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THE BIRTH OF THE EMPIRICAL TURN IN BIOETHICS

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ABSTRACT

Since its origin, bioethics has attracted the collaboration of few social scientists, and social scientific methods of gathering empirical data have remained unfamiliar to ethicists. Recently, however, the clouded relations between the empirical and normative perspectives on bioethics appear to be changing. Three reasons explain why there was no easy and consistent input of empirical evidence into bioethics. Firstly, interdisciplinary dialogue runs the risk of communication problems and divergent objectives. Secondly, the social sciences were absent partners since the beginning of bioethics. Thirdly, the meta-ethical distinction between 'is' and 'ought' created a 'natural' border between the disciplines. Now, bioethics tends to accommodate more empirical research. Three hypotheses explain this emergence. Firstly, dissatisfaction with a foundationalist interpretation of applied ethics created a stimulus to incorporate empirical research in bioethics. Secondly, clinical ethicists became engaged in empirical research due to their strong integration in the medical setting. Thirdly, the rise of the evidence-based paradigm had an influence on the practice of bioethics. However, a problematic relationship cannot simply and easily evolve into a perfect interaction. A new and positive climate for empirical approaches has arisen, but the original difficulties have not disappeared.

I INTRODUCTION

When Albert Jonsen[1] published *The Birth of Bioethics* in 1998, he could already look back on a field that had boomed since the late 1960s. A new discipline had emerged through conferences,

[1] A.R. Jonsen. 1998. *The Birth of Bioethics.* Oxford. Oxford University Press.

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symposia, and publications, bringing together scholars from such diverse academic disciplines as medicine, law, philosophy, and theology to discuss the disadvantages, inconveniences, and harm of certain scientific and medical developments. The term 'bioethics' received its canonical status from the titles of Warren Reich's *Encyclopaedia of Bioethics* and Daniel Callahan's 'Bioethics as a Discipline', published in the first issue of the *Hastings Center Report*.[2] In 1998, Albert Jonsen counted almost 200 centres, departments, and programmes in bioethics, and about 1000 members of professional associations of bioethics in the United States. He observed how both theology and philosophy presided over the birth of bioethics and shaped the bioethical movement. 'Each brought a distinct tradition and perspective, together with analytic skills sharpened by their disciplines. Together they produced an amalgam of ideas, methods, and educational structures that became bioethics. But (. . .) the field was interdisciplinary.'[3] Physicians, lawyers, nurses, and social scientists were active colleagues of philosophers and theologians. Albert Jonsen acknowledged, however, that the relationship between the social sciences and bioethics had always been clouded. The field of bioethics did not attract the collaboration of many social scientists.[4] Their methods of gathering data were unfamiliar to ethicists, and the methods of ethicists were seldom known to social scientists. As a result, there was no 'easy and consistent flow of empirical data into ethics',[5] and bioethics had a 'simultaneously aloof and strained relationship' with the social sciences.[6] Although in the past this relationship was mostly absent (and rather stiff when it did exist), signs have recently appeared indicating an interest in a dialogue between the fields, so that some authors are talking about an 'empirical turn in ethics.'[7] The clouded relations between the empirical and normative perspectives on bioethics will be the focus of this article, which formulates a set of hypotheses as to why a gap exists between the disciplines and why there are some recent indications that this gap is closing.

[2] D. Callahan. Bioethics as a Discipline. *Hastings Center Report* 1973; 1: 66–73.

[3] Jonsen, *op. cit.* note 1, p. 84.

[4] G. Weisz. 1990. Introduction. In *Social Science Perspectives on Medical Ethics.* G. Weisz, ed. Dordrecht. Kluwer: 3–15.

[5] Jonsen, *op. cit.* note 1, p. 344.

[6] R.C. Fox. 1989. *The Sociology of Medicine.* New Jersey. Prentice Hall: xiii.

[7] G.D. Hartogh. Empirie en theorievorming in de ethiek [Empirical Evidence and Development of Theories in Ethics]. *Tijdschrift voor empirische filosofie [Journal for Empirical Philosophy]* 1999; 23: 172–177, at 175.

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In concrete terms, this article will concentrate on the relationship of normative bioethics to literature that is categorised as sociological,[8] empirical,[9] or experimental,[10] but also focuses on bioethical themes. This alternative bioethical literature has methodological roots in the social sciences and uses methods such as case studies, surveys, experiments, and participatory observation. The common objective is the gathering of qualitative and quantitative data about ethical issues. Unlike studies of ethical dilemmas via *a priori* ethical theories, principles, or rules, empirical studies focus on 'ethics-in-action.'[11] The themes studied by means of empirical research vary from how theoretical concepts such as dignity and autonomy are interpreted in the respective contexts of terminal illness[12] or hospital practise,[13] to the norms and values that appear in relation to organ transplantation,[14] informed consent and truth-telling,[15] end of life decisions,[16] persistent vegetative states,[17] genetic testing and screening,[18] etc. There are empirical data relevant to almost every debate that takes place in the field of bioethics, which is logical

[8] R.C. Fox & R. De Vries. 1998. Afterword: The Sociology of Bioethics. In *Bioethics and Society. Constructing the Ethical Enterprise*. R. De Vries & J. Subedi, eds. New Jersey. Prentice Hall: 270–276.

[9] P. Singer, E. Pellegrino & M. Siegler. Research in Clinical Ethics. *Journal of Clinical Ethics* 1990; 2: 95–99.

[10] D.C. Thomasma. Empirical Methodology in Medical Ethics. *Journal of the American Geriatrics Society* 1985; 5: 313–314.

[11] H. ten Have & A. Lelie. Medical Ethics Research between Theory and Practice. *Theoretical Medicine and Bioethics* 1998; 19: 263–276, at 269.

[12] H.M. Chochinov, Thomas Hack, Susan McClement, Linda Kristjanson & Mike Harlos. Dignity in the Terminally Ill. A Developing Empirical Model. *Social Science and Medicine* 2002; 54: 433–443.

[13] M. Schemer. 2001. *The Different Faces of Autonomy. A Study on Patient Autonomy in Ethical Theory and Hospital Practice*. Doctoral dissertation. University of Amsterdam.

[14] A. Guttmann & R.D. Guttmann. Attitudes of Healthcare Professionals and the Public towards the Sale of Kidneys for Transplantation. *Journal of Medical Ethics* 1993; 19: 148–153.

[15] P. Dalla-Vorgia, K. Katsouyanni, T.N. Garanis, G. Touloumi, P. Drogari & A. Koutselinis. Attitudes of a Mediterranean Population to the Truth-telling Issue. *Journal of Medical Ethics* 1992; 18: 67–74.

[16] J.M. van Delden, P.J. van der Maas, L. Pijnenborg & C.W. Looman. Deciding not to Resuscitate in Dutch Hospitals. *Journal of Medical Ethics* 1993; 19: 200–205.

[17] K. Dierickx, P. Schotsmans, A. Grubb, P. Walsh & N. Lambe. Belgian Doctors' Attitudes on the Management of Patients in Persistent Vegetative State (PVS): Ethical and Regulatory Aspects. *Acta Neurochirurgica* 1998; 140: 481–489.

[18] K. Dierickx. 1999. Adolescents and Carrier Testing: Attitudes and Ethical Presuppositions. In *Genetic Information: Acquisition, Access and Control*. A. Thompson & R. Chadwick, eds. New York. Kluwer Academic: 175–182.

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because the empirical publications reflect theoretical debates that are currently being held in the field.

This article is certainly influenced by the perspective from which we, the authors, observe the emergence of empirical research in bioethics. Having been trained in a normative approach to bioethical issues, we were puzzled by the relations between empirical data, and normative reflection and decision-making. Therefore, the following analysis is not only a sociological account of the recent evolution, but also a bioethical gaze at the boundaries between the fields. At this point in the article, a terminological remark may be appropriate. We will use the terms, 'sociology', 'social sciences', and 'empirical approaches' in a broadly interchangeable fashion. In the context of our topic, it seems more important to stress the semantic similarities of these terms than to emphasise their differences. We consider the empirical field developed here to be an interdisciplinary one that benefits not only from the work of sociologists and social psychologists, but also from researchers in medicine and public health, epidemiologists, health economists, and physicians.

This article is divided into two parts that bound a pivotal middle section. The first part ('Laborious dialogue') will indicate three categorical reasons why the relationship between the empirical and bioethical fields is not optimal: (1) pragmatic reasons, (2) historical reasons, and (3) a meta-ethical reasons. The pivotal section ('Changing relations') will draw attention to scholarly voices that herald a *rapprochement* between the disciplines. The final section ('Laboratory dialogue') will outline three hypotheses on why this relationship has changed recently: (1) dissatisfaction with the dominant applied method in bioethics, (2) the influence of clinical ethics, and (3) the appearance of evidence-based approaches.

II LABORIOUS DIALOGUE

Renée Fox is one of the rare medical sociologists who pays a great deal of attention to bioethics. She writes about bioethics as a social and cultural phenomenon[19] and studies, from a sociological perspective, concrete bioethical issues such as medical research and

[19] R.C. Fox. Ethical and Existential Developments in Contemporaneous American Medicine: Their Implication for Culture and Society. *Milbank Memorial Fund Quaterly/Health and Society* 1974; 52: 445–483. R.C. Fox. 1989. The Sociology of Bioethics. In *The Sociology of Medicine. A Participant Observer's View.* New Jersey. Prentice Hall: 224–276.

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the use of human subjects,[20] the withholding of medical or surgical treatment and nutrition,[21] and organ transplantation and dialysis.[22] In spite of her considerable research, she remains displeased about the limited interaction between sociology and bioethics. In 1984, she conducted fieldwork with Judith Swazey[23] in the People's Republic of China, in order to examine the meaning of the Chinese term 'medical morality', and obtain a cross-cultural perspective on what Americans call bioethics. They observe that bioethics is viewed by its practitioners as a largely a-cultural and trans-cultural discipline. The authors are disturbed by this kind of 'cultural myopia',[24] with its 'systematic inattention to the social and cultural sources and implications of its own thought.'[25] Fox and Swazey criticise the exaggerated value that American bioethics gives to the concepts of individualism and rational calculation, and their universal applicability. They explain that as the field has evolved, it has lost sight of the significance of the groups and communities to which it belongs, and of the principles of responsibility, commitment, and reciprocal obligation.

For Fox and Swazey, their findings were a strong indication that bioethics needed more considerable sociological input. They regret that the ethos of bioethics was created by philosophers, theologians, jurists, physicians, biologists, and even economists, while the participation of anthropologists, political scientists, and sociologists was quite limited, and thus sociological publications on bioethics were relatively sparse. Nevertheless, Renée Fox continues to strive for strengthened co-operation between bioethics and social sciences, and she has recently been supported by

[20] R.C. Fox. 1959. *Experiment Perilous.* Glencoe. The Free Press.

[21] R.C. Fox. 1996. Medicine, Science and Technology. In *Applications of Social Science to Clinical Medicine and Health Policy.* L.H. Aiken & D. Mechanic, eds. New Brunswick. Rutgers University Press: 13–30.

[22] R.C. Fox, J.P. Swazey & E.M. Cameron 1984. Social and Ethical Problems in the Treatment of End-Stage Renal Disease Patients. In *Controversies in Nephrology and Hypertension.* R.G. Narins, ed. New York. Churchill Livingstone: 53–58. R.C. Fox & J. Swazey. 1974. *The Courage to Fail: A Sociological View of Organ Transplants and Dialysis.* Chicago. University of Chicago Press. R.C. Fox. 1978. Organ Transplantation: Sociocultural Aspects. In *Encyclopedia of Bioethics.* W. Reich, ed. New York. Simon & Schuster: 1166–1169.

[23] R.C. Fox & J.P. Swazey. Medical Morality is not Bioethics – Medical Ethics in China and the United States. *Perspectives in Biology and Medicine* 1984; 35: 336–360.

[24] Ibid. p. 337.

[25] Ibid. p. 338.

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sociologists Georges Weisz[26] and Raymond De Vries.[27] However, the question remains why bioethics has found it so difficult to take the empirical sciences seriously or incorporate empirical data into its normative concepts and judgements. The next paragraphs outline three hypotheses that may explain this difficult relationship.

Firstly, dialogues between disciplines run the added risk of communication problems and opposing objectives. Secondly, the social sciences have historically been absent partners since the genesis of bioethics. Thirdly, the meta-ethical distinction between 'is' and 'ought' has created a 'natural' border between bioethics and the social sciences.

i Pragmatic reasons

From its inception, bioethics has developed as an interdisciplinary field with methodological and epistemological input from many different disciplines, including law, philosophy, theology, medicine, biology, and the social sciences. This discourse of interdisciplinarity supports the notion that input from different fields can expedite and improve the analysis and solution of particular problems. However, interdisciplinarity does not always guarantee better results and also has drawbacks.[28] The biggest difficulty that interdisciplinarity carries is the intrinsic gap between the conversing disciplines. This gap can cause miscommunication, which may involve speaking past one another, cognitive and conceptual dissonance, different cultures and styles, a structural lack of background and knowledge to judge or criticise the research results of another discipline, etc. The interdisciplinary gap also can result in opposing objectives that limit the conversing disciplines in their interaction.

Ethics and the empirical approaches start from different research questions. While the first is interested in conceptual clarification and normative justification, the second is focused on empirical description, reconstruction, and analysis.[29] These divergent research questions make bioethics a prescriptive discipline whose task is moral evaluation, and empirical sciences a

[26] G. Weisz. 1990. *Social Science Perspectives on Medical Ethics*. Dordrecht. Kluwer.

[27] R. De Vries & J. Subedi, eds. 1998. *Bioethics and Society. Constructing the Ethical Enterprise*. New Jersey. Prentice Hall.

[28] D. Birnbacher. Ethics and Social Science: Which kind of Co-operation. *Ethical Theory and Moral Practice* 1999; 4: 319–336.

[29] V.H. Schmidt. Bounded Justice. *Social Science Information* 1994; 33: 305–333.

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descriptive discipline that stresses the cultural setting.[30] The empirical sciences study bioethics for their own scientific agenda and are not necessarily interested in helping bioethics make better decisions. Sociologists do not want to solve ethical problems or evaluate whether ethical problems are solved properly or improperly. They are interested in how ethical problems arise, how they are structured, and how they are managed. By contrast, bioethics looks for clarity and wants to analyse the principles that should guide decision-making.[31] If bioethics improves thanks to a sociological input, this is mostly an 'unintended and unavoidable outcome': De Vries and Subedi speak in this context about a 'sociological version of the bioethical idea of double effect.'[32] Therefore, it is not surprising that little interaction exists between disciplines that at first glance are strongly related with respect to content, but make use of different methods and try to solve divergent questions.

ii Historical reasons

The domain of bioethics has developed into an autonomous research field over the last four decades. This section analyses how bioethics evolved as a field originally grafted onto theology and philosophy, which left little room for the social sciences. The historical analysis will focus on the development of bioethics in the United States. However, the cultural background of the 1950s and the four events that explain the rise of bioethical reflection certainly can be transferred to a European context. Nevertheless, at the level of organisation and method, ethical reflection about medical and technological advances differs strongly depending on where it is practised.

The specific intellectual and cultural background that formed the substratum for the emergence of bioethics was dominated by the phantom of the atomic experience. After the atomic bombing of Hiroshima and Nagasaki, a tradition of ambivalence towards scientific progress was born: scientific research did not necessarily lead to a better world, but could lead to death and murder. Tina Stevens[33] is correct in her interpretation that historians of bioethics tend to underestimate the formative nature of the

[30] De Vries & Subedi, *op. cit.* note 27, pp. xi–xix.

[31] C.L. Bosk. Professional Ethicist Available: Logical, Secular, Friendly. *Daedalus* 1999; 128: 47–68, at 65.

[32] De Vries & Subedi, *op. cit.* note 27, p. xvii.

[33] M.L. Tina Stevens. 2001. *Bioethics in America. Origins and Cultural Politics.* Baltimore. The Johns Hopkins University Press.

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post-atomic culture of the 1950s. However, the ambivalent stance towards techno-scientific advances would not lead to a dominant bioethical posture of antagonism towards medicine and science. It would instead place bioethical reflection in the footsteps of the post-war 'responsible science movement', which called for greater thoughtfulness about the regulation of atomic power.[34] Nevertheless, bioethics could only emerge thanks to a combination of this cultural background and some catalysing events of the 1960s and 1970s.

The first development was the exponential proliferation of technological innovations in biotechnology, molecular biochemistry, and pharmacology, which challenged traditional medical knowledge and practise. More precisely, medical innovations such as dialysis and kidney transplant, artificial respiration, resuscitation techniques, and prenatal diagnosis invited profound reflection.[35] Secondly, the debates on equal access to health services and equitable distribution of limited economic resources also required ethical reflection. Thirdly, social changes led to an emancipatory movement for the patient. Previously, decisions at the bedside were almost exclusively the concern of the individual physician; the authority of the physician and the traditional paternalistic relationship was now put under review. The physician encountered a new kind of patient, one who wanted to be heard and involved in medical decisions.[36] Finally, the lack of a common interpretative framework of moral guidelines for daily action, which Jean-François Lyotard calls the 'postmodern condition',[37] strengthened the importance of ethical and bioethical reflection.[38] The coexistence of opposing moral opinions and the presence of an intrinsically pluralistic moral context called for bioethical reflection.

These events explain why bioethical reflection received increasing attention and why bioethics as a discipline could start. Initially, people from many different disciplines, such as medicine, law, theology, biological sciences, social sciences, philosophy, humanities, etc. entered the dialogue. However, in a process of professionalisation and institutionalisation, the bioethical discussions

[34] Ibid. p. 12.

[35] D. Gracia. 2001. History of Medical Ethics. In *Bioethics in a European Perspective*. H. ten Have & B. Gordijn, eds. Dordrecht. Kluwer: 17–50.

[36] D.J. Rothman. 1991. *Strangers at the Bedside*. USA. Basic Books.

[37] J.-F. Lyotard. 1979. *La Condition Postmoderne: Rapport sur le Savoir*. Paris. Editions de Minuit.

[38] H.T. Engelhardt Jr. 1986. *The Foundation of Bioethics*. New York. Oxford University Press.

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quickly became anchored in the fields of theology and philosophy.

In the United States, the establishment of the Hastings Center, the 'Leader of the Leaders'[39] (1969), and government advisory commissions (e.g., about research involving human subjects in 1973) had an enormous influence on the creation of the bioethics profession. According to John H. Evans,[40] different professions or potential professions competed for jurisdiction over ethical decision-making. At stake in the battle was the question of who was empowered to decide ethical issues. Evans describes how scientists were alarmed by the idea that bioethical reflection was poised to come under more direct public control through the creation of publicly accountable regulatory mechanisms (i.e., in the field of human genetic engineering). Scientists devoted themselves to the creation of government *advisory* commissions instead of *regulatory* agencies. The report of the government commission on human experimentation (Belmont Report) selected a set of principles that would become a standard method of argumentation in bioethics – although the three original principles (respect for persons, beneficence, and justice) were later enlarged to four (respect for autonomy, nonmalificence, beneficence, and justice).[41] These principles evolved into a method of argumentation that was formal, rational, highly calculable, and applicable to any situation that arose. Through commissions, conferences, and journals, a group of people began to call themselves bioethicists, rather than theologians, philosophers, or any other professionals. They created a profession and a professional field of action.

At the inception of bioethics, theologians were the chief challengers to the scientists.[42] Theologians' strong roles undoubtedly came about because religious communities had a long tradition of reflecting on life, sufferings, and death, and were more involved in moral action than the analytical philosophical tradition that was dominant at the time.[43] The attention to ethical problems in the medical field was well suited to moral theology

[39] Tina Stevens, *op. cit.* note 25, pp. 46–74.

[40] J.H. Evans. 2001. *Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate.* Chicago and London. University of Chicago Press.

[41] T.L. Beauchamp & J.F. Childress. 2001. *Principles of Biomedical Ethics.* New York. Oxford University Press.

[42] Evans, *op. cit.* note 40, p. 37.

[43] L. Walters. 1986. Religion and the Renaissance of Medical Ethics in the United States. In *Theology and Bioethics: Exploring the Foundations and Frontiers.* E.E. Shelp, ed. Dordrecht. Kluwer: 3–16.

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(the practical counterpart of systematic or dogmatic theology), which focuses on the study of such fundamental domains as Christology, ecclesiology, and eschatology. The most important theologians to make an intellectual contribution to the study of bioethical questions were the Protestants Joseph Fletcher, Paul Ramsey, and James Gustafson, and the Catholics Richard McCormick and Charles Curran. They incarnated a reorientation of theological reflection, distancing themselves from natural law in favour of ethics based more on Biblical, historical, and personal elements.

In addition to the theologians, philosophers such as Hans Jonas, Samuel Gorovitz, Danner Clouser, Dan Callahan, and Stephen Toulmin entered the bioethical debates. They encountered the challenge of renouncing their own philosophical tradition, which concentrated on meta-ethical and speculative questions.[44] Normative ethics, the field that discusses ethical questions and develops ethical theories, was not considered a proper task for philosophers, but rather the business of preachers, novelists, politicians, journalists, and other non-philosophers. These philosophers refigured the philosophical tradition and brought a renewed interest for normative issues. Using standard philosophical methods, they introduced, in a medical context, a philosophical discourse focusing on conceptual analysis, critical evaluation, the elaboration of ethical theories, and the construction of logical and rational argumentation.

Despite the different backgrounds of philosophers and theologians, and the challenges of setting up a dialogue between the disciplines, they made advances towards one another, and bioethics emerged as a common field. Once they entered the bioethical research field, moral theologians lost their theological identity.[45] James Gustafson observed rather early on that the theological contribution to bioethical debates had disappeared steadily, and moral principles and values were now grounded in mere rational justifications without any reference to a religious framework.[46] According to Albert Jonsen, theologians were like 'strangers in a strange land' who had to devise new forms of communication amongst themselves, with their scientific and

[44] R. Baker. From Metaethicist to Bioethicist. *Cambridge Quarterly of Healthcare Ethics* 2002; 11: 369–379.

[45] D. Callahan. Religion and the Secularization of Bioethics. *Hastings Center Report* 1990; 20: 2–10.

[46] J. Gustafson. 1975. *The Contribution of Theology to Medical Ethics*. Milwaukee. Marquette University Press.

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medical colleagues, and with the public.[47] Entering the public practise of ethics, most theologians lost their special religious insights:

> Many of the religiously trained thinkers in bioethics moved back and forth between secular and religious formulations, shedding the dictates of bioethics' secular philosophical vocabulary and canon when they wrote about bioethically related matters for religious journals and magazines. In this respect, they intellectually 'commuted' between two distinct subcultures, alternately complying to the norms of each.[48]

How dominant the discipline of theology has been for bioethics in terms of presence and levelling the bioethical debates, yet how modest its influence in elaborating the conceptual framework of bioethics.

Mainstream bioethics evolved towards becoming a philosophical undertaking with the aim of finding solutions for moral problems in an impartial, unprejudiced, and non-culturally biased way. Ethical practise now involved a consideration of advantages and disadvantages in the search to justify one particular ethical option. The objective of this type of argumentation was not an absolute and definitive answer for moral problems, but rather a coherent and rational way of problem-solving. Mainstream bioethics focused on the application of ethical principles to concrete moral questions – mostly ethical dilemmas in terms of micro-relations (i.e., doctor-patient interaction) or macro-relations (i.e., allocation of resources).[49] The most commonly used method of ethical decision-making became principlism, which 'itself has become an institution.'[50] People who entered the bioethical debates adopted this form of argumentation and began calling themselves bioethicists, rather than scientists, theologians, or philosophers.[51]

Other disciplines such as law, medicine, and biology latched onto the bioethical field. A number of medical sociologists and

[47] A.R. Jonsen. 1994. Foreword. In *A Matter of Principles? Ferment in U.S. Bioethics*. E.R. Dubose, Ronald P. Hamel & Laurence J. O'Connell, eds. Valley Forge. Trinity Press International: xii.

[48] C.M. Messikomer, R.C. Fox & J.P. Swazey. The Presence and Influence of Religion in American Bioethics. *Perspectives in Biology and Medicine* 2001; 44: 485–508, at 490.

[49] P.R. Wolpe. From Bedside to Boardroom: Sociological Shifts and Bioethics. *HEC Forum* 2000; 12: 191–201.

[50] J.H. Evans. A Sociological Account of the Growth of Principlism. *Hastings Center Report* 2000; 30: 31–38, at 36.

[51] Evans, *op. cit.* note 40, p. 37.

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anthropologists also had an interest in the bioethical debates. Their presence, however, was minimal, and certainly not wished for by most bioethicists. Mainstream bioethics was patterned after the field of philosophy (with the aim of logical reasoning, conceptual clarity, coherence, and rational justification), to produce a rational and decontextualised discourse.[52] Bioethicists depicted sociological studies as irrelevant to their discipline because they feared being influenced too strongly by historical and sociological contextualisation, which could bog them down in cultural and ethical relativism. The hegemony of the philosophical tradition in bioethics since the inception of the discipline has led to the present situation, in which the social sciences are considered epiphenomenonal and peripheral to dominant bioethical thought. A fundamental meta-ethical reason stands at the base of this fear.

iii A meta-ethical reason

The fundamental reason that bioethics keeps empirical approaches outside its borders has to do with the usually strict distinction between descriptive and normative ethics. Descriptive ethics is the field in which empirical data about moral issues are gathered. It is the domain *par excellence* of sociology, anthropology, psychology, and epidemiology, and it aims at describing peoples' temporal values, rules, preferences, norms, and actions. These disciplines describe how reality is constructed – they describe what 'is.' However, they can never tell how people ought to behave, or what kinds of decisions are morally acceptable. According to most authors, this fundamental distinction stems from a small paragraph of David Hume's *Treatise of Human Nature* (1740), and is traditionally called the naturalistic fallacy. It is a logical mistake to infer a necessary conclusion from premises that are contingent in their modality, or to assign contingency to a conclusion that is inferred from premises that are necessary in their modality. The naturalistic fallacy consequently stresses that it is false reasoning to draw an ought-conclusion from premises that entirely consist of is-statements – one can never extrapolate an 'ought' from an 'is.' For this reason, ethicists became convinced that the results of social science research could never be useful for ethical reflection. This stance was also adopted by Immanuel

[52] D.W. Light & G. McGee. 1998. On the Social Embeddness of Bioethics. In *Bioethics and Society. Constructing the Ethical Enterprise*. R. De Vries & J. Subedi, eds. New Jersey. Prentice Hall: 1–15.

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Kant (1724–1804), who stated that ethics 'should be completely purified from everything that is empirical and belongs to anthropology.'[53]

These three categorical reasons lay at the basis of the traditional relationship between the empirical sciences and ethics. Ethicists believed that the purpose of empirical contributions was to provide 'just the facts' to an ethical enterprise that made the judgements.[54] Since its origin, the task of ethics was to seek 'to understand how human beings should act and what kind of life is best for people.'[55] This distinction between descriptive and normative ethics was historically not only a matter of division of tasks, but also an unbridgeable gap between factual reality and desirable reality. The traditional relationship between the social sciences and ethics thus assigned responsibility to the social scientists for amassing data and to ethicists for assessing them. According to this perspective, ethics is the normative core discipline and the social sciences merely empirical auxiliaries.

III CHANGING RELATIONS

Due to the reasons described above, empirical contributions to bioethics before the 1980s were very limited. There were only a few studies relevant to the field (i.e., the social contexts of terminal illness and death in American hospitals, the use of human subjects in medical research).[56] These studies were rarely recognised in the bioethical literature because ethicists were not convinced of their potential contributions to bioethical reflection. However, the attitudes of some ethicists towards empirical contributions have changed in the last two decades. A growing number of bioethicists have welcomed empirical research in bioethics as a positive step for medical ethics and bioethics. In 1980, for example, Daniel Callahan wrote the prophetic words that 'those in ethics must learn to work more closely with those in the law and the social sciences.'[57] In 1985, David C. Thomasma

[53] I. Kant. 1785. *Grundlegung zur Metaphysik der Sitten*. Nachdruck der Akademieausgabe (1902–1955). Vol. IV: 389.

[54] J. Lindemann Nelson. Moral Teachings from Unexpected Quarters. Lessons for Bioethics from the Social Sciences and Managed Care. *Hastings Center Report* 2000; 30: 12–17, at 12.

[55] M. Slote. 1995. Task of Ethics. In *Encyclopedia of Bioethics*. W. Reich, ed. New York. Simon & Schuster: 720–727, at 720.

[56] For an overview see: Fox, *op. cit.* note 6; Weisz, *op. cit.* note 26.

[57] D. Callahan. Shattuck Lecture – Contemporary Biomedical Ethics. *The New England Journal of Medicine* 1980; 302: 1228–1232.

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optimistically described new experimental research from which important theoretic concerns, moral axioms, and standards of conduct could emerge. 'This is not to disparage intellectual efforts in medical ethics, but rather to say that use of the experimental method in medical ethics, just as in medicine, can only enhance the field's contributions to practical decision making.'[58] These statements illustrate the desire of a number of important voices in the bioethical research field for stronger involvement with the social, cultural, and cross-cultural aspects of morality; with the opinions, interests and beliefs of patients, families, physicians, nurses and others involved in care-giving; and with national and international policy.

There was more to this movement than a few little-noticed declarations, because the empirical field has evolved remarkably quickly over the last two decades. Scholars now suggest that the use of sociological, anthropological, epidemiological, and psychological methods to study ethical issues has emerged as a novel form of scholarship in bioethics,[59] that a 'new form of ethics paper' has appeared,[60] and that bioethicists' interest in empirical data continues to grow.[61] Research indicates that the empirical research field in bioethics grew during the 1980s. An investigation into postings on Bioethicsline (a database of the National Reference Center for Bioethics that is now available through the National Library of Medicine) calculated that the proportion of empirical research postings increased steadily from 1.5% in 1980 to over 5% in 1989.[62] The corpus of sociological research in bioethics covered themes that included experimentation with human subjects, informed consent, death and dying, genetic screening and counselling, resource allocation, organ transplantation, quality-of-life, abortion, and foetal research. Although there are no research data available for the last ten years, one glance at the peer-reviewed bioethical journals confirms that empirical research has apparently gained ground in bioethical research field. One significant change was the 1997 notice for

[58] Thomasma, *op. cit.* note 10, p. 313.

[59] B.A. Brody. Quality of Scholarship in Bioethics. *Journal of Medicine and Philosophy* 1990; 15: 161–178.

[60] R. Arnold & L. Forrow. Empirical Research in Medical Ethics: An Introduction. *Theoretical Medicine* 1993; 14: 195–196, at 195.

[61] A.C. Molewijk, A.M. Stiggelbout, W. Otten, H.M. Dupuis & J. Kievit. Implicit Normativity in Evidence-Based Medicine. A Plea for Empirical Ethics Research. *Health Care Analysis* 2003; 11: 69–92.

[62] J. Sugarman, Ruth Faden & Judith Weinstein. 2001. A Decade of Empirical Research in Medical Ethics. In *Methods in Medical Ethics.* J. Sugarman & D. Sulmasy, eds. Washington, DC. Georgetown University Press: 19–28.

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contributors to the *Journal of Medical Ethics*: for the first time, the editors gave guidelines for submitting manuscripts about empirical research. Despite the fact that empirical-ethical research remains a minority in the bioethical field, there is a growing support for these researchers and an increased willingness to publish their studies.

IV LABORATORY DIALOGUE

The next paragraphs advance a number of hypotheses as to why the relations between bioethics and empirical sciences have changed, and why bioethics now tends to make more room for empirical research. These hypotheses involve an analysis of (1) how a theory-driven bioethics that did not sufficiently take practical reality into account has been criticised, (2) how clinical ethics increased the awareness of empirical research in bioethics, and (3) how the paradigm of evidence-based approaches is taken up in the vocabulary of bioethics.

i Deficit of ethics?

The first part of this article analysed how theologians and philosophers dominated mainstream bioethics, modelled the new discipline after their own categories and concepts, and developed normative ethical theories to determine which general moral norms should guide and evaluate moral conduct. As well as conceptualising ethical theories, applied ethics attempted to use general norms and theories with reference to particular moral problems and contexts.[63] Unlike medical ethics, which concentrated on the deontological code and the internal morality of medical doctors, bioethics developed as an autonomous discipline, one that was not the exclusive domain of physicians. Its methods consisted of applying theoretical principles to the practise of health care – 'first principles, then practise.'[64] This was a translation of basic principles and rules into practise tools, thus making them available for everyday judgements and decisions. The concept of applied ethics is based on a top-down rationalistic and deductive model, and can be used for all kinds of ethical problems (i.e., suicide, abortion, animal rights, nuclear arms, euthanasia, etc.).[65] By applying ethical theories and principles,

[63] Beauchamp & Childress, *op. cit.* note 41.
[64] ten Have & Lelie, *op. cit.* note 11, p. 265.
[65] P. Singer. 1986. Introduction. In *Applied Ethics*. P. Singer, ed. Oxford. Oxford University Press: 1–7.

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professional ethicists can proffer practical recommendations and prescriptions on ethical problems supplied mainly by non-ethicists.[66]

In recent years, criticism has been levelled against this form of applied ethics. Applied ethics was considered too abstract, too general, too speculative, and too dogmatic.[67] At the same time, ethicists were criticised for being too far removed from clinical reality, insensitive to the peculiarities of specific situations, and unable to adequately consider the nature of diseases and the clinical contexts in which clinicians and patients were confronted with ethical problems.[68] Nor did applied ethics offer moral guidance in the chaos of conflicting moral principles,[69] because it lacked consensus on the particular theoretical framework that should guide the rational selection of principles to be applied. In the opinions of some authors, these failings resulted in the growing practical and intellectual irrelevance of applied ethics.[70] However, the foundationalist approach has since ceased to be the dominant paradigm in applied ethics.[71] Applied ethics is now considered to refresh the relationship between theory and practise. Applied ethics is no longer synonymous with applying theoretical principles or formal procedures to particular situations, but is an essential part of the search for a 'reflective equilibrium' between theory and practise.[72] Practising applied ethics involves concretising principles, norms, and concepts in order to make them useful for practise in a specific context.

In response to the critiques of the foundationalist approach in applied ethics, and as part of the attempt to operationalise its basic principles, the focus of bioethics drifted away from a purely theory-driven approach towards a moral theory that was more grounded in practical reality. Dissatisfaction with the one-sided interpretation of applied ethics constituted an excellent substrate

[66] H. ten Have. The Hyperreality of Clinical Ethics: a Unitary Theory and Hermeneutics. *Theoretical Medicine* 1994; 15: 113–131.

[67] R. Zussman. The Contributions of Sociology to Medical Ethics. *Hastings Center Report* 2000; 30: 7–11. K.D. Clouser & B. Gert. A Critique of Principlism. *Journal of Medicine and Philosophy* 1990; 15: 219–236.

[68] R.C. Sider & C.D. Clements. The New Medical Ethics: A Second Opinion. *Archives of Internal Medicine* 1985; 145: 2169–2179.

[69] B.A. Brody. 1988. *Moral Theory and Moral Judgments in Medical Ethics.* Dordrecht. Kluwer Academic Publisher.

[70] B. Hoffmaster. Can Ethnography save the Life of Medical Ethics? *Social Science and Medicine* 1992; 35: 1421–1431.

[71] Birnbacher, *op. cit.* note 28.

[72] L. Bouckaert. An Agenda for Applied Ethics. *Ethical Perspectives* 1995; 2: 39–42.

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for a plea in favour of integrating social and cultural contexts with ethical clarification and decision-making. These trends helped stimulate the incorporation of empirical research in bioethics. Some authors presumed that the use of empirical research in ethics could help translate more general and abstract principles into concrete and specific action-driven directives and guidelines that are both morally justified and workable in practise. Empirical studies could rectify bioethical short-sightedness and provide better, more workable solutions for moral dilemmas. The call for empirical research should make ethicists better able to take into account actual experiences, meanings, and moral decisions of caregivers and care-receivers in their ethical frameworks. The focus on empirical knowledge supports Hoffmaster's statement that moral decision-making has more to do with 'muddling through' problems than with rational problem-solving.[73] However, the call for empirical research has strengthened: changing attitudes within the ethos of bioethics and empirical researchers' increased attention to ethical themes were brought about by the emergence of clinical ethics (see sub-section IV.2) and the increasing attention to evidence-based approaches (see sub-section IV.3).

ii Clinical ethics

According to Robert Arnold and Lachlan Forrow, the stimulus to increase empirical research on bioethical issues came not from psychologists, anthropologists, or sociologists, but from clinical epidemiologists in particular.[74] The influence of clinical ethics here is clearly observable. In response to the previously described inadequacies of applied ethics, clinical ethics developed as a 'bedside' form of ethics that takes the reality of the clinician-patient encounter as its starting point. Clinical ethics evolved into a distinct field, with an emphasis on the ethical problems that arise in caring for patients and an aversion to the deductive model of ethical analysis. It focuses on elaborating a method of ethical evaluation that is particularly well-suited to individual clinical cases.[75] Clinical ethics also finds methodological support in the

[73] Hoffmaster, *op. cit.* note 71.

[74] Arnold & Forrow, *op. cit.* note 60.

[75] M. Siegler. Decision-making Strategy for Clinical-Ethical Problems in Medicine. *Archives of Internal Medicine* 1982; 142: 2178–2179. M. Siegler. A Legacy of Osler. Teaching Clinical Ethics at the Bedside. *Journal of the American Medical Association* 1978; 239: 951–959.

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renewal of interest for casuistry.[76] Clinical ethics is mainly practised by clinicians (such as physicians, nurses, social workers, etc.), and differs in that respect from applied ethics, which is most often practised by non-clinicians. Due to their solid medical knowledge, those clinicians with knowledge of an ethical vocabulary and methodology are considered by many to function better in a clinical setting than non-clinicians, who often are regarded sceptically by clinicians. It is not surprising that clinical ethicists became engaged in empirical research to measure the frequency of ethical problems, the practical impact of ethical policies, and the way in which ethical decisions are made. Clinical ethicists use the methods of the social sciences, decision analysis, clinical epidemiology, and health services research to collect and analyse relevant clinical and ethical data. In their desire to bring ethics closer to the realities of clinical practise, clinical ethicists have followed the path of ethnographic and sociological research.

The plea for contextualisation has been formulated not only by clinical ethics, but also by a spectrum of approaches including situation ethics, feminist ethics, casuistry, and the narrative approach. Joseph Fletcher's notion of situation ethics emphasises the social and cultural embeddedness of ethics. This Anglican theologian argues that there are no fixed principles or rules that can judge individual actions, but instead there are individuals who act in a certain way in a concrete context. To judge an act is to judge the situation in which the act occurred.[77] Feminist ethics criticises the abstract, universalised, and principled method of ethical reasoning propagated by men, and defends a feminine way of ethical reasoning which focuses on the concrete, relational, and contextual, and includes feelings and emotions.[78] Casuistry has been reintroduced in bioethics as a method for ethical analysis. Its aim is to keep moral reflection close to cases, paying attention to both principles and factual situations. Casuistry lines up similar cases and takes into account the particular circumstances of time, place, and person.[79] Linked to casuistry, the

[76] A.R. Jonsen & S.E. Toulmin. 1988. *The Abuse of Casuistry: A History of Moral Reasoning*. Berkeley. University of California Press. A.R. Jonsen. Casuistry as Methodology in Clinical Ethics. *Theoretical Medicine* 1991; 12: 295–307.

[77] J. Fletcher. 1966. *Situation Ethics: the New Morality*. London. SCM.

[78] C. Gilligan. 1982. *In a Different Voice: Psychological Theory and Women's Development*. Cambridge, MA. Harvard University Press.

[79] Jonsen & Toulmin, *op. cit.* note 76. Jonsen, *op. cit.* note 76. J.D. Arras. Getting Down to Cases: The Revival of Casuistry in Bioethics. *Journal of Medicine and Philosophy* 1991; 16: 29–51.

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narrative approach also has been used in bioethics. Narratives provide an opportunity for imaginative moral reflection and serve as a proving ground for moral argument. Narratives play a role in moral reasoning because they are exemplars as well as tests. Narratives act as situated knowledge because they locate events in peoples' lives and concerns.[80] Like clinical ethics, these approaches attempt to integrate the social and historical contexts of moral decisions into ethical considerations.

iii Evidence-based approaches

The emergence of evidence-based approaches in healthcare was typified by the systematic introduction of scientific proof in health-related interventions. This movement relies on the conviction that healthcare practises will improve by means of decision-making based on a careful appraisal of the best available evidence.[81] During the 1990s, evidence-based approaches became prominent on national and international agendas for health policy and research. Price Waterhouse Coopers' survey Health Cast 2010: 'Smaller World, Bigger Expectations' described the evidence-based approach as one of the most important trends of the next decade for healthcare services.[82] The earliest use of the term 'evidence-based medicine' (EBM) dates to 1992,[83] when the Evidence-Based Working Group stressed that clinical practise could no longer be based on unsystematic observations, medical intuition, pathophysiologic principles, traditional medical training, content experience, or clinical experience, but instead should be based on the most recent available medical evidence. Through the systematic use of scientific evidence in clinical

[80] R. Charon. 1994. Narrative Contributions to Medical Ethics: Recognition, Formulation, Interpretation, and Validation in the Practice of the Ethicist. In *A Matter of Principles? Ferment in U.S. Bioethics*. E.R. Dubose, Ronald P. Hamel & Laurence J. O'Connell, eds. Valley Forge. Trinity Press International: 260–283.

[81] J.A.M. Gray. 1997. *Evidence-based Health Care: How to Make Health Policy and Management Decisions*. New York. Churchill Livingstone.

[82] Price Waterhouse Coopers. 2000. *Health Cast 2010: Smaller World, Bigger Expectations*. Belgium.

[83] Evidence-Based Medicine Working Group. Evidence-Based Medicine, A New Approach to teaching the Practice of Medicine. *Journal of the American Medical Association* 1992; 268: 2420–2425. P. Borry, K. Dierickx & P. Schotsmans. De statistische dictatuur? Ethische kanttekeningen bij tien jaar evidence-based Medicine [The Statistical Dictatorship? Ethical Considerations on the Occasion of the Tenth Anniversary of Evidence-based Medicine]. *Tijdschrift voor geneeskunde en ethiek [Journal of Medicine and Ethics]* 2002; 12: 107–112.

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decision-making, practitioners of EBM hope to deliver better, more responsible care.[84] Those who defend EBM assert that patients do not always receive the best available care because of professional habits, ignorance, uncertainty, or financial motives. More diagnostic explorations and therapeutic interventions are executed and more drugs prescribed than is strictly necessary. According to EBM, healthcare could be adjusted and made more uniform by utilising the latest scientific evidence. Evidence-based medicine has designated itself as a new paradigm and assumed a position diametrically opposed to traditional medicine. Our personal dissatisfaction with the dualistic distinction between a scientific, ethical, 'good', evidence-based medical practise and an anti-scientific, unethical, 'careless', non-evidence-based medical practise has already been stated in another article.[85]

After 1995, use of the term 'evidence-based' has boomed. It appears in combination with words such as practise, nursing, healthcare, and decision-making, and even with ethics. Some authors employ the phrase evidence-based ethics (EBE), interpreting it either as the necessity of grounding ethical decisions in the best available medical scientific evidence,[86] or the necessity of testing ethical arguments and statements by means of empirical research.[87] The rise of the 'evidence-based' model in the last decade has certainly influenced the practise of bioethics. The rise of EBE represents the crystallisation of a growing desire to integrate empirical elements with ethical conceptualisation and decision-making, and reflects the trend to attribute more value to empirical research in bioethics. That our culture is imbued with the evidence-based doctrine emerges, among other ways, from the growing requirement to connect an empirical component to bioethical research in order to obtain research grants.[88]

[84] D.L. Sackett, William M.C. Rosenberg, J.A.M. Gray, R. Brian Haynes & W. Scott Richardson. Evidence based Medicine: What it is and what it isn't. *BMJ* 1999; 312: 71–72.

[85] Borry et al., *op. cit.* note 84.

[86] T.L. Major-Kincade, J.E. Tyson & K.A. Kennedy. Training Pediatric House Staff in Evidence-Based Ethics: an Exploratory Controlled Trial. *Journal of Perinatology* 2001; 21: 161–166. J. Tyson. Evidence-based Ethics and the Care of Premature Infants. *Future Child* 1995; 5: 197–213.

[87] R.P.S. Jansen. Evidence-based Ethics and the Regulation of Reproduction. *Human Reproduction* 1997; 12: 2068–2075.

[88] D. Magnus. Careers in Bioethics. *Penn Bioethics* 2002; 10: 6–7.

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V CONCLUSION

This article looks back on a field that has boomed over the last two decades. The empirical turn in ethics is a common denominator for the interests of sociologists, psychologists, researchers in medicine and public health, epidemiologists, health economists, physicians, and ethicists who take an empirical approach to bioethical issues. Unlike bioethics, which has been shaped into a new discipline, the amalgam of empirical contributions can be best described as a field, gathering researchers from different disciplines with an empirical orientation. The emergence of this 'new form of ethics paper',[89] based on empirical research of bioethical issues, is an important shift in the bioethical movement. From its inception, bioethics was dominated by philosophers and theologians who modelled the discipline according to their traditions – social scientists were rare strangers in the field. Only recently has empirical research come to the attention of bioethicists. In this article, three hypotheses have been outlined to explain the increasing amount of empirical research in bioethics: the criticism addressed towards mainstream bioethics, the rise of clinical ethics, and the development of the evidence-based paradigm.

An exclusive focus on the increasing use of sociological, anthropological, epidemiological, and psychological methods to study bioethical issues could, however, overshadow the inherent differences between the fields. It is unrealistic, undesirable, and certainly not the intent of this article to depict an idyllic scene in which the empirical approach merges smoothly with the normative approach in bioethics. The risk of an article that starts with an overview of reasons for a gap between two disciplines and ends with an overview of hypotheses as to why this gap is being closed, is the risk to be interpreted historically. However, the initial obstacles have not been removed. A new and positive climate towards empirical approaches has arisen, but the original difficulties have not disappeared.

At its start, this article promised to formulate some hypotheses as to why a gap exists between empirical and ethical approaches, and why there are some recent indications that this gap is closing. At the end of the article, this statement must be adjusted by adding that the gap will never be closed, nor is it desirable that it should close. The three reasons analysed in the first part of the article will be decisive for the future relations between the

[89] Arnold & Forrow, *op. cit.* note 60, p. 195.

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normative and empirical perspectives on bioethics. However, the reasons described are not static entities, but dynamic elements that must be reformulated continuously.

Firstly, the pragmatic reason makes it difficult for divergent fields to become closer to one another. Nevertheless, increased knowledge and intense collaboration can connect the fields. Secondly, history cannot be overruled. Mainstream bioethics was patterned after the disciplines of philosophy and theology. Insisting on conceptual clarity, coherence, and rational justification, theologians and philosophers rejected sociological studies that emphasised historical setting and social embedding and defended the value of contextualism. Critics of this conception of ethics argued in favour of integrating social and cultural contexts with ethical clarification and decision-making, and thus formulated a call to integrate more empirical research in ethics.

Thirdly, the sharp traditional distinction between the philosophical (normative) and social science (empirical) approaches to bioethics has been criticised. Robert Zussman, for example, considers the first more explicitly normative and the latter more explicitly empirical.[90] He retains the sectional distinctions and characteristics of both disciplines, but denies their structural incompatibility and acknowledges their fundamental complementarity. Zussman emphasises that the belief in an unbridgeable gap is mistaken. However, he never points out that a valid distinction cannot be made between 'is' and 'ought', or between empirical and normative approaches. Zussman does not want to derive what is morally right or wrong from empirical research, but rather believes in the positive value of incorporating empirical material in ethical reflection. What that contribution can consist of is a matter of discussion, but almost all social scientists and ethicists believe that there is a contribution to be made. This belief has opened the way to better relations between the disciplines and motivated mutual collaboration. The attitude of giving up the stringent difference between value and fact is what Clements calls 'the more optimistic Humean choice',[91] referring to an alternative reading of David Hume's *Treatise of Human Nature*.

That the empirical approach in bioethics has emerged over the last two decades is clear; how its emergence will change bioethical reflection and decision-making is, however, still unclear. This lingering uncertainty is the most controversial topic in the debate

[90] Zussman, *op. cit.* note 67.

[91] C.D. Clements. Bioethical Essentialism and Scientific Population Thinking. *Perspectives in Biology and Medicine* 1985; 28: 188–207.

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over the rise of the empirical approach in bioethics. While most ethicists admit the positive contributions of empirical methods in bioethics, the dialogue concerning its actual, concrete contributions is contentious. Many ethicists fear that the factual situation will dictate the way that we 'ought' to behave. Reflecting on the purpose, rationale, and limitations of the empirical contribution to bioethics is a necessary and important ethical and meta-ethical challenge. These debates must design an ethical framework, to give insight into the relationship between empirical data and ethical principles or theories, and a methodology, to allow the integration of empirical information in ethical reflection and decision-making. This reflection builds a bridge between a laborious dialogue, in which interaction and exchange is impossible, and a laboratory dialogue, in which interaction and exchange may occur.

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