices and consumer protection.

These regulations, however, show some difficulties in operating "in the context of the way that these services are offered: that is, via the Internet"[34].

One of the main problems is related to identifying the rules to be applied to DTC companies' activities: in this sense, for example let's consider the reality of the U.S., which appears fragmented and not uniform.

For example, in 2008 the New York Department of Health issued "cease and desist" letters to DTC companies warning that these firms would require a laboratory license to operate in the state and that consumers would need to go through a physician to order the tests.

The same approach was chosen by California Department of Public Health which sent similar letters to 23andMe, Navigenics and 10 other genomics firms requiring them to comply with state and federal regulations. According to deCODEme Service Agreement, moreover some other states have laws that:

> do not permit their residents to obtain certain information regarding genetic risk provided by the Genetic Scans, unless a qualified health care professional is involved in the ordering and the delivery of results. (As of the date of publication of this Service Agreement those states are AZ, CA, CT, GA, MD, MI, NJ, NY, PA, RI and WY. NY, MD & PA further require that laboratories providing measurements of genetic risk obtain a laboratory license issued by that state. To date deCODEme does not have such MD & NY licenses).

For the company this implies that, unless the analysis is ordered under the supervision of a physician who provides appropriate counselling, "the deCODEme service may omit certain genetic risk information to residents of states where providing such information is restricted (not available in MD & NY)".

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[33] A critic view in Eriksson S., Helgesson G. (2005), "Potential harms, anonymization, and the right to withdraw consent to biobank research", *European Journal of Human Genetics*, 13, pp. 1071-1076.

[34] Howard H.C., Borry P. (2012), "Europe and direct-to-consumer genetic tests", *Nature Reviews Genetics,* 13, 146, February.

The same Service Agreement contains further provisions which highlight matters about jurisdiction[35] which make things even more complex in the context under analysis.

In the U.S., for years, DTC genetic tests seemed to fall into a regulatory gap, considering that no government agency seemed to directly regulate these tests; just some regulation over the laboratory process were provided by the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA). More recently the FDA published online letters sent to 23 genomics companies informing them that they are manufacturing and selling *medical devices* without appropriate FDA premarket review and approval[36]. Once again the matter about "qualification" of the service emerges: for example, Pathway, which nonetheless engaged a discussion with FDA, continues to claim that it can sell its products without approval because they are not intended for use in diagnosis, treatment or for the mitigation or cure of a disease, and therefore fall outside of the Federal Food, Drug, and Cosmetic Act application. Some other companies, on the contrary, indicated that they would welcome more federal guidance, rather than having to deal with state authorities, like in the NY and California cases[37].

Notwithstanding difficulties in identifying general rules, the topic has been the object of specific attention by many different bodies even in the European context.

In this sense the European Society of Human Genetics adopted a Statement on direct-to-consumer genetic testing for health-related purposes, the European Parliament's Science and Technology Options Assessment unit reported the result of a specific study carried out about DTC genetic testing[38] and the European Group on Ethics in Science and New Technologies adopted a statement which points out "several serious problems in ethical, social and legal terms", raised by DTC genetic testing[39].

Some national organisations, moreover, tried to establish guiding principles: some examples are given by the statement on DTC genetic testing by the Swiss Society of Medical Genetics[40], the report elaborated by the German National Academy of Sciences[41]

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[35] The Service Agreement states that "This Service Agreement shall be governed by and construed in accordance with the domestic internal laws of Iceland (without regard to conflict of laws principles). Any action you may bring in connection with this Service Agreement shall be brought solely in the Reykjavik District Court of the Republic of Iceland".

[36] Medical devices are defined under Section 201(h)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

[37] Vorhaus D. (2010), "FDA Puts the Brakes on Pathway-Walgreens Pairing; What's Next for DTC?", *Genomics Law Report*, 13 May, [online], URL: <http://www.genomicslawreport.com/index.php/2010/05/13/fda-puts-the-brakes-on-pathway-walgreens-pairing-whats-next-for-dtc/>. More recently, 23andMe, specifically focusing on properly health-related tests (covering subjects such as disease risk and drug response), announced that it was seeking approval from the US FDA, because oversight by the FDA would increase confidence in genetic testing (online, URL: <https://www.23andme.com/about/press/fda_application/>).

[38] Available on the website, URL: <http://www.samenlevingentechnologie.be/ists/nl/pdf/rapporten/final_report_direct_to_consumer_testing_stoa.pdf>.

[39] European Group on Ethics in Science and New Technologies, *Statement by the on advertising genetic tests via the Internet*, 24 February 2003, [online], URL: < http://ec.europa.eu/european_group_ethics>.

[40] Fokstuen S., Heinimann K. (2009), "Statement of the Swiss Society of Medical Genetics regarding direct to consumer genetic testing", *Schweizerische Ärztezeitung*, 90, 9, p. 328.

[41] German National Academy of Sciences (2010), *Predictive Genetic Diagnostics as an Instrument of Disease Prevention*, Deutsche Akademie der Naturforscher Leopoldina, Halle.

and, in the UK, by several documents of the Human Genetics Commission (HGC)[42] and the more general Nuffield Council on Bioethics' report "Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age". In the formers, and in particular in the most recent Common Framework Report, the HGC – aiming at promoting "high standards and consistency" in the provision of DTC genetic tests by commercial providers, in order to "safeguard the interests" of consumers – addresses some essential principles with regard to the nature and quality of the test and the necessity that tests are carried out "only after the person concerned has given free and informed consent. Informed consent can only be provided when a consumer has received sufficient relevant information about the genetic test to enable them to understand the risks, benefits, limitations and implications (including the implications for purchasing insurance) of the genetic test". According to the Commission, moreover, "[t]he statement should include an explanation of what will happen to the consumer's biological samples and personal data if the controlling share of the company is taken over by a third party".

In the latter report, the Council, even if criticising the lack of sufficient evidence base for reliable clinical use of the tests, does not oppose the market for DTC genetic testing (except for those with no proven clinical utility), but rather advices firms to provide for greater degree of transparency in outlining the evidence and the potential harms[43].

As to binding documents, as already said, there are no specific regulatory instruments, but some rules which can prove their usefulness in this context.

First of all, an implicitly restrictive approach towards DTC genetic testing procedures can be found in those countries in which a piece of legislation states that tests for health purposes should only be offered under medical supervision and, as said before, together with specific activities of genetic counselling. Together with the already quoted statutory laws of France, Portugal and Switzerland[44], a clear example is that of German legislation. §7 of the *Gendiagnostikgesetz* requires that any "diagnostic" or "predictive" genetic examination is ordered and interpreted by medical doctors; moreover, results have to be disclosed to the individual only by the ordering physician (§11). Some questions remain nonetheless unanswered: which kind of tests have to be qualified as "clinical" or "medical"? What about whole-genome sequencing techniques, which can yield both clinical and non-clinical information?

German provisions seem to be in accordance with art. 7.1. of the Additional Protocol to the Oviedo Convention concerning genetic testing for health purposes, under which "a genetic test for health purposes, may only be performed under individualized medical supervision". As clarified in the Council's explanatory Report this article stems from:

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[42] In 2003 the Report *Genes direct. Ensuring the effective oversight of genetic tests supplied directly to the public* (online, URL: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf>), in 2007 *More Genes Direct. A report on developments in the availability, marketing and regulation of genetic tests supplied directly to the public* (online, URL: <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/More%20Genes%20Direct%20-%20final.pdf>), to come to 2010 *A Common Framework of Principles for direct-to-consumer genetic testing services* (online, URL: <http://www.bshg.org.uk/Principles.pdf>.

[43] In particular see point 9.45 of the report on the Council's website, URL: <http://www.nuffieldbioethics.org/>.

[44] Howard H.C., Borry P. (2012).

> the concern to enable the person concerned to have suitable preliminary information with a view to an informed decision regarding the carrying out of this test and, if appropriate, to have access to appropriate genetic counseling. A precise evaluation of the situation of the person concerned, involving direct contact with him or her, is a determining element in that respect. A mere telephone conversation with a medical doctor, for example, does not allow for such an evaluation[45].

These statements – though referred by some as "paternalistic" – appear to be strong and founded into the intention of protecting individuals from misleading, confusing or low-quality information; nonetheless, once again, problems are related to the thin distinction between making claims that directly affect healthcare decision-making and making health-related claims[46]. The variety of results offered by DTC genetic testing companies could challenge this existing regulatory framework.

Another crucial point is strictly connected with formal procedures for the ratification of this Protocol: to date it has been signed by six Council of Europe's Member States and ratified by two of them (Slovenia and Moldova).

Last, overarching consideration, is given by the fact that the enforcement of similar rules, even at the national level, seem to be deeply affected by technology: nevertheless, as it has been noted "[a]lthough such national legislation cannot control Internet orders, it clearly makes it very difficult or impossible for DTC companies to operate from these countries"[47].

4. Concluding remarks: personalisation vs. consumerisation

DTC genetic testing finds itself, as many other activities emerged by technological revolutions, and – in this peculiar case – by the merger of Internet services development and genetics advancements, between good and evil.

Advocates for these activities claim them to be the perfect way to be followed in order to realise a democratisation of medicine[48], to make all individuals responsible and aware of the need to act preventatively and to implement an existing right to access own personal genetic information. Nonetheless, in a field where lurking behind much of this "consumer health information" is a manifest profit motive, all of these pros have to counterbalanced with risks connected to these activities.

In particular, as this paper tried to outline, a substantial lack of knowledge, a lack of prove about the efficacy of tests, obstacles posed by interpreting activities, concerns re-

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[45] Council of Europe, *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Brussels*, 2008. For a more exhaustive panorama on existing and non existing legislation in some European countries see a recent article by Borry P. *et al.* (2012), "Legislation on direct-to-consumer genetic testing in seven European countries", *European Journal of Human Genetics*, 25 January.

[46] Borry P. (2008), "Europe to ban direct-to-consumer genetic tests?", *Nature Biotechnology*, 26, 7, pp. 736-737.

[47] Howard H.C., Borry P. (2012), "Europe and direct-to-consumer genetic tests", *Nature Reviews Genetics,* 13, 146, February.

[48] Foster M.W., Sharp R.R. (2008), "Out of sequence: how consumer genomics could displace clinical genetics", *Nature Review Genetics*, 9, 419, June.

lated to privacy of information and samples and issues about customers' information and consent, make it difficult to accept a purely business oriented approach with regard to this expanding phenomenon. A business ethics model[49] proves, nonetheless, to give some relevant insights: in particular, for example, 2010 UK Human Genetics Commission's Report, explicitly covering situations in which no physician is involved, advises that all marketing of tests should be truthful and transparent, the promotion and technical claims should accurately describe both the features and the limitations of the tests offered and should be supported by reliable scientific evidence, the test provider should provide easily understood, accurate and appropriate information to consumers, which has to be given in a context of pre- and post-test support, and the company should supply customers with information about health professionals who can offer proper counselling and advice. Moreover data should comply with quality assurance regulations.

Companies have to guarantee the respect of customers' right to self-determination, which necessarily implies a complete and accurate requirement of informed consent, before a genetic test may be purchased. Informed consent, for its part, has to rest on a proper degree of information as to the quality of the test, the reliability of results obtained and risks and benefits involved. In one word, companies have to ensure *transparency*, which seems to be the key in order to realise individual protection without stifling commercial innovation and individual exploration.

It is evident that further debate is needed in order to define the nature of services and information offered; nonetheless, regulation cannot renounce to its role of identifying sharable and harmonising principles and of setting quality and informative standards which have to be respected in order to realise a proper protection of health and safety of individuals. In this sense, personalisation of medicine has not to be confused with its "consumerisation".

[49] Piehl M. (2011), "Regulating hype and hope: a business ethics model approach to potential oversight of direct-to-consumer genetic tests", *Michigan State University College Law Journal of Medicine and Law*, 16, 59.

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Artificial Intelligence and Models of Legal Argumentation

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Abstract: From the Turing machine to Searle's Chinese Room, artificial intelligence systems have always been a fascinating challenge, not only for computer scientists but also for philosophers and jurists. The challenge of AI is to create intelligent systems that are able to imitate human reasoning with increasing accuracy, reaching a point at which they can replicate it as a whole. These artificial systems are destined to have a notable impact on the law, exerting significant influence on issues such as civil liability, the protection of personal data collected by the intelligent system and whether or not a certain degree of legal subjectivity may be attributed to the most sophisticated models. On the other hand, artificial intelligence engineers have found the law to be an ideal field for experimenting with new artificial agents since it is, at first sight, characterized by a heavy use of logic. The first expert systems were created in the 1970s. An expert system is a program with a broad base of knowledge in a specific sector with the ability to solve problems related to that area in an intelligent way. The simplest type of these programs uses inferential processes. Basing itself on a set of given rules (norms) this kind of program connects the condition to the appropriate legal effect, according to a line of reasoning such as: "If A (condition) then B (result)". This approach is called "formalism", as it views the law as a set of rules.

Simulating legal reasoning is not just a question of mechanically applying the right rule to the actual case. Other instruments are needed, as appropriate: interpretation, analogy, knowledge gained from experience (learning), *aequitas*. Reconciling the potential and characteristics of artificial systems with the nature of the law and legal reasoning is not just a matter of pure syllogisms. Thus the first approach is counterpoised by a second approach, "realism", which uses case-based reasoning founded on experience gained from precedent. The paper aims to provide an overview of models of intelligent systems that can be used to reproduce legal reasoning. After a general introduction on the relationship between artificial intelligence and the law, the paper will examine the models of artificial systems based on artificial neural networks and legal expert systems. It will then move on to consider legal theories based on the application of rules and on analogy based on precedent, legal dialectic, defeasible reasoning and the importance of learning, in an attempt to understand which constitutes the best approach to justified legal reasoning.

Keywords: artificial intelligence; expert systems; legal reasoning

1. Introduction

In recent decades the worlds of law and information technology have become progressively closer, something which has directly affected the methodology of law[1].

This paper aims to give an overview of the main methods of legal reasoning and their correlation with artificial intelligence systems.

The purpose of AI has always been the creation of intelligent machines[2]. Instead of aiming for the utopia of an automatic and artificial judge, AI research in the field of law has been directed at developing practical tools in order to support legal activities, building programs that emulate or simulate intelligent behaviour related to the resolution of a legal issue.

Historically, the question underlying AI has been "Can a machine think?". In this regard, the famous Turing Test[3] is fundamental. It studies the principle for determining whether a machine can think and concatenate ideas and express them as a human being.

The Turing Test, however, is based only on imitation of a human being (it is also called the Imitation Game Test). From a practical point of view, a Turing machine is intelligent because it is able to behave as such, i.e. it is able to behave as if it were thinking. The Turing Test is "merely behavioural"[4]. This has also been stressed by John Searle with his "Chinese Room" argument[5]: a system could pass the test without knowing what it was doing, and therefore the element of "understanding", which is essential for talking about intelligence in a human sense, is missing. A sort of "*Lady Lovelace's Objection*"[6]: the machine cannot "think" in the ways that humans think.

The question "*Can a machine think*?" is still an open question in the world of the Philosophy of Artificial Intelligence. Scholars of all fields have always been fascinated

[1] Fameli E. (1989a), "Informatica e procedimenti decisionali nel diritto", in Mariani P., Tiscornia D., *Sistemi esperti giuridici. L'intelligenza artificiale applicata al diritto*, Franco Angeli, Milano, p. 171.
[2] For the purposes of this paper, "machine" means software or computer programs. The reader is referred to other works for the study of other kinds of intelligent machines such as ICT, BCI or robots.
[3] Turing A. (1950), "Computing machinery and intelligence", *Mind*.
[4] Sartor G. (2008), *Corso di informatica giuridica, Volume 1. L'informatica giuridica e le tecnologie dell'informazione*, Giappichelli, Torino, p. 274.
[5] Searle J.R. (1980), "Minds, brains, and programs", *Behavioral and Brain Sciences*, 3/3.
[6] Kim E.E. Toole B.A. (1999), "Ada and the first computer", *Scientific American*, 280/5, p. 80. Ada Lovelace, daughter of the famous poet Lord Byron, was an English mathematician especially known for her work with the Analytical Engine created by Charles Babbage. She is remembered as the first computer programmer. The expression "Lady Lovelace's objection" was created by Alan Turing himself. See Turing A. (1950), p. 450.

by this challenge: from scientists to philosophers, even to jurists. The question could be turned around as follows: "*Can a machine think in a legal way*?".

However, prior to answering this question, we need to understand exactly what "thinking in a legal way" means.

2. The traditional approaches: Formalism vs. Realism

In order to simulate human reasoning, and especially legal reasoning, AI has traditionally adopted and adapted the structures of logic[7]. In fact, *weak* AI[8] can be used to make inferences[9].

The law, moreover, is often seen as an area dominated by the use of logic, since it is based on a set of rules, so much so that four adjectives are often associated with it: mechanical (it is approachable by computational methods and techniques), deductive (it is reducible to valid derivation from a set of existing axioms), formalistic (it is construed and applied disregarding any psychological, ethical or social consideration) and formal (as a set of concepts and rules to be identified according to content-independent)[10]. Each legal intelligent system necessarily embodies a theory of law and a theory of legal reasoning.

The theory that views the law as a set of axioms is known as *formalism*. Formalism derives from the need to use a scientific method to study law. It must therefore be based on an unambiguous language. The rule is seen as a "proposition which has a logic-linguistic structure independent of its content"[11].

According to formalism, legal reasoning becomes a rigid application of a predetermined set of principles and rules through the mechanism of deduction.

Because of the rigidity of the system, in the US this school of thought is known as *Mechanical Jurisprudence*[12]. The role of the judge is to apply the correct deductive processes in order to arrive at a decision, without any subjective/personal evaluation.

In opposition to this theory is that of *Realism*, which views the law and judicial decisions in a sociological dimension. What matters is not the correct application of a set of legal norms following a predetermined procedure, but the interpretation of reality in the actual context. Legal norms lose their importance and are replaced by experience as

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[7] Mariani P. (1989), "Intelligenza artificial e sistemi esperti", in Mariani P., Tiscornia D., (1989), p. 23 ff.

[8] Weak AI is related to problem-solving ability in a specific area, simply through the manipulation of symbols, which does not mean that the symbols are comprehended. See Searle J.R. (1980).

[9] Inference is the process whereby we pass from one truth to another, the second truth being considered true simply because of its link with the previous truth.

[10] Philips L., Sartor G. (1999), "Introduction: From Legal Theories to Neural Networks and Fuzzy Reasoning", *Artificial Intelligence and Law*, 7, p. 115.

[11] Mariani P., Tiscornia D. (1989), "Sistemi esperti giuridici: fondamenti teorici, tipologia, criteri per la costruzione", in Mariani P., Tiscornia D., *Sistemi esperti giuridici. L'intelligenza artificiale applicata al diritto*, Franco Angeli, Milano, p. 207.

[12] Pound R. (1908), *Mechanical Jurisprudence*, Columbia University Press. As Jerome Frank (an exponent of the opposite theory of realism) wrote "The Courts should employ judicial slot-machines, the facts being inserted in one end of the machines and the decision, through the use of mechanical logic, coming out at the other end", Frank J. (2009), *Law and the modern mind*, Transaction Publishers, New Brunswick, N.J., p. 223.

the real source of knowledge. Taking decisions based on judicial precedent is essential. A judge acquires considerable discretionary power; he may first make a decision and only at that point try to justify it by finding the correct premise by rationalizing previous cases[13]. The study of law becomes the analysis of judicial decisions. The law has nothing logical about it, because it is based on judicial experience[14]. Realism is a critical legal science which "explicitly recognizes the need to arrive at a political-evaluative choice from among the possible solutions" [15]. We are faced with the difference between a rule (rational, static, impersonal) and a decision (irrational, dynamic, personal).

The gap between these two theories, formalism and realism, has been mitigated by a third theory, Scepticism of Marxist origin. It attempts to rebalance positions by recognizing that there are always constants which influence the decision-making process and that nothing is left to the total discretion of the judge[16].

3. Legal expert systems

A system which aims to reason in a legal way must be able to easily handle the law, understood firstly as a set of information and secondly as a set of argumentation techniques.

Since the 1970s a number of systems with a wide base of knowledge in a specific domain have been created. They can solve, in an intelligent manner, problems which are connected to that particular domain[17], emulating the decision-making ability of a human expert.

Different kinds of legal expert systems have been created, according to the required legal activity[18]: classifying actual cases (legal analysis); searching for court decisions on cases that are similar to the one in question; supporting the activities of an attorney in giving an opinion to a client, or judicial decision-making activities. The use of these programs is limited to supporting legal activities, and judicial decisions cannot rely solely on them. This paper is focused on the possible use of an A.I. system in a judge's decision-making process on a legal issue.

There are two principal critical aspects of the working of expert systems: knowledge-base representation[19] and the need to find an adequate strategy to arrive at a solution and to justify that solution. Let us now consider the fundamental elements of an expert system[20].

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[13] Mariani P., Tiscornia D. (1989), p. 207.
[14] Stefanelli S. (2012), "Linguaggio, diritto e intelligenza artificiale".
[15] Fameli E. (1989a), p. 172.
[16] Mariani P., Tiscornia D. (1989), p. 208.
[17] Sartor G. (2008), pp. 280 ff.
[18] Lucatuorto P. (2006), "Intelligenza artificiale e diritto: le applicazioni giuridiche dei sistemi esperti", *Ciberspazio e diritto*, 2(7), p. 6 ff.; Iaselli M. (1998), *Sistemi esperti legali*, Esselibri-Simone, Napoli.
[19] Today, most expert systems are Knowledge Based Systems (KBS), because they contain representations of knowledge which can be used to solve problems. The difference between these and a traditional expert system is that in a KBS the knowledge base is separate from the reasoning algorithms. The knowledge base can thus be modified or enlarged at a later stage. See Mariani P. (1989), p. 36; Lucatuorto P. (2006), "Intelligenza artificiale e diritto: le applicazioni giuridiche dei sistemi esperti", *Ciberspazio e diritto*, 2(7).
[20] Mariani P. (1989), p. 37, Fameli E. (1989a), p. 192; Lucatuorto P. (2006); Iaselli M. (1998).

3.1. The knowledge base

The knowledge base include all information available in a specific domain, also including procedural and heuristic rules. The information is represented as structural data in the memory of the calculator. The greater the wealth of information in the domain of departure, the more accurate and precise (optimal) the solution to the problem.

The model of knowledge representation is called "formal", since it is inserted in a strictly planned machine-readable language[21]. Humans, instead, express themselves through "natural language", which is very flexible and requires interpretation according to the actual case. There is clearly a serious problem in getting these two kinds of language to dialogue. Natural language elaboration is based on the automatic processing of human language information through a calculator[22]. This task is made difficult by the various complexities of natural language, which is rich in ambiguity. A programming language which can interpret natural language in the most faithful way needs to be used.

Knowledge representation is also based on logic, which can "define the formal language *par excellence*, providing a natural method for handling language and being the closest to the machine's capacity of understanding and calculating"[23]. The use of mathematical logic schemes allows rigorous manipulation of knowledge. Natural language can be expressed well through symbolic logic than algorithms, so much so that logic may be defined as "the purest form of programming language"[24].

Automatic translators were among the first AI systems to be developed. They still have significant limitations, however, and cannot accurately translate a speech of a few dozen lines. This is because translation is not the mere automatic "transformation" of a word from one language to another. The system must understand the meaning of the text in order to be able to translate it properly[25].

3.2. The inferential engine

Knowledge must then be used to arrive at the solution to the problem. In order to do so, an AI system must be provided not only with a database which describes the domain in which it operates and which determines the objective but also a set of rules (operators) which describe the actions to be performed and a control strategy which determines which actions are to be performed and in which order (planning ability). Planning skill is essential in selecting the right sequence of intermediate and final objectives and the entire reasoning process. Resolution of a problem can be represented by a figure called the "decision tree". The base is the starting situation; the peak is the objective to reach. The various intermediate steps, or nodes, represent the progressive

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[21] Tiscornia D. (1989), "La rappresentazione della conoscenza", in Mariani P., Tiscornia D. (1989) p. 66.
[22] Sartor G. (1998). *I linguaggi di programmazione e il diritto*, Conference Procedings "L'Automazione incontra il diritto: riflessioni interdisciplinare su alcune questioni giuridiche" (Round Table, Grosseto (I), 8 May 1998).
[23] Tiscornia D. (1989), p. 77.
[24] Iaselli M. (1998).
[25] Mariani P. (1989), p. 27.

solution of the problem by the application of operators[26]. The control strategy allows navigation through the nodes (inferences) in order to get to the solution to the problem. Furthermore, for the sake of convenience, a complex problem can be divided into a number of simpler sub-problems (problem reduction). The system will then achieve the objective by applying an appropriate sequence of operators from the start situation of the domain.

Expert systems use heuristic rules[27]. These are rules which solve a problem by subsequent attempts guided by a predefined goal. The system chooses a path to follow among the countless possible strategies to solve a problem, all equally valid from a logical point of view. The choice of the path is not trivial and can determinate the number of steps that will be needed to arrive at solutions. It is naturally important to find the correct solution but it is also important to find an adequately good answer within a short space of time, even should it not be the best. It seeks not the optimal solution, but the most satisfactory one[28]: efficiency is attained to the detriment of completeness. Obviously, the more accurate the assessment made by the program, the more accurate the solution reached, the greater the probability that the solution found is close to the optimal solution. Heuristics allows the system to understand what knowledge is relevant in order to achieve the solution, unnecessary and unnatural lines of reasoning being avoided[29]. The result indicates the most advantageous strategy to follow. Heuristics is therefore a mechanism which guides the control strategy of the expert system.

The inference engine is the mechanism that moves the expert system, through interpretation of the content of the knowledge base. It connects the rules of the knowledge base so as to make a chain of inferences[30]. Deductive inference is a derivation method which uses the procedures of mathematical logic[31]. Starting from the premise (the knowledge base inserted in the system and the data of the actual situation) the system reaches a conclusion following an argument of this kind "IF A (assumption) THEN B (conclusion)". The rule connects an abstract situation to a specific legal consequence, according to a conditional rule: the "IF" describes a condition; the "THEN" describes the action that is executed when the rule is applicable[32].

Take for example the regulation of non-contractual liability under the Italian Civil Code (art. 2043 c.c.): IF Tom has caused undue damage to Dick THEN Tom must pay compensation. This series of logical deductions simulates expert reasoning by applying the appropriate legal norms to the facts of the case. The system is able to simulate the deductive reasoning of a jurist on the basis of the knowledge, which is constituted both

[26] Mariani P. (1989), p. 29 ff.
[27] In computer science, heuristics is related to using a problem-solving technique in which the most appropriate solution of several found by alternative methods is selected at successive stages of a program for use in the next step of the program; [online], URL: <http://www.thefreedictionary.com/heuristics>.
[28] Mariani P. (1989), p. 31.
[29] Tiscornia D. (1989), p. 70.
[30] Iaselli M. (1998).
[31] Tiscornia D. (1989), p. 68.
[32] Fameli E. (1989a), p. 189; Sartor G. (2008), p. 293.

by facts (rules) and resolution procedures[33]. Information management is based on logical relationships explicit in the system, but there is no understanding of the content set. As noted, simulation of human reasoning is rather limited[34].

3.3. The interface

After finding the right solution to the problem on the basis of inferential processes, the expert system gives the answer to the user. The goal is to provide the same answers that a human expert would provide, also managing to justify the conclusions. The task of assisting the user in solving a problem is thus performed.

The interface is the platform of communication with the user. It decodes the program data to make it understandable to the user. The interface often visualizes all steps of the path of reasoning leading to a solution and provides the justification for the solution, creating a dialogue between system and human being.

3.4. The limits of expert systems

Problems of translating the natural legal language in a formal language

The natural language problem is therefore a significant problem for AI models, since capturing all the rules of syntax and grammar is extremely difficult and interpretation according to context plays an especially important role. Legal expert systems use a formal representation of legal knowledge, which lends itself well, for the most part, to this rationalization. Legal knowledge (expressed through natural language) should thus be formalized, i.e. translated through a programming language in order to make it understandable to the system[35].

If the legal text can be represented as a logic program, this means that rules collected in the text are axioms from which the system can deduce, through inferential processes, the necessary logical consequences. Formalism once again. According to the opposing school of thought of Realism, the system should also be able to arrive at a solution from the previous case, identifying the major factors which led the judge to that decision.

The task is extremely difficult, if not impossible, especially when assessments made by the judge on the basis of his own personal convictions are taken into consideration. The expert system should, therefore, starting from identification of the factual elements relevant to resolution of the case, use a mixed strategy[36]: first choose from among the various applicable rules that which is most suited to the particular case and then trace the relevant precedent and use it according to a deductive process to formulate possible solutions with the corresponding factors of predictability (the percentage possibility of the decision being taken by a human judge).

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[33] Lucatuorto P. (2006).
[34] Mariani P, Tiscornia D. (1989), p. 231.
[35] Iaselli M. (1998).
[36] Mariani P, Tiscornia D. (1989), p. 237.

Problems in the construction of the knowledge base

Not all legal knowledge can be easily rationalized however. Identifying facts is a complex task not only for the machine. In order to use a formal representation of knowledge of law we must first identify rules (all legislation currently in force in a given state, as well as legal theory and case law) and reproduce them in a formal language. The task, however, is not as simple as it may seem. For example, there is the great problem of the complex structure of sources of law. The hierarchy of sources, with the overlapping of national, European and international sources, is not fixed but changing, contentious and sometimes unclear[37]. A great deal of attention therefore needs to be paid to the construction of the knowledge base.

In reality, the truth of premises does not always guarantee the truth of conclusions

The traditional approach concerns the application of schemes of classical logic. But in the resolution of actual cases, the correctness of the inference process, however, does not guarantee the truth/validity of its conclusions, as this depends on the truth of the premises upon which it is based[38]. According to the classical deductive logic, adding a premise does not change the conclusion (monotonic logic). However, as we shall see, this approach is inadequate for the task of handling the kind of information required in the world of law. Such information is often incomplete, sometimes unspoken, and, in any case, in need of interpretation.

Legal reasoning is, at times, characterized by deep personal feeling, and does not lend itself to being reduced to simple syllogisms, albeit repeated and complex. In legal systems there are often gaps, contradictions, ambiguities and vagueness. Furthermore, no legal system can provide a full discipline for all cases that may occur in practice.

Justification limited to the factors taken into account

As was previously observed, the legal expert system needs not only to simulate the reasoning that a human expert would make in the same context, but also to give an *a posteriori* explanation/justification (according to the transparency principle). Besides providing a solution to a problem, the system must thus justify the reasoning which led it to this solution, and be able to transmit it to the user in natural language, as if it were the grounds for a decision. Although deductive systems are able to provide justification for a conclusion reached, they are limited in that they bring to the attention of the user only those factors taken into consideration. In other words, they do not explain why they did not reason on the basis of a different premise.

[37] Santosuosso A., Azzini S. (2010), "Il caos di norme e istituzioni a livello mondiale: una prospettiva realistica nel campo della scienza e del diritto", in Santosuosso S., Garagna S., Bottalico B., Redi C.A. (eds.), *Le scienze biomediche e il diritto*, Ibis, Pavia, p. 25.
[38] Sartor G. (2008), p. 292.

4. The need of interpretation

The language of law is also plagued by the problem of vagueness. Although there is minimal lexical ambiguity, there are still semantic and syntactic ambiguities. The same legal norm may have different interpretations and, above all, it has these interpretations according to the interpretation given to the general system of legal norms. The process of rule interpretation plays a key role in the activity of a judge. It is the moment in which a judge connects the general and abstract case to the actual case and identifies the legal norm (or, more often, the set of legal norms) which determine the appropriate resolution, and in which he establishes whether the premises are suitable for application of the legal norm. In this case too, reasoning starts from an inference of the "IF A (condition) THEN B (conclusion)" type. Resolution of the problem (applying the legal norm) can be represented as a decision tree, where A is the case and B the legal effect.

Interpretation of the actual case and legal norms is essential. Any legal norm can have multiple meanings, among which the interpreter, basing on complex assessments, chooses the most appropriate solution. The interpretation inserts the first element of detachment from formal logic, as it does not run out with the mere examination of the text of rules.

Semantic network

Since an artificial system does not understand, in the human meaning of the term, the various pieces of information of the actual case, the use of a semantic network has been suggested[39]. A semantic network is a form of knowledge representation which represents relationships between concepts: for instance, it connects a word to other words with similar or related meanings. The system can thus recognize the relationship between hierarchies of concepts: on the one hand the subject-matter of the rule and, on the other hand, the subjective interpretation of the rule[40].

Having the ability to understand relationships between rules, the system can make a more intelligent choice. The kind of conceptual relationships to be put into practice changes according to the legal system in which we live. In civil law systems they are relationships between concepts, often designed to give general meaning to a number of terms (e.g. the concept of diligence), while in common law systems they are relationships between analogous and pertinent cases and the case in hand.

Fuzzy logic and nuances of reality

The rigidity of classic logic can be nuanced also with fuzzy logic. Fuzzy logic is an attempt to blur the precise contours of the rules of logic in order to adapt them to processes in which input data is not accurate (approximate reasoning).

[39] Mariani P, Tiscornia D. (1989), p. 232.
[40] Iaselli M. (1998).

Not being rigid, it has the advantage of offering a better approach to human reasoning and, above all, responds to natural language.

Fuzzy systems, being fuzzy, are characterized by a "level of membership". An element is not necessarily definitively in or out of a definition, but belongs to it at a certain level of membership (a certain percentage): the "degree of truth". Fuzzy logic, therefore, is not based on positive or negative values (X = A or X ≠ A), but an element can be 70% A. The logical inference is then based on different premises, as the starting conditions are perceived as nuanced[41].

Fuzzy logic can be used in legal decisions based on imprecise terms. The classic and most famous example is the Hart example, which demonstrates that even a concept that can seem clear, like "vehicle", can be legally indeterminate[42]. The decision to include a certain element in the category is based on an evaluation of various interests[43]. In order to assess whether or not a skateboard can be considered a "vehicle", therefore, the interest which gave rise to the bar on access of vehicles to the park needs to be assessed.

Law, however, all things considered, requires a clear and certain decision. Fuzzy logic can thus be a useful tool for understanding and analyzing the initial context, helping to frame the major issues.

Aequitas

Furthermore, the strict application of a legal norm in all the infinite range of possible cases of real life could determine situations of substantial injustice. In order to avoid it, and under certain conditions, some legal systems allow the Court to create and apply an ad hoc rule for the actual case. In these cases, albeit residual, the instrument in the hands of a judge is *aequitas*: the justice of the actual case[44] (referring to civil law systems)[45].

Aequitas is applied during the evaluation moment of the case and is a corrective to the strict application of the law. It is a residual instrument because legal systems usually prefer the certainty of law to the justice of the individual case. In the Italian system, for instance, a judge can follow *aequitas* only if expressly permitted to do so by the law[46]. The interpreter uses it in order to avoid interpretation that conflict with the sense of justice of the community, promoting balanced solutions. Since he is not able to apply the legal norm, generally he has to base the decision on a certain level of judicial experience. Also in this case, there is the problem of avoiding a high discretion of the judge.

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[41] Frixone M. (1994), *Logica, significato e intelligenza artificiale*, Franco Angeli, Milano.

[42] Hart H.L.A. (1961), *The concept of law*, Oxford University Press, London. It is unclear what is meant by the word "vehicle" (a car is certainly a vehicle but what about a bike or a skateboard?) in the legal rule "No vehicles are permitted in the park".

[43] Philips L., Sartor. G. (1999), p. 121.

[44] Torrente A., Schlesinger P. (2009), *Istituzioni di diritto privato*, XIX ed., Anelli F., Granelli C. (eds.), Giuffrè, Milano, p. 20.

[45] For express the equivalent of *aequitas,* common law systems use several terms, like "reason", "reasonableness", "fairness" and others. De Franchis F. (1984), *Dizionario Giuridico Inglese-Italiano*, Giuffrè, Milano, p. 697.

[46] That happens in a very limited number of cases (proceedings before the Justice of the Peace , or in the case of parties attributing this power to the judge).

5. Case-Based reasoning and analogy

In some cases uncertainty as to a judge's decision is due not to the choice of applicable law but to the assessment of the actual circumstances to be taken into account. A judge may, in fact, have a certain degree of discretion in the assessment of a number of factors (age, gender, income, lifestyle, professional or personal skills...).

In this case, the most correct solution seems to be that which moderates the formalism and makes the system work on a series of homogeneous cases which have already been resolved, so that it can identify the rate of incidence of each parameter. It is not just a question, therefore, of redrawing precedents but, however, some assumptions about how a legal precedent constrains judicial decision-making are necessary. Systems which use this technique are skilled in learning. Learning means the process of modifying the knowledge base that has been acquired through experience which may give rise to persistent change in the machine's behaviour[47]. Learning is therefore a skill that derives from memory and experience. The system can abstract general rules from a study of previous cases[48].

The risk of case-based reasoning is that case law is progressively standardized[49], with the production of a series of decisions which are all the same which may not be able to grasp the interesting nuances of the case. The advantage, however, is a reduction of discretion in judicial decisions. It is a delicate issue since reducing discretion in some areas of law, especially in criminal law, is not just a matter of the reasoning method used, but especially a matter of policy.

The use of examples helps in finding constant elements, especially in learning from previous cases. The AI system must be able to identify the relevant elements in the two cases. In order to do this the system must not only compare rules but must also have the same flexibility of interpretation as a human operator (working knowledge). Case-based reasoning involves a subset of analogical legal reasoning and tries to define criteria for determining which reasonable legal arguments by analogy should prevail[50].

Analogy is an additional tool in legal systems in the event of a certain case not being settled by the legislator. It is based on a sequence of reasoning steps: discovery (first study of possible analogies between two cases), confirmation or disconfirmation (a deeper analysis in order to confirm or not the analogies), and application (application of the rule that is used in the previous case to the actual case) [51]. It is said[52] that analogy is the principle of symmetry which counters logic with dialectics. In legal terms, it consists in

[47] There are different kinds of learning – cfr. Fameli E. (1989b), "Note in tema di apprendimento e di ragionamento per analogia", in Mariani P., Tiscornia D., (1989) – including: learning by observation (the system observes and imitates human experts which are taken to be sources of knowledge and behavioral models); learning by discovery (the machine can learn by itself through the creation of example and procedures); learning by being told (a human expert directly teaches the machine); learning by analogy (the system memorizes a serious of previous analogous cases which are used as models for learning).
[48] Mariani P. (1989), p. 26.
[49] Fameli E. (1989a), p. 187.
[50] Ashley K.D. (2002), "An AI model of case-based legal argument from a jurisprudential viewpoint", *AI and Law,* 10, p. 166.
[51] Brewer S. (1996), p. 962.
[52] Melandri E. (1968), *La linea e il circolo. Studio logico-filosofico sull'analogia,* Il Mulino, Bologna.

applying a rule designed for a different but similar case to a case which is not covered by legislation[53]. Analogical reasoning is based on the presumption that two situations which are similar in some relevant aspects should be sufficiently similar in others[54]. and that the legislator would have regulated the case to be resolved in the same manner as that in which it expressly regulated others (pre-logical inference which flows from one particular case to another particular case[55].

The common denominator must be the reason that justifies use of the same rule of law: the identity of the *ratio*.

Legal precedent thus becomes a legislative statement by extrapolating the formal rule that defines the resolution of the case. However, as in this case the *ratio decidendi* is the result of a judge's interpretation of the rule, it cannot always be considered correct[56].

Using experience gained from a comparison with previous cases, the system applies the rule to the new case. Analogy becomes essential to AI systems, as it is the instrument through which they can use the experience gained in solving previous problems[57]. A similar, but opposite, interpretative models the reasoning by disanalogy, which is based on the search of non-shared elements between cases[58].

If analogy is not sufficient in finding the solution to a case, the general principles of the legal system need to be resorted to (*analogia iuris*). From the particular we move toward an ever more general and complex analysis of the legal system. The principle of "coherence", by which a decision fits with past cases and general principles, should always be taken into account[59].

6. The justification. Dialectic and defeasible reasoning

After considering the interpretation of the factual and legal context, we now come to the final stages of reasoning: the decision and the justification. If a system relies on mere inference, it comes to a conclusion, but the grounds may be flawed. It indicates the premises, the solution and the path followed but does not say why other paths were not followed. It needs to be completed with an explanation of the different interpretations taken into consideration and the objectives and criteria followed, because in legal system an exception to a rule can "always" be found.

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[53] Torrente A., Schlesinger P. (2009), p. 56.
[54] Brewer S. (1996). "Exemplary Reasoning: Semantics, Pragmatics, and the Rational Force of Legal Argument by Analogy". *Harvard Law Review*, 109(5), p. 951.
[55] Fameli E. (1989b), p. 313.
[56] Mariani P, Tiscornia D. (1989), p. 234.
[57] Fameli E. (1989b), p. 309. An example of this kind of system is CATO, an intelligent tutoring environment intended to teach law students how to make basic legal arguments with cases. It is able to reinterpretate cases in arguments through a strategic way, emphasizing the legal significance of a distinction between a problem and a case cited by an opponent. It uses examples generate by itself (learning by discovery). About CATO see Ashley K.D. (2002), p. 176 ff.
[58] The disanalogical reasoning aims to distinguish two cases that at first glance may seem relevantly similar. See Brewer S. (1996), p. 1006 ff.
[59] Ashley K.D., (2002), p.176.

The debate between formalists and realists can be seen as a debate about what is sufficient for a justification of legal decisions: in fact, considered the first standards a sufficient basis for decisions, while the latter as essential to the multiplicity of human experiences, such as required by the individual treatment of cases. Neither approach, however, sufficiently indicates how the rules justify the decisions or, conversely, which elements are involved in the treatment of individual cases. Neither the realist nor the positivism legal realism are able to exhaustively explain how legal decisions are justified.

A systematic and complete elaboration of the concept of "decision" is difficult to find in legal theory. It may be said that formalism and realism differ from each other with regard to the level of depth required in the justification for the decision: formalists believe that the rules are sufficient while realists consider experience and the individual handling of cases to be essential[60].

Authoritative legal theory[61] on judicial decision-making maintains that a judicial decision arises from a choice made between different resolution possibilities. There are at least two: the two submitted by the parties to the Court. The Court must therefore choose, from the ranges of possible solutions, the decision that is the best in that context. The actual case may require a decision on various issues. For each question there is a range of possible solutions which multiplies the possible combinations of resolutions of the case. A judge, through studying the legal context and the factual context[62], decides which facts and rules are relevant in deciding the case. This reasoning has a dialogical/dialectical structure.

Recent studies have focused on the "theory of rational discourse"[63]. A decision is not made on the basis of pure syllogism, or on the basis of precedent, but is gradually built up through a comparison of opposing positions, in a dialectical process. Neither legal norms nor precedent are, of themselves, sufficient to justify a decision, but they may be useful in constructing arguments in support of one or the other argument submitted by the parties. Each party submits its version of events, often supported by objections against and rebuttals of the opponent's version. The two versions are often opposing and the Court must scrutinize each and the relative counter-arguments. Once a judge has come to a decision he has to justify it. He has to expound the reasoning which led him to believe one argument rather than the other. The two steps may have different bases: in the decision-making process a judge seeks the best possible decision in that context; while in expounding his grounds he tries to justify that decision to the parties.

The dialogic structure of the decision stems from the fact that it is the result of dialogue between the parties and the judge, in which the judge considers the arguments raised by the parties in support of their theories. It is essential that the decision, in order to be justified, does not only consider the arguments of the "winning" theory, but also those of the rejected theory, in order to demonstrate that the solution is the best that could

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[60] Stefanelli S. (2012), "Linguaggio, diritto e intelligenza artificiale".
[61] This paragraph is based on Taruffo M. (1998), "Judicial Decisions and Artificial Intelligence", *AI and Law*", 6, p. 311 ff.
[62] Taruffo M. (1998). "Judicial Decisions and Artificial Intelligence". *AI and Law*", 6, p. 312.
[63] For the "theory of rational discourse" see Alexy R. (1993), "Legal Argumentation as Rational Discourse", *Rivista internazionale di filosofia del diritto*, 2, pp. 165-178; Stefanelli S. (2012).

have been arrived at. As we have seen, in expert systems the decision-making process is as follows: the system identifies the legal case and then attempts to apply a legal norm; only if it cannot find the rule, does it go in search of adequate previous cases.

In the dialogical model, however, rules and precedents are invoked at all levels. The intelligent system must therefore be able to handle conflicting issue. A suggested solution is to use patterns of defeasible reasoning, which can also consider exceptions to the rules connected to the premises. The conclusion of the reasoning, according to this method, is true only if no objections or fundamental counterarguments arise[64].

This type of reasoning may be applied in all cases in which the same legal norm provides for certain circumstances which impede the production of normal legal consequences. Staying with the example of civil liability, we may think of reasons for ruling out liability. The knowledge base, rather than a set of assumptions and axioms, is a base which is rich in arguments on which to draw, depending on which argument is to be supported or refuted[65].

This kind of artificial system must be based on models of inference and knowledge representation which are different to those of expert systems, since the outcome of reasoning depends on the overall argumentative context of the case[66] (non-monotonic logic).

Consequently, arguments which may be decisive in a certain context may be unsuccessful or irrelevant if the context changes. The problem of inference is that premises may be weak and not consider some relevant elements, and contrast arguments by adding new premises is impossible. It raises the problem of defeasibility of legal rules[67].

Defeasible reasoning can save the dialectic between arguments and counter-arguments: "a defeasible argument is one in which the addition of premises can weaken the force of the conclusion" [68]. Each argument is linked to those arguments that support or attack. The user is informed at every stage of the reasoning process as to the point of the debate and what the possible new arguments or objections are. In conclusion, the thesis which is supported the most by valid arguments wins[69].

The disadvantage of such complex reasoning is that it is difficult to translate it into a formal language and a logical-uniform structure.

On the other hand, such a structure can be integrated with procedural notions of burden of proof. Whoever alleges a fact usually has to prove it: that is, once a proof burden is met, the burden should shift to the other party. The dialectical tree would be

[64] The most famous example is the Tweety's example, formulated by Marvin Minsky. According to the syllogism, since Tweety is a bird and birds fly, then Tweety can fly. But the conclusion changes if Tweety is a penguin because although penguins are birds they cannot fly. Thus, even though both original premises are true, the conclusion of the inference is not true, because it does not take into account a relevant information.
[65] Iaselli M. (1998).
[66] Sartor G. (2008), p. 309.
[67] Ashley K.D. (2002), p. 203.
[68] Brewer S. (1996), p. 1017.
[69] For an example in the criminal law field see Bex F, Prakken H (2008), "Investigating stories in a formal dialogue game", in: Besnard P, Doutre S, Hunter A (eds) *Proceedings of COMMA 2008*, IOS Press, pp 73-84. This system tries to find the best explanation of the facts of the case in a criminal law context.

affected by the mechanism of the burden of proof. Whoever asserts a thesis must also be able to support it with arguments that are not destroyed counter-arguments[70].

A judge has to identify the legislative premises and arrive at a solution. He starts with an analysis of the facts, taking the relevant ones and eliminating the irrelevant ones and then moves on to the next, more general, stage of comparing legislative statements[71]. This type of reasoning fits in very well with the dialogic structure of legal reasoning.

7. Neural networks

I just want here to briefly compare another type of AI system usable in the field of law which contradicts some basic tenets of the syllogistic model.

The other major development in AI programs concerns the so-called artificial neural networks. These systems are used as decision support in legal domains characterized by a wide margin of discretion[72]. They reproduce human intelligence in its responsive aspect, in a dynamic perspective, without going through knowledge representation and reasoning. They aim to respond to input provided by the experience, based mainly on statistics. There is no knowledge base given by a set of axioms. Intelligence is sought through the reproduction of the physical mechanisms (neural networks) of the human brain. The functioning of the neuron depends on the attainment of a threshold required for its activation[73]. The neural network is trained through a series of examples, which show the correct answer to associate with a certain input. Inputs are the conditions, while outputs are the possible legal consequences. The hidden units connect input and output, in such a way that all the different combinations of them are possible[74].

The network is also able to reprogram itself so that input and output always coincide on the basis of the pattern given. Incorrect results are sent back into the network and corrected by the learning pattern. If a new case is inserted, the solution is found by searching for the most similar known case (application of analogy). After a series of training examples, the neural network will thus be able to apply the process of solution learned to new, analogous cases (example-based learning). There are already a number of applications in the legal fields of these forms of artificial systems. The most interesting thing is that in the case of the Australian Split-up system[75], the analysis of legisla-

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[70] Prakken H., Sartor G. (1999). "A System for Defeasible Argumentation, with Defeasible Priorities", in Wooldridge M.J., Veloso M. (eds.). *Artificial Intelligence today. Recent trends and developments*. LNAI 1600, p. 365. In this paper, authors have built a system for defeasible reasoning. It takes in consideration also coherent, rebuttal and undercutting arguments.

[71] Mariani P., Tiscornia D. (1989).

[72] Lucatuorto P. (2006), p. 17.

[73] Sartor G. (2008), pp. 283 ff.; Hunter D. (1996). "Commercializing Legal Neural Networks". *The Journal of Information, Law and Technology (JILT)*.

[74] Philips L., Sartor. G. (1999), p. 119.

[75] e.g. the Split-Up system, used in Australia for the distribution of the assets of married people in divorce cases. The system recognizes as input the amount of assets and the spouse's contribution to the formation of the assets. Possible outputs will show the various and possible divisions of the assets between the spouses. Sartor, G. (2008), p. 290.

tion and judgments do not understand the precise rules whose application logic could lead to the solutions adopted by the judges.

Taking once again as our example the Italian rules on non-contractual liability, input will be all the elements of the legal standard (unlawful damage, intentional or negligent conduct, causation, absence of justification), while output will be, for instance: liable, not liable, diminished liability in the case of contributory negligence. Only one output unit will be activated, the one activated by the combination of inputs units in the actual case.

However, neural networks suffer from a 'black box' image resulting from the considerable difficulty attaching to the process of attempting to understand how they represent knowledge. Thus, it is difficult to establish the legitimacy of a network's results in terms of the law.

The great defect with these systems, however, is that they cannot offer justification for the solution. This defect is so great as to set aside them from our research into intelligent systems which are capable of reproducing justified judicial reasoning. Their role in the legal field, however, could be to support an attorney in assessing a client's chances of success.

It has been shown[76] how fuzzy logic and neural networks are two sides of the same coin, since both use interactive processes that can be corrected. Fuzzy logic can be of assistance if the applicability of a certain rule is uncertain, helping to track the level of membership in the case of semantic uncertainty, while neural networks are most useful when there is the need to choose between several but different possible solutions.

8. Conclusion on the use of A.I. system in law

Although the law is largely formed of a set of rules, mechanical application of these legal norms does not suffice for the purposes of performing satisfactory legal reasoning. Considering legal reasoning and its application in AI, the strict model of classical logic seems inappropriate. For all that the inferential processes of expert systems may be correct, the case needs to be interpreted by also using other tools, first of all analogy, in order to reproduce the ability of human and legal reasoning. Case-base models can be very useful in legal argumentation, and they have to optimize the analogical reasoning through a set of principles and criteria that highlight similarities and differences among cases, being able to assess which of them is relevant or determinant. Moreover, a justification must always be given.

The theory of rational discourse and defeasible reasoning have shown that legal reasoning is a process based on opposing arguments. Legal reasoning cannot be applied in a simple, mechanical, repetitive and predetermined way. In reasoning we can find elements of both logic and subjective interpretation. There is no clear distinction between logical and illogical, rational and irrational. It therefore seems that the model of defeasible reasoning is the one that best fits legal reasoning. The goal should be to create systems with the flexibil-

[76] Philips L., Sartor. G. (1999), p. 123.

ity needed for a better assessment of all elements, able to calibrate the strengths or weaknesses of opposite arguments in the actual legal and factual context. The skill of learning is useful for the accumulation of experience from the past decisions, augmenting the knowledge of the system.

Regarding the practical application, AI systems must be used in compliance with rules on privacy. Under Article 14 of the Italian Data Protection Code (Legislative Decree 196/2003) a machine cannot completely replace a human in administrative or judicial decisions which require assessment of human behaviour[77].

But, although based on these specific skills AI systems cannot by themselves play the role of a human expert, since they lack the cognitive skills required to fully appreciate the interests at issue. Since legal texts are ambiguous and, above all, no legal system will ever be omni-comprehensive, it is highly unlikely that an AI system can, by itself, automatically apply the law. The use of AI programs, however, can be a valuable support in the process of decision-making by a jurist, especially when dealing with very complex cases, in which the decision tree is very articulated. They can help to conceptualize a complex legal problem as an area of multilinked argument. The use of AI systems to assist in the decision-making process could also have the positive result of reducing the discretion of the decision, especially in criminal cases, so that unequal treatment may be avoided.

[77] This article is of considerable importance in the case of profiling carried out by a fully automatic system. Personal information may currently be collected in various databases. Re-assembling this information can lead to reconstruction of the so-called "electronic person", see: Iaselli, M. (2009), *I principi informatori del codice della Privacy tra teoria e pratica. La protezione dei dati personali alla luce del D. lgs. 196/2003*, p. 27.

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Can "Best Interests" Justify Child Participation in Medical Research?

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Abstract: This paper will look at how the best interests test in English law has been extended from its traditional role in medical treatment cases to cases of administering innovative treatment and conducting medical research. In doing so, this paper seeks to pose one fundamental question: is there sufficient justification for extending application of the best interests test into the realm of research? This paper will focus on cases of innovative treatment to illustrate that application of the best interests test in such matters is flawed because it focuses too narrowly on the interests of the individual child participant rather than viewing that individual child as being within a wider network of relationships. I propose that if we view "best interests" differently, through the lens of care theory, a theory that emphasises human interdependency and mutually supporting relations, there is greater potential to effectively accommodate both sets of interests involved and strike a more appropriate balance between these sets of interests: (I) the interests of the individual child participant with the interests of the community of children, and (II) the interests of the individual child participant with those in caring relationships with the child who will be impacted by any decision to participate in research in terms of caring for the child. To illustrate my argument with reference to cases of innovative treatment, I suggest that rather than claiming innovative treatment is in the "best interests" of the individual child participant, a more effective approach would be to consider a dual "interests" test: is the innovative treatment "not against the interests" of the individual child participant *and* "in the interests" of the community of children? And if the answer to both is in the affirmative then the innovative treatment should be administered.

Keywords: english law; best interests test; children; medical research; innovative treatment; ethics of care theory

1. Introduction

In English law the involvement of children in research that does not amount to a clinical trial on a medicinal product falls to the common law or the Mental Capacity Act 2005. In these circumstances, one must rely heavily on the law as it applies in the context of medical treatment because there is a body of law relating to the medical treatment of children but the law regarding child participation in medical research is comparatively undeveloped. This paper will look at how the best interests test has been extended from its traditional role in medical treatment cases to cases of administering innovative treatment and conducting medical research. In doing so, this paper seeks to pose one fundamental question: is there sufficient justification for extending application of the best interests test into the realm of research?

This paper will focus on cases of innovative treatment to illustrate that application of the best interests test in such matters is flawed because it focuses too narrowly on the interests of the individual child participant rather than viewing that individual child as being within a wider network of relationships. I argue that it is important to view an individual child participant as being within a wider network of relationships because when doing research the wider community of children and future children will be impacted by any decision, as well as the individual child participant and those in caring relationships with the child participant i.e. parents and/or guardians who will be impacted by any decision to participate in research in terms of caring for the child.

I propose that if we view "best interests" differently, through the lens of care theory, a theory that emphasises human interdependency and mutually supporting relations, there is greater potential to effectively accommodate both sets of interests involved and strike a more appropriate balance between these sets of interests: (I) the interests of the individual child participant with the interests of the community of children, and (II) the interests of the individual child participant with those in caring relationships with the child who will be impacted by any decision to participate in research in terms of caring for the child. To illustrate my argument with reference to cases of innovative treatment, I suggest that rather than claiming innovative treatment is in the "best interests" of the individual child participant, a more effective approach would be to consider a dual "interests" test: is the innovative treatment "not against the interests" of the individual child participant *and* "in the interests" of the community of children? And if the answer to both is in the affirmative then the innovative treatment should be administered.

I will first outline the history of regulating child participation in medical research and consider the impact of ethical guidelines and statutory instruments that aim to both facilitate research and protect child research participants. I will then introduce ethics of care theory, outlining key principles of care theory, how it has developed, and how care theory has already been considered in relation to decision-making in a healthcare context in order to emphasise that an approach based on the values of care theory is persuasive in dealing with the situation of a child patient and could potentially enhance the current approach to "best interests" decision-making to more effectively manage cases that involve children. Then I will move on to look at specific cases involving the administration of innovative treatments to analyse how the best interests test was applied

in these cases. In the case law analysis I hope to illustrate how we can effectively view "best interests" differently through the lens of care theory, and how a dual "interests" test would be more appropriate than the current "best interests" approach.

2. Children and medical research

Medical research on children is necessary to achieve progress in paediatric medicine. There are two main reasons behind this conviction: firstly, certain diseases are unique to childhood and therefore medical research must be conducted on children to find out more about these childhood diseases, and secondly, adults and children respond differently to drugs and treatment, particularly when it comes to dealing with metabolism and disease. It is found that adults and children differ significantly in both pharmacodynamics (the way a drug affects the body) and pharmacokinetics (the way the body responds to the drug), and so results obtained in adults cannot easily be transposed in minors[1].

It is unfortunate that the history of children participating in research is somewhat troubling. During the Nazi regime in Germany children were used as human guinea pigs in research conducted by Dr Josef Mengele[2], and other research scandals followed[3]. Minors were excluded from clinical trials in the aftermath of the Nazi experiments and the theory behind exclusion was one focused on protecting minors[4]. However, it soon became apparent that such a theory was flawed – denying minors access to

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[1] Pinxten W., Nys H., Dierickx K. (2008), "Regulating trust in paediatric clinical trials", *Medicine, Health Care and Philosophy*, 11, p. 439.

[2] Kodish E. (ed.). (2005), *Ethics and Research with Children: A Case-Based Approach*. Oxford University Press, New York, p. 5. Over 60 years ago, 23 German doctors and scientists were prosecuted for inflicting brutal and lethal procedures on the inmates of concentration camps between 1933 and 1945 in the name of medicine and medical research. The Nuremberg Code laid down ten principles to guide future medical research: Pattinson S.D. (2011), *Medical Law and Ethics* (Third Edition), Sweet and Maxwell, London, pp. 377-378, see also Annas G.J., Grodin M.A. (eds). (1992), *The Nazi Doctors and the Nuremberg Code*, Oxford University Press, Oxford and Shuster E. (1997), "Fifty Years Later: The Significance of the Nuremberg Code", *New England Journal of Medicine,* 337(20), pp. 1426-1140.

[3] Note for example the Tuskegee syphilis study: see Kampmeier R.H. (1972), "The Tuskegee study of untreated syphilis", *Southern Medical Journal*, 65(10), pp. 1247-1251, and also the Tuskegee University National Center for Bioethics in Research and Healthcare website, URL: <http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center.aspx> (last accessed 10 April 2012) which details the Syphilis Study and provides coverage of the Presidential apology by the then U.S. President, Bill Clinton. There is also discussion of the perceived impact that the study had on health care as a whole, emphasizing distrust of the medical establishment and government. The more recent case of *Grimes v Kennedy Krieger Institute, Inc.,* 782 A.2d 807 (Md. 2001) raised several important issues for research ethics, where children were knowingly exposed to lead-based paint as part of a research study to understand how successful different lead abatement programs were in reducing continued lead exposure to children. However, the researchers and their supporters defend the ethics of the research; see Ross L.F. (2002), "In Defense of the Hopkins Lead Abatement Studies", *Journal of Law, Medicine and Ethics*, 30, pp. 50-57, and also Ross L.F. (2006), *Children in Medical Research: Access versus Protection*, Clarendon Press, Oxford. Chapter 12.

[4] For more discussion regarding the protection of children in research, see Miller P.B., Kenny N.P. (2002), "Walking the Moral Tightrope: Respecting and Protecting Children in Health-Related Research", *Cambridge Quarterly of Healthcare Ethics*, 11, pp. 217-229 and Ross L.F. (1997), "Children as Research Subjects: A Proposal to Review the Current Federal Regulations Using a Moral Framework", *Stanford Law and Policy Review*, 8, p. 159; Hendrick J. (1997), *Legal Aspects of Child Health Care*. Chapman and Hall, London; Richardson J., Webber I. (1995), *Ethical Issues in Child Health Care*, Mosby, London.

clinical studies makes children "therapeutic orphans"[5] and results in an increased level of off-label[6] prescriptions[7]. Thus, while children are protected from the risks of clinical trials, they are hindered from receiving the benefits of pharmaceutical innovations obtained by adults[8]. Harry Shirkey is noted to be amongst the earliest advocates for greater access of children to participate in medical research, arguing that children would be "therapeutic orphans"[9] unless both the government and industry supported paediatric drug investigation[10].

There is now a plethora of international guidelines and statutory instruments to help regulate medical experimentation and research. The World Medical Association's Helsinki Declaration is probably the most famous international ethical guideline[11], and two European Directives have shaped the law in this area: the Clinical Trials Directive[12] and the Good Clinical Practice (GCP) Directive[13]. The Clinical Trials Regulations implemented the Clinical Trials Directive[14], and the Regulations were subsequently amended to give effect to the GCP Directive[15]. The Regulations apply only to clinical trials of medicinal products, and that is principally trials of new pharmaceutical products. Other types of medical research are regulated by a complex combination of legislation, common law principles, clinical governance, and professional guidance[16]. Whether it is the consequence of a complex regulatory framework or issues stemming from the troubled history of child participation in medical research, one must contend with the fact that a significant problem in paediatric medicine remains – too many drugs licensed for use in adults are not licensed for use in children[17]. Con-

[5] Shirkey H. (1968), "Therapeutic orphans", *Journal of Paediatrics*, 72, pp. 119-120, as cited in Ross L.F. (2006), p. 2 and Pinxten W. Nys, H. Dierickx K. (2008), p. 439.
[6] The prescribing of drugs not tested in children and not labeled for paediatric use.
[7] See Conroy S. *et al*. (2000), "Drug trials in children: problems and the way forward", *Journal of Clinical Pharmacology*, 49, pp. 93-97. Note also Tafuri G. *et al*. (2009), "Off-label use of medicines in children: can available evidence avoid useless paediatric trials?", *European Journal of Clinical Pharmacology*, 65, pp. 209-216.
[8] Halila R., Lotjonen S. (2005), "Children and medical research", *Medicine and Law*, 24(3), pp. 505-513.
[9] Shirkey H. (1968), also cited in Ross L.F. (2006, p. 2.
[10] Ross L.F. (2006), p. 2. Note that Ross questions whether the pendulum has in fact swung too far, in that new initiative perhaps place too much emphasis on access and not enough emphasis on protection. Ross talks mainly in the realm of "non-therapeutic" research as she questions and criticises how research is being done and how we as a community are protecting and failing to protect our children in research participation (pp. 2-4).
[11] Pattinson S.D. (2011), p. 378; see WMA [online], URL: <http://www.wma.net/en/30publications/10policies/b3/index.html> (last accessed 10 April 2012).
[12] Directive 2001/20/EC.
[13] Directive 2005/28/EC.
[14] Medicines for Human Use (Clinical Trials Regulations) 2004 (SI 2004/1031).
[15] Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 2006/1928).
[16] Pattinson S.D. (2011), p. 378. More detailed analysis of the relevant legislation, common law principles and professional guidance that apply in the UK is beyond the scope of this paper, see Medical Research Council (2007), *MRC Ethics Guide:Medical research involving children*, London; Biggs H. (2010), *Healthcare Research Ethics and Law. Regulation, Review and Responsibility*, Routledge-Cavendish, London; Edwards S.D., McNamee M.J. (2005), "Ethical Concerns Regarding Guidelines for the Conduct of Clinical Research on Children", *Journal of Medical Ethics*, 31, pp. 351-4; Brazier M., Cave E. (2011), *Medicine, Patients, and the Law*, (Fifth Edition). Penguin Books, London, pp. 472-6; Cave E. (2010), "Seen But Not Heard? Children in Clinical Trials", *Medical Law Review,* 18, p. 1-27.
[17] Svobodnik A. *et al*. (2010), "How to Improve Children's Research", *Applied Clinical Trials*: "Children and adolescents represent about 25% of the European population, however, most medicines given to children are

sequently, many drugs are prescribed for children "off-label"[18]. With a pressing need for more good quality paediatric clinical trials, the EU Regulation on Paediatric Medicines 2006[19] requires that new medicines, and also some existing drugs, be tested on children in accordance with an agreed Paediatric Investigation Plan (PIP) with a view to producing information for the drug label[20].

New networks to facilitate paediatric trials have also been established[21]. It is still however perceived that new rules and incentives are insufficient in terms of tackling the problem[22], as there remain significant barriers to paediatric research[23]. Examples of such barriers are that ethics committees and insurers automatically perceive paediatric clinical trials as high risk and there are further practical problems surrounding paediatric clinical trials such as hospital transfers between specialist units, training healthcare staff and adapting pill sizes to children[24].

In addition to the apprehension surrounding paediatric clinical trials that remains despite efforts to put in place investigation plans and establish networks to facilitate paediatric research, situations that fall to the common law are a cause for further concern and apprehension, where the research does not amount to a clinical trial on a medicinal product and so one must rely heavily on the law as it applies in the context of medical treatment because there is a body of law relating to the medical treatment of children but the law regarding child participation in medical research is comparatively undeveloped. This paper will look at how the best interests test in English law has been extended from its traditional role in medical treatment cases to cases of administering innovative treatment and conducting medical research. In doing so, this paper seeks to pose one fundamental question: is there sufficient justification for extending application of the best interests test into the realm of research?

I will first clarify what exactly I mean by cases of innovative treatment. I refer to circumstances where a doctor might act reasonably by offering treatment that has not been tested on humans because all conventional treatments have been looked at and the patient's condition is so serious to warrant trying a treatment that has not yet been

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used off-label. In hospital paediatric wards this is around 45% and in the neonatal intensive care setting this can be as high as 90%".

[18] See Royal College of Paediatrics and Child Health (2010), *The Use of Unlicensed Medicines or Licensed Medicines for Unlicensed Applications in Paediatric Practice* [online], URL: <http://www.rcpch.ac.uk/child-health/childrens-medicines/childrens-medicines> (last accessed 10 April 2012).

[19] EU Regulation on Medicinal Products for Paediatric Use Regulation (EC) No 1901/2006.

[20] But see Megget K. (2009), "The problem with PIPs", *Clinical Discovery*, 4(6), p. 10.

[21] See *European Medicines Agency, European Network of Paediatric Research at the European Medicines Agency*, [online], URL: <http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp&murl=menus/partners_and_networks/partners_and_networks.jsp&mid=WC0b01ac05801df74a> (last accessed 10 April 2012).

[22] Brazier M., Cave, E. (2011), p. 476; see European CRO Federation (2009), "Testing Medicines for Children in Europe", *Good Clinical Practices Journal*.

[23] This was confirmed in the 2009 review of the Clinical Trials Directive: see [online], URL: <http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm> (last accessed 10 April 2012).

[24] See European Commission Assessment of the Functioning of the Clinical Trials Directive 2001/20/EC: (2010) Summary of Responses to the Public Consultation Paper.

licensed for use in humans[25]. The Declaration of Helsinki endorses this approach, supporting the use of unproven treatment where there appears to be no other viable option[26]. By focusing on cases of innovative treatment, I hope to illustrate that application of the best interests test in such matters is flawed because it focuses too narrowly on the interests of the individual child participant rather than viewing that individual child as being within a wider network of relationships. I argue that it is important to view an individual child participant as being within a wider network of relationships because when doing research the wider community of children and future children will be impacted by any decision, as well as the individual child participant and those in caring relationships with the child participant i.e. parents and/or guardians who will be impacted by any decision to participate in research in terms of caring for the child.

I propose that we should view "best interests" differently, through the lens of care theory. Ethics of care theory seeks to move away from the picture of individuals with rights and interests that compete against each other to a model that emphasises interdependency and mutually supporting relations. Care theory has been applied in an increasingly diverse manner but has only managed to enter debates about children in law to a limited degree. Where care theory has managed to enter debates about children in law, those works emphasise that children need to be understood as "social" beings, rather than individuals or dependents in need of protection, and that incorporating an ethic of care into family law decision-making might be the best way in which to acknowledge the relational lives of children in the decision-making process[27].

So I propose that if we view "best interests" differently, through the lens of care theory, there is greater potential to effectively accommodate both sets of interests involved and strike a more appropriate balance between these sets of interests: (i) the interests of the individual child participant with the interests of the community of children, and (ii) the interests of the individual child participant with those in caring relationships with the child who will be impacted by any decision to participate in research in terms of caring for the child. To illustrate my argument with reference to cases of innovative treatment, I suggest that rather than claiming innovative treatment is in the "best interests" of the individual child participant, a more effective approach would be to consider a dual "interests" test: is the innovative treatment "not against the interests" of the individual child participant *and* "in the interests" of the community of children? And if the answer to both is in the affirmative then the innovative treatment should be administered. I will now discuss how ethics of care theory developed and outline key principles of care theory to help illustrate how care theory can potentially enhance the current approach to "best interests" decision-making.

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[25] Jackson E. (2011), *Medical Law: Text, Cases and Materials*, Oxford University Press, Oxford, p. 441; see also Nicholson R. (ed.) (1986), *Medical Research with Children: Ethics, Law and Practice (The Report of an Institute of Medical Ethics Working Party)*, Oxford University Press, Oxford.

[26] See par. 35, WMA [online], URL: <http://www.wma.net/en/30publications/10policies/b3/index.html> (last accessed 10 April 2012).

[27] Smart C., Neale B., Wade A. (2001), *The Changing Experience of Childhood: Families and Divorce*, Polity Press, Cambridge.

3. Ethics of care theory

The ethics of care can be traced back to philosopher Sara Ruddick's essay "Maternal Thinking", published in 1980[28]. Ruddick's analysis provides an important starting point as to how care theory developed and how it should be viewed. Ruddick aimed to show how women's experiences in an activity like mothering could provide the foundations for a distinctive moral outlook, and how the values that emerged from within it could be relevant beyond the practice of mothering itself.

Then in 1982 came Carol Gilligan's *In a Different Voice*[29]. It is stressed that the importance of Gilligan's work for moral theory has been its suggestion of alternative perspectives through which moral problems can be interpreted[30]: "a 'justice perspective' that emphasises universal moral principles and how they can be applied to particular cases and values rational argument about these; and a 'care perspective' that pays more attention to people's needs to how actual relations between people can be maintained or repaired, and that values narrative and sensitivity to context in arriving at moral judgements"[31]. Gilligan herself thought that both perspectives of justice and care are needed for a person to have an adequate morality[32]. But Marilyn Friedman considered how contemporary notions of justice are often deliberately constructed so as to avoid presumptions of mutual concern[33], looking particularly at John Rawls' theory of justice[34]. Friedman found this problematic and suggested that

> While such an account promises to disclose duties of justice owed to all other parties to the social contract, it may fail to uncover *special* duties of justice which arise in close personal relationships the foundation of which is affection or kinship, rather than contract. The methodological device of assuming mutual disinterest might blind us to the role of justice among mutually interested and/or intimate parties[35].

Friedman draws our attention to the earliest Greek code of justice, noting that friendship was placed at the forefront of conditions for the relation of justice, and that the rules of justice were construed as being coextensive with the limits of friendship[36] – there was no hesitation to link the notion of justice to relationships based on affection and loyalty. This issue raised by Friedman concerning how contemporary moral think-

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[28] See Ruddick S. (1989), *Maternal Thinking: Towards a Politics of Peace*, The Women's Press, New York.
[29] Gilligan C. (1982), *In a Different Voice*, Harvard University Press, Harvard; Gilligan C. (1993), *In a Different Voice. Psychological Theory and Women's Development*, Harvard University Press, Harvard.
[30] See Larrabee M.J. (1993), "Gender and Moral Development: A Challenge for Feminist Theory", pp. 3-18, in Larrabee M.J. (ed.), *An Ethic of Care: Feminist and Interdisciplinary Perspectives*, Routledge, New York and London. See also Blum L.A. (1993), "Gilligan and Kohlberg: Implications for Moral Theory", in Larrabee M.J. (1993), pp. 49-68.
[31] Held V. (2006), *The Ethics of Care: Personal, Political and Global*, Oxford University Press, Oxford, pp. 27-28.
[32] Gilligan C. (1993), p. 174 and see Chapter 6.
[33] Gilligan C. (1993), p. 174 and see Chapter 6.
[34] Rawls J. (1971), *A Theory of Justice*, Harvard University Press, Cambridge, cited in Friedman M., in Larrabee M.J. (1993), p. 264.
[35] Friedman M. in Larrabee M.J. (1993), p. 264.
[36] Friedman M., in Larrabee M.J. (1993), pp. 263-264.

ing deliberately avoids presumptions of mutual concern and thus avoids recognising a real connection between justice and caring relationships can explain why the law is so deeply immersed in individualism, unable to sufficiently incorporate values of care as represented by care theory.

Friedman suggested several ways in which justice pertains to close relationships[37], one of which centres on the family domain. Her discussion highlighting the relevance of justice to close relationships which centres on the family domain is most relevant to my analysis about concerns that stem from the current approach to "best interests" and lessons that can be learnt from care theory:

> Personal relationships may also be regarded in the context of their various institutional settings... Here justice emerges again as a relevant ideal, its role being to define appropriate institutions to structure interactions among family members, other household cohabitants, and intimates in general. The family, for example, is a miniature society, exhibiting all the major facets of large-scale social life: decision-making affecting the whole unit; executive action; judgements of guilt and innocence; reward and punishment; allocation of responsibilities and privileges, of burdens and benefits; and monumental influences on the life-chances of both its maturing and its matured members. Any of these features alone would invoke the relevance of justice; together, they make the case overwhelming[38].

Friedman's emphasis on the role of justice being to define appropriate institutions to structure interactions is insightful and captures in my view the central objective and relevance of justice to moral theory. Presenting the family as a "miniature society" illustrates effectively many issues that will influence "best interests" decision-making in the context of administering innovative treatment and conducting medical research, and Friedman's analysis is important when thinking about the extent to which care and justice, when recognised in partnership together, can promote the interests of each party affected by a decision made in the best interests of a child.

So if it is recognised and accepted that there is sufficient connection between the domain of justice and that of caring relationships then it is important that this connection be revived in an appropriate and meaningful manner to inform the law. I suggest that incorporating values of care theory could improve the current approach to "best interests" decision-making to allow sufficient appreciation of the different interests that must be accommodated when making a decision about whether innovative treatment should be administered to a child – (I) the interests of the individual child participant with the interests of the community of children, and (II) the interests of the individual child participant with those in caring relationships with the child who will be impacted by any decision to participate in research in terms of caring for the child. But something remains to be established: what exactly connects the interests of each individual?

In Gilligan's analysis and discussion concerning relationships[39], Gilligan focused on responsibility. She observed that the research findings about women's responses to

[37] Friedman M., in Larrabee M.J. (1993), p. 264.
[38] Friedman M., in Larrabee M.J. (1993), p. 266.
[39] Gilligan C. (1993), see particularly Chapters 2 and 3.

the "abortion dilemma" that she discussed "suggest a sequence in the development of an ethic of care where changes in the conception of responsibility reflect changes in the experience and understanding of relationships"[40]. In Gilligan's view, because these findings were gathered at a particular moment in history this represents one of the constraints that preclude the possibility of generalisation and so she concludes that it must be left to further research to sort out the different variables of culture, time, occasion and gender[41]. In following this perceived reality, that conceptions, experience and understanding are affected by "the current climate", I find it appropriate to focus on dependency in my discussion of how care theory can inform "best interests" decision-making processes that determine the administatrion of innovative treatments and participation in medical research.

On a similar note, Joan Tronto aimed to suggest that the widespread acceptance of Kantianism is not simply a question of which moral theory was viewed most insightful and convincing, but rather, that this approach to morality addresses the kinds of moral questions that seemed to be most problematic in the late eighteenth century and which remained the central moral questions until recently[42]. Tronto suggested that, in any age, the approach taken to moral theory is shaped by the broader constellation of historical, social, political, and intellectual aspects of life[43]. Thus Tronto sought to establish that changing the kinds of questions that are centrally important in moral life would change how and what constitutes moral theory[44]. Basing her analysis on the eighteenth century, Tronto observed that having noticed changes in social life produced changes in what moral arguments appealed to that century of thinkers, one must wonder what changes in later centuries might change our perceptions of adequate moral argument[45]. My reasoning is based on a similar notion. There is a drive to achieve progress in paediatric medicine and for this to happen it is necessary that innovative treatments be administered and medical research conducted. I argue that the current "best interests" approach that forms the basis of decision-making for administering innovative treatment and conducting medical research is not appropriate. It might have been seen to be the appropriate approach in an era that dealt with research scandals and child victims of medical research (i.e. the Nazi experiments and other research scandals), but this is no longer the case (we sincerely hope). The question now is not "should children receive innovative therapies and participate in medical research" but the question is "how to effectively accommodate and balance the interests of each party impacted by a decision to administer innovative treatment to a child and conduct medical research".

I therefore suggest that it is important to consider the extent to which values of care theory have the potential to enhance existing legal and ethical frameworks regulating the administration of innovative treatment and child participation in medical research. I propose that it is important to move beyond gender association as a criticism or weak-

[40] Gilligan C. (1993), p. 126.
[41] Gilligan C. (1993), p. 126.
[42] Gilligan C. (1993), p. 28.
[43] Gilligan C. (1993), p. 28.
[44] Gilligan C. (1993), p. 35.
[45] Gilligan C. (1993), p. 57.

ness and focus on the fact that a care ethic includes values traditionally associated with women that can positively enhance a universally applicable moral theory. For care theory to be understood and applied effectively, some relationship between care and justice should be established. And finally, the political context in which such ethical and legal issues are considered cannot be forgotten, as it is likely to have considerable influence on the approach adopted in dealing with the issue of administering innovative treatment and conducting medical research.

I will now look more specifically at how ethics of care theory can be applied to the situation of children in a healthcare context to consider caring relationships and human interdependency[46].

3.1. Children and ethics of care theory

My analysis in this section will focus on how ethics of care theory has already been considered in relation to decision-making in a healthcare context. I focus particularly on the work of Jonathan Herring. Herring does not confine his analysis to children and talks about patients generally, but I seek to emphasise that his approach is persuasive in dealing with the situation of a child patient and could potentially enhance the current approach to "best interests" decision-making to more effectively manage cases that involve children[47].

Herring looked at the social and legal position of "caregivers" to outline how an approach based on an ethic of care properly takes account of caring relationships[48]. Herring sought to emphasise that medical law and ethics is dominated by individualism[49], whereby focus is merely on "the person sitting in front of the doctor"[50] as the patient, when in fact this is far too simplistic because a patient's medical decisions will rarely affect only herself but will often have significant impact on those who depend on her and upon whom she is dependant[51]. Thus, any treatment provided will not only assist the person sitting in front of the doctor, but the various people that the individual patient has a relationship with[52]. Herring advocated that as individuals[53], "we are ignorant, vulnerable, in-

[46] For general discussion, see Tong R. (1997), *Feminist Approaches to Bioethics: Theoretical Reflections and Practical Applications*, Westview Press. USA; Tong R. (2004), "Feminist Approaches to Bioethics", in Khushf G. (ed.), *Handbook of Bioethics*, Kluwer Academic Publishers, Netherlands, pp. 143-161; Sherwin S. (1992), *No Longer Patient: Feminist Ethics and Health Care*, Temple University Press, Philadelphia; Sheldon S., Thomson M. (eds.) (1998), *Feminist Perspectives on Healthcare Law*, Cavendish Publishing Limited, London.

[47] For general discussion, see Bridgeman J., Monk D., (eds.) (2000), *Feminist Perspectives on Child Law*, Cavendish Publishing Limited, London.

[48] Herring J. (2008-2009), "Caregivers in Medical Law and Ethics", *Journal of Contemporary Health Law and Policy*, 25, pp. 1-37.

[49] Herring J. (2008-2009), p. 1.

[50] Herring J. (2008-2009), p. 1.

[51] Herring J. (2008-2009), p. 1.

[52] Herring J. (2008-2009), p. 1.

[53] Herring refers to the United Kingdom Government definition of "caregiver" at p. 2: "[S]omeone who looks after a friend, relative or neighbour who needs support because of their sickness, age or disability", citing Her

terdependent individuals, whose strength and reality is not in our autonomy, but our relationships with others"[54]. Therefore, rather than focusing on the individual, law should be "based on a norm of interlocking mutually dependant relationships"[55]:

> [W]e cannot consider the interests of the patient in isolation from those who are in caring relationships with them. However proudly the law may seek to trumpet our autonomy, our self-sufficiency and our rights, that is a false picture of our lives. We are not almighty, but vulnerable; not all knowing rationale people in control of our lives, but ignorant, vulnerable and subject to the responsibilities, ties and joys of our relations with others; not independent and self-sufficient, but dependent on others in countless ways[56].

Herring considers how ethics of care theory promotes a vision of people with interdependent relationships as the norm around which legal and ethical responses should be built[57], because the values promoted within an ethic of care are not isolated autonomy or the pursuance of individualised rights[58], the values promoted within an ethic of care are centred on the belief that dependency and care are an inevitable part of human life[59], and as such, are a good part of life[60]. Herring refers to the work of Kittay[61] and Tronto[62] to highlight support for this view and to emphasise that the law misses an important and inevitable aspect of life in failing to properly acknowledge care work[63]. Also, in relationships of caring and dependency our interests become intermingled[64], and an ethic of care emphasises the importance of responsibilities within caring relationships[65]. Herring's discussion relates to that of Held[66] in this respect, focussing on responsibility and obligation within caring relationships. Herring does in fact refer to Held's distinction between an ethic of care and an ethic of justice to illustrate how supporters of an ethic of care argue that focus should be on obligation as opposed to rights within the context of relationships, noting that Held clearly advocated that an ethic of care includes justice[67].

Herring's analysis is valued for its relevance to "care-giving" in contemporary society and dealing with the uproar of autonomy and rights culture that has dominated recent years in the context of healthcare. His analysis has an important role to play in

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Majesty's Government, *Introduction to Caring*, [online], URL: <http://www.direct.gov.uk/en/CaringForSomeone/CaringAndSupportServices/DG_10016779> (last accessed 10 April 2012).

[54] Herring J. (2008-2009), p. 10.

[55] Herring J. (2008-2009), p. 10.

[56] Herring J. (2008-2009), p. 37.

[57] Herring J. (2008-2009), p. 10.

[58] Herring J. (2008-2009), P. 10.

[59] Herring J. (2008-2009), p. 11.

[60] Herring J. (2008-2009), p. 12.

[61] Kittay E.F. (1999), *Love's Labor: Essays on Women, Equality and Dependency*, Routledge, cited in Herring, J. (2008-2009), p. 11.

[62] Tronto J. (1993), *Moral Boundaries: A Political Argument for an Ethic of* Care. Routledge, New York-London, cited in Herring J. (2008-2009), p. 12.

[63] Herring J. (2008-2009), pp. 11-12.

[64] Herring J. (2008-2009), p. 13.

[65] Herring J. (2008-2009), p. 15.

[66] Held V. (2006).

[67] Held V. (2006).

promoting greater awareness and understanding of the reality of "individuals" and emphasising particularly that *law* should reflect the mutually dependent relationships inherently associated with each individual. I find Herring's analysis particularly persuasive where the patient in question is a child. Even if one is not wholly convinced that the reality of every individual patient makes it necessary for the law to reflect the mutually dependent relationships inherently associated with each individual, it is difficult to deny that the reality of every child patient makes it necessary for the law to reflect the mutually dependent relationships inherently associated with each child.

I will now look at cases of innovative treatment to illustrate concerns with the current approach to "best interests" and show the extent to which these cases capture the complex situation of a child patient, a situation that makes it necessary for the law to reflect the mutually dependent relationships inherently associated with the child.

4. Application of "best interests"

I consider first the case of *Simms v Simms; A v A and another*[68]. In *Simms* the court ruled that an experimental treatment would be in the best interests of two patients suffering from variant Creutzfeldt-Jacob Disease[69] who were incompetent to consent to any treatment[70]. There was no guarantee that the treatment would in fact be beneficial, having never been tested on humans before, but without intervention they would both die. The mere possibility of the treatment being beneficial to the patients proved to be enough to tip the scales of best interests. It was held that treatment would be in their best interests in light of both the poor prognosis without treatment and the lack of viable alternatives.

The case of *Simms* is described as having taken "a broad view of best interests"[71]. Dame Butler Sloss referred to each patient's rights under Articles 2 (the right to life) and 8 (the right to respect for family life) of the European Convention on Human Rights[72] but her approach is criticised for the fact that she merely "made passing reference"[73] to the Convention rights and "offered no developed or systematic analysis of the import of these rights for the case at hand"[74]. Instead, Dame Butler-Sloss invoked the "very strong presumption in favour of a course of action which will prolong life"[75]. She focussed on the circumstances of each patient, discussing again their prospects with and without treatment[76]. She gave weight to the fact that there was no available

[68] [2003] 1 All ER 669, [2003] 2 WLR 1465, [2003] 1 FCR 361.
[69] vCJD, referred to as the human form of "mad cow disease", or Bovine Spongiform Encephalopathy (BSE).
[70] This was a result of the disease, which involves the progressive impairment of neurological functioning.
[71] Harrington J. (2003), "Deciding best interests: medical progress, clinical judgment and the *good family*", *Web Journal of Current Legal Issues,* 3, p. 6.
[72] [2003] 1 All ER 669, at 683 (par 61).
[73] Harrington J. (2003), p. 6.
[74] Harrington J. (2003), p. 6.
[75] See Lord Donaldson in Re J (Wardship: Medical Treatment) [1993] Fam 33, CA at p46, as cited in Harrington (2003), p. 6.
[76] See [2003] 1 All ER 669, par. 60-61.

alternative to PPS, although the outcome of therapy was uncertain, accompanied by the burdens and discomforts of administrating the therapy[77]. Of particular interest is the weight Dame Butler-Sloss attributes to the family circumstances of each patient, stating that "even the prospect of a slightly longer life is a benefit worth having"[78] as "[e]ach patient is at present within a devoted and wonderfully caring family and is being provided with the best life possible in these tragic circumstances"[79]. What is more, importance was attached to the wishes and feelings of the families beyond the issue of the future level of care that each individual would receive. It was perceived that both families had "their feet firmly on the ground and understand very well the limitations on the prospects of benefits and risks attached"[80], and in light of this, the families' strong views in favour of treatment "carried great weight"[81].

John Harrington emphasises that the court took a relational view of best interests in this case, "whereby the practical attitude and wishes of the incompetent patient's relatives set the parameters of decision-making concerning their future treatment"[82]. In her discussion of best interests, Dame Butler-Sloss began by stating that she had to "assess the best interests in the widest possible way to include the medical and non-medical benefits and disadvantages, the broader welfare issues of the two patients, their abilities, their future with or without treatment, the views of the families, and the impact of refusal of the applications" and that all such matters had to be "weighed up and balanced in order for the court to come to a decision in the exercise of its discretion"[83]. She concluded discussion with greatest focus on the views of the parents and the impact of refusal of the application on the parents: "In a finely balanced case I should give the views of the parents and the effect upon them of refusal great weight in the wider considerations of the best interests test which the court has to apply to each patient"[84]. Similarly, Dame Butler-Sloss gave importance to the views and wishes of family members in the cases of *Re T (A Minor) (Wardship: Medical Treatment)*[85] and *Re Y (Adult Patient) (Transplant: Bone Marrow)*[86]. In the former case, a mother opposed that her one-year old child be given a liver transplant and in the latter case, the removal of bone marrow from an incompetent patient was authorised for donation to her sister[87]. It is observed that *Simms*, *Re T* and *Re Y* represent an elision of interests whereby the worth of the incompetent patients' lives seems in part to be determined by the willingness and ability of their families to care for them[88] and Harrington notes that this elision of inter-

[77] See [2003] 1 All ER 669, par. 60-61
[78] See [2003] 1 All ER 669, par. 61.
[79] See [2003] 1 All ER 669, par. 60-61
[80] See [2003] 1 All ER 669, par. 64.
[81] See [2003] 1 All ER 669, par. 64.
[82] Harrington J. (2003), p. 7.
[83] [2003] 1 All ER 669, par. 60.
[84] [2003] 1 All ER 669, par. 64.
[85] (1996) 35 BMLR 63.
[86] (1996) 35 BMLR 111.
[87] For more detailed analysis of these cases see Elliston S. (2007), *The Best Interests of the Child in Healthcare*, Routledge-Cavendish, London and New York and Fox M., McHale J. (1997), "In Whose Best Interests?", *Modern Law Review*, 60(5), pp. 700-709.
[88] Harrington J. (2003), p. 7.

ests can in fact be seen as realising the ethic of care as articulated by feminist scholars like Gilligan[89].

But what about a situation where the patient's family is "indifferent or downright abusive" or where the patient is "more or less alone in the world" or "is enmeshed in a web of 'non-standard' relationships"[90] – what of the patient's interests in that situation? Harrington questions whether such a patient is considered to be worth less because they are valued less by their relatives, or because of "a lack of" relatives[91]. I would suggest that care theory provides assistance particularly when faced with such a situation because care theory promotes human interdependency and caring relationships and so would reflect the view that one must not stop at family, relatives, or non-standard relationships, considering the value of a patient in terms of the value to relatives or relationships but that it is necessary to cast the net much wider on the basis of human interdependency – so in the case of children, the individual child participant is valued by the community of children and future children that stand to benefit from any knowledge or progress achieved through innovative treatment or research. Held considers the extent to which moral problems are interpreted at two extremes within judicial reasoning, "as if they were conflicts between egoistic individual interests on the one hand, and universal moral principles on the other", whereby the "extremes of 'selfish individual' and 'humanity' are recognised, but what lies between those is often overlooked"[92], and she advocates that ethics of care theory focuses especially on the area between these extremes[93]:

> Those who conscientiously care for others are not seeking primarily to further their own *individual* interests; their interests are intertwined with the persons they care for. Neither are they acting for the sake of *all others* or *humanity* in general; they seek instead to preserve or promote an actual human relation between themselves and *particular others*. Persons in caring relations are acting for self-and-other together. Their characteristic stance is neither egoistic nor altruistic; these are the options in a conflictual situation, but the well-being of a caring relation involves the cooperative well-being of those in the relation and the well-being of the relation itself[94].

I suggest that we can pursue Held's analysis in the context of research participation to accommodate both the interests of the individual child and the interests of the community or class of children as a whole – thus Held's definition of "particular others" can encompass the community or class of children as well as the individual child.

The situation was different in the next case, where the patient's family opposed the administration of innovative therapy. In *An NHS Trust v J*[95] the patient, who was in a persistent vegetative state (PVS) after suffering a brain hemorrhage three years earlier,

[89] Harrington J. (2003), p. 7.
[90] Harrington J. (2003), p. 7.
[91] Harrington J. (2003), p. 7.
[92] Held V. (2006), p. 13.
[93] Held V. (2006), p. 13.
[94] Held V. (2006), p. 13.
[95] [2006] All ER (D) 290.

was to receive innovative therapy by way of postponing the withdrawal of artificial hydration and nutrition against the wishes of her family. According to two research papers, the insomnia drug Zolpidem sometimes enhanced neural responses in PVS patients and while experts were doubtful as to whether any benefit would be gained in J's case, they saw no harm in trying. The family however disagreed, in light of the extensive neurological damage suffered by J and the fact that any heightened awareness would bring her only further distress. Sir Mark Potter P accepted the expert opinion that the therapy was in J's best interests and ordered the therapy to continue[96].

Penney Lewis opines that the difficult question raised by this case is how the best interests test should be interpreted where there is a remote possibility of improvement in the patient's condition which is not based on scientifically rigorous evidence and where the decision not to proceed with the "faint hope" treatment will result in the patient's certain death[97]. Thus, "[i]f the alternative is death, should we always proceed with a 'faint hope' treatment?"[98] Lewis opines that "[i]n effect, a test akin to 'not against the interests' was used"[99] in this case, and expresses concern that, "[w]here the decision not to proceed with a 'faint hope' treatment will result in the patient's certain death, it is tempting to relax the best interests test" but that "[w]e should at a minimum require responsible medical opinion that supports the research on which the proposed treatment is based in relation to the class of patients to which the incompetent patient belongs"[100].

I think that it is important, though there is risk of bordering on insensitivity in a very delicate situation such as this, to highlight the fact that the administration of innovative therapy stood to impact the "class of patients" to which the incompetent patient belongs, perhaps more so than it was likely to have any positive long term impact on the patient in question (I would of course require more medical evidence before making any such claim confidently, but make this comment based on the medical opinions and evidence presented in the case). While I do not wish to take attention or importance away from the patient in question in this case and how the interests of the patient were carefully considered with particular focus on the fact that the patient would most certainly die as a result of not proceeding with treatment, one cannot overlook the fact that proceeding with the "faint hope" treatment was both "not against the interests" of the individual patient and "in the interests" of the community of children and future children. So I would suggest that rather than trying to justify that innovative treatment is in the "best interests" of the individual child participant, a more effective approach would be to consider a dual "interests" test: is the innovative treatment "not against the interests" of the individual child participant *and* "in the interests" of the community of chil-

[96] See Skene L., Wilkinson D., Kahane G., Savulescu J. (2009), "Neuroimaging and the withdrawal of life-sustaining treatment from patients in vegetative state", *Medical Law Review*, 17(2), pp. 245-261; Lewis P. (2007), "Withdrawal of treatment from a patient in permanent vegetative state: judicial involvement and innovative *treatment*", *Medical Law Review*, 15(3), pp. 392-399.
[97] Lewis P. (2007), p. 398.
[98] Lewis P. (2007), p. 398.
[99] Lewis P. (2007), p. 398.
[100] Lewis P. (2007), p. 399.

dren? And if the answer to both is in the affirmative then the innovative treatment should be administered.

5. Conclusion

The current "best interests" approach to decision-making insists on finding individual interests for the patient and shoehorns innovative treatment into the definition of "research". Looking at how care theory has been interpreted and applied by various theorists, one is encouraged that ethics of care theory has the potential to enhance the long established moral approaches that have been invoked during the last two centuries. It is changing the ways moral problems are often interpreted and changing what many think the recommended approaches to moral issues ought to be. Ethics of care theory provides a particular lens through which to read legal and ethical problems and should be appreciated as having the potential to deepen our legal judgments and enrich our justice system. I propose that if we view "best interests" differently, through the lens of care theory, there is greater potential to effectively accommodate both sets of interests involved and strike a more appropriate balance between these sets of interests: (i) the interests of the individual child participant with the interests of the community of children, and (ii) the interests of the individual child participant with those in caring relationships with the child who will be impacted by any decision to participate in research in terms of caring for the child. And I propose that a dual "interests" test, whereby the innovative treatment is "not against the interests" of the individual child participant *and* "in the interests" of the community of children, is more appropriate for cases in which doctors have an opportunity to try out new techniques on a patient who is not disadvantaged by them, and which carries great potential benefit for others.

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Neuroscientific Evidence and the Criminal Justice Process of England and Wales

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Abstract: This paper critically examines the implications of using neuroscientific evidence in the adversarial criminal justice process of England and Wales. By analysing the potential impact of a pilot concerning the use of polygraph evidence on "low-risk" sex offenders during the police interview. The paper highlights a number of potential breaches of the suspect's human rights. Although the pilot is voluntary, the paper identifies the need for reformation should the procedure become mandatory. Furthermore, the paper identifies and examines the use other types of neuroscientific evidence and how the techniques are being used throughout the world and the problems each case present. The paper concludes that the polygraph examination should only be used in the post-conviction offender management stage, as it is currently not reliable enough to satisfy the criminal burden of proof.

Keywords: polygraph evidence; suspect's rights; right to a fair trial; adversarialism

1. Introduction

This paper will critically examine the developing field of neuroscientific evidence and assess the impact of using such evidence at the trial stage in the adversarial criminal justice process. Currently, the use of such evidential techniques is in its infancy in England and Wales and has yet to reach the courtroom. In order to ascertain the impact of using neuroscientific evidence, the paper will briefly outline the implications of using the evidence in two international jurisdictions. The case law referred to will be the high-profile Indian case known as the *Sharma* case and the Italian *Como* case. These cases will not provide an analysis of the use of available neuroscientific evidence as they merely illustrate how the evidence is being utilized throughout the world.

This introduction to the international use of the evidence will lead into the primary focus; how neuroscientific techniques are being used in England and Wales. In particular, the paper will examine the use of the polygraph examinations on pre-charge "low-level" suspected sex offenders who volunteer to be subjected to the test. Although this pilot will only involve those who volunteer to participate, the paper will analyse the validity of such techniques; theorise what the police and prosecution will use the results of the examination for; and highlight inherent dangers the techniques hold for the fair trial rights of those who undertake the polygraph examination[1]. The paper will finally discuss if there are appropriate safeguards to use neuroscientific evidence in the adversarial setting of England and Wales. If there are not appropriate safeguards, the paper will identify the appropriate place for neuroscience in the criminal process.

2. The case of Aditi Sharma

The Indian case of Aditi Sharma concerned the murder of her husband, Udit Bharati, by poisoning. A substantial[2] cause for the conviction was the use of the Brain Electrical Oscillation Signature (BEOS) test. The prosecution claimed that the BEOS test would provide the court with a brain fingerprinting technique. The technique enables the person interpreting the data to distinguish normal brain activity from the stimulation of memory of experiential events[3]. This procedure is considered non-invasive and is achieved via the subject wearing an electrode cap with 32 electrodes. Thirty of these electrodes are placed on the head over corresponding parts of the brain where neural memory activity occurs and two electrodes are placed on the earlobe. The polygraph test measures "truthful response" through verbal feedback, which is potentially open to manipulation by the subject. However, the BEOS test supposedly circumvents this ma-

[1] It is important to state that, in the traditional sense, polygraph examinations might not fall under the umbrella of neuroscience. However, this paper accepts that the neuroscientific umbrella will include examining a person's nervous system. This is justified because currently any examination of brain activity has not permeated the criminal justice system. The polygraph examination is the first step being taken in England and Wales.

[2] Mascarenhas A. (October 1st 2008), "The Thought Police are Here", *The Indian Express*.

[3] Claydon L. (2011), "Law, Neuroscience and Criminal Culpability", in Freeman M. (ed.), *Law and Neuroscience*, Oxford University Press, Oxford, p. 142.

nipulation, as it does not require verbal feedback. The results or answers from the examination are adduced from the probing of the stored memory of the subject. At face value, this idea might be viewed as "fool proof" because you cannot hide or lie about stored memory. Whereas with the traditional polygraph examination there are various medications or techniques you can use to slow your heart rate in an attempt to "cheat" the test. In the *Sharma* case "Aditi" was read passages of description during the test. Some of these passages described the police view of what she had done to poison Udit, others were described as "value neutral" in terms of the test and included statements such as "the sky is blue..."[4].

According to the judge, the test was taken to demonstrate that Sharma had experiential knowledge[5] of the murder. This experiential knowledge is that which could only have been attained through veridical experience of actually murdering Udit. According to the BEOS examiner it was claimed that Sharma had stored memories of buying arsenic, telephoning Udit to arrange a meeting and administering the poison[6]. These factors all influenced Sharma's conviction. Sharma's conviction was eventually suspended and she was placed on police bail because doubt remained if Sharma administered the poison[7]. Interestingly, the bail hearing makes no reference to the BEOS test or its validity. Sharma has not formally been acquitted; she is still awaiting the Indian Supreme Court to review her case.

Whilst no one debates the potential significance of these techniques, there is concern about the use of neuroscientific evidence in its current state[8]. Until it can be strenuously tested and verified through empirical research, that correlation exists between a memory and a brain state, the information used in court must be considered inadmissible. The Indian National Institute of Mental Health echoed this claim when they stated that brain scans were too unreliable to be used as evidence in criminal cases[9].

3. The Como case

The *Sharma* case demonstrated how the prosecution used neuroscientific evidence in the trial of Sharma. The Como case will offer an example of how the defence utilized neuroscientific evidence in order to further the best interests of their client.

In the Como case, Ms. Albertini, a 28-year-old Italian female, was charged with the murder of her sister, kidnap and the attempted murder of her parents. What made this case particularly interesting was that her sentence was mitigated on the basis of various

[4] Claydon L. (2011), p. 142.
[5] Giridharadas A. (15th September 2008), "India's use of brain scans in courts dismay critics", *New York Times*, and Claydon L. (2011), p. 142.
[6] Natu N. (July 21st 2008), "The Brain Test Maps the Truth", in *The Times of India*.
[7] The full bail report can be read [online], URL: <http://lawandbiosciences.files.wordpress.com/2009/04/iditis-bail-order1.pdf> (last accessed 28th April 2012).
[8] Baskin J.H., Edersheim J.G., Price B.H. (2007), "Is a Picture Worth a Thousand Words? Neuroimaging in the Courtroom", *American Journal of Law and Medicine*, 33, p. 239.
[9] Ammembala N. (13th November 2008), "Panel Debunks Brain-Mapping", *Express Buzz*, as cited in Farrell B. (2010), "Can't Get you Out of My Head: The Human Rights Implications of using Brain Scans as Criminal Evidence", *Interdisciplinary Journal of Human Rights Law*, Vol. 4.

neurological abnormalities. The presence of the "Dissociative Identity Disorder" was discovered through memory deficits found in the "Autobiographical Implicit Association Test" and the "Time Agnostic Response Alethiometer Test". Albertini was also believed to be unable to properly distinguish between right and wrong, according to a Voxel Based Morphology examination. This demonstrated problems with the functionality of the anterior cingulated cortex, which is thought to be linked to compulsive and aggressive behaviour. However, the most significant and controversial piece of evidence was that Albertini was thought to be more prone to aggressive behaviour as a result of possessing a gene called MAOA-uVNTR. Possession of this gene meant that Albertini was genetically hardwired to act in a more aggressive manner[10]. It was argued that as a result of Albertini possessing this gene, she had a diminished capacity to regulate her behaviour, and therefore should not be held totally accountable for her actions. The judge accepted this argument and, as a result, Albertini's sentence was mitigated from thirty to twenty years.

The Albertini case highlights some of the concerns noted in Sharma about validity i.e. whether the presence of this gene can be directly linked to hardwired aggressive behaviour. This question was answered by a study conducted in 2002. The Dunedin Multi-Disciplinary Health and Development Study was conducted in New Zealand concerning the MAOA gene and its connection to anti-social behaviour. The authors of the study divided the participants into two categories; those participants with low MAOA activity and those with high MAOA activity. The study concluded that the gene had no statistically significant effect on anti-social behaviour. However, the study also stated that where a subject possessed low MAOA activity and had a history of childhood sexual molestation, there is potential of an increased risk of aggressive behaviour as an adult[11]. The combination of this "Warrior Gene" and a history of childhood sexual abuse allowed a defendant to successfully avoid the death penalty in a murder case[12]. With these findings in mind, it could equally follow that a person with low activity might never commit a criminal act. Although the research evidence and the case law appears to indicate that someone with low MAOA activity is predisposed to behave more aggressively than those with high MAOA activity, especially when this is coupled with a history of childhood sexual abuse.

What this section has sought to explore is just how neuroscientific evidence is being used in the criminal courts around the world. What is clear from the research is that the use of neuroscientific evidence is welcomed in a number of jurisdictions. The evidence is used as the sword of the prosecution and as the shield of the defence. This section is important because as yet such evidential techniques are not used in the criminal courts of England and Wales. However, neuroscientific techniques are taking their first steps in the

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[10] See Bottalico B. (2011), "The Albertini Case", *Neuroethics and Law Blog*, available [online], URL: <http://kolber.typepad.com/ethics_law_blog/2011/09/the-albertani-case-in-italy-bottalico.html>.

[11] Frazzetto G. *et al.* (2007), "Early Trauma and increased risk of physical aggression during adulthood: the moderating role of MAOA genotype", PLoS One, 2(5), and Caspi A., McClay J., Moffitt T.E., Mill J., Martin J., Craig I.W., Taylor A., Poulton, R. (August 2002), "Role of genotype in the cycle of violence in maltreated Children", *Science*, 297, available [online], URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1872046/?tool=pmcentrez> (last accessed 12/4/12).

[12] Although the defendant was sentenced to thirty two years imprisonment. For further reading on this case, please see [online], URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1872046/?tool=pmcentrez> (last accessed 12/4/12).

pre-trial investigation and this paper shall shift focus to examine neuroscience through the lens of the criminal justice process of England and Wales. This sub-section is not designed to be a comparative analysis of the international use of neuroscientific evidence versus the approach utilized by England and Wales. The sub-section is merely to provide the reader with a flavour of how neuroscientific evidence is being used in courtrooms throughout the world.

4. The impact of neuroscience in England and Wales

This section of the paper will critically examine the use of polygraph examinations and what impact the implementation of such investigative techniques hold for two fundamental values of the criminal justice process; the privilege against self-incrimination and the right to a fair trial. Further to this primary aim, this sub-section will also examine the use of the tests in other jurisdictions and analyse the reliability of the examination results. Furthermore, the section will also analyse if interrogating suspects at the police station via a polygraph examination could violate the suspect's human rights. Finally, the paper will conclude if the polygraph examination has any place in the criminal process and what safeguards may be necessary to prevent any future miscarriage of justice.

5. The use of the polygraph examinations in India and the United States

Before examining the stance of England and Wales in respect of polygraph examinations, it is important to understand how other jurisdictions deal with the tests. The Indian criminal process already implements a number of neuroscientific techniques. The unreported case of Smt. Selvi and Others v State of Karnatake highlights a number of concerns of which our own criminal justice process should take heed. This case concerns the use of narco-analysis, polygraph examination and brain mapping. For the purposes of this paper, we will only concentrate on the use of the polygraph examination. The polygraph test monitors a person's physiological responses to questions in order to ascertain if the answers provided are lies or are a truthful response. The responses that are monitored are a person's pulse, respiration, blood flow, blood pressure and galvanic skin resistance. In the Indian criminal justice process, these techniques are not only reserved for people suspected of committing a criminal offence, but witnesses are also tested, as are victims of sexual offences to examine the veracity of their allegations. The Supreme Court of India held that all three techniques were unconstitutional as they violate the privilege of self-incrimination. This privilege is enshrined in Article 20(3), which provides: "No person accused of an offence shall be compelled to be a witness against himself". The Court rejected the notion that the results of a polygraph test should be classed as physical evidence, similar to the analysis of bodily substances such as blood, hair and semen, and therefore concluded that polygraph tests fell outside the scope of Art. 20(3). The results from a polygraph exam are not dissimilar from the admissions contained in written or oral statements, as inferences from the examination

will allow the examiner to derive knowledge from the mind of the subject which otherwise would not have been available. It is this inference that differs from the bodily evidence described above, as the test subject's physiological responses are directly correlated to their mental faculties.

In the United States of America, it was held in Marcum v State that a person given a polygraph examination as part of a court ordered probation is not required to receive a Miranda Warning. The general notion is that the results from the examination, for example, information about past victims, indications of a sex offender's pattern of offending, is of significant value to many in the criminal justice process. The case of Frye held that polygraph evidence was inadmissible under the heading of "scientific evidence". The court held that admissible scientific evidence must be based on methods that have the general acceptance of the relevant expert community. This traditional stance altered in the early 1990s when the Supreme Court held that it is for the judge to make an assessment of the reliability and relevance of the evidence. In Daubert, the Supreme Court ruled that the 1923 Frye test was superseded by the 1975 Federal Rules of Evidence, specifically Rule 702 governing expert testimony. Rule 702 originally stated:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

However, a number of jurisdictions in the United States still use the Frye standard, although the Daubert case opened the door for polygraph data to be admissible in post-conviction sex offender management. In Kansas v Lumley a defendant appealed against a prison sentence that resulted from a "failed" question he answered on a polygraph examination concerning contact with a child. The appeal judge found the reliability of the examination was robust enough to satisfy any evidential threshold required by a parole or probation hearing; as the standard of proof is lower than in a criminal trial.

6. Polygraph tests in England and Wales: The traditional stance

Traditionally, polygraph tests have played no part in either the pre-trial investigation or the trial stage in England and Wales. Archbold[13] states that "evidence produced by the administration of a mechanically or chemically or hypnotically induced test on a witness as to show the veracity or otherwise of that witness is not admissible in English law"[14]. This stance relates to both the use of the evidence as the sword for the prosecution or the shield of the defence. In *Application No.9696/82*[15] the applicant was con-

[13] Archbold Criminal Pleading, Evidence and Practice is commonly referred to as "Archbold". It was first written in the 19th Century and is the leading practitioners text for criminal lawyers. The authority is so great, it is often quoted at trial.
[14] Archbold (2005), par. 8-158.
[15] (1983 Unpublished) 2 Dig. Supp. 6.1.1.4.4.5 at 6 as cited in Emmerson B., Ashworth A., McDonald A. (2007), *Human Rights and Criminal Justice*, 2nd Edition, Sweet and Maxell, London, p.660.

victed of murder and the trial judge refused to allow him to use the findings from a polygraph examination in order to prove his innocence. He claimed that this violated his right to a fair trial. The Commission stated that this claim was manifestly ill-founded and "[it is] not possible to obtain fully reliable results by the use of the lie detector [...] it is justified that no general right for the use of lie detector is granted to suspected persons or convicted persons [... the use of the test] would inevitably influence the position of other persons who would refuse to be subjected to a lie detector. Their refusal might be interpreted as a sign of guilt".

Despite this traditional approach of prohibiting polygraph examinations at both the pre-trial or trial stage, one police force in England and Wales is reversing this stance. In April 2012, Hertfordshire police force commenced a trial on twenty-five "low-level" sexual offenders[16]. The police force claim that the tests will be administered pre-charge and with the aim of "speed[ing] up the risk assessment process"[17]. Although this twelve-month trial is voluntary, it raises a number of questions of the potential impact for the suspect at the police station stage.

The Association of Chief Police Officers (hereafter, ACPO) readily admit that polygraph tests are "not a single solution for solving crimes"[18] and any evidence elicited will not be admissible at the trial stage. According to a BBC report, the findings of the examination may inform the decision of whether or not a particular suspect should be charged with an offence. This provides a fundamental problem; the evidence obtained from the polygraph test will not be admissible at trial. So if the evidence will not be admissible at trial, what will the police use their discoveries for? To charge a suspect in England and Wales, the Full Code Test needs to be satisfied. This test has two stages. Firstly, the evidential stage must be satisfied[19], this means that "the prosecutor must be satisfied that there is a realistic prospect of conviction against each suspect on charge". In arriving at this conclusion the prosecutor has to judge if the evidence can be used in court and whether or not the evidence is reliable[20]. The second stage is the Public Interest stage; here the prosecutor must weigh up if the prosecution is in the public interest. To define if a prosecution is in the public interest, the Crown Prosecutor must weigh a number of factors that tend in favour of prosecution against factors that tend against prosecution[21]. If this test cannot be satisfied, owing to insufficient evidence, the prosecutor can apply the Threshold Test. The first stage of the test asks whether or not there is reasonable suspicion that the person to be charged has committed the offence, in doing so the prosecutor must consider all the evidence he currently has before him and he must be satisfied that the evidence is relevant and it will be admissible at trial[22]. To sat-

[16] [Online], URL: <http://www.bbc.co.uk/news/uk-16371043 (last accessed 27th May 2012).
[17] [Online], URL: <http://www.bbc.co.uk/news/uk-16371043 (last accessed 27th May 2012) at par. 5.
[18] [Online], URL: <http://www.bbc.co.uk/news/uk-16371043 (last accessed 27th May 2012) at par. 4.
[19] The Crown Prosecution Service, The Code for Crown Prosecutors, The Full Code Test, par. 4.5.
[20] The Crown Prosecution Service, The Code for Crown Prosecutors, The Full Code Test, par. 7. The Prosecutor will also have to satisfy the "public interest test". This test is satisfied by weighing factors that tend in favour or against pursuing a prosecution. It is hard to imagine a prosecutor not satisfying this stage when cases concern sexual offences.
[21] For examples of factors that tend in favour or tend against prosecution please see The Crown Prosecution Service, The Code for Crown Prosecutors, The Full Code Test, par. 16-17.
[22] The Crown Prosecution Service, The Code for Crown Prosecutors, The Full Code Test, par. 5.7(a), (b) and (c).

isfy the second stage of the test, the prosecutor must believe there are reasonable grounds that the continuing investigation will provide further evidence within a reasonable period of time. This further evidence will lead to the prosecutor establishing a reasonable prospect of conviction in accordance with the Full Code Test[23].

This poses a theoretical problem for the criminal justice process of England and Wales; any evidence obtained through the polygraph test will be inadmissible at the trial so immediately the evidential stage of the Full Code Test cannot be satisfied. Similarly, the Threshold Test is not satisfied because any evidence is not admissible for presentation at trial. It is difficult to agree with the police that the lie detectors will "aid charging decisions" because the evidence obtained will not satisfy either the Full Code or Threshold Tests. Without this satisfaction, the suspect will not be charged with the commission of a criminal offence.

So, if the tests cannot inform charging decisions, what can the police use the tests for? The police may be able to ascertain whether a particular person has been in a certain place at a given time. For example, whether or not the suspect is breaching the terms of their probation order by being present near a school at 9 am on a weekday. However, it is arguable that the police may have little interest in these "offences" and this might be viewed as a job for the probation service or parole board rather than the police.

Furthermore, whilst at the police station the suspect is entitled to legal advice, which is seen to be a valuable shield against the might of the "overzealous state". Section 58(1) of the Police and Criminal Evidence Act 1984 (PACE 1984) allows for a person to speak to a solicitor, privately, at any time. As stated, this is to protect the suspect from oppressive police questioning. That said, this safeguard is currently circumvented by the fact that the examination is voluntary. However, if we assume that the taking of a polygraph examination in the police station was mandatory, it would be interesting to see how this would impact on the defence lawyer's role in the police station.

The privilege against self-incrimination is built from the notion that the accused should be compelled to answer a question that could expose him to criminal punishment. The European Court of Human Rights has explicitly stated that the "early access to a lawyer is part of the procedural safeguards to which the court will have particular regard to whether a procedure has extinguished the very essence of the privilege against self-incrimination"[24]. By administering the tests on a voluntary basis, the safeguard of the privilege against self-incrimination will not be breached. Although, if the test were mandatory, an argument might exist that it breaches the privilege and ultimately his right to a fair trial. In addition, the undertaking of a mandatory polygraph examination potentially dilutes the role of the defence lawyer in the police station; here, the lawyer acts as the suspect's shield and can offer valuable legal advice. The polygraph examination will circumvent any advice, as the answer will be given without verbal communication.

[23] The Crown Prosecution Service, The Code for Crown Prosecutors, The Full Code Test, par. 5.9.
[24] ECtHR 24 September 2009 *Pishchalnikov v Russia*, No.7025/04.

7. Dangers of polygraph evidence at trial

You can see from examples of the Indian and American jurisdictions that there are inherent dangers posed by the use of and reliance on the findings of the test. In order to fully understand the implications of polygraph evidence in England and Wales, it is of critical importance to examine what the state officials will do with the findings from the polygraph exam. As the paper has argued, it is difficult to accept that the findings will assist in making the charging decision because any evidence gathered shall be inadmissible. What would happen should the police obtain evidence regarding an offence that they were not investigating or were not aware had been committed? The effect of these findings must have an impact on the pre-trial right to legal advice. Will this advice be rendered useless because of the "admissions" that have been made during the polygraph exam? Although the evidence is inadmissible, who will be made aware of the findings of the test? Will a magistrate or jury have any indication that the defendant has "failed" a polygraph exam? Furthermore, if the participant is subsequently charged, will he be allowed to show the findings of the "passed" test to the court?

If the polygraph test became a uniform part of the pre-trial process, would this lead to any incriminating evidence being leaked to the public? There may be undue pressure from the public for the authorities to administer swift justice in certain situations[25], especially where the crime is horrific and shaken the local community. The pilot scheme is currently voluntary, so it is not mandatory for a person to be subjected to the test. However if the test is implemented on a full time basis, inherent dangers lie ahead if it becomes a mandatory provision that a person is to take part. If this was the case, what are the consequences from refusing to participate? Could it potentially lead the judge or jury to draw inferences from the refusal of the suspect to not take the examination; you cannot be convicted by inferences alone, but inferences can potentially strengthen a weak case and ultimately lead to potential conviction of the defendant.

8. The implications for England and Wales: A new stance?

The right to a fair trial is explicitly mentioned in Article 6 of the European Convention on Human Rights (hereafter, ECHR), what is not explicitly mentioned is the privilege against self-incrimination. Despite the lack of any Convention acknowledgement, the privilege is a "generally recognized international standard, which lies at the heart of fair procedure"[26]. The basic rationale for this is to ensure the accused is protected from improper compulsion by the state and thereby avoids any potential miscarriage of justice. Furthermore, this privilege presupposes that in a criminal case, it is for the prosecution to prove their case against the defendant without resorting to evidence that was obtained through illegitimate methods such as oppression or coercion[27].

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[25] Case Comment, *International Journal of Evidence and Proof*, 2010, 14(4), at 377.

[26] Please see *Funke* v *Funke* (1993) 16. E.H.R.R 297. Here, the court recognized the privilege (and the right to silence) as part of the concept of the right to a fair trial as prescribed by article 6(1).

[27] Please see Cape E., Namoradze Z., Smith R., Spronken T. (2010), *Effective Criminal Defence in Europe*, Intersentia, Antwerp, p. 28, for a further discussion.

Although the current use of polygraph examinations is on a voluntary basis, if the regime became mandatory, it would pose a number of conflicts with the ECHR; of particular concern are Articles 3 and 6. Article 3 provides that "no one shall be subjected to torture or to inhuman or degrading treatment or punishment". Could one argue that having a suspect strapped to a polygraph machine, answering a number of questions about a certain offence, constituted a violation of Article 3? The case of *Toomey v United Kingdom*[28] may shed some light on this potential problem. Toomey underwent Penile Polygraph Testing as part of his assessment for suitability for the Sexual Offenders Treatment Programme (SOTP). The applicant was subjected to a test that lasted for eighty minutes; he was in a room with no windows and the door was bolted closed. At eye level was a VCR and he was monitored whilst inside the room via a microphone and a camera, the applicant had to remove his underwear and trousers. Throughout the course of the assessment he had a sensor clip attached to his penis. The applicant was shown a number of images, including nude images of young children, scenes of consensual sex, rape, and non-sexual violence. Each slide was left on the screen for approximately twenty seconds and he was shown each slide six times. The test continued with a "key score" pad on which the applicant had to mark his sexual attraction to the slides on a scale of 0-9. The applicant underwent a similar second test. Both tests indicated that he did not hold a deviant profile and was not suitable for the SOTP. The applicant complained to the European Commission that this was a violation of Article 3 of the Convention. The Court stated that ill treatment must reach a minimum level of severity to fall within the scope of Article 3 and this minimum level is relative to the circumstance of each case. The Court agreed that the test was humiliating for the applicant but when looking at the circumstances of the case, including the duration, physical and mental effects, age and state of health of the victim, the court did not believe the treatment was degrading under the scope of Article 3. It is hard to imagine a circumstance under which a traditional polygraph examination could be a violation of Article 3 if the Penile Polygraph Examination does not constitute a violation.

A suspect's right to a fair trial under Article 6 may also be breached. Although, any breach may not be explicit, it may be an implicit violation. What are the consequences for the suspect should he refuse to take a polygraph examination? Will the refusal be known to the court; will the prosecution be permitted to draw adverse inferences from his refusal? If a suspect elects to remain silent at trial, the jury may be directed to draw a proper inference if the silence can only be sensibly attributed to the defendant having no answer or none that would stand up to cross-examination[29]. There has been a wealth of common law decisions that has helped define the area of right to silence and adverse inferences yet, despite this, the area of law is still relatively controversial. If the court could draw an inference from a suspect's failure to take the examination, what steps would the court have to consider to ensure the suspect is not the subject of a miscarriage of justice?

[28] *Toomey v United Kingdom* (Application No 37231/97).
[29] *R v Cowen* [1996] Q.B. 373 sets out five steps that a court must take prior to a s.35 Criminal Justice and Public Order Act 1994 adverse inference being drawn.

Article 6(3)(c) gives the accused the right to legal assistance and s.58(1) Police and Criminal Evidence Act 1984 states that "a person arrested and held in custody in a police station or other premises shall be entitled, if he so requests, to consult a solicitor privately at any time"[30]. However, this right could conflict with a mandatory request to take a polygraph examination. What if the suspect refuses to take a test upon the advice of his lawyer? How would this affect his position at trial, could the court still draw an adverse inference from this? If so, safeguards will need to be established to ensure everyone who stands by the advice of their lawyer is not penalized for doing so. Of course, this so far assumes that everyone who is questioned by the police in England and Wales takes up their right to legal advice. This notion is untrue, in fact only forty-eight per cent of all suspects in the police station consult with a lawyer[31]. So what of the fifty-two per cent who do not take up their right to legal advice? Could the police exert pressure on the suspect to take the test? Could this lead to a number of false confessions or admissions.

The phenomenon of false confessions is well established and has been discussed at great length elsewhere[32]. However, for the purpose of this paper, there are three types of false confessions that could lead to suspects making false admissions during the polygraph examination. He could make a "coerced-compliant" confession. Here the suspect is aware that the confession or admission is false but he is willing to make admissions the police want to hear in order to escape the experience of police custody. This may be due to the oppressive nature of interviewing by the police. Coerced-compliant confessions were a key feature of several miscarriage of justice cases in England and Wales[33]. The "coerced false belief" confessions may also be a result of oppressive questioning. Here the suspect doubts his own memory and they temporarily believe the police assertions that they have indeed committed the alleged offence. The final type of false confession or admission is the "coerced passive" confession. The questioning tactics of the police will lead the suspect to make an admission without understanding the substance of the admission. Mike McConville gives the following example of a coerced passive admission that took place in the police station:

Police:	Did you intend to break the windscreen?
Suspect:	No.
Police:	So you just swung your hand out in a reckless manner?
Suspect:	Yes, that's it, just arguing […] just arguing, reckless, it wasn't intentional to break it[34].

[30] There are a number of circumstances where this right can be delayed by s.58(6) PACE 1984 but they are not relevant to this paper.
[31] Skinns L. (2009), "I'm a Detainee; Get me Outta Here", *BJ Crim*, 49(3), p. 399.
[32] For a detailed analysis of the phenomena of false confessions please see Gudjonsson G., Mackeith J. (1990), "A Proven Case of False Confession: Psychological Aspects of the Coerced-Complaint Type", *Med Sci Law*, 30, p. 187.
[33] For example, *R v Paris*, *Abdullahi and Miller* (1992) 97 Cr App R 99. Also known as "The Cardiff Three" case.
[34] McConville M., Sanders A., Leng R. (1991), *The Case for the Prosecution*, Routledge, London, p. 70 as cited in Sanders A., Young R., Burton A. (2010), *Criminal Justice*, 4th Edition, Oxford University Press, Oxford, p. 315.

Here, the police were not offering the suspect a "way out" of guilt but in fact, they are offering him a "way in" to admitting his guilt by establishing the mens rea for criminal damage. Section 1 Criminal Damage Act 1971 provides that damage can be committed either intentionally or recklessly.

From these three examples above, it is clear that the suspect in the police station requires the shield of legal advice to protect him from oppressive police interrogation tactics. However, this advice may be greatly diluted by any admissions made under the polygraph examination. If an unrepresented suspect makes admissions during the examination that lead to a new, unknown offence, it will be difficult to see how the shield of legal advice can adequately offer advice to the suspect. It should be noted that currently, s.78 PACE 1984 allows the court to exclude any evidence that "would have such an adverse effect on the fairness of the proceedings […]". It is my belief that any evidence discovered as a result of the polygraph would be excluded by the court owing to the adverse effect it will have on proceedings.

Criminal law in England and Wales would require great reformation should polygraph examinations become normalized practice at the pre-trial stage. If neuroscientific evidence is going to play a part in the pre-trial or trial stage[35] in England and Wales, it is clear that the law needs to adapt to the changing requirements. The current safeguards for the suspect are not sufficient to protect him from the "overzealous" State. The Irish Law Reform Commission have suggested a test which makes an effort to establish both the reliability and legitimacy of the evidence prior to it being admitted at trial. The points suggested by the Commission are almost identical to the *Daubert* test and includes the questions "what are the conclusions reached by the expert" and "is this evidence supported by sufficient evidence that they have logically derived from theoretical principles".

The Commission asked what is the known or potential error rate, has the theory or practice been subjected to a peer review and is the theory generally accepted[36]? It is questions like these that will require an answer before any polygraph evidence is either admitted at trial or used for the basis of a decision to charge.

9. Conclusion

Concerns remain about the accuracy of the polygraph. An American study showed that in mock crime situations conducted in laboratory settings, 82 percent of exams resulted in correctly identifying deception[37]. For nearly all of the study, inconclusive

[35] Please note: neuroscientific evidence is already being used as evidence in some civil trials. Here the standard of proof is far lower than the criminal courts. The standard of proof is "on the balance or probabilities" opposed to "beyond all reasonable doubt" required in a criminal court.

[36] Danaher J. (2011), "The Future of Brain-Based Lie Detection and the Admissibility of Scientific Evidence", *Irish Criminal Law Journal*, 21(4), p.100.

[37] English K., Jones L., Pasini-Hill D., Patrick D., Cooley-Towell S. (2003), *The Value of Polygraph Testing in Sex Offender Management*, U.S. Department of Justice (Document Number 199673), p. 23. Furthermore, a Ministry of Justice Research Summary found that people undertaking the examination may not disclosure the entirely truthful answers for fear of the consequences of their disclosure. Which surely defeats the object of

results are excluded from the averages and therefore may overstate accuracy states. However, in a laboratory setting there is very little at stake. This may allow the examiner to more readily identify a truthful response from a deception. The setting is very different in the police station, where the ordinary person is already likely to be more tense and anxious. This could pose problems when attempting to identify a truthful response from a deception because of the change in your physiological state, owing to the circumstances you find yourself in.

Whilst the inconclusive findings do not exonerate one completely, it merely means that there was insufficient information available to score the exam. What would the police do when faced with a subject with an inclusive result, is he released from police custody or will he be subjected to further polygraph exams or other modes of investigatory procedures? If it is the latter, how long will this go on for, how many tests will he be subjected to? Concerns like these will require an answer to adequately protect the suspect from abusive practices from the police.

This paper has posed a number of theoretical concerns about the use of the polygraph examination in the criminal justice process of England and Wales. These concerns may never see the light of day because the pilot, which commenced in April 2012, may not prove to be worthwhile. However, it is important to note and explicitly state the importance of the police station investigation and what occurs in that setting. With that in mind, the suspect in the police station needs both protection and advice. The best way to ensure this happens is by providing the suspect with the right to legal representation, the right to a fair trial and the shield of privilege from self-incrimination. In order for polygraph examinations to play a role in the pre-trial process, the law would have to reform to ensure the suspect is adequately protected. As we have discussed, any polygraph evidence would be inadmissible and perhaps any other evidence obtained may also be excluded from trial. If any prosecution evidence would have such an adverse effect on proceedings the court can currently exclude it[38]. It is hard to imagine evidence being admitted at trial that was discovered by the polygraph examination conducted in the absence of legal advice. Therefore the use of such techniques will be more suited to the risk assessment of the post-conviction stage rather than as a pre-trial investigative tool for the police and prosecution[39]. At the post-conviction stage the accuracy levels are of a lower standard and the person has already been convicted. Should England and Wales ever adopt polygraph examinations as a pre-trial tool, the rules of evidence will require great reformation in order to adequately protect the suspect.

However, Courts around the world are willing to welcome the use of neuroscientific evidence into their trials. It would be naïve to believe that the courts of England and Wales will not follow suit at some stage. The criminal justice process has to rec-

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such a test. For further information on the Ministry of Justice's findings please see: [online], URL: <http://www.ohrn.nhs.uk/resource/policy/InvestigatingDisclosureSexualOffenders.pdf> (last accessed 29 February 2012).

[38] S.78 (1) Police and Criminal Evidence Act 1984.

[39] This is already implanted in England and Wales. Section 28 Offender Management Act 2007 allows for polygraph conditions to be placed on certain offenders who are released on license.

ognize the advancement of neuroscientific research and will ultimately have to deal with the consequences of such findings. Although this is in its infancy, it is necessary to think of the implications of advancements in science for any criminal justice process throughout the world. Nevertheless, if England and Wales deviates from either of the fundamental adversarial tenets; the privilege against self-incrimination or the right to a fair trial, we are running the risk of allowing a miscarriage of justice. Any miscarriage of justice will, once again, rock the very core of our adversarial criminal justice process.

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Two Approaches to Issues of Liability Involving Artificially Intelligent Beings

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Abstract: We have yet to see an artificial entity that can be described as intelligent in the similar way as a human is. But we can look ahead to a scenario in which that prediction comes true – it's just too bad that all the metaphors we have for thinking about the attendant issues seem to pit humans against artificial entities. I submit, by contrast, that we should view ourselves as sharing a space *with* these entities: we should consider *our own* liability for actions that could bring harm to them, and we can appreciate as much if we only look at our relation to animals. I argue that we can draw on that relation to better frame our relation to artificial entities.

Keywords: artificial entity, human being, rights, liability

1. Introduction

For all advancements made in artificial intelligence, robotics, and related fields, we have yet to see artificial intelligent entity whose "intellect" cannot be distinguished from mine or yours. But because we can at least envision a scenario in which artificial entities become in several important respects humanlike, and in which we accordingly entrust them with larger and larger tasks, we have been debating for some time now about who is to be held accountable for the consequences of their actions, or how any loss or injury resulting from such actions is to be redressed. Several views have been put forward in attempt to answer this concern: we can treat artificial entities as (a) fully competent humans; (b) legal persons; (c) minors, for whom we, their guardians, are responsible; or (d) tools at our disposal, and whose use can be negligent or reasonable.

Each of these views rests on a central metaphor whereby an artificial entity is treated *as if* it was an *x:* we just replace the *x* with one of the foregoing ideas (*x* is a fully competent human, a legal person, etc.), and we accordingly work out a way to go about solving the question of liability. It seems clear that these views invariably cast humans *against* artificial entities, in a relation where the human being is assumed to be the party needing protection from the other party through a reliance on an appropriate legal toolkit. I call this the standard view: it is a human-centric approach where the main question is, who is to be held accountable when something goes wrong, or who is *liable*? But in this paper I take a different angle: I suggest that we step back and take a broader perspective, viewing ourselves as cohabitants *with* the artificial entities we create, in an environment where the parties on *either* side of the relation stand in need of legal protection. This I call this the "inclusive" approach, on which the question Who is *liable*? is filtered through the more-basic question What *rights* do the parties concerned have? This inclusive approach does away with the dichotomy between humans and machines, and so cannot be described as human-centric, but it is not for that reason blind to human welfare. Indeed, precisely because it considers artificial entities as part of the human environment, the idea of recognizing certain rights for these entities is framed with the best interests of humans in mind.

So, in what follows I explore the idea that we should not confine ourselves to considering human liability for an artificial entity's actions (or designing new legal tools to make the artificial entity itself liable) but should also explore our own liability for actions that could bring harm to these entities. I would argue that it's helpful in this regard to consider our relation to animals, because a similar idea can be observed in that area, too: traditionally, our main concern in the law has been to protect ourselves from animals or to make their owners liable if they cause injury to us, and in truth the idea is still current, but the animal-rights movement has reframed our relation to animals by arguing that there is no inherent difference between humans and animals as subjects of rights. The idea is still controversial in the law, but at least it has prompted us to think about the issue in a different way by questioning some long-held assumptions. I believe that the same trajectory can be explored in treating the question of our relation to artificially intelligent creatures.

2. Two approaches, different priorities

I would set the stage for this discussion by noting that the artificially intelligent entities we have today are not yet intelligent in the sense we understand a human being to be intelligent, that is, they may have greater computational skills, but they lack the autonomy, social abilities, and mental capacities needed to do what human beings do: even Watson, the recent winner of «Jeopardy!», cannot be understood as a properly human-intelligent machine[1]. Still, the prospect of that development should not just interest us in science fiction but is a matter to be taken for its real-world implications. As Marvin Minsky puts it[2]:

> Whatever happens, where or when, we're prone to wonder who or what's responsible. This leads us to discover explanations that we might not otherwise imagine, and that helps us predict and control not only what happens in the world, but also what happens in our minds.

What can be distilled from this statement, if we set aside Minsky's specific interest in prediction and control, is the twofold idea that (*a*) we need to think *now* about the issues of responsibility that are certain to arise in the future, and (*b*) we need to have an open attitude in thinking about those issues. And this is where the human-centric approach comes into play, in that the first question we seem to naturally turn to in that regard is, how can we protect ourselves from such intelligent entities and ensure that we can control them? Solum describes this concern as "paranoid anthropocentric", arguing that "if AIs [artificial intelligences] will pose a danger to humans, the solution is not to create them in the first place"[3], while Koops and his colleagues comment as follows: if it is artificial entities that one day will be deciding whether *we* should be granted legal personhood, they will not treat us as we currently treat animals[4].

What come into focus through these comments are two contrasting views: on the one hand is the human-centric approach on which humans come first and all nonhuman things should either serve a human interest or remain within the sphere of human control; and on the other hand is the inclusive view, which accepts these premises but does not draw from them the conclusion that we should thereby fear artificial entities or establish a strict hierarchy or put up a wall of separation between "us" and "them". The inclusive approach, in other words, sees the contradiction inherent in working hard to give artificial entities the Promethean gift of fire (namely, intelligence), while striving to keep these entities shackled[5].

Depending on which of the two approaches we take, we will bring different concerns into the foreground: the human-centric approach, with its exclusive preoccupation with protecting human interests, will make primary the issue of damages and liability,

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[1] Searle J. (2011), "Watson Doesn't Know It Won on «Jeopardy!»", *The Wall Street Journal*, February 23, 2011.
[2] Minsky M. (1988), *The Society of Mind*, Simon & Schuster, New York, p. 232.
3 Solum L.B. (1992), "Legal Personhood for Artificial Intelligences", *North Carolina Law Review* 70, p. 1261.
[4] Koops B.J., Hildebrandt M., Jaquet-Chiffelle D.O. (2010), "Bridging the Accountability Gap: Rights for New Entities in the Information Society?", *Minnesota Journal of Law, Science and Technology*, 11/2, p. 561.
[5] Lehman-Wilzig S.N. (1981), "Frankenstein Unbound: Towards a Legal Definition of Artificial Intelligence", *Futures,* 13/6, p. 445.

while the inclusive approach takes a "longer" view, by proceeding from the premise that the question of liability ought to be considered in conjunction with that of rights, understood as more basic than that of liability, or as vantage point from which to work out issues of liability. But let us see what this means by considering the two approaches in turn.

3. The human-centric approach: A unilateral focus on liability

It was just noted that on the human-centric approach a strict hierarchy is set up: there is a dominant interest (human welfare) and an auxiliary or subservient one which is to preserve the functionality of artificial entities as promoters of human welfare. This hierarchy of interests is such that any question of redress for damages arising in connection with the use or functioning of artificial entities is resolved by identifying in a narrow way the human interest that was injured: we identify the specific human party or parties who have suffered a loss and try to make those parties whole without considering how that might affect the broader interest in achieving a functional human-machine relation. The focus on liability is unilateral precisely because it fails to take account of this broader interest and the rights it calls into play. We can see this narrower, unilateral logic at play in the four basic metaphors that have so far been worked out in dealing with the issue of liability: two of these are "animate" (the artificial entity as a human being and as a minor), while the other two are "inanimate" (the artificial entity as a legal person and as a tool)[6]. So let us consider these two pairs in turn.

3.1. Two animate metaphors: Artificial entities as humans and as minors

Under this first pair of metaphors, artificial entities are likened to humans, and for this reason this pair comes closer than the inanimate pair to what I have called the inclusive approach. It does so because it is easier under the animate metaphor than under the inanimate one to view artificial entities as holders of rights, or at least it is easier through this lens to take the broad view of human welfare as inherently dependent on the resources through which such welfare is attained – the resources in this case being artificial entities in their supporting role in helping to streamline otherwise tedious or complex human tasks. And I should stress here that the notion of people treating technological tools as if they were humans is not new[7]. Still, the idea of a supporting role is filtered through a human-centric perspective narrowly focused on the question of liability. For example, questions emerge such as: What kinds of penalties would artificial entities be made to incur when they cause injury? If the penalty is financial, how can artificial entities be made to suffer money damages? Or what human entity should be made to pay such damages? And if the penalty is instead criminal, what sense would it make to

[6] I call metaphors what are strictly speaking similes, but since both figures of speech involve a comparison, the reader will forgive me for using the term more loosely than a rhetorical understanding of it would allow.
[7] Reeves B., Nass C. (1996), *The Media Equation: How People Treat Computers, Television, and New Media Like Real People and Places*, Cambridge University Press, Cambridge.

imprison or even destroy an artificial entity[8]? Or, again, we would ask: Can we work out an artificial analogue of the reasonable person standard? That is, could there be such a thing as a "reasonable computer" standard? What would its behavior look like? Might punishment come in the form of reprogramming[9]?

The same focus on liability can be observed as we turn to the second of the two animate metaphors: that of the artificial entity as a child or a minor. The idea is that a minor is not responsible for what he or she does, and that such responsibility falls on the parent or guardian as the person having better wisdom and tutelage[10]. Two points of analogy can be identified between an artificial entity and a child: first, neither have moral responsibility (the former cannot "compute", and the latter cannot appreciate, the harm that may result form their actions or the *meaning* of such harm); and, second, the one and the other alike get "training": a child receives an upbringing that reinforces its parent's most cherished values, while an artificial entity can be programmed for a purpose serving some human interest[11]. And even though both a child and an artificial entity can learn from experience, that capacity is not deemed so developed as to confer any moral or legal responsibility. And so a range of questions come up raising concerns similar to those we saw under the previous metaphor: Who would have guardianship: the artificial entity's owners, its users, its programmers, its manufacturer, or a combination of the above? Which is tantamount to asking: How should liability be allocated, to what extent should each party be held liable, and for what range of actions? What makes this a human-centric approach is that, even as we compare an artificial entity to a child, and so to someone in need of protection, we are still more concerned to attach liabilities than to work out forms of protection.

3.2. Two inanimate metaphors: Artificial entities as legal persons and as tools

The pair of metaphors under which an artificial entity is compared to a legal person, on the one hand, and to a tool, on the other, falls more easily within the human-centric approach than does the pair just considered, inasmuch as the two terms of comparison (legal persons and tools) more easily lend themselves to the view that, crudely stated, might be summarized in the motto «Humans first!», with the implication that whatever is nonhuman should either be made to advance human welfare or should at least not pose a threat to such welfare. Which is fine as far as that goes, were it not that the view tends to elicit a retractive attitude, such as can be seen at work in the first of the two metaphors under this heading: that of the artificial entity as a legal person.

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[8] Solum L.B. (1992), "Legal Personhood for Artificial Intelligences", *North Carolina Law Review* 70, p. 1245.
[9] Freitas Jr. R.A. (1985), "The Legal Rights of Robots", *Student Lawyer*, 13, p. 56.
[10] The controlling legal theory is that of vicarious liability, which under *respondeat superior* also covers an employer's liability for the actions of an employee acting within the scope of employment, and a principal's liability for what an agent does within the authority granted by the principal. So, the metaphor of the artificial entity as a minor can be grouped along with that of the artificial entity as an employee or as an agent.
[11] Lehman-Wilzig S.N. (1981), "Frankenstein Unbound: Towards a Legal Definition of Artificial Intelligence", *Futures*, 13/6, p. 450.

The legal person is the device through which the law for certain purposes pretends that something is a person even though it clearly isn't, in such a way that certain actions and capacities can be attributed to that entity, even though it cannot really be said to have acted or to have its own ability to engage in action[12]. The two paradigmatic examples are the corporation and the partnership as legal persons: they are deemed that way because we want them to be able to make contracts, for example, or to sue and be sued. And so the idea is that, just as a corporation can be regarded as a person for the purposes of the law, so can an artificial entity. What distinguishes this metaphor from that of the artificial entity as a human being is that in the former case the artificial entity is understood as having *its own* capacity for action (a robot, for example, can *itself* do certain things), whereas under the legal fiction of the legal person, that capacity is *ascribed*: the artificial entity as a human being is actually human-like in the sense of its being able to carry out *on its own* certain tasks that human beings would otherwise have to carry out themselves; the legal person, by contrast, is never its own source of action; it exists *separately* from those who undertake such action, and is accordingly understood as a fiction in that we *pretend* (without fooling ourselves) that such action is autonomous. So, what counts in either case, with the artificial entity as a human being and as a legal person alike, is the capacity for action, but only in the former case is that capacity real: in the latter case it is ascribed (it is a fiction), and it is in this sense that the artificial entity as a legal person is treated as an inanimate being. And that makes it easier to look at this capacity not so much as a source of rights but as a source of liabilities: the artificial entity as a legal person is an entity we must guard against, because its (ascribed) capacity for action means that some of this action may have consequences for which someone is to be held accountable.

Similar concerns account for the conception of artificial entities as tools. The idea in this case is to treat an artificial entity as a product, and that brings up all the issues relating to product liability. Negligence is a big part of product liability, and so, just as the approach to artificial entities as minors calls on us to think about who is to be held responsible for the minor's actions (the issue of the allocation of responsibility), so on this approach the question becomes: Whose negligence was involved in bringing about the injury resulting from an artificial entity's action? And how do we allocate such negligence? The problem becomes especially thorny when complex technologies are involved whose use and development cannot fully be ascribed to any single individual but is rather distributed among an indefinite number of people and entities forming an organization or web of interconnected people. This also brings into play the user's responsibility, where we face the twofold problem of determining what amounts to negligent use of the product (a complex technology opens the prospect of "reasonable misuse", as I would call it) and of factoring into the equation the user's role in the design process (a problem arising when the product is made to suit a user's specifications)[13]. A

[12] Teubner G. (2007), "Rights of Non-humans? Electronic Agents and Animals as New Actors in Politics and Law", *Max Weber Lecture Series*, 2007/04, p. 5.

[13] See Chopra S., White L.F. (2011), *A Legal Theory for Autonomous Artificial Agents*, University of Michigan Press, Ann Arbor, p. 126, proposing an allocation scheme under which design flaws should be the

related issue is that no one – product user or designer – may be able to predict a complex program's behavior.

And another issue still is that of industry standards, which may altogether be lacking in artificial intelligence[14]. But the larger point, here too, is that the metaphor we use for thinking about liability predisposes us to think about the problem from the defensive standpoint where the question "How can we protect ourselves from what artificial entities do?" precludes us from taking any broader view of the problem.

3.3. Moving beyond the standard view

As can be appreciated from the foregoing discussion, the four liability scenarios previously considered all share a common pattern. Which is to say that they are all human-centric: in their drive to protect human interests, they assume that artificial entities are dangerous and can harm us, and so that we have to take certain measures to defend ourselves. We see ourselves as potential victims and the counterparty (artificial entities) as potential tortfeasors or criminal offenders, as the case may be, and we accordingly set out to devise a scheme of legal remedies and penalties. We conveniently assume that the artificial entity is a moral *agent* – with a capacity to distinguish right from wrong and to act accordingly – but we don't take into account the possibility of its also being a moral *patient*, that is, an entity on the receiving end of action that can be morally qualified as good or bad[15]. We only see *ourselves* as moral patients and cannot also imagine artificial entities in that role.

So in what follows I will see if we can use our imagination to explore this more inclusive approach, attempting to flesh out what it means to view artificial entities not only as a potential source of harm but also as subjects to which harm may be done. I will argue that in this way we will be able to work out a more balanced, "holistic" view in relating to these entities, and that we will also be better prepared to embrace in a fluid and coherent manner what appears to be an inevitable transition toward an environment marked by a closer and closer interaction between humans and artificial entities.

An important disclaimer before we start: in no way do I want to suggest that we should not concern ourselves with the problem of liability for the action of artificial entities. In fact this is precisely the problem we are looking at. What I am rather arguing is that an approach narrowly focused on liability understood as the question of who will pay damages amounts to missing the forest for the trees. For in failing to consider that question next to a set of related questions, especially that of rights, we make it hard for ourselves to see the larger picture those questions paint, providing a context within

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manufacturer's responsibility, while the user should be responsible for preventing the artificial entity from doing harm to third parties.

[14] Asaro P.M. (2007), "Robots and Responsibility from a Legal Perspective", *Proceedings of the IEEE Conference on Robotics and Automation*, [online], URL: <http://www.peterasaro.org/writing/ASARO%20Legal%20 Perspective.pdf>.

[15] Floridi L., Sanders J.W. (2004), "On the Morality of Artificial Agents", *Minds and Machines*, 14(3), pp. 349-379.

which to think about liability in ways that will promote our future prosperity in the technological era. With that said, we can now enter into the inclusive approach.

4. The inclusive approach: A broad focus on rights

The four liability scenarios previously considered appear to be informed by the concern that if fully capable artificial entities were with us today, their use and functioning might undermine (rather than promote) human welfare, and they might actually turn *against* humans. When this concern takes up our entire field of vision, we get the narrowly focused liability scenarios and a corresponding set of legal tools.

So let us see how we can loosen up these strictures. I suggest that we step back and take in a broader view where artificial entities appear to us not as "unknown quantities" – or as "known unknowns" or, even more disquietingly, as "unknown unknowns", to quote one secretary of state in the US who so expressed himself not too long ago in considering the landscape in a far-removed occupied country – but as "partners in action", meaning that the relation between humans and artificial entities should not be set up as one of distrust and potential enmity but should look more like a collaborative enterprise: the two parties can be viewed not as competitors but as cohabitants in a single environment in which neither is in principle excluded from legal protection. I call this the inclusive view because it considers the question of liability as correlative to that of rights and recognizes rights not only for humans but also for artificial entities, as well as because it considers artificial entities an integral part of the human environment (rather than an appendage) and a source of human welfare (rather than a potential threat).

The difference between the two views can be illustrated by way of a distinction between two forms of power that O'Manique makes in his anthropological inquiry into the origins of justice[16]: he distinguishes power exercised *over* other people from power exercised *with* them. The human-centric approach tends to envision a world in which power is exercised by some *over* others, while the inclusive approach envisions a world in which power is exercised *with* others. The same distinction can be expressed through the contrast between dominator communities, where power is based on *ranking*, and partnership communities, where power is based on *linking*[17]. And on top of this distinction we might place the economic distinction between the economy as a zero-sum game (where one man's gain equals another's loss) and the economy as an exchange system where the creation of wealth depends on the ability of different economic players to interact on an equal footing, and where formal and substantive equality (not inequality) figures as a basic premise of growth.

We can see how these distinctions can be brought to bear on the problem of liability for the harm an artificial entity may cause: the human-centric approach falls in line with the power-*over* model of societal life because the narrow focus on liability can only be explained if we assume a strict hierarchy whereby a human interest will always,

[16] O'Manique J. (2003), *The Origins of Justice*, University of Pennsylvania Press, Philadelphia.
[17] Eisler R. (1988), *The Chalice and the Blade*, Harper, San Francisco.

invariably trump a nonhuman interest; whereas the inclusive approach falls in line with the power-*with* model because it views humans and artificial entities as coequals joined in a common effort to sustain human welfare, in such a way that liability is made to work in both directions, that is, liability arises not only for harm caused to human beings but also for harm caused to artificial agents. I believe this paradigm shift is not so eccentric as it might strike one at first: we just need to look at the way we've changed over time in relating to animals. In other words, we have recognized rights for animals (at least as a matter of principle), so why not ascribe to artificial entities rights that would make *us* liable for injuries we may cause to *them*?

4.1. Artificial entities as animals

It has so far been argued that the question of liability for any harm an artificial entity may bring about can be approached by (*a*) viewing the concept of liability in correlation with that of rights (we are only liable to someone if this person is entitled to certain rights that we have infringed) and, consequently, (*b*) extending rights to artificial entities (rather than recognizing rights only for humans). And it has also been suggested that we can effect this extension of rights by looking at the similar extension we have made in recognizing rights for animals. So let us see what this similarity is that we are using as a basis for recognizing artificial entities as having rights in parallel to the rights that animals are recognized as having.

I begin by noting that the idea of animal rights has had a long history and is not just a development of the 1960s[18]: the discussion goes back to Plato and Aristotle, and later drew in Spinoza and Descartes (both opposed to the idea) and also Montaigne, Voltaire, Bentham, Mill, and Shaw (all in favor)[19]. And it is this debate that has given rise to the animal rights movement and to a new area of the law known as animal law. This shows that the law is, after all, receptive to public and academic discourse, and that there is no reason why it should not also become receptive to a similar debate on the rights of artificial entities.

So now we ask: How has our relation to animals changed over time? And, even more importantly, how can we extract from this development a criterion on which basis to ascribe rights to artificial entities by analogy to the ascription animals have had? The former question can be answered by noting that the shift is similar to the shift I am advocating from the human-centric to the inclusive approach: our main concern has tradi-

[18] A distinction can be drawn between animal rights and animal welfare, the former view objecting to *any* use of animals as means by which to further a human interest, the latter view taking the more relaxed stance that only opposes the cruel and inhumane treatment of animals. But because of the way I am setting up my argument, I prefer to use *animal rights* as a broad term inclusive of both views. More on that distinction in Sunstein C.R. (2004), "What Are Animal Rights?", in Sunstein C.R., Nussbaum M. (eds.), *Animal Rights: Current Debates and New Directions*, Oxford University Press, New York, p. 4.

[19] I might note, as concerns Descartes, that he too drew a parallel between animals and artificial entities but went in the opposite direction from that in which I am working: he compared animals to automata, and I artificial entities to animals. More on the history of philosophical accounts on animal position in Midgley M. (1983), *Animals and Why They Matter*, Penguin Books, Harmondsworth.

tionally been to protect ourselves from animals or to make their owners (custodians) liable if they cause injury to us or to our possessions, but we have since moved closer to the idea that there is no inherent difference between humans and animals as subjects of rights. And the law's take-up of this idea is actually part of a broader trend, with the law expanding the class of subjects recognized as rights holders: we saw this earlier with the idea of the legal person (the legal fiction under which corporations in the 19th century were recognized as rights holders), but that is not the end of it. As Teubner remarks in discussing the question of trees[20],

> law is beginning to re-engineer its procedural and conceptual machines for producing the new inhabitants of the political ecology. The inclusion of ecological rights in political institutions, the gradual juridification of animal rights, the change in legal language from the semantics of «protection of nature» via «ecological interests» to «rights» of living processes, the slow process of granting standing to ecological associations, the expanding conceptualization of ecological damages without attribution to an individual are indicators that the law is preparing again to create a new breed of actors. Trees do have standing.

I focus on animals, rather than on trees, because animals bear a closer resemblance to artificial entities than do trees. But the point is to learn from the larger trend of the law in embracing an increasingly larger set of rights holders.

And this brings us to the second question, namely, on what basis can we ascribe rights to nonhuman entities, and what analogies can be established between artificial entities and animals in such a way that we can justify our extending rights to the former as we have done to the latter? I answer this question by making two points: one general, regarding the rationale behind *any* extension of rights to nonhuman beings, and the other case-specific, regarding the ways in which artificial entities can specifically be analogized to animals. The general point is that you can only extend rights to something that (*a*) contributes to your own welfare and (*b*) can be damaged in such a way as to undermine that welfare. We saw this earlier when we considered artificial entities as promoters of human welfare, but the idea can be extended to *any* entity that passes those two tests. I should note that this is not so much a *moral* basis for extending rights as it is a *practical* basis: we presumably do not want to damage the environment, because we recognize that as a mainstay of our own subsistence, such that to damage the environment would be tantamount to undermining our own welfare; ergo, natural resources have rights. The same applies to artificial entities: they help humans do their work, such that to damage them would be tantamount to making life harder for ourselves; ergo, artificial entities have rights. The reason why this does not quite make it as a moral argument lies in its underlying criterion, which is that something has rights only insofar as it contributes to our welfare. The argument therefore has the disadvantage of predicating the attribution of rights on an economic criterion (maximizing the pro-

[20] Teubner G. (2007), p. 16. The whole notion of trees having standing in court goes back to a 1972 article by Christopher D. Stone (1972), "Should Trees Have Standing? Toward Legal Rights for Natural Objects", in *Southern California Law Review*, 45, p. 450. Curiously, Stone appears to have been the first to ask whether one day we will not have to consider the same question with respect to *nonliving* entities, such as computers.

spect of future human gains) but has the advantage of conceiving humans and artificial entities as part of a single environment: the argument is human-centric in the former respect (because it introduces artificial entities solely as means to the end of human welfare), but is inclusive in the latter respect because it nonetheless takes a long view of human welfare as tied to the condition of the resources on which such welfare depends; it reinforces a *ranking* relation on the one hand (in that artificial entities represent a subservient interest) and a *linking* one on the other, because it recognizes the mutually reinforcing nexus between human and nonhuman agents. It is thus a Janus-faced argument: we might call it "enlightened self-interest", precisely because the idea is to maximize our own human welfare but not at the expense of the resources which sustain that purpose.

If we want a fully moral argument for ascribing rights to artificial entities, we have to regard these entities as *inherently* deserving such rights[21] regardless of whether artificial entities contribute to human welfare, and this is where the analogy to animals comes into play. The early defenders of this idea – Montaigne, Voltaire, Bentham, Mill, and Shaw, among others – can be grouped as having tied this recognition of rights to our sense of humanity, arguing that it's part of what it means to be a human to also recognize nonhumans as worthy of respect[22]. What I am looking for, however, is an account that can explain this ascription of rights by invoking not a *human* trait but a trait of the "object" to which rights are ascribed. To this end I would go back to the notion of capacity for action (previously considered in Section 3.2.) and tie it to what Martha Nussbaum in her discussion of animal rights has called the capabilities approach[23]. An artificial agent's capacity for action as previously discussed, on the human-centric approach, raises questions about the *consequences* of such action: these may turn out to be negative, hence the need for a liability scheme narrowly focused on the problem of protecting ourselves from such consequences. But capacity for action can be a reason to ascribe *rights* to the acting agent at the same time as we hold the agent liable: as the expression suggests in its very name, we just shift our focus from the *consequences* of action to the underlying *capacity* for action. Nussbaum has similarly identified an

[21] The question of the legal and moral standing of artificial agents is widely debated: see, among many others, Kasaro P.M. (2006), "What should we want from a Robot Ethic?", *International Review*, 12/6, pp. 9-16; Freitas Jr. R.A. (1985), "The Legal Rights of Robots", *Student Lawyer*, 13, pp. 54-57; Chopra S., White L.F. (2011), *A Legal Theory for Autonomous Artificial Agents*, University of Michigan Press, Ann Arbor; Lehman-Wilzig S.N. (1981), "Frankenstein Unbound: Towards a Legal Definition of Artificial Intelligence", *Futures*, 13/6, pp. 442-457; Coleman K.G. (2001), "Android Arete: Toward a Virtue Ethic for Computational Agents", *Ethics and Information Technology*, 3, pp. 247-265; and Koops B.J., Hildebrandt M., Jaquet-Chiffelle D.O. (2010), "Bridging the Accountability Gap: Rights for New Entities in the Information Society?", *Minnesota Journal of Law, Science and Technology*, 11/2, pp. 497-561.

[22] An alternative, empirical explanation of how we come to extend to nonhuman beings something like the moral and legal recognition otherwise reserved for human beings is based on the thesis that it makes evolutionary sense for us to expand our "social likings": we start out with ourselves and bring within this "area of liking" our immediate friends and family, then the community, then the different races, then the handicapped, and finally animals. This is similar to the enlightened self-interest argument just considered. On the evolutionistic approach, see Darwin C. (2004 [1971]), *The Descent of Man*, Penguin Classics, Bury St. Edmunds.

[23] Nussbaum M. (2006), *The New Frontiers of Justice: Disability, Nationality, Species Membership*, Belknap, Harvard.

agent's capabilities as the criterion for ascribing rights: these capabilities are what enable an agent to lead a flourishing life, and once we adjust this notion of a flourishing life to the standards specific to the species or class of agents in question, we will have identified what it is that makes an agent – human or nonhuman – its own source of rights.

This is a broad criterion that requires us to come up with lists of species-specific capabilities: for the human species, for the animal species, for the inanimate species. I previously suggested the ability to suffer harm as a sort of capability, and this is certainly something that artificial entities have in common with animals, however much animals can suffer in a way that artificial entities cannot (the former being sentient beings and the latter not). To this we can add the ability to follow instructions, learn form experience, interact, have a purpose, and behave rationally in achieving that purpose. And for these abilities we can design corresponding rights. Thus, the ability to suffer harm can support a right not to be harmed (a right that would have to be inflected in different ways depending on the different ways in which an agent can suffer harm), the ability to interact can support a right to engage in interactive activities, the ability to rationally pursue an end can give rise to a corresponding freedom of movement, and so on. So the capabilities approach affords a criterion on which basis we can reason about why we should recognize different species or classes of agents as inherently equipped to be subjects of rights: it is admittedly a malleable criterion, but is it not thereby useless; in fact it enables us to single out relevant analogies under which the rights recognized for one species can also be recognized for another.

4.2. Critical points

"The devil is in the details!", one might reply in rebutting the capabilities approach as just outlined, in that any list of species-specific capabilities and matching rights is bound to be contentious at some point along the way and may break up the analogies we construct. But I believe that for each objection one can find a response.

Thus, Descartes argued that an animal's inability to speak a language should be a reason not to endow animals with rights. But we can now reply that language comes in many forms (they need not be verbal), and that this might not be a controlling criterion anyway[24].

Similarly, Bentham identified the ability to feel pain as the single, most important criterion for ascribing rights to animals: "The question is not, Can they *reason*? Nor Can they *talk*? But Can they *suffer*?"[25]. And there is no doubt that artificial entities are not sentient in the way animals are, but then there are at least three ways in which we can rebut this point of criticism. First, we can figure out ways in which artificial entities can suffer even while not feeling any pain: it might be argued, for example, that any infliction of malfunctioning amounts to an artificial entity suffer-

[24] More on the criticism to Descartes's approach in Regan T. (1983), *The Case for Animal Rights*, Routledge & Kegan Paul, London, pp. 1-33.
[25] Bentham J. (1823 [1789]), *Introduction to the Principles of Morals and Legislation*, W. Pickering, London, p. 311.

ing. Second, we can argue with Peter Singer that a being's suffering counts not because it belongs to a certain species but as something that can be "counted equally with the like suffering […] of any other being's"[26]. And, third, we can argue with Martha Nussbaum whether it is right to raise the question of pain in the first place, as it signals an obvious bias against any form of being which is not like ours[27].

Or again one might raise the objection of self-consciousness as a relevant capacity, not only in ascribing rights but also in drawing interspecies analogy between artificial entities and animals. To which we might again reply in three ways. First, as Dennett has argued, consciousness, and so also self-consciousness, is "gappy and sparse, and doesn't contain half of what people think is there!"[28] which makes it hard to determine what consciousness is in the first place, nor does it solve the question of the type and level of consciousness is required to pass the self-consciousness test for the ascription of rights. Second, it is by no means ruled out that artificial entities will one day be able to gain consciousness and self-consciousness (an awareness of their own internal states)[29].

And, third, it can be argued that a self-conscious being is capable of language,[30] and (assuming language is a relevant criterion) this is an area in which artificial entities certainly outstrip animals (at least on an understanding of language as a verbal skill), and if we agree that animals are conscious, how can we not recognize consciousness in something that possesses the kind of skill (language) that only conscious and self-conscious beings can possess?

The point of these remarks is not so much to show that for every possible objection there is a counter-objection but to realize that each of the capabilities offered as a relevant criterion for an ascription of rights and for an accompanying interspecies comparison is debatable, not in the pejorative sense that the criterion doesn't stand up to scrutiny but in the sense that it offers room for debate.

Which is precisely how conceptions are forged and revised. The capabilities approach offers a macro-criterion – an agent's capabilities as a source for its rights and as a gauge by which to assess points of analogy between different species – and it is then up to us to shape the macro-criterion into a workable and convincing conception.

5. Closing remarks

The main thrust of this paper is that we need to take a more balanced, "holistic" view in treating liability issues involving artificial entities: we cannot just focus on developing liability scenarios, in which the question of damages and liability becomes paramount, but need to also think about what duties we might have toward artificial entities as holders of rights; that is, we should ask ourselves whether, next to *our* right to claim

[26] Singer P. (1976), *Animal Liberation*, Avon Publishers, New York, p. 8.
[27] Nussbaum M. (2006).
[28] Dennett D.C. (1991), *Consciousness Explained*, Little, Brown and Co., Boston, p. 366.
[29] See Koops B.J., Hildebrandt M., Jaquet-Chiffelle D.O. (2010), p. 561.
[30] Koops B.J., Hildebrandt M., Jaquet-Chiffelle D.O. (2010), p. 516.

damages for injuries we suffer through the operation of artificial entities, there are any rights that these entities could claim *from us*. I have argued that there are, and the argument was constructed by setting up two related questions: (*a*) What might be the overarching rationale behind *any* ascription of rights to any entity other than a human being? And (*b*) what concomitant approach might be used in ascribing rights to a specific species and striking relevant analogies between two such species? The former question was answered through a *practical* holistic argument: anything that promotes human welfare is a potential subject of rights if it is susceptible of harm that may in turn undermine human welfare. The latter question was instead answered through a *moral* holistic argument, by first identifying a being's *capabilities* as a criterion for ascribing rights to it, and then specifically working out ways in which artificial entities can be analogized to animals as rights holders.

The point to be stressed here, as we wind down, is that our recognizing rights for artificial entities should in no way be seen as a threat to the human position. Quite the contrary: it would be a misconception to view one party's rights as antagonistic to the other's, because on the inclusive, holistic approach I am putting forward, rights and liabilities interlock into a power-*with* relation between humans and artificial entities. And I would further argue that a relation so understood is mutually beneficial. For example, we would be prompted to build into artificial entities features that favor interspecies relations beneficial to us (features such as beneficence and accessibility), all the while enhancing an ascription of rights to them[31]. In this way, in thinking about these questions on the basis of the inclusive approach I advocate, we can lay the groundwork for a smoother, more fruitful relation between humans and artificial entities as forgers of a single environment they both share.

[31] For a fuller account of the features we should want to build into artificial entities, see Coleman K.G. (2001), pp. 247-265.

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The Impact of Modern Reproductive Technologies on the Legal Determination of Fatherhood: A Human Rights Perspective

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Abstract: Scientific progress has been one of the driving forces behind the heightened dissolution of the previously coextensive family practices of sex, marriage and parenthood. In particular, the employment of assisted reproductive technologies allows for different aspects of the conventional parent role to be shared between two or more individuals.
Clearly, this fragmentation is not easily reconcilable with the heterosexual two-parent family, which has consistently been considered the "norm" by the law. As a result, modern medicine offers the opportunity for a constructive reconsideration of the determining factor(s) in the legal assignment of parental status.
Since the existing body of literature focuses largely on women, this paper is aimed at examining how medical progress has contributed to redefining the rights and responsibilities of fatherhood, which have traditionally followed the genetic paradigm. More specifically, the impact of modern reproductive techniques on the legal definition of "father" will be critically considered with regards to the jurisprudence of the European Court of Human Rights, when considering alleged violations of the right to respect for private and family life (Article 8 ECHR) by a contracting party.

Keywords: assisted reproductive technologies; fatherhood; human rights.

1. Introduction

Popular culture thinks of individuals as having two parents, one mother and one father, each of whom is partly responsible for the child's biological inheritance[1]. Similarly, the heterosexual two-parent family has traditionally been considered the "norm" by the law[2]. In the real world, however, this conventional pattern of parenting might be bypassed in a variety of different ways, including adoption, fostering and extra-pair mating[3]. In modern times, assisted reproductive technologies (ARTs), which are further challenging the "norm" resulting from biology, offer the opportunity for a constructive reconsideration of the determining factor(s) in the legal assignment of parental status.

The existing body of knowledge exploring the impact of bioethics on parenthood has primarily focused on women's choices or women's roles in artificial procreative scenarios, such as surrogacy and in vitro fertilisation[4]. Surrogacy, in particular, has fomented an intense debate over its possible connotations of baby-selling, its alleged comparison with prostitution, and the potential for women's exploitation and children's commodification.

Despite the heightened interest in fathers' issues, very few scholars have investigated the implications of modern techniques on the notion of "fatherhood". This lack of research is partly explained by the fact that many of the authors who have attempted a gendered analysis of parenthood in the context of ARTs have applied a feminist lens, thus considering the impact of such practices on women[5]. Additionally, the central emphasis on motherhood might reflect the existing differences between males' and females' biological functions, in terms of temporal and physical involvement in the procreation process[6]. Otherwise stated, third party substitution for female functions has been far more disputed than third party replacement of male roles. This might be due to sexist customs that assume the mother-child relationship to be characterised by a more intrinsic and irreversible connection than the relationship existing between father and child[7].

In light of these considerations, it seems to me that there is scope for a study which is centred on fatherhood. In particular, it appears interesting to examine how medical progress has contributed to the fragmentation of the traditional "father figure" and thus to redefine the legal conception of "fatherhood", which has traditionally followed the genetic connection. In the present paper, the impact of ARTs on the legal notion of "father" will be critically considered within the context of the European Convention on Human Rights (ECHR) and its application by the Strasbourg Court (ECtHR).

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[1] Johnson M. (1999), "A Biological Perspective on Parenthood", in Bainham A., Day Sclater S., Richards M., *What is a parent? A socio-legal analysis*, Hart, Oxford, p. 47.
[2] The concept of "normality" that presupposes biology is discussed by O'Donovan K. (2002), "*Real* Mothers for Abandoned Children", *Law & Society Review*, 36(2), pp. 347-378.
3 Johnson M. (1999), p. 48.
[4] Callahan D. (1992), "Bioethics and Fatherhood", *Utah Law Review*, p. 735.
[5] Sheldon S. (2005), "Fragmenting Fatherhood: The Regulation of Reproductive Technologies", *Modern Law Review*, 68, p. 526.
[6] Shultz M. (1990), "Reproductive Technology and Intent-based Parenthood: an Opportunity for Gender Neutrality", *Wisconsin Law Review*, p. 312.
[7] Shultz M. (1990), p. 312.

Although the relevant case-law is quantitatively limited, its contribution to the afore-mentioned purposes is qualitatively significant. The Court does not explicitly address the question: who is a father? Nonetheless, the establishment of the legal tie of fatherhood has been interestingly discussed in a number of cases concerning the use of ARTs, where the Court has indirectly emphasised the presence of specific factors as crucial for the determination of legal fatherhood.

The first part of the paper will provide the theoretical framework on the basis of which the analysis of the ECtHR jurisprudence will be conducted. Three main conceptions of "fatherhood" will be proposed, each of which emphasises a specific aspect of fathering. In particular, I will suggest a tripartite distinction between the "genetic father", the man who provides the sperm that leads to conception; the "nurturing father", the individual who is morally responsible for the child and intentionally "performs" paternal functions; and, finally, the "cultural father", the person who is assumed to be the father according to the dominant ideology of the family and, therefore, in response to changeable expectations, standards and practices.

In the second part of the paper, I will critically analyse three judgments held by the ECtHR in cases pertaining to the use of reproductive techniques: J.R.M. v the Netherlands[8], X, Y and Z v the United Kingdom[9] and Dickson v the United Kingdom[10]. Using the above theoretical framework, I will seek to establish which conception of "father" has been upheld by the Court in each of the selected cases. This study will enable a more comprehensive evaluation of the relevant case-law aimed at assessing whether the conception adopted by the Court is unitary or, contrarily, it encompasses internal contradictions.

To conclude, I will attempt to determine which of the three definitions of "father" would be the most desirable within the context of ARTs. To the purpose, the implications deriving from the adoption of each specific definition on the legal determination of fatherhood will be considered. The final choice will be made by taking into account the interdependent nature of the relationships that bind men, women and children together. Therefore, the desire for gender equality and the best interests of the child will play a fundamental role in the identification of the conception that better tackles the fragmentary effects of ARTs on the "father figure".

2. The theoretical framework: Three main constructions of "fatherhood"

Recent developments in ARTs have led to the "depersonalisation" of the procreation process: the biological contribution can be separated from the social context of interpersonal relationships[11]. In relation to fatherhood, the employment of assisted reproductive techniques allows for different aspects of the traditional father role to be shared between two or more individuals. In the simplest reproductive scenario, two persons are

[8] J.R.M. v the Netherlands Application No 16944/90 8 February 1993, Commission Decision.
[9] X, Y and Z v the United Kingdom Application No 21830/93 22 April 1997 ECtHR.
[10] Dickson v the United Kingdom Application No 44362/04 18 April 2006 ECtHR (Fourth Section); 4 December 2007 (Grand Chamber).
[11] Shultz M. (1990), p. 300.

involved in parenting roles: the genetic father and the man (the mother's husband or unmarried partner) who assists the mother throughout the medical treatment.

The ability of social and scientific developments to confuse paternal ties should not be underestimated. Contrarily, these phenomena should be perceived as precious occasions for reflecting on which types of connections are more relevant in making someone a father. To do so, three different conceptions of fatherhood will be presented, each of which celebrates a specific kind of tie as the crucial component of the father role.

According to a genetic-based construction of fatherhood, paternal rights and responsibilities (PRRs) should be accorded to the "genetic father". The latter refers to the man whose sperm successfully fertilises an ovum that, after the usual phases of gestation, results in a child. Interestingly, Callahan bases the causal relation between PRRs and the genetic tie on a basic and essential moral axiom, according to which human beings are morally responsible for their own voluntary acts that have an impact on the life of other individuals[12]. Accordingly, fathers bear a moral responsibility for the children they voluntarily procreate. In other terms, the genetic link entails a set of irreversible moral obligations imposed on a father towards the children he procreates, unless he is mentally or financially incapable to undertake those responsibilities[13]. As a result, fatherhood represents a biological condition and therefore it cannot be overridden by personal wishes or legal dispensations[14].

Consequently, in the event of artificial insemination (AI) arrangements, the anonymous sperm donor is as much a "genetic father" as the known sperm inseminator in a typical heterosexual relationship and sexual intercourse[15]. The fact that the donor does not intend to act as a father and the woman, whose ovum is fertilised, does not want him to parent the resulting child constitute irrelevant considerations for the purpose of identifying who bears PRRs[16].

Those who wish to endorse a conception of fatherhood grounded on notions of genetic causation have considered the introduction of AI techniques as inappropriate in a civilised society. In fact, emerging technologies have furtively circumvented genetic fathers' moral obligations to care for and nurture their children[17]. Similarly, Nelson asserts that the possibility to divide genetic and social fathering promotes the adoption of a "consumer-choice" approach by families[18]. In his view, the legal determination of being a father ought to be based on causal, as opposed to contractual, obligations[19].

Contrarily, supporters of a non-genetic or functional conception of fatherhood have welcomed the advent of artificial reproductive arrangements as a means of amplifying the potential for manifestation and realisation of personal intentions in the procreation process[20]. In this view, intention and actual commitment have to be regarded as the de-

[12] Callahan D. (1992), p. 737.
[13] Callahan D. (1992), p. 738.
[14] Callahan D. (1992), p. 739.
[15] Callahan D. (1992), p. 739.
[16] Callahan D. (1992), p. 739.
[17] Callahan D. (1992), p. 740.
[18] Nelson quoted by Fuscaldo G. (2006), "Genetic ties: are they morally binding?", *Bioethics*, 20(2), p. 66.
[19] Fuscaldo G. (2006), p. 66.
[20] Shultz M. (1990), p. 302.

termining factors in the legal assignment of paternal status. Accordingly, paternal duties and privileges will be conferred on the "nurturing" father, namely the individual who intends to become a father and coherently acts as such.

As suggested by Shultz, the term "intention" defines a "behaviour that is unambiguous in purpose and that selects from among available alternatives" [21]. Evidently, the recourse to modern procreation arrangements manifests and effectuates an unambiguous intent to procreate. Indeed, artificial reproduction does not occur by accident, but rather it constitutes the expected outcome of a purposeful conduct[22].

However, intention does not per se constitute a sufficient ground for fatherhood and considerable importance has to be attached to the extent to which expressed intentions to become a father are reflected in actual paternal involvement in the child's life[23]. Thus, fatherhood is not determined as a being or a genetic fact, but as an intentional doing and therefore as a function deliberately fulfilled. In relation to AI arrangements, Hill suggests that the sperm donor does not acquire parental duties and privileges, where his "pre-conception intention" was to act purely as a gamete provider and not to parent his own child[24]. Therefore, in a similar reproductive scenario, PRRs should be attributed to the person who willingly embarks on a course of treatment services with the mother and takes care of the resulting offspring.

As concerns the third definition, the use of the adjective "cultural" reflects the main assumption on which this construction is based: the legal designation ought to follow the changing culture of fatherhood and, more generally, the changing notions of family and kinship within society. A classical example of the aforementioned approach is represented by the so-called "marital presumption", whereby the children born within a marriage are presumed to be the biological children of the mother's husband.

Evidently, a similar definition of father upholds a societal perception of marriage as a long-term commitment to one partner and thus as the sole context in which a child can be legitimately created. Despite the challenges posed by DNA technology, the establishment of the marital presumption indubitably demonstrates that cultural prescriptions are frequently enclosed in legal attitudes towards fatherhood.

Apart from being relevant to the legal status of unmarried fathers, the dominant cultural construction of the family has the potential to determine the outcome of issues related to the employment of ARTs by single parents, same-sex couples or transsexuals. For instance, restrictions on the availability of procreative techniques to same-sex couples might be perceived as the result of the enshrinement of the heterosexual two-parent cultural "norm" by the law[25]. Accordingly, alternative family arrangements – one single

[21] Shultz M. (1990), p. 396.
[22] Shultz M. (1990), p. 310.
[23] For discussion of these ideas see Sheldon S. (2009), "From 'absent objects of blame' to 'fathers who want to take the responsibility': reforming birth registration law", *Journal of Social Welfare and Family Law*, 31(4), pp. 373-389 and Jordan A. (2009), "'Dads aren't Demons, Mums aren't Madonnas', Constructions of fatherhood and masculinities in the (real) Fathers 4 Justice campaign", *Journal of Social Welfare and Family Law*, 31(4), pp. 419-43.
[24] Hill J.L. (1991), "What does it mean to be a 'parent'? The claims of biology as the basis for parental right", *New York University Law Review*, 66, p. 414.
[25] Similar restrictions might be imposed within the context of adoption. The acceptance of the heterosexual two-parent family as the "norm" might prevent same-sex couples as well as single parents from adopting a child.

parent, two mothers, two fathers – are regarded as an inappropriate basis for the legal designation of parental status.

In addition to reproducing the practical consequences of AI arrangements, the proposed subdivision prepares the ground for the following analysis of the significant jurisprudence of the ECtHR. The three conceptions offer an exhaustive range of determinants that can be employed when designating legal fatherhood. Therefore, it will be interesting to discover which of the suggested factors is (are) considered by the Court as defining who is a father. Any multiple outcomes might be due to a lack of internal consistency within the relevant case-law as well as to the possible convergence between the cultural approach and, alternatively, the genetic or functional conceptions within a specific case.

3. Critical analysis of the jurisprudence of the European Court of Human Rights: The upheld construction(s)

"Fatherhood" and "motherhood" are concepts that are not specifically discussed by the ECtHR, when considering alleged violations of the right to respect for private and family life (Article 8) by a contracting party. As a matter of fact, the Court prefers to approach the question of who is a father or a mother by considering whether or not family life has been established in the specific case.

The establishment of family life, in turn, follows the employment of a "test of intentionality"[26]. As pointed out by Choudhry and Herring, the Court will first examine whether there is evidence of the intention to create family life through the conventional forms of relationships, such as marriage and civil partnership[27]. As to any relationship outside this pattern, the Court will carry out a more "functional-based analysis" of intentionality[28]. In particular, the "real existence in practice of close personal ties"[29] will be tested in order to assert the existence of family life.

However, the test of intentionality employed to establish the existence of family life between father and child does not correspond to that applied to mothers. In particular, the existence of family ties between father and child is not necessarily dependent upon his biological contribution to the childbirth or upon the fact that he has been officially registered as the legal father on the birth certificate[30]. The insufficiency of genetic relatedness to establish family life is evidently asserted in Lebbink v the Netherlands, where the Court held: "The Court does not agree with the applicant that a mere biological kinship, without any further legal or factual elements indicating the existence of a close personal relationship, should be regarded as sufficient to attract the protection of Article 8"[31]. Therefore, it appears interesting to identify those legal or factual conditions

[26] Choudhry S., Herring J. (2010), *European Human Rights and Family Law*, Hart, Oxford, p. 170.
[27] Choudhry S., Herring J. (2010), p. 170.
[28] Choudhry S., Herring J. (2010), p. 170.
[29] Choudhry S., Herring J. (2010), p. 170.
[30] Choudhry S., Herring J. (2010), p. 172.
[31] Lebbink v the Netherlands Application No 45582/99 1 June 2004 ECtHR, par. 37.

revealing the existence of a close personal relationship between father and child as well as to assess whether the absence of a genetic link might preclude the existence of family life between them. These questions will be carefully investigated in relation to the specific context of ARTs through the analysis of the pertinent ECtHR case-law.

3.1. J.R.M. v the Netherlands

In this case, the applicant agreed to act as a sperm donor in order to satisfy the desire of a lesbian couple to have and raise a child together. During the first months after the child's birth, the applicant visited the couple and the baby on a regular basis. Afterwards, relying on alleged previous agreements concerning the raising of the child, he informed the couple that he wished to establish certain visit arrangements. In response, the two women interrupted their relationship with the applicant and prevented further contact between him and the child.

The applicant's request for access was refused by the Dutch authorities on the basis that no family life, within the meaning of Article 8 of the ECHR, existed between the sperm donor and the child. The applicant alleged that the Dutch courts' decision amounted to a violation of his right to respect for family life under Article 8, his rights under Article 13 in conjunction with Article 6 paragraph 1 and, finally, a discrimination contrary to Article 14 of the Convention. Although the application was eventually declared inadmissible, the analysis carried out by the Commission focuses upon the requirements for the establishment of family life between father and child and thus provides an interesting contribution to the general debate on what defines a father in artificial reproductive scenarios.

First of all, the Commission asserted that the existence or non-existence of family life is essentially a question of fact depending upon the real establishment in practice of close personal ties. For instance, cohabitation by two or more persons might be evidence of the existence of family life. However, as previously held in Price v the United Kingdom, cohabitation represents only one factor among many others to be taken into consideration when examining the establishment of family ties[32]. With regard to the particular circumstances of the concerned case, the Commission affirmed that: "[…] The situation in which a person donates sperm only to enable a woman to become pregnant through artificial insemination does not itself give the donor a right to respect for family life with the child"[33].

The Commission further observed that the contact between the applicant and the child had been of summary nature, both in terms of time and intensity. Additionally, the applicant had never contemplated to financially contribute to the child's upbringing. In light of these considerations, the applicant's contact with the child, even in combination with his donorship, was regarded as constituting insufficient grounds for the conclusion that close personal ties had developed between them, and thus their relationship fell

[32] Price v the United Kingdom Application No 12402/86 14 July 1988, Commission Decision.
[33] J.R.M. v the Netherlands, under 'THE LAW' par. 5.

within the protection of Article 8. Accordingly, the Dutch authorities' refusal of the applicant's request did not amount to a lack of respect of his family life.

Furthermore, the Commission was of the opinion that the applicant had been provided with appropriate legal means to submit his request for visiting arrangements and therefore the complaint under Article 13 in conjunction with Article 6 paragraph 1 was manifestly ill-founded. Finally, in view of the significant differences between the applicant and a father of a legitimate child, the Commission concluded that no question of discrimination contrary to Article 14 arose in the concerned case.

A clear rejection of the genetic construction of fatherhood emerges from the analysed decision. In particular, the Commission explicitly opposed the argument that family life exists ipso jure between a biological father, including a sperm donor, and his child. The mere fact of biological fatherhood does not automatically result in family life being found. As a consequence, genetic relatedness cannot be considered as an indisputable source of parental rights and responsibilities. The establishment of family life requires, apart from biological fatherhood, the existence of further conditions.

It must be noticed that the Commission, when ascertaining the insufficiency of genetic relatedness, placed its emphasis on the final aim pursued by the applicant through the sperm donation. The purpose being to enable a lesbian couple to have and raise a child, the initial intention of the applicant was not to become and act as a father towards his own biological child. The Commission's reference to the ultimate goal of donation appears to be inspired by notions of intention, commitment and choice, typically characterising a functional conception of fatherhood.

However, the Commission seems to consider only the "pre-conception intention" of the applicant and to totally ignore his subsequent change of mind. Considering the applicant's behaviour after the child's birth, his intention to participate in the child's upbringing might be easily inferred from his contact with the child during the first months and his subsequent attempt to obtain visiting rights. Evidently, a full adoption of the functional approach would have taken these additional factors into account[34].

The Commission's disregard of the "post-conception intention" might be perceived as reflecting cultural prejudices against the legal recognition of more than two individuals performing parental functions. The consideration of the applicant's attempt to establish a connection with the child would have implied the acceptance of the involvement in the child's life of a third person, in addition to the parenting couple. The foreseen outcome would have inevitably clashed with the idea of the bi-parental family, embedded in the dominant culture as the "norm".

Alternatively, the decision held by the Commission might appear justified in light of the paramount importance placed on the best interests of the child, where issues related to the child's upbringing are at stake. In this particular case, the awarding of access rights to the applicant could have jeopardised the best interests of the child on the basis of two interrelated reasons. First of all, the fundamental differences of opinion

[34] The factual circumstances of the concerned case emphasise the most significant shortcoming of the functional approach: it presumes that intentions remain unaltered throughout the time and therefore potential afterthoughts are not contemplated.

between the lesbian couple and the sperm donor were likely to obstruct the development of positive interactions between the applicant and the child.

Furthermore, having regard to the child's age, the introduction of a third party could have compromised the stability of the family unit with negative implications for the child's wellbeing.

To conclude, in J.R.M. v the Netherlands, the Commission does not approach the question of what generates PRRs in clear-cut terms. Whilst the unconditional rejection of the genetic conception is incontestable, the lack of consideration for the applicant's successive intent to become involved in the child's life enables only the partial predominance of the functional approach to be stated over the genetic construction of fatherhood. Finally, the Commission's reasoning appears to be informed by cultural bias against the recognition of more than two parental figures in any child's life.

3.2. X, Y and Z v the United Kingdom

X, a post-operative female-to-male transsexual, had lived with the female applicant Y as her male partner since 1979. More than a decade later, the couple applied jointly for and ultimately succeeded in obtaining AI treatment with sperm by an unanimous donor to enable Y to have a child. X was involved throughout that process and had acted as Z's father since the child's birth (1992).

However, X was not allowed to be registered as the child's legal father under English law. In particular, the Registrar General was of the opinion that only a biological man could be considered as a father for the purposes of registration. Therefore, the applicants submitted that the lack of recognition of the relationship between X and Z amounted to a violation of Article 8 and discrimination contrary to Article 14.

Conversely, the Government denied that Article 8 was not applicable at all, since the relationships between X and Y and X and Z did not amount to family life. In particular, the union of a transsexual and partner could be equated to that of two women living together, since X was still regarded as female under domestic law. Similarly, X did not enjoy family life with Z because he was not related to the child by blood, marriage or adoption.

In relation to the applicability of Article 8, the Court recalled that the notion of "family life" is not confined solely to marriage-based relationships and might also comprehend de facto family ties[35]. Moreover, the establishment of family life is dependent upon the existence of a number of factors, including cohabitation, the length of the relationship or the degree of commitment shown[36]. Having regard to the applicants' cohabitation, X's involvement throughout the treatment and subsequently in Z's life, the Court asserted that de facto family ties existed among the three applicants[37].

Nonetheless, the majority concluded that there had been no violation of Article 8 and, as a result, there was no need to examine the issue again in the context of Article 14. In

[35] Judgment, par. 36.
[36] Judgment, par. 36.
[37] Judgment, par. 37.

their analysis, the Court emphasised the absence of a common European approach with respect to the granting of parental rights to transsexuals or about the manner in which the social relationship between a donor-conceived child and the individual who acts as a social father should be recognised in law[38]. The relevant law being in a transitional stage, a wide margin of appreciation must be afforded to the respondent State[39].

The Court further acknowledged that the community as a whole had an interest in preserving a coherent system of family law that prioritised the best interests of the child[40]. In this respect, it was considered to be unclear whether the registration of X as Z's father would have actually benefited Z[41]. Furthermore, the amendment of the law sought by the applicants might have had adverse repercussions in other areas of family law[42]. For instance, the legal system could have been subjected to criticism on the ground of inconsistency, if a female-to-male transsexual was permitted to become a legal father, while still incapable of contracting marriage to a woman[43].

In conclusion, it was held that the disadvantages suffered by the applicants did not outweigh the outlined general interests, since X was not inhibited from acting as the social father of Z[44]. The Court also noted that X could have applied for a joint residence order with his partner, which would have automatically attributed full parental responsibility to him with respect to Z[45].

Similarly to the decision of the Commission in J.R.M. v the Netherlands, the judgment of the ECtHR in X, Y and Z v the United Kingdom does not appear to uphold a unitary conception of fatherhood. Whilst the establishment of family ties between X and Z directly stems from the role de facto played by the transsexual both during the process of conception and after the child's birth, the Court's finding that a breach of Article 8 has not occurred appears more oriented towards a cultural approach.

Prior to the present case, the ECtHR had been addressed to consider only family ties existing between biological parents and their offspring. Diversely, the issue at the core of X, Y and Z v the United Kingdom concerns the relationship between X, a transsexual, and Z, a donor-conceived child who is genetically unrelated to the first. Drawing on the factual circumstances of the present case, the Court seems to expand the protection of Article 8 to those ties that are not referable to the "legitimate" family through the employment of a "reality test"[46].

More specifically, the analysis carried out by the ECtHR is aimed at assessing the existing emotional involvement between the concerned individuals and, more generally, the effective concreteness of their relationship. In the present case, X's constant engagement both before and after the child's birth is regarded by the majority as provid-

[38] Judgment, par. 44.
[39] Judgment, par. 44.
[40] Judgment, par. 47.
[41] Judgment, par. 47.
[42] Judgment, par. 47.
[43] Judgment, par. 47.
[44] Judgment, par. 50.
[45] Judgment, par. 50.
[46] Stalford H. (2002), "Concepts of family law under EU law – lessons from the ECHR", *International Journal of Law, Policy and the Family*, 16, p. 413.

ing the evidence of an intention to create family life. Social reality, as opposed to the compliance with conventional forms of relationship, proved decisive. However, despite the establishment of family life between X and Z, the Court concludes that, given the wide margin of appreciation accorded to the Contracting States within the area of transsexuality, the application of Article 8 does not entail the respondent State's obligation to recognise a person who is not genetically connected to the child born by AI as his or her legal father[47].

Although the complexity of the scientific, legal, moral and social issues raised by transsexuality is undeniable, the Court might have relied on the doctrine of the margin of appreciation as a means of validating specific cultural prescriptions. In particular, the substantive variant of the doctrine seems to have been applied by the ECtHR to address the relationship between individual freedoms and collective goals[48]. In the present case, in fact, the Court has exercised its review jurisdiction and has accordingly declined to intervene because the authorities in question had acted within their margin of appreciation. Thus, the doctrine has been used as a "conclusory label"[49] to conceal the true basis on which the ECtHR decides whether or not the interference of the domestic authorities is justifiable.

The actual ground on which the assignment of legal fatherhood was denied to X emerges more expressly from the concurring opinion of Judge De Meyer, according to whom: "[…] It is self-evident that a person who is manifestly not the father of a child has no right to be recognised as her father"[50].

Although X had irrevocably changed many of his physical characteristics, it is deemed culturally unacceptable to attribute paternal rights and responsibilities to a person who does not possess the basic requirements for being publicly recognised as a father, since he is not a biological male.

In conclusion, the Court's judgment in X, Y and Z v the United Kingdom evidently rejects a genetic approach to parenthood, by arguing that a "parent" is not necessarily the person who procreates, but the person who acts as such in a social sense[51]. However, the adoption of a purely functional construction appears subsequently precluded, as a result of the assertion of parenthood as a gender-specific concept.

Despite its deference to the doctrine of the margin of appreciation, the Court seems to support a cultural definition of fatherhood: the legal father of a child does not necessarily need to be his biological father, but does need to be born biologically male[52].

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[47] Judgment, par. 52.
[48] See Letsas G. (2007), *A Theory of Interpretation of the European Convention on Human Rights*, Oxford University Press. Oxford, ch. 4. Interestingly, the author distinguishes between the substantive concept and the structural concept of the margin of appreciation.
[49] Singh R. (1999), "Is there a role for the 'margin of appreciation' in national law after the Human Rights Act?", *European Human Rights Law Review*, 1, p. 20.
[50] Judgment, Concurring Opinion of Judge De Meyer.
[51] Bainham A. (1997), "Sex, gender and fatherhood: does biology really matter?", *Cambridge Law Journal*, 56, p. 514.
[52] Bainham A. (1997), p. 514.

3.3. Dickson v the United Kingdom

The first applicant, Mr Dickson, was convicted of murder and sentenced to life imprisonment. The second applicant, Mrs Dickson, met her husband while she was also imprisoned. Subsequently, she was released and they married in 2001. Since the applicants desired to have a child, they applied for facilities for AI. Considering Mr Dickson's earliest expected release date (2009) and Mrs Dickson's age, the couple were unlikely to be able to have a child together without the employment of AI arrangements. Nonetheless, their application was eventually refused by the Secretary of State, in accordance with a specific policy concerning requests for AI by prisoners.

Having exhausted all domestic remedies, the couple lodged an application with the Strasbourg Court arguing that the refusal of AI facilities breached their right to respect for private and family life guaranteed by Article 8 as well as their right to found a family under Article 12 of the Convention. In response, the Government based the justifiability of the contested policy on three distinct principles: losing the opportunity to beget children was an inevitable and necessary consequence of imprisonment; public confidence in the penal system would be compromised if the punitive and deterrent elements of a sentence were circumvented by allowing prisoners convicted of serious offences to conceive children; and the inevitable absence of one parent for a long period would have negative implications on the child and, consequently, on society as a whole.

The ECtHR examined the contested policy and considered its two principal aims, namely the maintenance of public confidence in the prison system and the welfare of any child, to be legitimate[53]. Having regard to the difficult situation in which the applicants found themselves, the Chamber observed that careful consideration had been given by the Secretary of State to their circumstances[54]. In view of the wide margin of appreciation afforded to the national authorities, the Chamber went on to find that the impugned restriction was neither arbitrary nor unreasonable and, by four votes to three, held that there had been no violation of Articles 8 or 12 of the Convention[55].

Subsequently, the judgment of the Court was referred to the consideration of the Grand Chamber. With regards to the applicability of Article 8, the Court noted that the notions of "private" and "family life" incorporate the right to respect for the decision to become genetic parents[56]. As pointed out by the Grand Chamber, the core issue in the present case was precisely whether the national authorities had struck a fair balance between the conflicting public and private interests involved[57].

As to the applicants' interests, the vital importance of the issue at stake was acknowledged by the Court, since AI remained their only realistic hope[58]. Subsequently, the three justifications advanced by the Government to support the policy's consistency with the Convention were attentively examined. In relation to the first, it was held that the inability to procreate was not an inescapable consequence of imprison-

[53] Chamber Judgment, par. 34.
[54] Chamber Judgment, par. 38
[55] Chamber Judgment, par. 39-41.
[56] Grand Chamber Judgment, par. 66.
[57] Grand Chamber Judgment, par. 71.
[58] Grand Chamber Judgment, par. 72.

ment[59]. Secondly, there is no place under the Convention framework for the automatic forfeiture of rights by prisoners based merely on what might offend public opinion[60]. Thirdly, the State's positive obligations to guarantee the effective protection of children cannot go so far as to prevent a couple from attempting to conceive a child, particularly in circumstances similar to those of the present case[61]. In fact, the second applicant was capable of taking care of the child until the husband was released.

The Court also noted that any real weighing of the competing individual and public interests was excluded by the peculiar structure of the contested policy. The latter provided that requests for AI arrangements by prisoners would only be granted in exceptional circumstances and thus precluded the required assessment of the proportionality of a restriction in each specific case[62]. Given the fundamental importance of the matter for the applicants, the Grand Chamber concluded that the respondent State had overstepped its margin of appreciation, since no fair balance between the conflicting interests had been struck[63]. Accordingly, a violation of Article 8 of the Convention was found. Since no separate issue arose under Article 12, the Court considered not necessary also to examine the applicants' complaint under this provision[64].

Whilst the prevailing constructions of fatherhood emerge more manifestly from the Chamber's judgment, the actual basis on which the Grand Chamber has grounded its conclusions remains obscure and controversial. Although the wide margin of appreciation afforded to the national authorities was a key-consideration in the Chamber's reasoning, the overall tone of the judgment is one of hostility towards single-parent families, exasperated by the first applicant's status as a prisoner[65]. The need for legal scrutiny of men's ability to act as good fathers is expressly raised by Judge Bonello. In his concurring opinion, he argues:

> I am far from persuaded that kick-starting into life a child in the meanest circumstances, could be viewed as an exercise in promoting its finest interests. The debut of life in a one-parent family, deprived of the presence of the father and of a father-figure, offspring of a life prisoner convicted for the most serious crime of violence, would not quite appear to be the best way of giving a child-to-be a headstart in life[66].

Both a functional and a cultural approach appear to be adopted by the Court, when assessing the potential suitability of Mr Dickson as the father of any child conceived through AI. On the one hand, the concept of "family life" requires more than the simple provision of sperm from a distance. In particular, the establishment of family ties is precluded in circumstances where the donor is unable to meaningfully participate in any function related to fatherhood. On the other hand, the desirability of children being

[59] Grand Chamber Judgment, par. 74.
[60] Grand Chamber Judgment, par. 75.
[61] Grand Chamber Judgment, par. 76.
[62] Grand Chamber Judgment, par. 82.
[63] Grand Chamber Judgment, par. 85.
[64] Grand Chamber Judgment, par. 86.
[65] Codd H. (2007), "The slippery slope to sperm smuggling: prisoners, artificial insemination and human rights", *Medical Law Review*, 15, p. 227.
[66] Chamber Judgment, Concurring Opinion of Judge Bonello.

raised by two parents in a stable family unit is advanced as a means of legitimising the denial of access to AI techniques by prisoners. Accordingly, in light of moral and ethical values, it is considered unacceptable for a child to be fathered by a life prisoner convicted for the most serious crime of violence.

The individuation of the definition(s) of fatherhood upheld by the Grand Chamber requires a more sophisticated analysis of the judgment. Despite the negative impact that the absence of a father would have on the welfare of any child, the Court acknowledges the extraordinary nature defining the circumstances of the present case and consequently rejects a purely cultural construction of fatherhood.

Although the best interests of any child are better preserved within an uncomplicated family unit, the Court is of the opinion that prisoners should not be stigmatised by society and denied the right to procreate as a means of further punishment for their illegal conduct. Consequently, public opinion is excluded from playing any decisive role in establishing who has the right to become a father.

To the contrary, the so-called "pre-conception intention" of Mr Dickson is attributed significant relevance in assessing whether there had been a violation of Article 8. In fact, the inconsistency of the first applicant's inability to immediately act as a carer with the best interests of the child is considered as capable of attenuation by virtue of the second applicant's potential involvement. Accordingly, the Grand Chamber notes that Mrs Dickson is at liberty and therefore able to take care of the child, in anticipation of the husband's release[67].

Given the exceptional situation of the applicants, daily contact is not deemed as necessary and indispensable for the exercise of a meaningful paternal role. As suggested by Codd, allowing a prisoner to found a family through AI could produce overall beneficial results. The wellbeing of the resulting child could be safeguarded through a series of recently introduced programmes directed to enhance contact between imprisoned fathers and their children[68]. Furthermore, becoming a father could play a rehabilitative function in the inmate's life and facilitate his future reintegration within society[69].

In conclusion, the cultural biases embedded in the Chamber's judgment are subsequently overcome by the Grand Chamber. However, the construction of fatherhood endorsed by the ECtHR does not entirely comply with any of the three definitions outlined in Part I of the paper. The prevailing approach could be defined as an ad hoc functional approach: the emphasis on the child's need for actual paternal involvement is decreased, as a result of the particular circumstances of the applicants.

Despite his temporary status as prisoner, Mr Dickson is perceived as a prospective functional father and thus a victim of a violation of his right to respect for his decision to become a genetic father.

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[67] Grand Chamber Judgment, par.76.
[68] Codd H. (2006), "Regulating reproduction: prisoners' families, artificial insemination and human right", *European Human Rights Law Review*, p. 47.
[69] Codd H. (2006), p.47.

4. Conclusion

Although the aforementioned judgments were delivered over the last two decades, their analysis provides exhaustive coverage of the current legal issues arising out of the employment of modern reproductive techniques within the domain of fatherhood. The topicality of the matter at issue emerges even more clearly if the need for redefining fatherhood is contextualised with the broader debate concerning the changing nature of the family.

In this respect, scientific progress has been one of the driving forces behind the heightened dissolution of the previously coextensive family practices of sex, marriage and parenthood[70]. As such, modern medicine has also been a vehicle for challenging the legal primacy of the so-called "sexual family"[71], thus dismantling deeply ingrained misconceptions about non-biological fatherhood.

However, despite scientific progress' potential for change, the legal definition of fatherhood has not yet totally freed from socio-cultural constructions of parenthood. In fact, while the advent of DNA technology has marked the end of the marital presumption, the traditional paradigm of the heterosexual two-parent family has maintained a significant role in defining who deserves the attribution of PRR.

The suggested trend becomes apparent from the analysis of the ECtHR jurisprudence concerning the use of AI techniques. The overall picture resulting from the examination of the relevant case-law denotes the total rejection of the genetic definition of fatherhood and the continuous overlap of the other two constructions. Therefore, the Court does not adopt a unitary definition of fatherhood, but refers to the concept of "nurture" or to cultural norms, depending on the specific circumstances of each case.

However, despite these internal contradictions, the full endorsement of the functional construction constitutes a rare occurrence. In J.R.M. v the Netherlands, the Commission voluntarily disregards the "post-conception intention" of the applicant and automatically complies with the stereotype of the bi-parental family, profoundly entrenched in the dominant culture. The Court's judgment in X, Y and Z v the United Kingdom unambiguously prioritizes the cultural definition over the functional one: it is indispensable to "start life as a biologically male"[72] to be legally determined as the father of a child. Not even in Dickson v the United Kingdom has the overcoming of the culturally-constructed aversion against one-parent families and prisoners as fathers led to the endorsement of a purely functional definition.

In light of these considerations, there seems to be a sort of hierarchal framework whereby the ECtHR is moving in certain interesting directions. The genetic notion of fatherhood is being increasingly deprived of its historical importance to the advantage of the functional construction. Contemporaneously, the endorsement of a purely functional con-

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[70] Collier R., Sheldon S. (2008), *Fragmenting Fatherhood: A Socio-Legal Study*, Hart, Oxford, p. 234.

[71] Fineman M. (2009), "The Sexual Family", in Fineman M., J. Jackson, A. Romero, *Feminist and Queer Legal Theory: Intimate Encounters, Uncomfortable Conversations*, Aldershot, Ashgate, p. 45. See also Fineman M. (1995), *The Neutered Mother, the Sexual Family and Other Twentieth Century Tragedies*, Routledge, New York.

[72] Bainham A. (1999), "Parentage, parenthood and parental responsibility: subtle, elusive yet important distinctions", in Bainham A., Day Sclater S., Richards M., *What is a parent? A socio-legal analysis*, Hart, Oxford, p. 25.

ception of fatherhood is prevented in order to respect the dominant socio-cultural conceptions of the family.

Considering the particular context of ARTs, the total overcoming of the genetic conception of fatherhood ought to be perceived positively. Those who wish to support the importance of genetic relatedness have generally argued that attributing legal fatherhood to genetic fathers preserves "the reality of paternal identity"[73]. Presumably, donor-conceived children would benefit from knowing the truth about the circumstances of their conception, in accordance with the increasingly asserted child's right to genetic truth.

However, declaring the donor to be the legal father of the resulting child would imply prioritising the mere genetic link over the genuine value of social parenting. In other words, this would mean to disregard the actual involvement of who intended to be the father of the child and consequently was present at conception, during pregnancy, at the birth and, more significantly, who has acted as the child's father since his or her birth and wishes to be the father until the day he dies[74].

Similar effects might result from the accommodation of socio-cultural perceptions and prescriptions within the legal definition of fatherhood. Despite its nature of science in context, the law ought to distance itself from those constructions that are the products of pure biases and therefore do not reflect any fundamental need or interest of the individuals involved. To the purpose, the ECtHR has the potential to eradicate unfounded cultural constructions by regulating the width of the margin of appreciation that is granted to the Contracting States in relation to specific questions.

To conclude, the positive implications derived from the redefinition of fatherhood around the notions of "intention" and "commitment" ought not be underestimated. Intention being a gender-neutral concept, an intent-based system would promote men's involvement in child-care responsibilities, thus reducing gender asymmetries that have traditionally defined the contexts of procreation and parenthood[75]. Moreover, although parents-by-intention are not necessarily better parents than those determined by ordinary methods, deliberate intentions concerning child-rearing are more likely to lead to good quality parenting. Thus, apart from its quantitative implications, a functional approach ought to be preferred because it contributes to the realisation of children's welfare and the wellbeing of other caregivers[76].

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[73] The Leeds Teaching Hospital NHS Trust v Mr A, Mrs A and Others (2003) EWHC 259 (QB), (2003) 1 FLR 1091.

[74] Tizzard J. (3 march 2003), "Who's the daddy?", *Bionews*, available [online], URL: <http://www.bionews.org.uk/page_37663.asp> (last accessed on 23 February 2011).

[75] Shultz M. (1990), pp. 303-304.

[76] Dowd N. (2003-2004), "From genes, marriage and money to nurture: redefining fatherhood", *Cardozo Women's Law Journal*, 10, p. 136.

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Medical Data Sharing vs. Privacy Protection: Where Science Meets Law

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Abstract: Based on a study of official European legal texts and international publications on the ethics of data sharing in the field of human health, this paper suggests that there is an urgent need for lawyers and scientists to work together. Medical data sharing is more sensitive than the sharing of other data because of ethical and privacy-related issues. In particular, in order to ensure fairness and an effective protection of the rights to privacy and to personal data, there must be clarity over the conditions under which medical data sharing may be justified by (I) ethical requirements; (II) financial constraints; (III) the protection of public health; and (IV) the provision of individual cross-border healthcare.

Keywords: personal data; privacy; health; fundamental rights; transborder flow of information

1. Introduction

Sharing medical data, even though bearing the risk of violating the individual's right to privacy and data protection, may be justified by the protection of individual and public health. We can think of several scenarios of medical data sharing: first, when a patient seeks help from a healthcare professional in his or her personal interest[1]. Secondly, in the interest of humankind, for purposes of health care research[2]. Here, a distinction has to be drawn between primary use of medical records in research, such as for clinical trials or medical treatment[3] and the new "information based" forms of inquiry which involve secondary use of data[4]. With regard to the more and more frequent use of electronic health information, it is predicted that "the ability to carry out analytics on medical data will increase"[5], which is supposed to lead to "significant medical advances"[6]. This is due on the one hand to "[n]ewly developed technologies, in particular high-throughput, low-cost sequencing, [which] are being applied to increasingly large human genome and phenome data sets"[7]. On the other hand, an ageing population "favours increased and improved datasharing in bioscience research"[8]. In the eyes of many, the increasing use of new technologies together with the demographic evolution of Western societies call for a shift in emphasis in the fields of medical informatics and bioinformatics, which implies to rethink the protection of "health information privacy"[9], especially with regard to governance and regulatory approaches[10].

Under EU law, the right to the protection of personal data is recognized explicitely by Art. 16 § 1 Treaty on the Functioning of the European Union (hereinafter "TFEU"), Art. 8 § 1 Charter of Fundamental Rights of the European Union (hereinafter "CFREU")[11], Directive 95/46/EC on the protection of individuals with regard to the pro-

[1] Lunshof J.E. *et al.* (2008), "From genetic privacy to open consent", *Nature*, 9, pp. 406-411.
[2] Lunshof J.E. *et al.* (2008), pp. 406-411.
[3] Singleton P., Wadsworth M. (2006), "Consent for the use of personal medical data in research", *BMJ*, 333, pp. 255-349.
[4] Institute of Medicine of the National Academies, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research 112 (Nass S.J. *et al.*, eds., 2009), quoted by Schwartz P.M. (2010), *Data Protection Law and the Ethical Use of Analytics*, [online], URL: <http://www.huntonfiles.com/files/webupload/CIPL_Ethical_Undperinnings_of_Analytics_Paper.pdf> (last accessed on 30 April 2012).
[5] Schwartz P.M. (2010), *Data Protection Law and the Ethical Use of Analytics*, [online], URL: <http://www.huntonfiles.com/files/webupload/CIPL_Ethical_Undperinnings_of_Analytics_Paper.pdf> (last accessed on 30 April 2012), p. 14.
[6] Schwartz P.M. (2011), "Data Protection Law and the Ethical Use of Analytics", *Privacy & Security Law Report*, 10 *PVLR* 70, 01/10/2011, p. 3.
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[8] Harmon S.H.E., Chen K.H. (2012),"Medical research data-sharing: the *public good* and vulnerable groups", *Medical Law Review*, p. 8.
[9] Lunshof J.E. *et al.* (2008). As concerns the term "health information privacy", the authors refer to Curran W.J. *et al.* (1968), "Privacy, confidentiality and other legal considerations in the establishment of a centralized health-data system", *N. Engl. J. Med.* 281, pp. 241-248.
[10] Knoppers B.M. (2010), "Consent to *personal* genomics and privacy", *EMBO reports*, vol. 11, no. 6, pp. 416-419.
[11] On the implicit protection of personal data by Art. 7 CFREU through the strong link between the protection of the right to privacy and the right to personal data see the decision of the Court of Justice of the European Union of 9 November 2010, Joint Cases C-92/09 and C-93/09, *Schecke*.

cessing of personal data and on the free movement of such data[12], Regulation (EC) No. 45/2001 applicable to the Community institutions and bodies[13] and Directive 2002/58/EC on privacy and electronic communications[14]. Since the abolition of the pillar structure of the European Union (hereinafter "EU") with the entry into force of the Lisbon Treaty, Art. 16 § 2 TFEU has been providing for a legal basis enabling the adoption of a uniform EU-wide data protection law, which pursues two goals: remedying the currently fragmented legal framework and adapting to the fundamental changes that have occurred in the way of processing personal data since the adoption of the data protection directive in 1995. In a Communication of 25 January 2012, the European Commission came up with a proposal for such a revised, more coherent and ideally, more comprehensive legal framework for EU data protection rules[15] consisting mainly two instruments: one Regulation[16] and one Directive[17].

The right to the protection of personal data is also recognized by several sources of the law of the Council of Europe, be it implicitely through Art. 8 of the ECHR or explicitely through the provisions of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data[18], Recommendation 97 (5) on the protection of medical data[19] or Recommendation 86 (1) on the protection of personal data used for social security purposes[20]. In a decision of 17 July 2008, the European Court of Human Rights stated that "[p]ersonal information relating to a patient undoubtedly belongs to his or her private life" and thus falls within the scope of application of article 8 ECHR[21]. In this case, the applicant, a nurse working on fixed-term contracts in a public hospital in Finland complained about the failure of the hospital to guarantee the security of her health data against unauthorized access. Working at the polyclinic for eye diseases,

[12] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
[13] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
[14] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector.
[15] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM(2012) 11 final, 25.1.2012; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safeguarding Privacy in a Connected World: A European Data Protection Framework for the 21 Century", COM(2012) 9 final, 25.1.2012.
[16] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM(2012) 11 final, 25.1.2012.
[17] Proposal for a Directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data, COM(2012) 10 final, 25.1.2012.
[18] Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, European Treaty Series, No. 108.
[19] Recommendation No. R (97) 5 on the protection of medical data adopted by the Committee of Ministers on 13 February 1997 at the 584th meeting of the Ministers' Deputies.
[20] Recommendation No. R (86) 1 on the protection of personal data used for social security purposes adopted by the Committee of Ministers on 23 January 1986 at the 392nd meeting of the Ministers' Deputies.
[21] Decision of the ECtHR in I v. Finland of 17 July 2008, no. 20511/03, § 35.

after having been diagnosed as HIV-positive, she regularly paid visits to the polyclinic for infectious diseases of the same hospital. Her temporary contract not being reviewed, she suspected unauthorized access to her medical data and discrimination on these grounds. However, she did not succeed in providing firm evidence about unauthorized access to her health record and consequently, lost the civil suit before domestic courts. The European Court of Human Rights, on the contrary, held that there has been a violation of Art. 8 of the ECHR, considering that "to place such a burden of proof on the applicant is to overlook the acknowledged deficiencies in the hospital's record keeping […] had the hospital provided a greater control over access to health records by restricting access to health professionals directly involved in the applicant's treatment or by maintaining a log of all persons who had accessed the applicant's medical file, the [latter] would have been placed in a less disadvantaged position before the domestic courts"[22]. It thus seems that similarly to the wide interpretation of the right to privacy, the personal and material scope of the right to protection of medical data is interpreted widely. It covers any person, including unborn children[23]. As critics of the use of security scanners at EU airports have argued, it extends to images which reveal "a detailed display of the human body […as well as] medical conditions, such as protheses and diapers"[24].

From a linguistic point of view, both terms, "medical data" and "health data" are used for describing data related to health. They are considered to cover medical data in a strict sense, such as doctor referrals and prescriptions, medical examination reports, laboratory tests, radiographs, but also administrative and financial data relating to health such as hospital admissions, the social security number or invoices for healthcare services. In this contribution, we use the term "medical data" in a large sense and as a synonym to "health data". We base ourselves on Recommendation No. R (97)5, according to which "the expression medical data refers to all personal data concerning the health of an individual. It refers also to data which have a clear and close link with health as well as to genetic data". ISO 27799, which is a technical standard on information security management in health defines "health data" also broadly as:

> any information which relates to the physical or mental health of an individual, or to the provision of health service to the individual and which may include: (a) information about the registration of the individual for the provision of health services; (b) information about payments or eligibility for healthcare with respect to the individual; (c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; (d) any information about the individual collected in the course of the provision of health services to the individual; (e) information derived from the testing or examination of a body part or bodily substance; and (f) identification of a person (healthcare professional) as provider of healthcare to the individual.

[22] Decision of the ECtHR in I v. Finland of 17 July 2008, no. 20511/03, § 44.
[23] Recommendation No. R (97) 5 on the protection of medical data, § 4.5.
[24] Communication from the Commission to the European Parliament and the Council on the Use of Security Scanners at EU airports, COM(2010) 311 final, § 50.

Compared to other personal data[25], medical data enjoys a particularly strong protection under Art. 10 of Regulation (EC) 45/2001 and Art. 8 of Directive 95/46/EC. This special confidential treatment of health data is justified by its inherent, identity revealing characteristics related to "intimate areas in which public intrusion would be an unwarranted encroachment on the natural barriers of self"[26]. Recently still, in a decision of 2008, the European Court of Human Rights confirmed that "medical data […] is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention"[27]. Despite the generally accepted broad definition of medical data, it remains unclear whether biological materials of human origin like organs, tissues, cells or blood are as such to be qualified as personal data. To the extent, however, that the processing of biological materials often aims at extracting information relating to an identified or identifiable natural person, "it is undisputed that such materials can be used as sources of personal information"[28]. As the European Data Protection Supervisor (hereinafter "EDPS") stressed, "even without such a purpose, the biological materials are often accompanied by such extracted information"[29].

It follows from the abovementioned sources of law that the processing of medical data must be in conformity with the rights to privacy and protection of personal data. More precisely, this means that personal data concerning health may not be processed unless either the data subject has given his or her free, express and informed consent or, alternatively, "[the] processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, [given that] those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy"[30]. Accordingly, donation of human tissues or cells is subject to the donor's consent "including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained"[31].

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[25] "*Personal data* shall mean any information relating to an identified or identifiable natural person (*data subject*); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity": Directive 95/46/EC, art. 2 (a).

[26] These are the terms in which Judge Bonello refers to the constant case law of the ECtHR on the protection of the right to privacy under Article 8 ECHR in his partly dissenting opinion under the *Rotaru v. Romania* Judgment of 4 May 2000, § 6.

[27] Decision of the ECtHR in *I v. Finland* of 17 July 2008, no. 20511/03, § 38.

[28] Opinion of the European Data Protection Supervisor on the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (2009/C 192/02), § 12.

[29] Opinion of the European Data Protection Supervisor on the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (2009/C 192/02), § 12.

[30] Directive 95/46/EC, art. 8 § 3.

[31] Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, Annex IV, § 2.4.(a).

It should be noted however that Member States may lay down exceptions to the prohibition of processing health data without having obtained prior consent of the concerned data subject or his or her legal representative. These exceptions must be justified by reasons of substantial public interest foreseen by national laws transposing Directive 95/46/EC, or by decisions of national Data Protection Authorities, provided that they create suitable safeguards. For example, the processing of personal data by Member States may be authorized if it is related to an "event posing a health threat, […or] to the health conditions of […] infected persons and of persons potentially exposed to contamination […] within the [Early Warning and Response System]"[32]. Another example concerns genetic data: whereas their collection and processing may be allowed in the presence of an overriding interest in predicting illness, a uniform approach as regards this justification is lacking. Four different approaches can be identified in national legal systems:

> In the first, the national data protection authority authorizes disclosure of the information in the interest of 'others', which includes family members. In the second system, shared medical data is considered as 'personal' data with respect to each family member [and may thus not be disclosed without consent]. The third system makes it the duty of the physician to inform relatives, and the fourth places a duty on the individual to initiate the process of giving information to his/her relatives, either directly and personally or through an intermediary body[33].

As examples, we may quote the case of "the Italian Privacy Authority (1999) [which] authorized a hospital to disclose the father's data (against his will) to his daughter who had to decide whether to have children or not"[34]. A New Jersey Court went further by stating "that physicians do have a duty to warn individuals known to be at risk of avoidable harm from a genetic condition"[35]. The latter solution seems problematic with regard to the protection of fundamental rights as it allows for the limitation of the right to informational autonomy not only of the patient, but also of the family members who carry a health risk and do not want to be informed about it. Is there a right not to know[36]? The question of individual control of medical information arises with increasing frequency as biomedical technology proceeds[37].

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[32] Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS) (2012/73/EU), § 4.

[33] Boussard H. (2010), "Individual Human Rights in Genetic Research: Blurring the Line between Collective and Individual Interests", in Murphy T. *et al*. *New Technologies and Human Rights*, Oxford University Press, Oxford, p. 262.

[34] Santosuosso A., Redi C.A. (2003), "The need for scientists and judges to work together: regarding a new European network". *Health and Quality of Life Outcomes*, 1, p. 4.

[35] Safer v. Estate of Pack (1996) N.J.Sup.Ct., App.Div., quoted by Santosuosso A., Redi C.A. (2003), p. 4.

[36] In favor of the right not to know with regard to the communication of medical data derived from genetic testing: See Mc Nelly E., Combon-Thomsen A. (2004), *25 Recommendations on the ethical, legal and social implications of genetic testing*, Brussels, especially p. 15, available [online], URL: <http://ec.europa.eu/research/conferences/2004/genetic/pdf/recommendations_en.pdf> (last accessed 1 May 2012); "An essential issue connected with informed consent in genetic tests is the right not to know. It results from the domination of prognostic genetic tests that allow one to detect rare monogenic diseases for which there is a lack of an effective method of treatment and the awareness of being ill is a psychological burden for the patient": Pawlikowski J. (2011), "Biobank research and ethics: the problem of informed consent in Polish biobank",

Inversely, it is to be noted that in certain circumstances, Member State law can determine that even consent of the data subject cannot lift the prohibition of the processing of personal data[38]. Indeed, it must be stressed that "[p]articularly in the context of biomedical research and genetic research, the standards set by the EU provide for a fair margin of discretion for Member States […which] is very significant to the protection of sensitive information, particularly regarding […] justifications for derogation pertain[ing] to scientific purposes and research that presumably benefits society"[39].

In any case, the collection and processing of medical data may only be authorized if done by healthcare professionals or individuals or bodies subject to the same rules of confidentiality. When doing so they must respect the principles of lawfulness, necessity, proportionality and purpose limitation. Correspondingly, in a democratic society, each individual whose personal data are being processed must be recognized the rights of access to his or her personal data, as well as the rights of rectification, erasure or blocking of such data[40].

Compliance with data protection rules shall be subject to the control of independent authorities[41]. Here lies "[o]ne of the main features of the EU data protection legal framework"[42]. Whereas the processing of personal data by EU institutions and bodies is supervised by the EDPS, the processing by natural and legal persons, national public authorities, agencies or other bodies in the Member States is supervised by their respective national Data Protection Authorities (e.g. in Italy the Garante per la protezione dei dati personali, in France the Commission Nationale de l'Informatique et des Libertés, in Germany the Bundesbeauftragte für den Datenschutz und die Informationsfreiheit).

As of today, there is no denial that whereas for scientists, the sharing of medical data is increasingly becoming an imperative (2), it continues to remain a challenge for lawyers (3).

2. Medical data sharing: An imperative for scientists

Scientific researchers argue that the sharing of medical data is justified not only by ethical requirements (2.1.), but also by financial constraints (2.2.). It is argued that research budgets being limited, they should be devoted to creating generalizable knowledge. Indeed, considering that knowledge is a "socio-moral or human value",

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Arch Med Sci, 5, pp. 896-901; Pierce K.R. (2009), "Comparative Architecture of Genetic Privacy", *Ind. Int'l & Comp. L. Rev.* 89; see also Article 29 Data Protection Working Party, Working Document on Genetic Data of 17 March 2004, especially pp. 8-9.

[37] Pierce K.R. (2009).

[38] Directive 95/46/EC, art. 8 § 2 (a); Regulation (EC) No. 45/2001, art. 10 § 2 (a).

[39] Pierce K.R. (2009); Beyleveld D. *et al.* (2004), *Implementation of the Data Protection Directive in Relation to Medical Research in Europe*, Ashgate, Hants, 473 p.

[40] Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS) (2012/73/EU), § 9; Opinion of the European Data Protection Supervisor on the Communication from the Commissin to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions – "A comprehensive approach on personal data protection in the European Union", §§ 27 and 28; Art. 8 § 2 CFREU; Recommendation No. R (97) 5 on the protection of medical data, § 8.

[41] Art. 16 § 2 TFEU; Art. 8 § 3 CFREU.

[42] Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS) (2012/73/EU), § 3.

its generation is "a valuable pursuit. If the biosciences are to fulfil their promise of both generating knowledge and translating that knowledge into socially beneficial products and practices, then research data and subsequent findings must be shared widely and rapidly"[43].

2.1. Medical data sharing justified by ethical requirements

Ethical requirements call for the sharing of medical data in so far as "more transparent information can contribute to the development of further research helping to ensure that better trials are designed, requiring fewer patients and avoiding unnecessary duplication"[44]. However, in order for medical data sharing to be fully in line with ethical requirements, notably respect for the dignity and autonomy of persons, informed consent of each research participant has to be obtained prior to his or her participation in human subject research. There are several manners for obtaining consent in clinical research worldwide (implicitly/explicitly[45], opt-in/opt-out[46]). Its form may vary, depending on the risk, age and condition of the research subject (open/purpose-related, narrow/broad[47], children/adults, living/deceased persons[48]). The Biomedical Convention of the Council of Europe (hereinafter "Oviedo Convention") sets out general rules requiring consent to be free and informed. It contains specific rules regarding the protection of persons not able to consent, persons who have a mental disorder, emergency situations and situations where the person is not in a state to express his or her wishes[49]. With regard to persons undergoing research, art. 16 of the Oviedo Convention requires that consent has been given "expressly, specifically, […] is documented [and …] may be freely withdrawn at any time". As a consequence, we can assume that whenever

[43] Harmon S.H.E., Chen K.H. (2012).

[44] Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004, OJ C 168, 3.7.2008, p. 3; see also European Society of Human Genetics (ESHG) (2003), "Data storage and DNA banking for biomedical research: technical, social and ethical issues", *Eur J Hum Genet* 11, pp. 906-908, quoted by Knoppers B.M. (2010), p. 417: "there is an ethical imperative to promote access and exchange of information, provided confidentiality is protected".

[45] E.g., by holding out one's arm for an injection without expressing consent explicitely, or by nodding, saying yes or signing a form: Singleton P., Wadsworth M. (2006).

[46] Singleton P., Wadsworth M. (2006).

[47] "Consent can be narrow and specified, broad or blanket; blanket consent implies that there are no restrictions to the scope and duration of the consent. Obviously, broad or blanket consent can never be fully informed. Consent might include a further layer: the consent to be re-contacted and give re-consent, for example, when new information becomes available that is relevant to the research subject, or if further research is being considered. However, including the option of re-contacting and obtaining re-consent implies, by definition, maintaining identificability and traceability of research participants": Lunshof J.E. *et al.* (2008); Pawlikowski J. (2011), pp. 896-901.

[48] Pawlikowski J. (2011), pp. 896-901.

[49] 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, Oviedo, 4.IV.1997, especially articles 5-9.

consent was validly given and as long as it has not been withdrawn, the sharing of medical data is fully in line with the ethical principle of respect for persons.

In the absence of harmonized practice[50] and with regard to the "wide range of data privacy and consent issued in today's social networks and bioinformatics systems"[51] the assessment of fully valid consent remains however problematic. Even within one legal system, assessing the validity of consent may leave room for appreciation and thus instability. For example, France's new law on human subject research adopted on 21 February 2012 has opted for a concept of modulated consent, according to which consent must be proportionate to the risk to which the research participant exposes him- or herself. The higher the risk, the stricter the conditions for consent (e.g. oral/written)[52].

On top of being necessitated by ethical requirements, the sharing of medical data may also save costs and thus, be justified by financial constraints.

2.2. Medical data sharing justified by financial constraints

With regard to the principles of accountability and of spending public resources in a responsible manner, the sharing of medical data may also be justified by cost-saving re-use of existing health care data[53]. Mladovsky *et al*. argue that "publicly funded research should benefit everyone, and [that] easy access to research data represents sound stewardship of public resources"[54].

As Singleton and Wadsworth emphasize, "[o]ptimising the use of data […] is appropriate not only scientifically but also for fostering collaboration between research groups and promoting value for money"[55].

However, an efficient, sustainable use of medical data requires long-term planning, avoiding that where similar studies are realized in different institutions at the same time period, the collected samples – "usually due to a shortage of funds necessary to store them"[56] – are destroyed after the research project financing the collection and storage is finished. It follows from these arguments that open access to data should be promoted for publicly funded research projects.

As examples of data sharing initiatives which are accessible free of charge, we may quote the European social survey and the survey of health, ageing and retirement in Europe funded by the EU[57].

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[50] "The International Bioethics Committee of UNESCO, WHO and some authors suggest a blanket consent to possible future scientific research, others a presumed consent with opt-out […] CIOMS (the Council for International Organizations of Medical Sciences) believes that in cases of minimal risk the ethical commission can waive the requirement of obtaining informed consent for successive research": Pawlikowski J. (2011), pp. 896-901.
[51] Knoppers B.M. (2010), pp. 416-419.
[52] "Un guichet unique pour les recherches cliniques", *Le monde*, 25 February 2012, p. 7.
[53] "In terms of efficiency and consistency of results, it is preferable to re-use data rather than re-collect it": Singleton P., Wadsworth M. (2006).
[54] Mladovsky E. *et al.* (2008), "Improving access to research data in Europe", *BMJ*, 336, pp. 287-288.
[55] Singleton P., Wadsworth M. (2006).
[56] Pawlikowski J. (2011), pp. 896-901.
[57] Mladovsky E. *et al.* (2008), pp. 287-288.

3. Medical data sharing: A challenge for lawyers

Following the dual approach to health by law, as both an individual right to the protection of health and an overriding exception of general interest to the exercise of other rights and liberties, lawyers tend to distinguish between the individual and collective dimensions of health protection. As a consequence, we suggest to consider separately the sharing of medical data justified by the protection of public health and the sharing of medical data justified by the provision of individual cross-border healthcare.

3.1. Medical data sharing justified by the protection of public health

Sharing of medical data may be authorized whenever it aims at the prevention and control of communicable diseases or the promotion of human subject research.

3.1.1. Prevention and control of communicable diseases

The Early Warning and Response System (hereinafter "EWRS") was created in 1998 and has been operated since 2005 by the European Centre of Disease Prevention and Control (ECDC), situated in Stockholm, Sweden. The mission of the ECDC is "to identify, assess and communicate current and emerging threats to human health from communicable diseases". In the past, the EWRS has been dealing with SARS, avian influenza in humans and other major communicable diseases. Additional kinds of health threats, such as biological, chemical, environmental and other hazards likely to spread across borders motivated the Commission to adopt a proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health. Art. 3(c) of the Proposal allows for "contact tracing", that is adopting "measures implemented at national level in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are potentially in danger of developing or have developed a disease"[58]. The processing of such health-related data thus does not only contain a threat to the privacy of the concerned persons, but also a risk of restricting their freedom of movement (as it may justify quarantining or refusal of entry of that individual in a Member State).

In February 2012, the European Commission provided EWRS users with guidelines "in which the functioning of the EWRS from a data protection perspective is explained in a user-friendly and easily understandable manner", with the aim of "rais[ing] awareness and promo[ting] best practices and a consistent and uniform approach to data protection compliance among EWRS users in the Member States"[59].

[58] Proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health, COM(2011) 866 final, 8.12.2011.
[59] Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS) (2012/73/EU), Annex, § 2.

The EDPS, in his opinion on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health welcomes the fact that contact tracing is being implemented on the national level and that according to Art. 18(3), information sharing is limited to what is strictly necessary concerning content and retention periods. Furthermore it must be stressed that the obligation for national authorities to inform their counterparts of any unlawful notification of personal data for the purpose of contact tracing is a privacy safeguard.

However, the EDPS regrets that the concept of contact tracing is not defined more clearly (as to the object, determination of contacts, way of informing concerned individuals, data retention periods). According to his opinion, legal certainty, consistency across the EU and the respect of the principle of proportionality require that these issues be addressed on the European level. For instance, concerning communicable diseases, he claims that at least the nature of the disease, its severity, infectivity and context in which exposure occurred be determined. It will be crucial for lawyers and scientists to cooperate. As contact tracing of health threats other than communicable diseases is concerned, the purpose seems not to be sufficiently defined according to the EDPS. Last but not least, the EDPS considers it necessary that the main categories of the processed data (e.g. name and contact details of the infected persons who might have been in contact with him/her, travel routes, name of the disease) be outlined on the European level[60].

3.1.2. Promotion of human subject research

Whenever possible, medical data relating to human subjects which is used for scientific research purposes should be anonymous[61]. If this is the case, the rules on the protection of personal data do not apply as the right to privacy is not at risk[62]. Only in limited cases where anonymisation "would make a scientific research project impossible, and the project is to be carried out for legitimate purposes", the processing of personal data may be permissible, subject however to strict conditions[63]: either the data subject or his or her legal representative has given his/her informed consent or "disclosure of data for the purpose of a defined scientific research project concerning an important public interest has been authorised by the body or bodies designated by domestic law, but only if (I) the data subject has not expressly opposed disclosure; and (II) despite reasonable efforts, it would be impracticable to contact the data subject to seek his consent; and (III) the interests of

[60] Opinion of the European Data Protection Supervisor on the proposal for a decision of the European Parliament and of the Council on serious cross-border threats to health, 28.3.2012.
[61] Recommendation No. R (97) 5 on the protection of medical data, § 12.1; Recommendation No. R (86) 1 on the protection of personal data used for social security purposes adopted by the Committee of Ministers on 23 January 1986 at the 392nd meeting of the Ministers' Deputies, § 9.3.
[62] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, Recital 26.
[63] Recommendation No. R (97) 5 on the protection of medical data, § 12.2; Recommendation No. R (86) 1 on the protection of personal data used for social security purposes adopted by the Committee of Ministers on 23 January 1986 at the 392nd meeting of the Ministers' Deputies, § 9.3.

the research project justify the authorisation; or d) the scientific research is provided for by law and constitutes a necessary measure for public health reasons"[64].

3.2. Medical data sharing justified by the provision of individual cross-border healthcare

Finally, the sharing of medical data may also be justified by reasons of individual health protection, be it on paper or electronically in the framework of individual cross-border healthcare.

3.2.1. Paper-based exchange of health data

The EU's economic development "goes hand in hand with the introduction and the marketing of new technologies and services"[65]. However, people will only trust these new technologies and services if their data are efficiently protected.

According to the case law of the European Court of Human Rights, "[r]especting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general"[66].

As a consequence, providing for a trustworthy data protection framework is not only necessary from a fundamental rights protection standpoint; it is also beneficial for Europe's economy.

Directive 2011/24/EU establishes a Community framework for the provision of cross-border healthcare within the EU[67]. Its implementation requires the exchange of patients' health data between healthcare organisations and healthcare professionals.

It provides that the Member State of treatment shall ensure that "the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC"[68].

In order to ensure continuity of care, this directive sets out the right for patients who have received treatment in one Member State to obtain a written or electronic medical record of such treatment, and the right to access to "at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the

[64] Recommendation No. R (97) 5 on the protection of medical data, § 12.2 (c) and (d).
[65] Opinion of the European Data Protection Supervisor on the Communication from the Commissin to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions. "A comprehensive approach on personal data protection in the European Union", § 21.
[66] Decision of the ECtHR in I v. Finland of 17 July 2008, no. 20511/03, § 38.
[67] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45.
[68] Directive 2011/24/EU, art. 4 § 2 (e).

protection of personal data, in particular Directives 95/46/EC and 2002/58/EC"[69]. It requires that the Member State of affiliation shall ensure this right to access[70].

3.2.2. E-health

The purpose of E-health, which is to be defined as the "deployment of proven information and communication technology-enabled solutions" is to contribute to "[r]esolving existing and future challenges to European healthcare systems"[71] by enabling healthcare providers to have "timely and secure access to basic, and possibly vital, health information [of patients …] in conformity with [their] fundamental rights to privacy and data protection"[72].

Telemedicine is "the provision of healthcare services at a distance"[73]. It currently encompasses "teleradiology[74], telepathology, teledermatology, teleconsultation, telemonitoring[75], telesurgery and teleophtalmology", but also extends to other services such as "call centres/online information centres for patients, remote consultation/e-visits or videoconferences between health professionals"[76].

E-health and telemedicine applications are based on the exchange of electronic data such as vital signs or images, most of the times jointly with "other existing electronic healthcare information systems residing on the Member States of treatment and affiliation"[77]. As examples of such applications we may quote systems operating at a patient-to-doctor basis, such as remote monitoring and diagnosis, electronic prescrip-

[69] Directive 2011/24/EU, art. 4 § 2 (f).
[70] Directive 2011/24/EU, art. 5 § (d).
[71] Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, Recital 2.
[72] Commission Recommendation of 2 July 2008, § 1.
[73] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, p. 3.
[74] Teleradiology "involves the electronic transmission of radiographic images from one geographical location to another for the purposes of interpretation and consultation": Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, p. 5.
[75] Telemonitoring aims at "monitoring the health status of patients at a distance. Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool": Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, p. 4.
[76] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, p. 3.
[77] Opinion of the European Data Protection Supervisor on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (2009/C 128/03), OJ C 128, 6.6.2009, § 25.

tions[78] or electronic referrals[79], but also systems relying on a doctor-to-doctor basis, such as teleconsultations between healthcare professionals for expert advice.

Many Member States are presently working on the creation of an electronic summary of patients' health records in order to allow healthcare providers to access key information wherever treatment of the patient is needed[80]. Three scenarios are to be distinguished: in the first one, the summary record is created on a purely voluntary basis. In the second scenario, the Member State offers a moderate financial incentive for choosing the e-health record. In the third scenario, patients who refuse the e-health system suffer from a disadvantage, as they "have to pay a substantial extra cost compared to the previous tariff system and the processing of their file is considerably delayed"[81]. However, what is problematic in the latter case is that consent is not completely free.

Such electronic health record systems "form a fundamental part of eHealth systems"[82]. Whereas on the one hand, they provide for the free cross-border flow of health data, on the other hand, they enhance at the same time the risk of patient information to be accidentally exposed or accessed unlawfully. This risk is even higher as interoperable electronic health record systems "enabl[e] greater access to a compilation of the personal data concerning health, from different sources, and throughout a lifetime"[83]. In order to preserve privacy, the European Commission therefore suggests that particularly sensitive data such as genetic or psychiatric information "be excluded from online processing […] or at least be subject to especially strict access controls"[84]. Also, in order to ensure a high level of privacy protection, it suggests to make sure that any processing "takes place within jurisdictions applying Directive 95/46/EC or those with an adequate level of protection of personal data"[85]. In order to ensure maximum compliance with the fundamental right to protection of personal data in electronic health record systems, assistance is provided to Member States through a guid-

[78] Electronic prescriptions are synonym to "medicinal prescription[s], as defined by Article 1(19) of Directive 2001/83/EC of the European Parliament and of the Council, issued and transmitted electronically": Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, § 3 (g).

[79] European Commission (2007), *Towards the Establishment of a European eHealth Research Area*, eHealth ERA Report, available [online], URL: <http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-era-full-report.pdf> (last accessed on 13 April 2012).

[80] Article 29 Data Protection Working Party, Opinion 15/2011 on the definition of consent adopted on 13 July 2011, p. 15; Electronic health records are to be defined as "comprehensive medical record[s] or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes": Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, § 3 (c).

[81] Article 29 Data Protection Working Party, Opinion 15/2011 on the definition of consent adopted on 13 July 2011, p. 15.

[82] Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, Recital 2.

[83] Commission Recommendation of 2 July 2008, § 12.

[84] Commission Recommendation of 2 July 2008, § 14 (e).

[85] Commission Recommendation of 2 July 2008, § 14 (j).

ance document issued by the Working Party set up under Article 29 of Directive 95/46/EC[86].

The EDPS notes however that a serious obstacle continues to prevent the provision of individual cross-border healthcare to be fully in line with the fundamental rights to privacy and data protection: the absence of a commonly accepted definition of an "appropriate" security level for healthcare within the EU[87].

In both cases, concerning paper-based or electronic exchange of personal data in cross-border healthcare, safeguards aimed at the protection of privacy must be implemented. For example, with regard to cross-border exchanges of organs, "special attention should be paid to pseudonymisation possibilities to be used for the identification of donors and recipients"[88] in order to ensure confidentiality and security. Indeed, the principle of proportionality requires that pseudonymisation or anonymization be privileged over the processing of personal data, "insofar as this is possible and the effort involved is reasonable in relation to the desired level of protection"[89].

In the framework of the on-going reform of the EU data protection legislation, it is planned to lay down a new principle in secondary law texts having binding effect: the privacy by design-principle[90]. The aim of this principle is the "integration of data protection and privacy from the very inception of new products, services and procedures that entail the processing of personal data"[91]. Applying the privacy by design-principle to the development of medical data processing devices could be a solution in the fight and prevention of identity theft and other privacy-intrusive attacks. To quote another example, one could imagine embedding data protection safeguards in the design and implementation of electronic health record systems. The inclusion into organ donors' registers of all the necessary security requirements from the initial implementation stage on would be another application of the privacy by design-principle[92].

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[86] Working Document 131 of 15 February 2007 on the processing of personal data relating to health in electronic health records referred to in the Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems at § 13.

[87] Opinion of the European Data Protection Supervisor on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (2009/C 128/03), OJ C 128, 6.6.2009, § 28.

[88] Opinion of the European Data Protection Supervisor, §§ 40 and 49.

[89] Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, § 14 (c).

[90] See contribution papers of Anne Cammilleri-Subrenat, Laurène Graziani, Alexandra Guérin-François, Claire Levallois-Barth et Rémy Prouvèze to the workshop organized by the CERIC with the support of the French National Research Agency ANR in Paris in March 2012 about the Privacy by design principle, [online], URL: <http://www.ceric-aix.univ-cezanne.fr/autres/manifestations-scientifiques-de-l-umr-6201/atelier-privacy-by-design-paris-msh-23-mars-2012.html> (last accessed on 17 August 2012); Cammilleri-Subrenat A., Prouvèze R., Verdier-Büschel I. (2012), N*ouvelles technologies et défis du droit en Europe. L'imagerie active au service de la sécurité globale*, Bruylant, Bruxelles, p. 385.

[91] Opinion of the European Data Protection Supervisor on the Communication from the Commissin to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions – "A comprehensive approach on personal data protection in the European Union", 7.3., § 108; Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS) (2012/73/EU), § 7.

[92] Opinion of the European Data Protection Supervisor on the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (2009/C 192/02), §§ 36 and 48 (c).

4. Conclusion

At present both a uniform and sound data protection approach and a specific, coherent framework providing for the protection of the rights to privacy and personal data in the field of human health are lacking in Europe. Consequently, there is a need for research to be promoted on the "[w]ays how consent is gained for medical research, how data are gathered by researchers, and how such data may be archived or preserved"[93] and, last but not least, shared for scientific purposes[94]. One must admit however that healthcare privacy and medical data are not left completely unprotected either. They are ensured through diverse legal texts which require that free, explicit and informed consent of the data subject be obtained prior to the processing of the data or that the data be anonymized, that the processing is purpose-related and that storage periods be limited. With regard to the strengthening of the protection of fundamental rights within the EU – thanks especially to the case law of the European Courts in Strasburg and Luxemburg and the binding character of the CFREU since the entry into force of the Lisbon Treaty –, but also with regard to the promotion of healthcare research and the further development of cross-border healthcare, including through the use of information technology, there is a real and urgent need for scientists and lawyers to work together[95]. Indeed, the desired more coherent approach on medical data sharing in Europe requires the enhancement of, at the same time, technical interoperability of computing systems, data security and legal certainty. It thus necessitates interdisciplinary cooperations. Undoubtedly, the current incomplete protection of medical privacy leaves room for the adoption of clearer and more detailed legislation. We suggest that it offers an opportunity for the construction of a comprehensive framework made of transnational law, that is, nourished by "liberal values"[96] in combination with ethical requirements and fundamental rights such as provided for in national, regional and international legal instruments. Training of healthcare professionals and medical research staff, informing patients and raising awareness among consumers are possible solutions for maximizing data protection while at the same time, informing about its limits.

[93] Singleton P., Wadsworth M. (2006).
[94] Mc Nelly E., Combon-Thomsen A. (2004); OECD Guidelines on Human Biobanks and Genetic Research Databases (2009), p. 53, available [online], URL: <http://www.oecd.org/dataoecd/41/47/44054609.pdf> (last accessed on 1 May 2012).
[95] Santosuosso A., Redi C.A. (2003), "The need for scientists and judges to work together: regarding a new European network", pp. 1-6.
[96] "Quite obviously, for the ECJ and the ECtHR, liberal values constitute a source of European unity": Bignami F. (2010), "Constitutional Patriotism and the Right to Privacy: A Comparison of the European Court of Justice and the European Court of Human Rights", in Murphy T. *et al. New Technologies and Human Rights*, Oxford University Press, Oxford, p. 159.

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2012 Law & Science Young Scholars Informal Symposium

A cura di Alessandra Malerba – Laura Massocchi – Amedeo Santosuosso

Il "2012 Law & Science Young Scholars Informal Symposium" è un evento promosso e realizzato dal Centro di Ricerca Interdipartimentale "European Centre for Law, Science and New Technologies" (ECLT) dell'Università di Pavia in collaborazione con il Collegio Ghislieri e l'Istituto Universitario di Studi Superiori (IUSS) di Pavia.
Il Simposio è dedicato a giovani ricercatori nel settore Diritto e Scienza che desiderano far conoscere il proprio lavoro, confrontarsi con altri giovani studiosi in un clima stimolante e informale e ottenere un prezioso *feedback* sul proprio elaborato. I lavori presentati sono, infatti, valutati da una Commissione internazionale di esperti in materie giuridiche e scientifiche, che seleziona i partecipanti e fornisce loro osservazioni puntuali sul contributo presentato.
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I contributi selezionati e raccolti afferiscono a varie aree di ricerca interne all'ampia categoria Diritto e Scienza, spaziando dall'intelligenza artificiale alle neuroscienze e alla genetica. La scelta della lingua inglese come unica lingua di lavoro nonché la selezione dei partecipanti tramite un processo di revisione in più fasi, svolto da un gruppo di esperti provenienti da tutto il mondo, assicurano la qualità scientifica degli articoli.

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Alessandra Malerba conduce la sua attività ricerca in collaborazione con il Centro ECLT.

Laura Massocchi è attualmente iscritta al Master in Diritto dell'Unione Europea presso il *College of Europe* (Bruges) e collabora con il Centro ECLT.

Amedeo Santosuosso insegna *Law, Science and New Technologies* presso l'Università di Pavia ed è tra i fondatori e attuale Presidente del Centro ECLT. È altresì il promotore del Simposio dedicato ai giovani ricercatori.