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Bioethical Decision Making and Argumentation

Springer

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Foreword

The roots of *Bioethical Decision-Making and Argumentation* lie in a research project funded by the Spanish government[1] and carried out by a group of Philosophy of Law lecturers and researchers with a long-standing interest in bioethics and in the theory and practice of argumentation, especially in legal contexts. The goals of this project were threefold:

1. First, to provide a critical analysis of the prevailing paradigm in bioethical decision-making, namely, North American principlism, propounded by Beauchamp and Childress
2. Second, to provide a similar critical analysis of other proposals arising from the debate surrounding the above
3. Finally, to put forward the fundamental lines of an alternative model combining substantive principles and procedural guidelines, robust enough not only to overcome the shortcomings of principlism and its alternatives but also to stand up to the criticisms usually levelled at ethics, regardless of whether they focus on moral contents or merely on discursive procedures

The initial hypothesis is that the principlist model of decision-making is open to improvement and replacement by a model combining substantive principles and procedural guidelines, the former consisting of a set of basic rights that are part of the Western cultural heritage and the latter of criteria relating to prudent discursive practical reasoning. Such a model makes it possible to conserve the more valuable elements of the principlist model whilst avoiding some of the pitfalls highlighted by its critics.

The team of academics working on the project took as their starting point the close links between bioethics and law, not only in the historical or genetic sense,

[1] Research project *Principialismo y teorías de la argumentación en la toma de decisiones médicas* (DER2010-17357), led by Professor Pedro Serna and funded by the Spanish Ministry of Science and Innovation.

which is hardly open to discussion, but also in a much deeper sense. Indeed, in modern Western societies, the goods at stake in the doctor-patient relationship are protected by law and usually at the highest possible level, that of the constitution. This in turn permits us to suppose that the principles and forms of argumentation developed in the field of the law are able to throw light on the task of constructing a bioethical decision-making model, with particular reference to the clinical sphere, able to withstand the most pertinent criticisms made against principlism. Thus, the contemporary debate on principles and their application to individual cases, normative systems theory, balancing theory and its practice and, more broadly, argumentation theories together with the constitutional dogmatics of basic rights supplies useful elements with which to design a biomedical decision-making model containing both substantive elements (human rights) and procedural ones (discursive argumentation and prudential models).

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Ever since it was first formulated in the United States in the late 1970s, principlism has been the paradigm for biomedical ethics, particularly in the clinical field. This, however, has not spared it from numerous critiques attacking its ambiguity and incompleteness and putting forward alternatives such as casuistry, virtue bioethics or the model based on so-called common morality. Moreover, a specific form of principlism has developed in Europe that proposes replacing the principles of non-maleficence, beneficence and justice with those of dignity, integrity and vulnerability, whilst retaining that of respect for autonomy. Some authors have proposed other modifications to principlism, such as the introduction of hierarchies governing the application of principles, whilst others go further, assuming many of the critiques as valid and proposing a more flexible model that replaces the four principles with a decision-making process based on balancing values.

One of the common characteristics of modern Western societies is that they are home to a variety of groups and individuals who hold different and partially incompatible moral ideas ("comprehensive doctrines", according to the expression coined by Rawls,[2] or "moral communities", in Engelhardt's words[3]). As is well known, the existence of this radical pluralism poses some of the biggest challenges faced by the theory of justice and, more widely, by the law today. Bioethical problems are no exception to this and indeed even constitute the field in which the conflicts deriving from this irreducible pluralism are most sharply expressed, and thus the one in which the models used to channel and resolve them must prove their effectiveness most robustly. Similarly, just as in the medieval world it was inconceivable to think of ethics without the idea of God and salvation, in the modern world, it is impossible to conceive of models of social ethics that fail to take this pluralism into account. For some authors, Rawls amongst them, this implies a political rather than metaphysical idea of justice and social ethics in general.

[2] *Political Liberalism*, Columbia University Press, New York, 1993.

[3] *The Foundations of Bioethics*, 2nd ed., Oxford University Press, New York, 1996.

Furthermore, bioethics is specifically destined to be the source of the paradigm of ethics in modern society, precisely because it deals with problems arising from scientific and technological progress, coming at a time when the theocentric world-view is fast losing currency.[4]

A specific feature of modern bioethics is that generally speaking the problems it poses arise not from a traditional deontological perspective, i.e. that of a doctor or health professional's moral obligations, but from a relational standpoint, i.e. within the framework of the relationship between health professional and patient or user of health services, which are usually considered as public services in the social and democratic constitutional state that is generally accepted as the model in the societies we are referring to. This obliges us to consider whether bioethics is really, as some insist, part of morality or ethics in the traditional sense or, on the contrary, whether the problems it deals with are inevitably legal ones, since the goods at stake in the relation referred to above (life, physical and moral integrity, health, personal autonomy, etc.) are recognised and protected by law in the whole of the Western world.

It therefore comes as no surprise that proposals for the "juridification of bioethics" have been made as a consequence of the above.[5] Indeed, the origins of bioethics as a discipline cultivated by a professional and academic community are legal ones in the countries in which it arose: to cite only the cases of the United States and Canada, the legal system itself has encouraged, if not forced, this juridification in the form of a judicialization that should be credited as having been the starting point for bioethics considered as an academic discipline.[6] This, however, is not without its perverse effects or consequences; a case in point would be the way in which it has modified the doctor-patient relationship, traditionally characterised by features of debatable value, such as paternalism, but also by others whose value is beyond discussion, such as trust, and which are nowadays severely threatened, especially in Western societies.

Juridification, in the sense of judicialization, allows the great majority of bioethical conflicts to be resolved a posteriori but at the same time fails to provide social and healthcare professionals with a decision-making model enabling them to decide their course of action within a time frame that is at best limited and at worst almost non-existent. This may be the reason behind the tendency to exacerbate the principle of patient autonomy as the key governing factor in the clinical relationship, with the de facto consequence that it functions more as a defence mechanism or a means of offloading responsibility on the part of health professionals than as an expression of respect for a patient's autonomy or a manner of exercising informed consent. For

[4] Cf. Drane, "What is Bioethics? A History", in Lolas and Agar (eds.), *Interfaces Between Bioethics and the Empirical Social Sciences*, Regional Program on Bioethics OPS/OMS Publication Series, Santiago de Chile, 2002, downloadable from http://www.paho.org/English/BIO/interfaces.pdf.

[5] Atienza, "Juridificar la bioética. Una propuesta metodológica", *Claves de razón práctica* 61 (1996).

[6] On the influence of the law on the shaping of bioethics, see Annas, *Standard of Care. The Law of American Bioethics*, New York, Oxford University Press, 1993.

this reason, the most appropriate form of juridification would appear to move in the direction of the contribution that the modern theory of law and legal argumentation can make as a reasoning tool in the decision-making process.

There are those who consider bioethics to be based on substantive principles, normally originating from comprehensive views of the world, mankind and human existence that are very often linked, either implicitly or explicitly, to religious outlooks on life. However, the prevailing paradigm in modern-day biomedical ethics is the one put forward by T.L. Beauchamp and J.F. Childress (henceforth Beauchamp and Childress) in *Principles of Biomedical Ethics* (1979), now considered a classic work in the field and widely endorsed in both academic and professional circles. Nevertheless, and in spite of its widespread acceptance, the 1990s saw the appearance of intense debate and criticism of this model, causing its authors to modify their stance in subsequent editions, of which there are now seven, the most recent of which was published in 2013. Curiously enough, this debate has until now been circumscribed to the North American social and cultural stage, even though European authors are involved in it.

Beauchamp and Childress' proposal (henceforth principlism) is based on a set of ideas which clearly display the influence of John Rawls, an author whose work they cite profusely; they include the irreducible nature of the substantive moral concepts that co-exist in our societies and the numerous ethical and philosophical theories that currently abound, rendering any kind of bioethics based on material principles unworkable and making it necessary to base proposals for bioethical decision-making models on intermediate-level principles.[7] Although the content of these intermediate principles is substantive, they show a noticeable tendency to operate in a formal and procedural way. According to Beauchamp and Childress, the principles in question are respect for autonomy, non-maleficence, beneficence and justice, and their model deals fundamentally with the decision-making process, leaving little room for what would have constituted the basic elements of a more traditional view of medical deontology, namely, the ethos of doctor-patient relations, on the one hand, and the virtues of health professionals, on the other. Although Beauchamp and Childress deal with both of these matters, they do so only marginally.

The principlist proposal has been widely scrutinised in the bioethical literature, being criticised by some authors whilst others defend it or suggest amendments. The critics who propose alternative models to principlism can be divided into two camps: those who approach the subject from the point of view of casuistry and those who do so from the standpoint of so-called common morality. Both schools of thought, however, generally coincide in pointing out the lack of functionality of the principlist model, attributing it to the fact that the principles listed above are by themselves insufficient to create a normative system endowed with unity, consistency and completeness (or fullness).

[7] In the sense put forward by Wildes, "Principles, Rules, Duties, and Babel: Bioethics in the Face of Postmodernity", *Journal of Medicine and Philosophy* 25/3 (2000) and subsequently accepted by Beauchamp and Childress in the 5th edition of their classic work (2001), p. 407.

Casuistry[8] has its roots in both the theories of moral casuistry and the Anglo-North American legal tradition, based on precedent. True to its origins, casuistry makes no claim to construct a system and instead proposes a problem-solving method that is not without issues of its own, including those deriving from the constantly shifting scenario and the constant novelty that is a characteristic of ethical problems, linked to the ongoing progress of life sciences in general and biotechnology in particular.

For its part, so-called common morality[9] holds that intermediate principles are unable to fulfil the objectives for which they were created, namely, to take the place of substantive moral theories and act as guidelines for deciding on the morally correct course of action. The authors who take this view stress principlism's lack of unity and consistency and highlight its conceptual and epistemic gaps, precisely with regard to what exactly constitutes a principle and how to work with them. With this as their starting point and drawing the distinction between morality and moral theory, they propose a model based on the former in which public or commonly accepted morality becomes the source for bioethical criteria, since it is recognisable and acceptable to any serious moral agent.

Beauchamp and Childress, together with some of their followers, have based their response to their critics on a strategy of eclectically integrating a selection of the proposals put forward as critiques of their theory. For example, in order to redress the lack of functionality and consistency, they have seen fit to add two further elements to the principlist model: specification and balancing. Specification has mainly been dealt with by Richardson,[10] whilst the authors who have developed the concept of balancing include, amongst others, DeMarco and Ford.[11] Beauchamp, meanwhile, has answered his critics directly in a number of journals,[12] even though some of the suggestions relating to balancing and specification were added to the principlist model in the fifth edition of *Principles of Biomedical Ethics* (2001). Curiously enough, it is the very lack of precision and consistency denounced by

[8] Cf., for example, Jonsen and Toulmin, *The Abuse of Casuistry*, Berkeley, University of California Press, 1988; Arras, "Getting Down to Cases: The Revival of Casuistry in Bioethics", *Journal of Medicine and Philosophy* 16 (1991); Wildes, "The Priesthood of Bioethics and the Return of Casuistry", *Journal of Medicine and Philosophy* 18/1 (1991); Strong, "Specified Principlism: What Is It, and Does It Really Resolve Cases Better than Casuistry?", *Journal of Medicine and Philosophy* 25/3 (2000); and Jonsen, "Strong on Specification", *Journal of Medicine and Philosophy* 25/3 (2000).

[9] Cf., for example, Clouser and Gert, "A Critique of Principlism", *Journal of Medicine and Philosophy* 15 (1990); Green, Gert and Clouser, "The Method of Public Morality vs. the Method of Principlism", *Journal of Medicine and Philosophy* 18 (1993).

[10] Cf., for example, Richardson, "Specifying, Balancing, and Interpreting Bioethical Principles", *Journal of Medicine and Philosophy* 25/3 (2000).

[11] "Balancing in Ethical Deliberation: Superior to Specification and Casuistry", *Journal of Medicine and Philosophy* 31 (2006).

[12] Cf. initially, Beauchamp, "Reply to Strong on Principlism and Casuistry", *Journal of Medicine and Philosophy* 25/3 (2000); Beauchamp, "Methods and Principles in Biomedical Ethics", *Journal of Medical Ethics* 29 (2003); and the 5th (2001), the 6th (2009) and the 7th (2013) editions of Beauchamp and Childress, *Principles of Biomedical Ethics*, Oxford University Press, New York.

their critics that makes their strategy possible, and in this regard, it can be considered far from satisfactory. It therefore makes sense to reiterate a number of these criticisms, as is done in some of the chapters in this book.[13]

Finally, proposals have also been made to steer the biomedical decision-making issue in the direction of professional deontology and/or virtue ethics[14] or to adopt an approach based on Gadamerian hermeneutics.[15]

Europe has also been strongly influenced by North American principlism but not without significant criticism.[16] Furthermore, it has been home to the development of a different principlist model involving four principles (autonomy, dignity, integrity and vulnerability) of which only the first coincides with those listed in North American principlism.[17] The mere enumeration of these principles reveals the different moral sensitivity to which they owe their origin (particularly in the case of dignity and vulnerability), although this only serves to confirm, rather than eradicate, the epistemological, systematic and conceptual difficulties highlighted by the critics of North American principlism.

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[13] An overview of this debate can be found in Smith Iltis, "Bioethics as Methodological Case Resolution: Specification, Specified Principlism and Casuistry", *Journal of Medicine and Philosophy* 25/3 (2000) and Davies, "The Principlism Debate: a Critical Overview", *Journal of Medicine and Philosophy* 20 (1995). Amongst authors writing in Spanish, cf. Ferrer and Álvarez Pérez, *Para fundamentar la Bioética: teorías y paradigmas teóricos en la Bioética contemporánea*, Bilbao, Desclée de Brouwer, 2003; Requena Meana, "Sobre la aplicabilidad del principialismo norteamericano", *Cuadernos de Bioética* 65 (2008); and Campos Serena, "Bioética principialista. El papel de la tradición norteamericana", downloadable at http://cfj.filosofia.net/2008 (last accessed 16 January 2016).

[14] Cf., for example, Pellegrino and Thomasma, *The Virtues in Medical Practice*, New York-Oxford, Oxford University Press, 1993.

[15] Cf. Lingiardi and Grieco, "Hermeneutics and The Philosophy of Medicine: Hans-Georg Gadamer's Platonic Metaphor", *Theoretical Medicine and Bioethics* 20 (1999); Svenaeus, "Hermeneutics of Clinical Practice: The Question of Textuality", *Theoretical Medicine and Bioethics* 21 (2000); and, by the same author, "Hermeneutics of Medicine in the Wake of Gadamer: the Issue of Phronesis", *Theoretical Medicine* 24 (2003), together with their accompanying references.

[16] In the Spanish context, the most noteworthy critical approach is that adopted by Gracia Guillén, who is undoubtedly the most influential author writing on bioethics in Spanish. From a standpoint that he himself defines as Aristotelian, Gracia at first accepted the postulates of principlism, although he established different levels between the principles concerned (cf. Gracia, *Fundamentos de Bioética*, Madrid, Eudema, 1989; Gracia, *Procedimientos de decisión en ética clínica*, Madrid, Eudema, 1991), but subsequently considered it too narrow, proposing that balancing should be carried out with regard to values rather than principles (cf. Gracia, "La deliberación moral: el método de la ética clínica", *Medicina Clínica* 117 (2001); Gracia, *Como arqueros al blanco. Estudios de Bioética*, San Sebastián, Triacastela, 2004).

[17] The proposal was published in 2002, as the outcome of a European BIOMED II research project (1995–1998) involving 22 professionals from a number of European Union member states. Cf. Rendtorff, "Basic Ethical Principles in European Bioethics and Biolaw: Autonomy, Dignity, Integrity and Vulnerability – Towards a Foundation of Bioethics and Biolaw", *Medicine, Health Care and Philosophy* 5 (2002); "Update of European Bioethics: Basic Ethical Principles in European Bioethics and Biolaw", *Bioethics UPdate* 2 (2015).

As we have seen, the debate is far from over on both sides of the Atlantic. Furthermore, at times insufficient attention is paid to the fact that the answers to a number of the problems, and even the problems themselves, have to be formulated in the light of the significant contextual differences between Europe and the United States in the field of healthcare. These differences include but are not necessarily limited to:

(a) The lack of a universal social healthcare model in the United States, in contrast to the universal social security model that prevails in Europe as an expression of the social and democratic constitutional state
(b) The prevalence of an individualistic mentality compared to the family- and community-based mentality that still prevails in Europe, particularly in Mediterranean countries
(c) A heightened liberalism, which leads to the doctor-patient relationship being seen as a private legal relation between individuals, with consequences that are considerably aggravated by the civil liability system characteristic of North American law, whilst in Europe healthcare enjoys the status of a public service, so that on the whole clinical and caregiving relations fit within an administration-constituent relational framework and the civil liability system lacks the punitive dimension to be found on the other side of the Atlantic
(d) The differences in mentality regarding the technique of legal and practical reasoning between the United States, where the common law method applies, and the majority of European countries, where practical rationality seeks to base decisions on more or less universal criteria (general norms of a legal, ethical or other nature)

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Bioethical Decision-Making and Argumentation owes its structure to a combination of the above-mentioned considerations and the order in which its chapters appear. The first three of these, which are general and expository in nature, provide a framework for debate and a context for the subsequent chapters, which introduce principlism (Chap. 1) and two of the main alternative biomedical decision-making methodologies: a deliberative and value-based approach (Chap. 2) and a human rights-based approach (Chap. 3). The next two chapters offer a critique of the prevailing principlist model from a dual perspective: its lack of sufficient grounding and functionality (Chap. 4) and its systematic shortcomings (Chap. 5). Chapters 6 and 7 highlight the importance of characterising both action and method (in this case deliberative) in biomedical decision-making processes, stressing the relevance of practical reasoning. The final two chapters of the book deal with the legal and institutional aspects of the debate: Chap. 8 appeals to the principle of proportionality or reasonability, from which standpoint it interprets the principle of double effect, whilst Chap. 9 considers the way in which the previous contributions act on decision-making processes taking place within the institutional framework of bioethics committees.

The book opens with an updated presentation of principlism by its leading representative, Tom L. Beauchamp, who in Chap. 1 describes the salient feature of his four-principle model, enriched by having incorporated the main criticisms levelled at it from the standpoints of virtue ethics and, above all, common morality, together with its use of specification to resolve concrete ethical problems in biomedical practice and research. In Chap. 2, Diego Gracia puts forward an alternative approach to that of the previous model, based from a substantive standpoint on the triad of facts, values (as opposed to principles) and duties and from a procedural one on deliberation, with its roots in Aristotelian philosophy. A view that comes closer to European principlism is presented in Chap. 3, where Roberto Andorno approaches bioethical and biotechnological problems from the human rights angle, describing its principal normative instruments at international level, the reasons for adopting such a perspective and, finally, its principal shortcomings, which are most visible in the biotechnology sphere.

In Chap. 4, Carolina Pereira highlights the difficulties principlism faces in justifying the moral norms underpinning bioethics, seen as a set of universally shared moral beliefs, and in providing rational guidelines for action in the biomedical field: in her view, the principlist model is handicapped by a certain degree of intuitionism and its abandonment of rational justification. Chapter 5, on the other hand, offers a critique of principlism in which Óscar Vergara approaches the issue from the perspective of normative systems, which apply to both ethics and the law. His analysis, of a kind not commonly encountered, reveals certain systematic shortcomings (e.g. lack of completeness, inconsistency and partial indeterminacy) that not only make it impossible for it to be taken as a comprehensive biomedical decision-making model but also render it unworkable in certain cases.

Pilar Zambrano devotes Chap. 6 to an aspect of the problem that instead of principles takes as its starting point the classification of actions, an issue that bioethical theories tend to ignore. If the purpose of ethics is to guide actions and determine their correctness, it is therefore essential to individualise and classify them in order to establish a correspondence between actions and principles or values. The author develops this view from the theoretical standpoint and provides a working example in the form of life-saving care, closely following Anscombe's thinking, with its roots in Aristotelian philosophy. This approach needs to be filled out with a description and evaluation of the form of reasoning followed in the biomedical decision-making process, which is provided in Chap. 7 by José-Antonio Seoane, who analyses the structure and principal characteristics of reasoning and the deliberative method in the field of bioethics, suggesting how it can be improved by incorporating elements from the legal theory and the theories of legal argumentation.

The final two chapters of the book are much more legal in nature. In Chap. 8, Juan Cianciardo studies the link between the legal principle of proportionality or reasonableness and the moral principle of double effect, classical in origin but of enormous relevance in the current ethical debate, in order to explore their validity and methodological suitability in the context of biomedical decision-making, where

to all appearances contradictory human rights come into play. Finally, Vicente Bellver devotes Chap. 9 to a more institutional approach, analysing the conditions needed to ensure good bioethical deliberation through a comparison of the most significant bioethical committees on the international stage, pointing out their respective strengths and weaknesses.

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May 2016

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