Quo Vadis Medical Healing

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Editors

Quo Vadis Medical Healing

Past Concepts and New Approaches

Springer

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Preface

"Healing in Medicine" – the subject of this volume evolved in part as the continuation of an earlier gathering in 1999 in Berlin, when an interdisciplinary group of scholars came together to discuss some of the medical issues confronting us at the brink of the new millennium (now as *Medical Challenges for the New Millennium: An Interdisciplinary Task*[1]). Already during our earlier meeting it became clear that the question "what do we mean by medical healing" poses similarly profound challenges that are, once again, best addressed by an interdisciplinary group of scholars.

At first sight the answer to the question "what do we mean by medical healing" appears to be straightforward. However, to know what "medical healing" means implies knowledge or at least some cognizance of the assumptions that underlie our understanding of "health," and, concomitantly, how we define well-being and its opposites, illness and disease. Or to use the words with which Galen opened his *The Art of Medicine*: "[M]edicine is the knowledge of what is healthy, what is morbid, and what is neither; it makes no difference if one uses the term 'diseased' instead of morbid. … What is healthy, what is morbid and what is neither – each of these comes in three different categories – of the body, cause, and sign."[2]

Galen's notions of health – and here we come to one of the most central aspects revealed by our volume – were formulated within a cultural context which had a fairly cohesive and widely shared worldview that provided both Galen as well as his "elite" audience with rather clear and thus relatively easily communicated ideas about health and morbidity. Yet even Galen, operating in a far more homogeneous cultural universe (in which, for example, a person's dietary regime but also the place where he came from and resided formed part of "medicine") than we do today, contradicted his own definitions of health and morbidity on a number of occasions. Many of his contemporaries, especially his medical competitors, disagreed profoundly with his definitions: then as now, in other words, health and healing, and what we mean by them, are both culturally determined yet also individually and physiologically specific.

Since Galen, much, of course, has changed. Today, health, health care (business, wellness, recreation), and medicine (especially research-driven scientific medicine) have become, at least in part, separate entities with different institutions, budgets, marketing philosophies, and "corporate cultures." What has remained relatively

unchanged since the times of Galen, however, is the fact that what healing is and how to achieve it is not the same for everyone. The place where one lives still matters today – health and healing do not mean the same from continent to continent. What it means to be healthy and especially to attain or maintain health differs depending on the developmental state of the country in which one resides, developing or developed, and does not mean the same even within such "contexts," i.e., there are profound differences among the respective states of the USA or in the different member states of the European Union. Even within the nation state, rural versus urban residence and cultural patterns will determine approaches to health care. A country's and a person's wealth, legal framework, medical traditions, prevailing religious foundations, in short, its cultural constructs are all determining factors of what healing and health mean in practice. Globalization may work for Coca Cola, but it stops short in the arena of medical healing.

If, as has always been the case, one person's "poison" is another person's "cure" – the Greek term *pharmakon* aptly means both – then what are some of the factors that influence our notions of health, healing, health care, medicine, and medication, in Western developed nations and elsewhere? Watson and Crick's discoveries 50 years ago have opened recent avenues (and in few cases the reality) of "healing" on a molecular level, tailor-made for each and every one of us. The sometimes virulent debates regarding stem cell research, pre-implantation diagnostic, "cloning," genetic engineering and so on are well known to all of us, as are the profoundly different reactions of ethics panels, researchers, health advocates, and legislators not only between, but even within countries.[3] Related issues are the market forces and financial considerations undergirding notions of health: What drives pharmaceutical research? Who makes decisions regarding the fate of cures or at least the containments of illnesses that affect millions, but where effective medication has been difficult to develop, inefficient to produce profitably, or hard to patent securely? Why aim for the development of highly costly treatments for conditions that affect only a few thousand but which guarantee a high return on investment? What does a venture capitalist want to see before investing in a biomedical start-up, and why? What are the "ethical" costs of investing millions of research dollars into drugs that are a necessity for few but a "lifestyle" enhancer for many?

Both Viagra as well as fertility treatments (and thus the hotly debated "raw-materials" that are their byproduct) may be seen as such "lifestyle" cures. They do not, arguably, treat diseases affecting many thousands, as does, for example, malaria, yet they are by now standard aspects of health care, not least because they affect another issue that is central to our debate: quality of life. As we all know, of course, healing, health, and quality of life and their inverse are – again – individual and subjective, yet at the same time and in no small part also culturally determined. What is "quality of life" and who should have the authority to decide its relevance for each and every autonomous "patient"? And, intrinsically related to these questions, what role does pain play for us today? Do we have clinical definitions of pain that work as well as our various legal ones? Historically, pain and suffering played a central role in Western (Christian) culture, but what exactly was that role? Has the role of pain and suffering changed, and if so where and how? To what degree is the

recourse to religious heritages justified when answering questions related to modern ethical challenges surrounding notions of health, be it the evaluation of pain, the use of stem cells to ameliorate suffering, or the delay of AIDS vaccine trials? In short, what does medical healing mean for us today? We believe that a comprehensive approach to these issues, one that takes into account the historical, scientific, corporate, and legal dimensions of healing offers much in the way of fruitful and multifaceted analysis.

This volume brings together chapters on, and discussions of, these and similar topics that took place in the course of a symposium at Schloss Elmau, Bavaria, in May 2003. We are very grateful to all the participants in our symposium, both the presenters and our audience, for their enthusiasm and personal initiative. Special thanks are due to Dieter Müller-Elmau and his staff, who welcomed us at the lovely Schloss Elmau, an ideal setting for intensive yet enjoyable debates. We further wish to express our thanks to AstraZeneca for their financial support. Dr. Anne Berghöfer and Tatjana Ossowski were invaluable in their help with the organization of the symposium and the compilation of this volume. Springer (formerly Kluwer Academic Publishers) once again provided their expertise and guidance in the production of this book.

Susanna Elm and Stefan Willich

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3. See, for example, the differing legislative approaches in California and on the US federal level regarding stem cell research; or the related articles in the *FAZ* (e.g., February 19, 2003) which features series regarding genetics and related topics, reflecting widely divergent opinions from theologians, ethicists, geneticists, etc. See also Paul and Nettesheim in this volume.

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Part I
Philosophical and Ethical Foundations

The initial chapter provides an ethical framework for health care from a political perspective. Annette Schulz-Baldes from Zurich University Centre for Ethics describes different strategies to address the scarcity of resources for health care and analyses respective of ethical and economic consequences. She argues that the future of health care will be more or less political depending on the management of rationing decisions. In the following chapter, Thomas Heinemann, who holds joint degrees in philosophy and medicine, offers definitions of the terminology of healing, curing, and health and their ethical and medical implications, and discusses the reciprocity between the concepts of disease and of medical action.

How Political Is the Future of Health Care? Allocating Scarce Resources in Liberal Democracy

Annette Schulz-Baldes

1 Introduction

Medical progress has radically changed human health. Today, we can cure more diseases than ever before. The number of centenarians has never been higher, and premature babies can be kept alive after less than 25 weeks of gestation. Physical and mental abilities are being enhanced beyond natural boundaries. Moreover, genetics makes it possible to predict disease decades in advance. In the future, we may even be able to clone human life.

Science and cutting-edge technologies have not only changed the limits of what is possible, but also caused health systems' costs to skyrocket, thereby putting us and future generations at risk. These trends raise questions the disciplines of science and medicine cannot themselves answer. Should we employ all technical means to create, select, prolong or predict human life? Who should have access to costly and possibly risky new technologies when not all can for economic reasons? This chapter will discuss to what extent answers to these questions will have to be political, i.e. based on negotiation, bargaining and preference aggregation rather than moral argument. Most of us have strong intuitions against simple preference aggregation (i.e. majority rule) when existential interests and fundamental moral values or principles are at stake. We think that good moral reasons, not voting, should govern decision-making about these issues. However, when reasonable people disagree about what counts as a good moral reason, the line between ethics and politics can become blurred. Using the example of allocating scarce resources in a liberal democracy,[1] I will try to demonstrate that the procedures we choose for limit-setting decisions will largely determine the extent to which the future of health care will be political rather than ethical. I will argue that decision-making procedures which are informed by conceptions of a good life are likely to yield more ethical outcomes.

[1] I will focus on democratic and industrialized countries although it seems obvious that health care in developing countries will be among the prime challenges in the twenty-first century. I will also disregard the impact of "external" factors on health care, such as the international spread of disease (i.e. the anticipated pandemic influenza), the global trade in human body parts (i.e. the international circulation of human cell and tissue products), medical 'tourism' (transplant 'tourism' being the most controversial form), and so forth.

S. Elm, S.N. Willich (eds.), *Quo Vadis Medical Healing,*

2 The Future of Health Care (Part I): Scarcity of Resources

Scarcity of resources will significantly shape the future of health care in industrialized countries as medical progress and demographic changes are pushing health care expenses upward. With more and more sophisticated diagnostic and therapeutic interventions available for more and more patients, both the frequency and the costs of medical care will continue to rise. Health expenses correlate with the proximity of death (Zweifel et al., 1999), and consequently, costs increase in aging societies.

The scarcity of resources is amplified by decreasing revenues for public health care spending. Low mortality rates at all ages and the simultaneous decline in birth or fertility rates have led to societal aging and a subsequent decline in income for traditional 'pay-as-you-go' social insurance systems. It is projected there will be more Italians, Germans and Japanese over 80 than under 20 years of age by 2050 (Center for Strategic and International Studies, 2000). More people will therefore be dependent on the income of fewer workers; aging may additionally hamper economic growth. And since aging is a global phenomenon – in fact, many developing countries are aging now at much faster rates than industrialized countries – immigration will at best mitigate the societal effects of aging (Center for Strategic and International Studies, 2000). Already today, what can be done medically cannot be financed solidarily. This trend will acuminate in the future.

3 How Should We Address the Scarcity of Resources for Health Care? The Case for Explicit Rationing

There are five basic strategies to address the scarcity of resources for health care: Society can let the market balance health care costs (Strategy I), preserve a publicly financed health care system by rationalizing services (Strategy II), increase funds for health care (Strategy III), or introduce measures for implicit (Strategy IV) or explicit rationing (Strategy V) (Marckmann, 2007). The following discussion will demonstrate that there are both economic and ethical reasons to reject the first four options. From an ethical perspective, explicit rationing should be embraced under reasonable resource constraints.

3.1 Strategy I:A Free Market for Health Insurance

The market leads to the efficient production and distribution of goods and services in many areas of cooperative activity. It functions without coordinated procedures for the allocation of goods and services, provided that free competition, accountability and informed consumer choice are guaranteed. Because non-market distributive procedures are complex, costly and potentially divisive, in addition to potentially

restrictive when it comes to the autonomous choices of individual consumers (and patients), there seems to be a *prima facie* case for a market solution also in the health sector. Why not let the market match patient preferences to different health insurance packages?[2] Both economic and ethical arguments speak against this solution. Compared to the purchase of other goods or services – for example, a car or a laundry provider – uncertainty about one's future health needs is significant even in the wake of new technologies such as comprehensive genetic testing. Moreover, information about the outcome of different health insurance packages is often insufficient in countries without universal access to health care (Daniels and Sabin, 1997). Since the informed consumer (patient) choice and accountability conditions are unmet, a free market for health insurance would not function properly from an economic perspective.

Furthermore, it would not be justified from an ethical perspective. Justice gives us social obligations to protect the fair opportunity range of all citizens so that all can participate in the political, social and economic life of their society (Rawls, 1971). Health care – which comprises medical as well as long-term care and preventive health measures – protects an individual's fair share of the normal range of opportunities. It is one precondition for people to choose among the life plans they can reasonably pursue, given their talents and skills, and the society in which they live. Providing health care is therefore one way of meeting the social obligation to protect the fair opportunity range of all citizens (Daniels, 1985).

In a free market for health insurance, however, individual ability to pay would determine access to health care. Only those who could purchase insurance would be able to protect their normal range of opportunities. And because ability to pay is significantly determined by the natural and social lottery – the skills, talents, and socio-economic conditions a person is born with essentially depend upon luck – a free health insurance market would undermine fair equality of opportunity and hence be unjust. Both economic and ethical reasons speak against a similar market.

3.2 Strategy II: Rationalizing Public Health Services

A public, and thus solidarily funded health care system, is therefore needed to protect the fair opportunity range of all citizens.[3] So how do we address the scarcity of resources in a public health care system? An obvious strategy would be to decrease

[2] I do not consider the option of a free market for health care services, since it would clearly violate the informed consumer choice condition. Many patients who find themselves in acute need of medical insurance are unable to compare different health service offers and cannot make a rational decision about these offers.

[3] There is no room to detail the extent of coverage in a public health care system here. It should be mentioned, however, that the 'fair equality of opportunity' approach does *not* necessarily imply universal coverage – contrary to a widespread intuition – and is indeed compatible with a tiered health care system (Krohmal and Emanuel, 2007).

spending by rationalizing services. In fact, today's health care is inefficient in numerous ways: Some health interventions are ineffective altogether; effective interventions are being provided without the right clinical indication; effective care exists at lower costs; and more effective treatment could be provided for the same costs. The potential for rationalizing services is therefore large. However, it is questionable that tapping this potential will in fact decrease health expenditures. Measures to rationalize health care require a solid basis of clinical evidence, which is itself costly to attain and often reveals a need for better care rather than a potential to save in costs. Furthermore, rationalizing usually mandates expensive structural changes in the health care system (i.e. a better coordination of ambulatory and hospital care or more emphasis on preventive medicine). But even if savings outweighed expenses, the effective cost containment would probably be limited given that costly medical practices and demographic changes will probably cause increased health expenditures. It seems unlikely that rationalizing health care will be sufficient to address the scarcity of resources for health care – even though there may be other reasons, not grounded in economics, for making services more efficient. For example, the principle of nonmaleficence requires health personnel to omit ineffective interventions and to provide care with the fewest possible diagnostic and therapeutic interventions.[4] The expected economic impact of rationalizing health care, however, is at best weak.

3.3 Strategy III: Additional Funding for Public Health Care

Additional funding for public health care would be another obvious strategy to offset the scarcity of resources for health care. However, several arguments speak against it. First, although medical progress has improved thousands of lives, many innovative medical interventions have a diminished marginal utility. For example, some oncology treatments could arguably be characterized in this way. When the cost of care becomes disproportionate to the gain in medical benefit, additional funding is no longer cost-effective. Medical progress is a leading cause of increasing health care costs, and simply pouring more money into marginally better health care is not an economic solution.[5]

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[4] A thorough ethical evaluation of measures to rationalize health care is not the goal of this chapter. Nevertheless, the reader should note that a focus on efficiency implies a bias for interventions that are suited to provide 'solid' clinical evidence (ideally gathered in randomized-controlled trials) and in addition risks neglecting equity considerations in the provision of health care.

[5] This argument presumes that the primary purpose of a public health care system is to provide care, not to advance science. Were a rigorous distinction between research and therapy to be implemented, additional funding for research – both public and private – would be necessary to maintain medical progress. The present argument may also be oversimplifying from a macroeconomic perspective, as the provision of medical services and related industry account for increasing percentages of employment in many industrialized countries.

Second, health care is not the only determinant of health. Although social determinants of health are poorly understood, empirical evidence shows that our physical condition is influenced not only by access to medical prevention and treatment, but also by the cumulative experience of social conditions over the course of our lives. Absolute and relative socio-economic status has a significant impact on individual health (Daniels et al., 1999). Measures to reduce social inequalities – for example, better educational opportunities – may well be more (cost-)effective than excessive investments in health care.

Third, because public budgets are finite, additional resources for health care imply cuts in public funding for education, protection of the environment, poverty relief, homeland security, and so forth. Even though activities in these areas could be seen as more or less instrumental for health, physical well-being is not the only good individuals or a society would want to pursue. However important health and health care are, other social goods exist and should be pursued (i.e. education). Furthermore, preserving and restoring health is not sufficient to protecting the fair opportunity range of all citizens. A society that maximizes health care but has no resources left to provide fair opportunities for education, for example, is not just. It would not comprehensively preserve the ability for its citizens to participate in societal life as normal collaborators and competitors.

There are no natural limits to health care spending. A society has to decide how much of its public resources should be devoted to health care, based on value judgments about health (and other goods), but also based on empirical facts such as medical and economic development. Excessive additional funding for health care, however, is neither an economic nor an ethical option.

3.4 Strategy IV: Implicit Rationing in Public Health Care

If rationalizing health services cannot adequately contain costs and additional funding for health care is neither an economic nor an ethical way to address existing scarcities, we are left with two ways of budgeting finite resources: implicit and explicit rationing. Implicit rationing uses incentives for providers and patients to save costs at an institutional or individual level; explicit rationing sets priorities for areas of medical activity or medical interventions within the health care system. Both forms of rationing are problematic since they limit access to health services that are expected to have a positive impact on people's longevity or quality of life. However, the costly medical progress and demographic changes leave no viable alternative. Rationing in health care has become a practical necessity.

Implicit health care rationing is present in most industrialized countries today. Even those countries or states that embrace explicit rationing – for example, Sweden, Norway, the Netherlands, the United Kingdom and the State of Oregon in the United States – have implemented some instruments for implicit rationing. The goal of these instruments is to change the behaviour of providers and patients through financial incentives. Restricted budgets, diagnosis-related groups in hospital

care, capitation in ambulatory care and bonus-malus systems are designed to make the provision of care more efficient (and more calculable for private investors). Franchises and out-of-pocket payments – fixed sums or percentages of fees – are meant to reduce the demand for care to what is truly necessary.

Implicit rationing has several advantages. It flexibly adapts to the wide range of situations, needs and preferences of patients, and the uncertainties of the care process. It also easily accommodates the rapidly changing character of medical knowledge (Mechanic, 1997). Those affected by the provision of care – patients and medical professionals – can make individual decisions about what needs to be done. Furthermore, implicit rationing avoids lengthy and costly processes of explicit priority-setting that, some authors fear, may be divisive for society (Hunter, 1993; Sommer, 2002),

However, implicit rationing also has major disadvantages. From an economic perspective, it is difficult to judge whether diagnosis-related groups actually lead to reductions in health care spending. Any system that is primarily based on egoistic motives can be 'played' to the user's advantage. More importantly, implicit rationing risks making access to medical care non-transparent and highly dependent upon the individual physician's motivation, the clinical department's financial situation or the individual patient's ability to insist or pay. Emerging inconsistencies in the provision of care are difficult to justify both medically and ethically, in particular because instruments of implicit rationing are designed to control costs, not quality of care. In countries where diagnosis-related groups have been or are being introduced without comprehensive obligatory quality management, the impact on the quality of care is difficult to estimate.

In addition to uncertain outcomes, instruments for implicit rationing risk violating fundamental principles of justice. A high variability in the provision of care, if unjustified, is incompatible with formal principles of justice ('like cases should be treated alike'). And if access to care becomes dependent upon ability to pay – for example, through increasing out-of-pocket expenses – there is a risk that fair equality of opportunity is undermined. Although implicit rationing features practical advantages and is likely to persist for pragmatic reasons, it has important shortcomings from an ethical perspective.

3.5 Strategy V: Explicit Rationing in Public Health Care

The final strategy to address the scarcity of resources for health care is explicit rationing. Explicit rationing implies that priorities in the provision of care are defined and implemented within the health care system, usually through the introduction of standards of care or through the exclusion of particular services. Standards of care are general diagnostic and therapeutic guidelines for particular clinical conditions, which can factor economic and quality-of-care considerations as well as patient preferences. They limit and exclude – or broaden and include, depending on the scientific evidence – clinical indications for interventions on a systemic level (in

contrast to implicit rationing which operates on an institutional or individual level). Priority-setting is an instrument for structuring health care that is *prima facie* neutral: it can be used either to contain health care spending, or to improve the quality of care. When priority-setting is used explicitly to exclude health services because of reasonable resource constraints, explicit rationing takes place.[6]

Explicit rationing has numerous advantages from an ethical perspective. It is compatible with formal principles of justice because standards of care are equally binding for all treatments within the publicly funded health care system. The general guidance provided by standards of care makes both the allocation of scarce medical resources and clinical decision-making more consistent. At the same time, standards of care leave room for individual treatment decisions. Because standards of care are based on economic and quality-of-care considerations, explicit rationing allows managing quality and costs jointly. This has the great advantage of allowing health care institutions to monitor the impact of cost-containment measures on the quality of care and adapt these measures accordingly. The joint consideration of economic and quality considerations also opens significant potential for rationalizing services. Finally, because standards of care or the exclusion of particular services is explicit, patients can easily retrace and verify the impact of economic considerations on individual treatment decisions. It is likely that this promotes trust between patients and physicians interacting under conditions of reasonable resource constraints. Certainly, explicit priority-setting and rationing are complicated, lengthy and costly strategies that some authors fear will be disastrously divisive (Sommer, 2002). But, when compared to other strategies for cost containment, the advantages of explicit rationing clearly prevail.

4 Explicit Rationing: Substantive or Procedural?

The previous section came to the following conclusions: (1) a free market for health insurance is unjust; (2) rationalizing alone cannot contain health care expenditures (even though other non-economic arguments speak in its favour); (3) excessive additional funding for health care can be justified neither economically nor ethically; (4) implicit rationing has practical advantages, but good ethical reasons speak against making it the sole strategy to address the scarcity of resources for healthcare; and (5) good ethical reasons support explicit rationing, but its opponents point to important practical limitations of this approach. Nonetheless, the case for explicit rationing seems strong from an ethical perspective. The rest of this chapter will therefore discuss ways of conceptualizing it in more detail.

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[6] I will continue to use the term 'explicit rationing' despite its negative connotation, in particular in European debates. Many scholars prefer referring to 'priority-setting' when discussing the allocation of scarce resources. However, since this chapter is concerned with cost containment under reasonable resource constraints, and since 'priority-setting' is merely an instrument that allows excluding and including particular health services, it seems more precise to refer to 'rationing' here (and more readable than 'limit-setting').

There are basically two ways to implement explicit rationing in a public health care system. First, health care institutions can develop a set of priority criteria that, when applied to concrete cases of scarcity, allow for the exclusion of health services in a more or less principled way ('substantive approach'). Second, health care institutions can devise a set of procedural conditions, which define a fair process that yields fair rationing decisions in concrete cases of scarcity ('procedural approach').[7] Both approaches have been implemented in countries that embraced explicit rationing from the 1980s onwards. However, there has been a shift from principled to procedural approaches over the past two decades. Today's practices are predominantly based on procedure rather than priority criteria or principles (Holm, 1998).

The first phase of explicit rationing was driven by the idea of developing a complete set of criteria for prioritizing and rationing a given service in relation to other services. For example, the Norwegian Parliamentary Commission Lønning I (1985–1987) devised priority criteria including factors such as severity of disease, utility of treatment and the level of evidence for the clinical efficacy of treatment (Norges Offentlige Utredninger, 1987). The first Oregon Health Services Commission (1989) excluded health interventions on the basis of cost-effectiveness (Oregon Health Services Commission, 1991). Necessary care, effectiveness, efficiency and personal responsibility were the criteria the Dutch Committee on Choices in Health Care (1991) agreed upon in the Netherlands (Government Committee on Choices in Health Care, 1992); and the Swedish Priorities Commission (1992–1995) endorsed the principles of human dignity, need and social solidarity (Swedish Parliamentary Priorities Commission, 1995). But experience showed that these priority criteria did not provide sufficiently concrete enough guidance for the exclusion of services (i.e. Norway); some of them even required revision because of their counterintuitive and morally unacceptable outcomes (i.e. Oregon).

The persistent practical need to make distributive decisions about scarce resources in some publicly defensible way led to the development of procedural approaches. Norway, for example, complemented its substantive approach by adopting procedural elements. It implemented speciality specific working groups to rank conditions in line with the existing priority criteria. Also, a National Priorities Commission was established (Norges Offentlige Utredninger, 1997). Countries that have embraced explicit rationing only recently have chosen procedural approaches early on. The National Institute of Clinical Excellence, for example, which has advised health professionals in the United Kingdom's National Health Service on how to provide patients with the highest clinical standard of care since 1999, has operated with Advisory Boards and a Citizens Council from its beginnings (Rawlins and Culyer, 2004). The practice of explicit rationing clearly points to procedural approaches. But what speaks in their favour from a theoretical perspective?

[7] The development of priority criteria can of course be itself subject to procedural requirements.

5 The Future of Health Care (Part II): Reasonable Pluralism

The answer to this question is related to another widely accepted feature of democratic and industrialized ("Western") societies that is relevant for health care rationing. An important characteristic of Western societies has been detailed above: costly medical progress and demographic changes lead to a scarcity of resources that should be addressed by explicit rationing (at least primarily). Another important characteristic of these societies will be discussed now: Western societies are governed by liberal democracies,[8] and – according to the American philosopher John Rawls – reasonable pluralism is the "inevitable result of the powers of human reason at work within enduring free institutions" (Rawls, 1996: 47).

John Rawls details the sources of reasonable pluralism in his book on political liberalism. According to Rawls, many of our most important judgements are made under conditions where it is not expected that conscientious and reasonable persons will all arrive at the same conclusions (assuming there is no oppressive use of state power). There are various burdens of judgement[9] that lead to reasonable disagreement. Consequently, reasonable people hold different views on the same issues: they make conflicting claims on scarce resources, they disagree about what constitutes a fair distribution of these resources, and they weigh the many goals of public health care in various reasonable ways.

However, if we embrace reasonable disagreement as an inevitable consequence of human reason at work in a liberal society, a paradox arises that needs to be addressed by any (liberal) theory of health care rationing: how can we make legitimate decisions about the distribution of scarce resources in a society for which disagreement is constitutive? The twist in Rawls' answer to this question is to revert to a normative concept of the reasonable. Rawls primarily defines the reasonable person as having two characteristics: first, the willingness to propose fair terms of

[8] A normative justification of liberal democracy is not the topic of this chapter. There are good ethical reasons in favour of democracy (i.e. that it embodies the idea of equality and mutual respect) while some may speak against it.

[9] Rawls identifies six of the more obvious sources of reasonable disagreement: '(a) The evidence – empirical and scientific – bearing on the case is conflicting and complex, and thus hard to assess and evaluate. (b) Even where we agree fully about the kinds of considerations that are relevant, we may disagree about their weight, and so arrive at different judgments. (c) To some extent all our concepts, and not only moral and political concepts, are vague and subject to hard cases; and this indeterminacy means that we must rely on judgment and interpretation … within some range … where reasonable persons may differ. (d) To some extent … the way we assess evidence and weigh moral and political values is shaped by our total experience, our whole course of life up to now; and our total experiences must always differ. (e) Often there are different kinds of normative considerations of different force on both sides of an issue and it is difficult to make an overall assessment. (f) Finally … any system of social institutions is limited in the values it can admit so that some selection must be made from the full range of moral and political values that might be realised. … Many hard decisions seem to have no clear answer' (Rawls, 1996: 56–57; notes removed).

cooperation and to abide by them provided others do, and second, the willingness to recognize the burdens of judgement and accept their consequences for the use of public reason in directing the legitimate exercise of political power in a constitutional regime (Rawls, 1996: 48–58).[10] Since judgements about conflicting comprehensive doctrines are practically impossible, the reasonable person will seek to justify fair terms of cooperation with arguments that do not refer to such doctrines. When matters of justice or the basic structure of society are concerned, he or she will only rely on what Rawls calls 'free-standing' arguments. These arguments are the focus of an 'overlapping consensus' affirmed by all citizens and (accepted as) valid without reference to comprehensive religious, philosophical or other doctrines.[11]

Assuming that our thinking is likely to be more or less caught in a particular reasonably comprehensive doctrine, it will be difficult to deliberate upon free-standing arguments alone. Those who are willing to recognize the burdens of judgement and their consequences for the use of public reason must therefore devise an adequate process for identifying the overlapping consensus about rationing in health care. It seems that recognizing the practical implications of the idea of reasonable pluralism has been the prime motivation for shifting from substantive to procedural approaches in those countries that already embrace explicit rationing today.

6 The 'Accountability for Reasonableness' Framework by Norman Daniels and James Sabin

Arguably, Norman Daniels and his colleague James Sabin, have developed the most elaborate theory of a Rawlsian-inspired fair process for health care rationing. Their 'accountability for reasonableness' framework (A4R) has heavily influenced debates about health care rationing in the past decade. Originally devised for the managed care context in the United States, Daniels' and Sabin's A4R has gained worldwide acceptance and become one of the dominant paradigms in the field of (liberal) health policy.[12]

A4R invokes a fair procedure because general principles of distributive justice are too indeterminate and more fine-grained principles, rules or criteria are subject to reasonable disagreement. 'The basic idea is that the outcome of a fair procedure

[10] Rawls bases his concept of the reasonable on Thomas Scanlon's claim that we have a basic desire to be able to justify our actions to others on grounds they could not reasonably reject (Rawls 1996, 49–50, note 2).

[11] More generally, Rawls also argues that the basic structure of a liberal society is effectively regulated by a conception of justice that is the focus of an overlapping consensus of at least the reasonable comprehensive doctrines affirmed by its citizens. His political conception of justice is itself based on free-standing arguments.

[12] A4R has been implemented in various countries (i.e. Flood, 2005; Manning and Paterson, 2005; Norheim, 2005).

will then count as fair, even if we cannot cite a substantive distributive principle by reference to which the outcome is fair' (Daniels, 1996: 327).

A4R proposes four conditions that should govern rationing processes (Daniels and Sabin, 1997; 1998b; 2002):

- *Publicity condition*: Rationing decisions in health care and their rationales must be publicly accessible.
- *Relevance condition*: The rationales for rationing decisions must appeal to evidence, reasons and principles that are accepted as relevant by 'fair-minded' people who are disposed to finding mutually justifiable terms of cooperation.
- *Revision and appeals condition*: There must be a mechanism to revise rationing decisions in the light of new evidence, arguments or critique.
- *Regulative or enforcement condition*: An adequate mechanism ensures that the above conditions of a fair process are met.

Although Daniels and Sabin never make explicit reference to it, A4R is obviously rooted in John Rawls' idea of political liberalism. The justification for A4R, that reasonable people disagree about fine-grained rationing principles, evokes the idea of reasonable pluralism. Abandoning a principled approach assimilates the impossibility of reaching political agreement based on truth judgements about comprehensive doctrines. And the relevance condition resonates the idea of an overlapping consensus and the use of public reason in justice matters. One of the central ideas behind both A4R and Rawls' overlapping consensus is that, by restricting the kinds of reasons that are acceptable for rationing decisions, we can limit the scope of disagreement and provide the grounds on which disputes can be adjudicated.

However, does A4R establish a sufficiently fair procedure for rationing decisions within a liberal framework? I will offer a number of reasons that warrant a cautious answer to this question. Central conceptual elements of A4R are so vague that it risks turning into a largely political undertaking with a questionably low degree of stakeholder involvement.

First, it is unclear that we can all agree about what should count as a relevant reason (as stipulated by the Relevance Condition). Daniels and Sabin themselves admit that disagreement about relevance can be intractable. They illustrate this point with the argument of continued competitiveness and profitability in private health care institutions and suggest, without further justification, to exclude reasons of controversial relevance from decision-making (Daniels and Sabin, 1997: 335–336). However, when even the authors of A4R cannot draw a line between relevant and irrelevant reasons, how should decision-makers be able to do so? Without a clearer concept of relevance, A4R fails to give a convincing account for its substantive constraint on rationales. Furthermore, if disagreement about the relevance of reasons cannot be avoided, there is a potential that excluding reasons will be subject to bargaining and negotiation.

Second, A4R cannot offer a reasoned account for weighing conflicting relevant reasons. Certainly, this point seems to be begging the question, since reasonable disagreement about fine-grained rationing principles is in fact the starting point of

A4R. But the consequences are important to recognize. Even if there is no disagreement about the relevance of reasons, it is probable that some of them will conflict. Almost any reason appears construable as somehow relevant to ensuring fair terms of cooperation in health care, given the vagueness of the Relevance Condition.[13] With a vast range of relevant reasons, some of them will require incompatible actions; and there is no reason to believe that the weighing of relevant reasons should be any less controversial than identifying relevant reasons (Friedman, forthcoming). In order to eventually produce a decision, A4R must rely on a procedure which is in itself not deliberative.[14]

Daniels and Sabin argue we should accept the outcomes of voting as long as alternative rationales satisfy the Relevance Condition.[15] The idea is that 'the minority can at least assure itself that *the preference of the majority rests on the kind of reason that even the minority must acknowledge appropriately plays a role in the deliberation*' (Daniels and Sabin, 1997: 339). But should we really accept the outcomes of A4R's voting process as reflecting the preference of the majority?

Third, it seems that if A4R foresees to resolve much of the existing disagreement by vote, the framework does not provide for sufficient stakeholder involvement. Daniels and Sabin insist that stakeholder involvement, although desirable, is only instrumental to A4R. The primary role of stakeholders is to increase the spectrum of potentially relevant reasons and to foster publicity; their presence in the decision-making process is not required for fair rationing (Daniels and Sabin, 1998a: 61). Rationing decisions that meet the A4R conditions are fair as long as reasonable rationales are public and stakeholders can appeal to decisions. However, if the idea is that we have – within the range of relevant reasons – a choice among 'equally fair' rationing schemes, making such choices should be more inclusive and sensitive to public input. A4R does not bind the decisive majority vote to participation of those actually affected by rationing decisions. This half-hearted turn to deliberative democracy seems difficult to justify to patients, and again, there is the potential that votes will be based on very particular preferences or interests. It seems the dominant (liberal) procedural approach to rationing in health care, A4R, risks determining an essentially political future of health care.

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[13] Daniels and Sabin's prime example of irrelevant reasons are religious reasons and mere disadvantage (Daniels and Sabin, 1997: 331).

[14] Some authors, however, are optimistic that the politically relevant questions in bioethics can be resolved by an exclusive appeal to free-standing arguments (Pauer-Studer, 2006).

[15] This thinking is in line with John Rawls: 'Institutions within the permitted range are equally just, meaning that they could be chosen; they are compatible with all the constraints of the theory. Thus on many questions of social and economic policy we must fall back upon a notion of quasi-procedural justice: laws and policies are just provided that they lie within the allowed range, and the legislature, in ways authorized by a just constitution, has in fact enacted them' (Rawls 1971, 201).

7 The Political Future of Health Care?

The prospects of a political future of health care seem disconcerting. After all, we have a strong intuition that moral matters should not be settled by a mere political *modus vivendi*. A4R is indeed an important step towards more transparent, accountable and consistent decision-making in health policy (and is, of course, far from representing a mere *modus vivendi*). However, A4R has significant shortcomings: it does not offer clear grounds for excluding particular reasons from rationing decisions and fails to provide for sufficient stakeholder involvement. But then how should we address the scarcity of resources when we must do so as a matter of justice?

The easiest answer would be to challenge that A4R, despite being a dominant paradigm in health policy, should be seen as the best liberal procedural approach to rationing. Refining A4R's decision-making process, for example, through giving more weight to the views and preferences of those affected by limits to care, could be suggested. However, critics of the Rawlsian liberal tradition have long argued that this neutral form of liberalism is compelled to turn to democratic procedures in order to make choices between equally just schemes of health care services (i.e. schemes that equally promote fair equality of opportunity). But while democratic procedures aggregate preferences, they fail to provide a moral solution to rationing problems. To solve these problems, their argument goes, we must inevitably make reference to substantive conceptions of a good life and to deliberative processes to debate what makes life worth living. And since conceptions of a good life are typically not shared by everyone, this implies downsizing the deliberative community of present and future patients into numerous community health plans, each of them guided by a different idea of what constitutes a good life. Ezekiel Emanuel has laid out the boldest, liberal communitarian vision of doing so (Emanuel, 1991: 178–249).

Parcelling out health care, however, entails various practical difficulties. Choosing a community health plan is likely to depend on one's own health status (not only one's conception of a good life), and this leads to adverse selection and instability of insurance plans. It is also questionable whether there really is a need to downsize as much as Emanuel proposes. After all, it is not altogether implausible to unify a broader, even diverse, population for the purpose of a common health care scheme. First, we are not looking to agree on a comprehensive conception of a good life, but 'only' on a health-related conception. Second, in the health care context, presumably much would be gained if we accorded on a *negative* conception of a good life (i.e. conditions we would like to avoid). Third, conceptions of a good life are shaped by basic human needs that persist even in modern pluralistic societies. Fourth, health-related conceptions of a good life are formed through historically and culturally changing inquiries about human suffering and death which allow for a certain amount of leeway in shaping them (Marckmann, 2005). However, no matter which procedural approach(es) to explicit health care rationing we develop, the future of health care will be more or less political, depending on how well we manage to inform rationing decisions with conceptions of a good life.

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The Concept of Disease and Medical Action – A Reciprocal Relationship and Its Relevance to Modern Medicine

Thomas Heinemann

Reflections about healing inevitably lead to reflections about the concept of disease. Disease is the constitutive term for the wide field of actions we summarily call medicine. It is disease that defines the goals of these actions, their intentions and ethical legitimation, as well as their justification. Thus disease assumes a normative, action-guiding function. Whenever we perceive and diagnose a disease in a fellow human being, we are obliged to take action. Depending on the nature of the disease, this can involve administering curative or palliative medical treatment, nursing a patient, or giving support and attendance in life's final stages until death. Whenever we detect the threat of a potential illness, we are obliged to take preventive action and seek to protect the person involved from acquiring the disease. The obligation to provide such help can be found across all religions and cultures, despite their otherwise great differences. It can thus be regarded as one of the cornerstones of an ethos that has its foundations in the recognition and acknowledgement of the special dignity of the human being. For a disease not only poses a threat to the union of mind and matter that makes us creatures of nature,. Iit also threatens us as individuals by affecting our power of self-determination and our freedom of action as governed by reason. Disease thus endangers not only our physical existence, but also the personal expression of human dignity that is represented by each and every individual.

This traditional view of medicine and its ethical legitimation is based on the causal relationship between disease and medical action. It is the disease that provides the cause for medical action. Medical actions and their intent are thus goal-oriented consequences of the disease. An ethical legitimation of medical action based on this argumentation, however, requires a consistent concept of disease. Here the difficulties begin. As indicated above, there is, on the one hand, a basic consensus concerning medical actions made necessary because of a disease, such as diagnosis, therapy, palliation and prevention. On the other hand, such a consensus is quickly lost when trying to precisely define the term 'disease' and clearly formulate a list of obligatory medical actions and goals. In order to achieve the former, some of the following questions need to be answered: iIs 'disease' to be defined as a deviation from a norm or as a different type of normality? How do we define the term 'norm' in the context of disease? What are the consequences of the various

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definitions of ‘norm’ when formulating the aims of medical actions? And when do these actions become obligatory?

Questions such as these demand, first of all, a closer look at the difficulties involved in defining the fundamental medical term ‘disease’. After this, we will turn our attention to the traditional goals of medicine, or healing or restoring health. The third section will then concentrate on the reciprocal relationship between the aims of medical action and the definition of disease, pointing out some of the potential ethical consequences for medical action in the context of modern medicine.

1.1 What Is Disease?

In his book, L. King first addresses this question by highlighting the various roles of the participants in this matter: ‘If I pose the question, “What is disease?” the answer will depend on whom I ask. There is the patient who has a disease, and the physician or healer who tries to cure him. There is also the scientist, who may or may not be a physician. […] The patient seeks relief, the physician tries to provide it, and the scientist seeks understanding’. These different roles and their respective relationships to disease can also be described as ‘subjective’ or ‘objective’ concepts of disease, both of which will be described below.

The patient perceives disease as a subject: he suffers, feels pain, experiences weakness and offence. If we look at disease as something that is perceived subjectively, it cannot be reduced to empirical data alone. Rather, it becomes the prism through which the subject affected by the disease relates to and interprets his socio-cultural context. From a subjective perspective, disease is not what a physician may diagnose during a medical examination, but signifies a feeling – an individual’s very self-perception. From this perspective, a disease cannot be defined by the affected organ. Rather, the organ can only be called diseased either in analogy to the ill subject or metaphorically as an organ limited in its performance like the patient himself or herself. The patient’s self-perception relates him or her to his or her disease and is thus a self-interpretation, which can, on the one hand, be described as a reflection-to-self and is, on the other hand, inseparable from the subject’’s socio-cultural context.

On the one hand, disease threatens the subject’s psychosocial well-being, and very existence. A subject experiences this as a conflict with himself or herself – a self that is both corporeal and psychological, identical with its body and yet psychologically separate from it. Disease is thus perceived as an alienation from the self, but also as self-identification, as can be seen when people use the phrase ‘my disease’.

On the other hand, humans are social beings. Therefore, any self-interpretation related to a disease is also determined by its the social ramifications, such as possible changes in interpersonal relationships, the ability to work, an individual’s economic or living situation, or the fact that a patient may be labelled as ‘sick’ in a society so strongly oriented towards competition and professional achievement.

It should be noted that a subject's self-interpretation in the face of disease need not always be negative. Under certain circumstances, disease and disability may also be perceived by the subject as a positive development. For example, a disease may trigger compassion in other people, leading them to devote more attention to the afflicted individual. Or the individual may attain a long-awaited disability status, early retirement, or illness-related change of workplace. An individual's relationship to disease is thus considerably influenced by factors that stem from the sociocultural context of each individual case.

When examining these factors, it is important to consider not only the patient's relationship to his disease, but also to those around him who are not ill. From this latter relationship, there may result a number of specific obligations for both parties. The patient is obliged not to abuse the fact that he has an illness: despite possible privileges granted as a result of the disease, such as being relieved from certain social functions, the patient is expected to desire an improvement in his condition and, in doing so, to consent to medical treatment, for example. Moreover, because disease is generally understood to be a consequence of fate and not something that is caused purposefully, the patient is expected not to simulate or self-inflict a disease. By the same token, those who are not affected by a disease are obliged not to exclude from society those who are. Ensuring the availability of medical care and to relieving of afflicted individuals from certain social duties are an important part of this obligation.

From the perspective of the scientist, however, disease is regarded as an object. An approach based on objectivity raises the question of which standards should be used to measure and identify disease. One fundamental hypothesis might be to define disease as an clearly visible deviation from a psychophysical state that is generally thought of as normal and regarded as healthy. Defining psychophysical normality based on objective criteria depends, however, on observing and describing naturally occurring phenomena. The terms 'normality' and 'naturalness' are often used interchangeably when speaking about human health. This is based on the assumption that health is the embodiment of a natural norm that may serve as an objective standard for assessing all deviations. However, taking an objective approach to this matter, it must also be possible to describe deviations from the norm as natural phenomena, so that diseases, – from an objective perspective, – can be regarded as entities, as certain natural forms of being, which can be considered norms in themselves. But how can we recognise a natural norm in the context of health and disease?

If we consider a norm in terms of what is usual or customary, it can be established statistically (statistical norm). It is possible, for example, to determine the frequency and distribution of certain features within a population and to define a norm based on the average values thus obtained. This is a strictly descriptive procedure, which means that actions, that would seem imperative due to a deviation from a statistical norm rely on an assessment that cannot be generated by the statistical procedure itself. The result of a blood sugar test, for example, can be regarded as too high or too low with reference to a statistic average, or norm, value. The action taken by the physician, however, is not based on the simple fact of raised

blood sugar values. Nor does it follow from expecting potentially life- threatening damage to various organs, which could all be defined as deviations from the norm. Medical action establishes a relationship between the norm deviation and the affected individual. This shows that a statistical norm cannot form the foundation of a normative assessment of health and disease. Other examples are diseases which affect large sections of the population, so-called 'common illnesses'. Statistically speaking, the number of individuals in Germany suffering from dental caries might be large enough to define the statistical norm for the population; yet the consequence would not be that dental caries does not need to be treated. In the reverse case, people with an IQ of 180 + may fall outside the statistical norm for the general population, but it would not occur to anyone to regard this as a disease.

Another way to look at a norm is to consider it as an ideal, a desired goal worth striving for, itself based on a value judgement (ideal norm). With regard to the concept of disease, such an ideal norm could be defined as a state of health that is characterised by the absence of disease, as formulated, for example, in the well-known WHO definition of 1946. A mere juxtaposition of complementary terms, however, does not contribute to their definition, nor is it likely that a consensus concerning the definitory scope of this ideal of health can be reached, since these criteria are subject to highly individual assessments. Falling back on the aspect of naturalness does not offer an objective foundation for a decision either. Moreover, an assessment of health and disease with regard to a natural norm has to take into account current scientific findings. These, however, are insufficient in many aspects of aetiology, physiology and psychology and are often at the heart of controversial scientific debates. Finally, the crucial point is the fact that one of the decisive characteristics of nature is its variability itself. As a consequence, the call for a natural norm can only relate to phenotypic and genotypic variability. This, however, does not contribute much to the concept of an ideal norm. Both the concept of a statistical norm and an ideal norm presuppose certain evaluations that neither can generate by itself. Therefore, both of these types of norm are an insufficient foundation for a definition of disease. Without doubt, however, both are necessary for the formulation of such a definition, if it is to serve as an operational starting point for medical action.

There is, moreover, a third type of norm: the individual norm. Normality viewed against this backdrop is neither a statistical phenomenon within a population, nor a virtual ideal. Rather, the individual norm refers to an individual's mode of existence as defined by his own singular norm as it occurs within the wide spectrum of variabilities that occur in nature. Disease, in this context, can be defined as a deviation in an individual's psychophysical state from this particular individual's very own normality. However, this approach also clearly reveals the fundamental problems involved when attempting to create an objective definition of 'disease'. Even though this deviation may be diagnosed through the objective description of natural phenomena, its evaluation as a disease relies mainly on the subjective interpretation of the individual. If, therefore, such an evaluation can only be made by the affected individual, an objective formulation of the concept of disease can only be achieved via subjectivity.

So far, our considerations have shown that a purely objective approach to the concept of disease is clearly impossible. A definition of disease that relies solely on objective parameters will always run the risk of being reductionist. What then is the scientist's task when striving for objective criteria? The sciences try to explain disease with reference to natural phenomena without, however, identifying these phenomena with the disease itself. Methodologically, this involves determining statistical norms, as explained above, as well as certain ideal norms resulting from the statistics, which form the foundation for a taxonomic classification of norm deviations. Knowledge acquired in the natural sciences, however, cannot declare natural phenomena to be diseases, since such a qualification relies on the subject's interpretation. The principal dissociation between the subjective concept of disease and an objective criteriology allows for five different scenarios. Only one of them is anticipated to be a 'normal' case, i.e. the intersection of subjective perceptions of disease and objectifiable norm deviations. The other four options in practice are characteriszed by specific problems that, in some instances, are very difficult to solve.

The first and least problematic scenario seems to be a case in which the patient does not feel ill, nor is there any norm deviation that can be diagnosed by objective standards and would make an examination, such as a preventive medical check-up, necessary. The mere suggestion of an examination may, however, in some individuals raise fears of disease – fears that, that in themselves, may already be defined as pathological. The second case is more difficult to deal with: a patient feels ill, but no deviation from objective norms, such as laboratory parameters, radiological results, etc., are discernable. Without any doubt there is a disease in need of remedy, and any denial because of the absence of objectifiable norm deviations, for example, by qualifying the patient as a malingerer, does not do justice to the person involved. A third case could prove similarly problematic: there are discernable deviations from an objectively established norm, but the patient does not feel ill. In such a case it would be difficult to speak of a patient's disease. Case number four is the most problematic: the scenario is that of the individual who cannot or can only to a limited degree fulfil the task of self-interpretation. This would be the case for example with an unconscious patient, a newborn infant, or a toddler. The interpretation would then have to be made by proxy.

2.2 Task And and Goals Of of Medical Action

So far we have only looked at the patient and the scientist with regard to disease and to their respective approaches in defining disease. The next question must be: what role does the physician play? The physician's role differs from both that of the patient and the scientist primarily because he or she is obliged to act. The considerations in the previous paragraphs have already shown that the specific task of the physician does not allow him or her to side entirely with either the subjective approach of the patient or with the objective approach of the scientist. For a physician, it is only possible to deal with a disease as a subjective perception via

the individual subject. There is thus an insoluble link between objective parameters and subjective perceptions of a disorder. The physician's task here is obviously to bridge and overcome the dissociation of both parties. His role can be characterised as providing assistance for the subject's self-interpretation of the disease and the exclusion of potential misinterpretations. In doing so, he can use objective results. From this perspective, an objectifiable deviation from a norm cannot define a disease;. Nnor can normal values, however objectively they may have been acquired, define health. They are arguments for the patient's self-interpretation, arguments provided by the physician. In the case of an unconscious patient, the physician does not necessarily lose this role as a mediator. What is necessary here is the physician''s interpretation on behalf of the patient, a role that establishes a special relationship of trust between the patient and the physician.

If, however, both health and disease depend on subjective interpretations, and if objective results are obviously not the only decisive criteria in this qualification, the following question needs to be raised: what are the aims and obligations of medical action?

With regard to the aims of medical action, it is the aspects of healing and the restoration of health that play a central role. The historical background and genesis of both terms has been dealt with extensively. In contemporary German, both terms are generally used as synonyms, even though their precise terminological congruence is not entirely established. Healing can either be understood as a process or an action, whereas health describes a state of being. Healing can thus be seen as the process restoring health. This, however, also describes a state, which differs from health, but which at the same time does not necessarily qualify as a disease. It could rather be called a kind of intermediate stage, or neutralitas. On the other hand, healing (Heilung) in German can also be used to describe the completed process of healing and could thus be regarded as a synonym for health. With regard to setting goals for medical action, these differentiations could become paradigmatic in character. If healing in the sense of process depicts the permanent real state of an individual, the first and foremost goal of medical action would be to secure an acceptable quality of life for the individual. This may also include a re-interpretation of disease by the individual and a re-definition of the individual state of normality. If healing is understood in the sense of health, however, medical action will then be committed to reaching this ideal state and will try to influence the subject's self-interpretation on the basis of an objective criteriology. Varying formulations of goals for medical action can thus influence the definition of disease. As a consequence, goal-oriented medical action may gain a normative function.

3 Medical Action Influencing the Definition of Disease

At the beginning of this chapterpaper, we stressed the normative function of disease for goal-oriented medical action. The considerations discussed above, however, indicate that goal-oriented medical action may itself have a normative function with respect to

the concept of disease. This would lead to an understanding of the relationship between disease and medical action as reciprocal. However, the goals of medical action are not the only defining principle behind the concept of disease. The link between the concept of disease and the subject's self-interpretation prepare the way for influences on the definition of disease that have their roots in socio-cultural norms and fashions rather than in medicine. This becomes particularly obvious when these norms lead to a widening of the semantic scope of the term ''disease', as happens with the various forms of 'improvement''' or 'enhancement'. Individual features such as form and size of the female breast, small stature or facial asymmetries, which are not caused by pathological factors, are variants of the natural norm that nevertheless pose no threat to a patient's physical health. Yet, social preferences may lead to their perception as a disease and to calls for medical treatment. A similar phenomenon can be observed in the context of individual developmental changes, such as moderate acne in puberty or hair loss with advanced age. Even if only a few individuals perceive these variations as a disease, whereas others are entirely indifferent, the development and provision of medical therapies for them alone may assume a normative character. For example, small stature in adult age would then no longer indicate a natural individuality, but would give visible evidence of a former decision against a therapy – a decision that could be assessed as right or wrong and might force the person in question to defend this decision. New diagnostic possibilities brought about by genetics fit perfectly into such a socio-culturally determined ideal of health. As absurd as it may be to speak of genetic normality, such socio-cultural ideals of health can also be projected onto an individual's genetic disposition. And the development of DNA-chip technology allowing the immediate diagnosis of thousands of genetic features will pave the way to perform such diagnoses on a much larger scale.

Even on the objective level, however, medical action in the context of genetic diagnostics may lead to a problematic widening of the concept of disease. An early predictive genetic diagnosis may cause the individual involved -– who is by objective criteria not ill -– to think of himself or herself as ill due to his or her knowledge of his or her genetic predisposition. For example, certain mutations in the tumour-suppressing genes BRCA1 or BRCA2 indicate a risk of 50 + per cent for women to develop breast cancer; the ''normal'' risk would be at about 10% percent. Younger women cannot lower the risk of dying of breast cancer through a higher frequency of preventive medical check-ups. However, removing both breasts by surgery leads to a significant risk reduction, even though the risk cannot be eliminated entirely. No matter what decision the woman takes, she will never live without this genetically fixed background of a possible disease and always run the danger of perceiving this possibility as a disease. Another, no less severe, burden potentially caused by a genetic analysis would be a diagnosis of a mutation for which there are no possible therapies or means of prevention, as for example in the case of the gene responsible for Chorea Huntington. Predictive genetic diagnosis holds the danger of identifying a genetic mutation with a disease. This could possibly already apply to a recessive monoallelic disposition. Such a concept of disease affects the individual's very substance: disease in such a sense is part of the genetic uniqueness from the very first moment of the individual's existence.

A reductionist concept of disease, as described above, which looks at disease deterministically as an entity characterised by natural phenomena, holds the methodological danger of decisionism. With regard to the individual, this is the danger of medical dirigism and paternalism. The examples given above, however, show that a concept of disease based on the individual's self-interpretation is no less dangerous. It is influenced by the ambivalence of socio-cultural norms and demands a categorical distinction between prevention and therapy on the one hand, and enhancement on the other. It also demands the explanation of this distinction to the individual in the process of self-interpretation. Another danger is that the individual's self-perception might lead to fundamentally problematic assumptions, for example if, in the case of genetic diagnosis, the individual's genetic uniqueness, which is the basic condition of his personal identity, becomes subsumed into the context of disease. Here, it is an ethical demand on medical action to provide and propagate categorical distinctions. This task of medical action cannot be restricted to the individual alone, but has to develop its full clarifying and normative effects in society as a whole.

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Part II
Concepts of Healing in History

Part II seeks to address aspects of the evolution of notions of suffering, healing, and medicine in three different yet related historical contexts, namely ancient Greece, the Roman Empire, and early Judaism. This section thus introduces the extraordinary importance of culture and context in the individual's and society's construction of illness, healing, and health, as well as forces that might lead to changes in the perception of these notions. Oliver Primavesi's chapter on Empedocles illustrates the revolutionary introduction of the "elements" into Greek medicine and its subsequent transformation of Greek medical notions of healing. Susanna Elm's chapter addresses the relationship between "pain" and healing by asking whether or not the rise of Christianity was related to a prior shift in the Roman understanding and conceptualization of pain. John Efron also addresses the universal human condition of pain to ask why, given some very similar cultural preconditions, and in particular in light of the later prominence of its physicians, there never evolved a specifically "Jewish" medicine, analogous, say, to a "Greek" or a "Chinese" medicine.

Medicine Between Natural Philosophy and Physician's Practice: A Debate Around 400 BC

Oliver Primavesi

"Sanguine, phlegmatic, choleric, melancholic types": in this classification of the four temperaments survives a doctrine that influenced Western medicine into the nineteenth century, the doctrine of the four homours, blood (*haima, lat. sanguis*), phlegm (*phlegma*), yellow bile (*chole*) and black bile (*melaina chole*), the ratio of which was thought to cause health and sickness. This chapter tries to reconstruct the debate that resulted in this doctrine. This was a medical discussion of methods that occurred at the turn of the fourth century BC concerning the e*pistemological* foundations of medicine, namely its relation to the natural sciences. The battle lines in this debate were drawn up differently than we might expect today: on one side were sober practitioners who were equally averse to religious fantasies and the construction of scientific theories, and on the other a philosophical poet, who had many traits of a world-redeeming guru, and yet at the same time laid the basic foundations for the physical theories of the ancient world.

1 The Scientific Rivalry Between Hippocratic and Western Greek Doctors

Galen, the famous doctor, medical historian and philosopher of the second century AD (129–ca. 216), writes the following about the controversy that interests us, which at the time was already four centuries in the past.

1.1 Galen, De Methodo Medendi 1, 1; X 5–6 Kühn (Trans. Hankinson 1991, 5)

> Even in the old days there was no shortage of dispute, as those in Cos and Cnidus strove with each other to make the greater number of discoveries; for there were still two schools of Asclepiads in Asia. … And with them strove (but with that beneficial strife that Hesiod praised) the Italian doctors, Philistion, Empedocles, and Pausanias, and their colleagues. Thus three remarkable groups of doctors contended with one another.

This text starts by mentioning a rivalry *between* the Eastern Greek schools of doctors in Cnidus in Asia Minor and on the island of Cos, which lies across from it. In this

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regard the rivalry was an internal one, because both schools considered themselves 'Asklepiads' (i.e. sons or successors of Asklepios, the god of healing). Another common point was found in the fact that the Coan and Cnidian schools had made the most important contributions to medical research in the decades around 400 BC, documented in the *Hippocratic Corpus*, the canonical collection of Greek medical writings. Whether or to what degree the writings in this corpus can be attributed individually to the Coan or Cnidian schools is another question; in any case, most of these writings come from the period between 430 and 370 BC.

Another rivalry, which the reference to Hesiod identifies as fruitful, is depicted by Galen as existing between the two schools of Greek Asia Minor and certain 'doctors in Italy'. These, too, were Greeks, in this case, residents of the Western Greek colonies of Sicily and Southern Italy. In the first place Galen names Philistion of Locri, whom the second apocryphal letter of Plato mentions as the personal physician of the tyrant Dionysius II of Syracuse, and who may have later moved to Athens according to a comedy of Epicrates.[1] The second doctor mentioned is Empedocles of Agrigento, the Sicilian natural philosopher who lived roughly between 490 and 430 BC, significantly earlier than Philistion; and finally Empedocles' student Pausanias, to whom Empedocles dedicated his didactic poem 'On nature'. Philistion can also be called a student of Empedocles: he probably did not know him personally,[2] but his medical theory, as we will see, takes up certain ideas of Empedocles. It is thus all the more remarkable that Galen does not name Empedocles first, but rather the younger Philistion. Did the introduction of the philosopher Empedocles into this medical debate need to be justified by mentioning Philistion first, since he was a follower of Empedocles, but unambiguously recognizable as a doctor? If so, what was Empodocles's contribution to the productive rivalry in medical research mentioned by Galen?

2 Empedocles as a Doctor

In the surviving fragments from Empedocles' two poems, professional medical practice and Empedocles' own activity as a doctor and medical teacher are mentioned in only a few places, and what appears there leads us into a domain that seems to have little to do with our ideas of professional medicine. Empedocles, in fact, assumes transmigration through multiple lives; in this transmigration, the highest and last place that souls, which were banished long ago from communion with the gods, can reach before returning to the sphere of the gods is occupied by doctors, along with prophets, bards and princes.[3]

2.1 Empedocles B 146, D.-K. (Trans. Barnes 1987, 196)

> In the end they are seers and hymn-writers and doctors
> and princes among earth-dwelling men;
> and then they arise as gods, highest in honour.

In Empedocles' proud depiction of his own appearance in the introduction to the 'Purifications' (*Katharmoi*), one of his two poems, he seems in his activity as prophet and doctor to have reached the stage of godliness already.

2.2 Empedocles B 112, 4–12 D.-K. (Trans. Barnes 1987, 192)

> [A]n immortal god, no longer mortal,
> I travel, honoured by all, as is fitting,
> garlanded with bands and fresh ribbons.
> Whenever I enter a thriving town
> I am revered by men and women. They follow me
> in their thousands, asking where lies the path to gain:
> some want prophecies, others for diseases
> of every sort request to hear a healing word.

Based on the doctrine of reincarnation, assumed by the two last citations, Empedocles takes the remarkable step of regarding the killing and eating of living things as pollution and arguing vehemently for its abolition: for in every animal the divine soul of a deceased human, perhaps a close relative, may be incarnated. This ban is revolutionary for ancient thought, since it would imply doing away with the traditional cult of sacrifices. However, for our purposes, the conflict between established religion and Empedocles' dietary regulations is less important than the religious – and thus for our way of thinking, non-medical and non-scientific – reasons given for this regulation. The religiously motivated idea of pollution corresponds to the work's title, the 'Purifications'.

The title 'On nature', as well, which is transmitted along with Empedocles' other poem, should not be misunderstood as limited to a scientific or rational argument in our sense; in several of the fragments that can be securely identified as part of this work, the doctor's activity appears in a magical context instead. To his student Pausanias, to whom the poem is dedicated, Empedocles holds out the prospect that his teachings will result in the following practical abilities.

2.3 Empedocles B 111, 4–12 D.-K. (Trans. Barnes 1987, 162)

> What drugs there are for ills and what help against old age
> you will learn, since for you alone shall I accomplish all this.
> And you will stop the power of the tireless winds which sweep over the earth
> and destroy the crops with their breath,
> and again, if you wish, you will bring on compensating breezes.
> And after black rain you will produce a seasonable drought
> for men, and after the summer drought you will produce
> tree-nurturing streams which live in the ether.
> And you will lead from Hades the power of dead men.

The particularly remarkable promise of the ability to bring dead people back to life may be meant in the weaker sense that the pupil will learn to restore patients in a

coma to consciousness; this ability is ascribed to Empedocles himself in a legend in which he was able to awaken an apparently dead woman named Pantheia (Empedocles A 1 D.-K., Ch. 67). However, the clearly magical traits in the depiction of Empedocles are intensified by other legends: another of his students, Gorgias, supposedly saw him conjuring (Empedocles A 1 D.-K., Ch. 59), he is said to have calmed harmful trade winds (Empedocles A 2 D.-K.) and finally is said to have feigned his own apotheosis by secretly jumping into Mount Aetna and thus disappearing without a trace (Empedocles A 1 D.-K., Ch. 69).

3 Hippocratic Criticism of Medical Charlatans

According to what we have said so far, Empedocles must look like the prototype of a pre-scientific charlatan, far from the marked sobriety we associated with the doctors from Cos and Cnidos, the authors of the *Hippocratic Corpus*. A passage from the Hippocratic text on epilepsy directed against superstitious beliefs and practices sounds like it was aimed at Empedocles.[4]

3.1 Hippocratic Corpus, on the Sacred Disease 1.27–30 (Trans. Jones 1959, 139–141)

> Now while men continue to believe in its divine origin because they are at a loss to understand it, they really disprove its divinity by the facile method of healing which they adopt, consisting as it does of purifications and incantations. But if it is to be considered divine just because it is wonderful, there will be not one sacred disease but many, for I will show that other diseases are no less wonderful and portentous, and yet nobody considers them sacred. For instance, quotidian fevers, tertians and quartans seem to me to be no less sacred and god-sent than this disease, but nobody wonders at them. Then again one can see men who are mad and delirious from no obvious cause, and committing many strange acts.

This is not simply a matter of new against old, scientific progress against outdated superstition: rather, the author of this text on the sacred disease explicitly identifies himself as someone of conservative values, who objects above all to the impiety of the 'magicians, expiators, beggar priests and braggarts', as he calls them ('On the Sacred Disease' 1.10). Whether they were impious or not – from doctors like the ones attacked here, we would hardly expect an outstanding contribution to medical research, as Galen claims for Empedocles. In fact, Empedocles' place in medical history rests neither on his activities as a doctor nor on the legends which grew up around his life, but on the principles of his natural philosophy.

4 Empedocles' Physics

Empedocles adopts from Parmenides, the slightly older philosopher from the Greek West, the principle that nothing can arise from Non-Being, and that Being is imperishable (B 11, B 12).[5] But in diametrical opposition to Parmenides,

Empedocles assumes a plurality of Being. There are six kinds of Being: first of all, four primordial and imperishable basic substances: fire and water, earth and air (B 17.18), which he calls 'roots' in one passage (B 6.1), and which have been referred to since Plato and Aristotle as the four Empedoclean *elements* (*stoicheia*). In addition, according to B 17.19–20, there are the two powers Strife (*Neikos*, *Kotos*) and Love (*Philotes*, *Philia*), which are also primordial and imperishable (B 16).

Love and Strife affect the four roots: the effect of Love is to bind the roots together, that of Strife to separate them out again.[6] But Empedocles does not depict the relationship between roots and forces as a relationship between materials and energy. That he does not regard the four roots as merely inert 'matter' is clear from the fact that he attributes to them effort, perhaps even consciousness (B 110.8–10), perhaps also from the fact that he refers to them once with the names of gods (B 6). On the other hand, he presents Love and Strife as almost corporeal: the pupil is told of the 'weight' of Strife (B 17.19), the 'length and breadth' of Love (B 17.20), of the 'limbs' of Strife (B 35.11; cp. 30.1), of the 'space' which is first 'occupied' and then 'relinquished' by Strife (B 35.12–13).

The teacher derives everything that has arisen and perished from Being – that is, from the four roots and from Strife and Love. The homogeneous masses consisting of just one root (B 38) – that is, the sun (from fire), the atmosphere (from air), the sea (from water) and our planet (from earth) – supposedly formed when Strife separated out a mixture of all four roots that had existed previously.[7]

This cosmogony is an example of the principle, attributed by Aristotle to Empedocles' teachings, that like attracts like.[8] One frequently cited sentence of Empedocles in particular seems to explain knowledge with the relationship of like to like: we recognize earth with earth, water with water, air with air, fire with fire, love with love, and strife with strife (B 109). Empedocles promises his student Pausanias that knowledge attained through proper study will attract further, similar knowledge by itself, but that if he becomes dull, it (knowledge – the roots?) will leave him and, longing for itself, return to its own kind (B 110).

Mixtures of different roots, on the other hand, are created by Love. All living things consist of such mixtures: plants, people, animals and even the traditional gods (B 21.9–12). Empedocles even knows in what proportions the roots occur in various organic materials. Bones, for example, consist of two parts earth, two parts water and four parts fire.

4.1 Empedocles B 96 D.-K (Trans. Barnes 1987, 187)

> Kindly earth in her well-made hollows
> received of the eight parts two of bright Nestis
> and four of Hephaestus. And they became white bones,
> wonderfully fitted together by the glue of Harmony.

Blood and flesh, on the other hand, consist of one part each of earth, water, fire, and air, although the proportion of earth can vary slightly.

4.2 Empedocles B 98 D.-K (Trans. Barnes 1987, 169)

> Earth, roughly equal to them, happened together with
> Hephaestus and Rain and shining Ether,
> anchored in the perfect harbours of Aphrodite,
> either a little more earth or less where they were more.
> And from them came blood and different forms of flesh.

From this analysis it follows that, strictly speaking, we should not talk of the separation or binding of imperishable roots as 'coming into being' or 'death' (B 8).

5 Empedocles' Theory of the Elements as a Medical Axiom in Philistion

Empedocles seems to have started from these principles in expounding his medical theories as well. At least fragment B 111, already cited, in which he holds out to his student Pausanias the prospect of disposing over drugs and over the power of reawakening the dead, can be read in this way: understanding the teachings of natural philosophy *in their totality* will *also* give the student medical powers. But how natural philosophy and medical practice were connected remains unknown. So it is all the more important that the use of Empedocles' theory of the four roots as an axiom of medical theory is explicitly attested for a later member of the Italian 'school' mentioned by Galen: Philistion of Locri.

5.1 Philistion, Frag. 4 Wellmann (Trans. Jones 1968, 81)

> Philistion thinks that we are composed of four 'forms', that is, of four elements – fire, air, water, earth. Each of these too has its own power; of fire the power is the hot, of air it is the cold, of water the moist, and of earth the dry. … According to him diseases occur in many ways, but speaking quite generally and in outline we may call them three: (1) because of the elements; (2) because of the condition of our bodies; (3) because of external causes. … The elements cause disease when the hot and the moist are in excess, or when the hot becomes less and weak.

According to Philistion, the human body consists of the four elements fire, air, water and earth; like Empedocles (B 17.28), Philistion attributes a specific power to each of the four elements; the individual qualities of the elements heat, cold, damp and dryness, which are named by Philistion, are associated with Empedoclean theory by ancient testimonies (Empedocles A 33). But beyond the *physiological* assumptions attested for Empedocles, this testimony attributes to Philistion the further step of using the elements to explain diseases. The causes of disease accepted by Philistion can be divided into three classes: one of them has to do with the reciprocal relationship of the four elements: we become sick, among other reasons, when

the elements in our body are out of balance. Nothing in medical literature is closer to Empedocles' physics than Philistion's works; no other medical author in antiquity adopted Empedocles' physics without any changes. But the fundamental methodological idea that living organisms are made of the same materials as the cosmos also made it into the *Hippocratic Corpus*, as we will show with one example in the following.

6 The Assumption of the Same Basic Materials for Human Beings and the Cosmos in *De Carnibus*

The text 'On Fleshes' (*De carnibus*) starts by programmatically asserting the necessity of discussing, however briefly, the cosmos as a whole and its origins in order to explain the physiology and pathology of humans and other living things (1.2). There follows the outline of a cosmogony (2.1).

6.1 Hippocratic Corpus, De carnibus (Trans. Potter 1995, 133 And 135)

> (1, 2) About what is in the heavens I have no need to speak, except insofar as is necessary in order to explain how man and the other animals are formed and come into being, what the soul is, what health and sickness are, what in man is evil and what good, and where his death comes from. From here on, then, I present opinions that are my own.
>
> (2, 1) I believe that what we call heat is in fact immortal, that it perceives all things, and sees, hears and knows all that is and all that will be. Now at the time that the universe was in a state of turbulence, the greatest part of this heat separated off into the uppermost revolving vault of heaven. This the ancients, I believe, called the 'aether'. The second portion of material below this is called earth; it is cold, dry and in great motion, although it too contains much heat. The third portion is the air closest to the earth; it is moistest and thickest.

This cosmogony describes how the immortal and omniscient 'Heat', which apparently existed in primordial solitude, entered into a state of turbulence, which then led to the separation of two other elements from the Heat and to a cosmogony. The structure of this process corresponds to the cosmogony described by Empedocles (A 49.2). But instead of the four elements in Empedocles' theory, in this text only three elements arise[9]:

1. The Heat (= Aether)
2. Earth (cold, dry, and turbulent)
3. In the middle, the Aër which is closest to Earth (very damp and thick)

Despite this important difference this schema is quite similar to the cosmogony of Empedocles: in Empedocles (A 49), too, Fire and Air separated out first, leaving Warmth; the separation of Damp from Earth appears as a secondary process.

The fact that in *De carnibus* Fire appears first, but Air in Empedocles, may be related to the fact that the word 'Aither' is used in *De carnibus* for Fire, in Empedocles for Air. But for us, the most important thing is that *De carnibus* agrees with Empedocles in explaining the organic materials of living things as combinations of the elements that separated out in the cosmogony.

6.2 Hippocratic Corpus, De carnibus (Trans. Potter 1995, 135)

> (3, 1) Now while these things were mingled with one another in a state of turbulence as they rotated, much heat was left behind at various places in the earth, in some places great amounts, in others lesser amounts and in still others very small amounts, but these many in number. As with time the earth was dried out by this heat, the materials left behind engendered putrefactions about themselves, which had the form of tunics. Now what was heated for a great time and happened to arise from the putrefaction of the earth as fat, and containing the least moisture, quickly burnt up and became bones. That, on the other hand, which happened to be more gluey and to contain cold could not be burnt up on being heated or become dry … for this reason it took a form rather different from the other things, and became cords and vessels.

Similarly, in the following chapters 3–12 on the two intermediate stages of the fatty and gluey explains the origin of all parts of the human body, one after the other: bones, blood vessels and nerves, throat, digestive tract, stomach and entrails, lungs, spleen, kidneys, muscles, limbs, nerves, spit, fingernails and toenails, teeth. The methodological parallel to Empedocles' 'formulas' for bones, blood and flesh, cited above, is obvious.

7 Hippocratic Protest Against the Natural Science Paradigm

Precisely the basic premise in texts like 'On Fleshes', deriving the elements of individual living things from the structure of the cosmos in the manner of Empedocles, was vehemently opposed by other authors in the *Hippocratic Corpus*. The text 'On ancient medicine', in the only passage of the *Hippocratic Corpus* that mentions Empedocles by name, makes the provocative attempt to reverse the hierarchy of the domains of knowledge established in the texts we have cited so far: according to it, natural philosophy is not only irrelevant for the healing arts, it is also doomed to failure in so far as it is not based on medicine.

7.1 Hippocratic Corpus, De Vetere Medicina 20.1–2 (Trans. Jones 1957, 53)

> (1) Certain physicians and philosophers assert that nobody can know medicine who is ignorant what a man is; he who would treat patients properly must, they say, learn this. But the question they raise is one for philosophy; it is the province of those who, like

> Empedocles, have written on natural science, what man is from the beginning, how he came into being at the first, and from what elements he was originally constructed. (2) But my view is, first, that all that philosophers or physicians have said or written on natural science no more pertains to medicine than to painting. I also hold that clear knowledge about natural science can be acquired from medicine and from no other source.

Here Empedocles, in contrast to the image with which we started, is criticized not as a pre-scientific charlatan, but as a speculative natural philosopher. The mention of painting is particularly malicious if it refers, as seems plausible, to fragment B 23 of Empedocles. There, painters who mix various colours in painting animals, birds, fish, people and gods, are used as a poetic figure for Love, which creates the various living things by mixing the four elements. But the polemical rejection of Empedoclean natural philosophy in 'On ancient medicine' was not the last word. Instead, the relationship of ancient medicine to natural philosophy was determined for a long time to come by the text 'De natura hominis', which can be read as an intelligent balance between the two positions we have described.

8 Polybus

The text 'De natura hominis', which we will now examine, is the only one in the *Hippocratic Corpus* that can be attributed to a definite author. It was written ca. 410–400 BC by Polybus, a student of Hippocrates.[10] Polybus begins by formulating his basic assumption that living creatures are made up of, and disintegrate again into, a fixed number of components. He does not identify these components. But he characterizes them by attributing to each of them one of the four qualities of damp, dryness, heat and cold that we have seen associated, for example in Philistion, with the four Empedoclean elements.

8.1 Hippocratic Corpus (Polybus), De Natura Hominis 3.2 (Trans. Jones 1959b, 11)

> (3.2) Therefore, since such is the nature both of all other things and of man, man of necessity is not one, but each of the components contributing to generation has in the body the power it contributed. Again, each component must return to its own nature when the body of a man dies, moist to moist, dry to dry, hot to hot and cold to cold. Such too is the nature of animals, and of all other things. All things are born in a like way, and all things die in a like way…

In a second step, he then names the four humours present in the human body: blood, phlegm, yellow bile and black bile. Human health depends on these four humours staying in the correct proportions of quantity and strength, and on their being well mixed together.

8.2 *Hippocratic Corpus (Polybus), De Natura Hominis 4.1 (Trans. Jones 1959b, 11–13)*

> (4.1) The body of man has in itself blood, phlegm, yellow bile and black bile; these make up the nature of his body, and through these he feels pain or enjoys health. Now he enjoys the most perfect health when these elements are duly proportioned to one another in respect of compounding, power and bulk, and when they are perfectly mingled. Pain is felt when one of these elements is in defect or excess, or is isolated in the body without being compounded with all the others.

How are these four fluids related to the components cited from chapter 3.2? It is characteristic of Polybus that he does not identify them with each other. The reason for this is obvious: he could never claim about the four fluids what he said about the components in chapter 3.2, namely that they return like to like after the disintegration of the human body. For this claim would imply that for each of these components there is a corresponding reservoir in the cosmos, as in Empedoclean physics: the fire in our body makes its way to the sun after our death, the water to the sea, the earth to the earth, and the air to the atmosphere. To assume corresponding cosmic reservoirs for blood, phlegm, yellow bile and black bile would obviously be absurd. Polybus obviously accepts the four Empedoclean elements as components of the human body. But these components stand in no relation to the four humours that cause sickness and health. Rather, the four humours (like the human body as a whole) *are made of* the components, and their individuality is shown not least by the fact that the elementary qualities of the components are present to varying degrees in each humour; the individuality of the humours is thus just as evident as that of – and here Polybus does for once refer to two of the Empedoclean elements by name – fire and water.

8.3 *Hippocratic Corpus (Polybus), De Natura Hominis 5,2 (Trans. Jones 1959b, 13 + 15)*

> (5, 2) First I assert that the names of these according to convention are separated, and that none of them has the same name as the others; furthermore, that according to nature their essential forms are separated, phlegm being quite unlike blood, blood being quite unlike bile, bile being quite unlike phlegm. How could they be like one another, when their colours appear not alike to the sight nor does their touch seem alike to the hand? For they are not equally warm, nor cold, nor dry, nor moist. Since then they are so different from one another in essential form and in power, they cannot be one, if fire and water are not one. From the following evidence you may know that these elements are not all one, but that each of them has its own power and its own nature.

So Polybus assumes, like the author of ‘De carnibus’, that the human body is made of the same materials as the cosmos; in addition, like Philistion, he identifies these materials with the four elements of Empedocles. But Polybus avoids the

mere adoption of teachings from natural philosophy, criticized in writings like 'De vetere medicina': according to Polybus, it is not the four elements themselves, as in Philistion, that determine the health and sickness of humans, but rather the four humours that are made up of them. Thus, on the one hand Polybus links himself to the traditional humoral pathology which was deeply rooted in medical practice. On the other hand, by settling for *four* liquids, he provides the structural precondition for combining humoral pathology with the Empedoclean theory of the elements.

This intelligent compromise was all the more attractive for late antiquity because the Empedoclean theory of the four elements had become generally acknowledged ever since Aristotle had incorporated it into his physics of the sublunary realm. When Galen, in the passage we cited at the beginning, remarked on the fruitfulness of the intellectual competition between the Hippocratic and Italian doctors, he may well have been thinking of this compromise and its assumptions, especially since it was Galen himself who canonized the resolution found by Polybus and thus led to its universal acceptance in the following centuries.

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1. Epicrates, frag. 10 Kassel/Austin, lines 27–29.
2. Wellmann (1901: 68–69) presumes that Philistion was actually not the physician of Dionysius II, but Dionysius I. That would bring him one generation closer to Empedocles.
3. Empedocles is cited according to the collection of fragments by Diels and Kranz 1951; fragments preceded by B contain original texts, those by A ancient testimonies *about* Empedocles.
4. Wellmann (1901: 29–31), note 1 to p. 29; Burnet (1892: 201–202); Jouanna (1961).
5. Here and in the following, Empedocles is cited according to the numbers in the Diels-Kranz collection 1951, with A (for testimonies) or B (for original fragments).
6. B 17, 7–8; B 20, 2–5; B 21, 7–8; B 26, 5–6.
7. A 49 (ii) (Aetius); B 50 (ascent of the fire); B 55 (the sea sweated out by the earth).
8. Aristotle, Nicomachean Ethics 8, 2; 1155 b 6–8. Cp. Aristotle, Eudemian Ethics 8, 1, 1235a 9–12.
9. For a long time this text was read in an expanded version which, if it were original, would lead to the conclusion of Jouanna (1961: 453) that the author also accepted Empedocles' theory of the four elements. But Diller (1936: 372 = 148 with n. 18) already showed that this expansion is not authentic, but was introduced into a late Greek manuscript (Paris. gr. 2255 = E) from the Latin translation of Calvus (Rome 1525) via the Greek text of Cornarius (Basel 1538).
10. Jouanna (1992 : 552).

Roman Pain and the Rise of Christianity

Susanna Elm

Omne animal, simul atque natum sit, voluptatem appetere eaque gaudere ut summo bono, dolorem aspernari ut summum malum et, quantum possit, a se repellere, idque facere nondum depravatum, ipsa natura incorrupte atque integere judicante.[1]

1 Pain

Healing, as this volume once again indicates, and what we mean by "health" are seemingly straightforward yet complex issues with numerous and variegated implications. Notions of health, so seemingly natural, are in no small part determined by cultural specifics and hence shift over time, so that every attempt at defining what we mean by healing and health instantly gives rise to new sets of questions. The same holds true for one particular facet of health and healing, namely pain. Regardless of the manifold definitions of health and healing discussed in this volume, processes of healing share one common aspect: they are inextricably linked to pain. Indeed the old adage cited in the *Hippocratic Corpus* (ca. 430–380 BCE) still holds today, namely that "pain cures pain"; that "pain signifies" the locus of illness and is essential to diagnostics and the medical interventions necessary to effect healing.[2] Yet, today notions of health, both physiological and psychological, presuppose levels of pain and its cognitive evaluation, suffering, which do not impair the well-being of the person concerned. Indeed, today health and to a large degree the process of healing involves patients who are ethical and juridical persons with the right to the greatest possible minimization and alleviation of "negative" pain and, ideally, suffering.[3] Some advertisements promising "freedom from pain" to the contrary, minimization of pain does not mean to be pain-free. Complete absence of pain is itself an illness; what we wish for is "healthy," normal rather than pathological pain.[4]

Such observations – as will be discussed by John Efron in his volume as well – require some definition of what pain actually is, and therein lies the crux of the matter. The American Medical Association (AMA) and the International Society for the Study of Pain define pain as an unpleasant sensation resulting from tissue

S. Elm, S.N. Willich (eds.), *Quo Vadis Medical Healing,*

damage and respectively as "a particularly complex signal broadcast over nerve ends leading from the site of injury to the brain … until the injury heals."[5] Anyone knows, of course, that pain is far more than that. Acute and chronic pain, though recognizable as localized and specific, are sensations that profoundly affect the entire human being, body and mind alike. More to the point, pain is a sensation that has always and continues to affect all beings, human (and animal), throughout recorded history.[6] All human beings at all times in every society have sought to alleviate pain and continue to do so: anyone who watches television knows that nearly half of the medications advertised promise to relieve pain – both physical and emotional, acute and chronic. A now dated study by the NIH from 1983 estimated that 90 million Americans suffer from chronic pain, and that the partial disabilities resulting from that caused the loss of 750 million workdays – but we also know that such figures shift according to levels of unemployment: the higher the competition for jobs the lower such figures.[7] Further, such figures as a percentage of the total workforce shift dramatically from country to country. For example, the *per capita* consumption of painkillers in France is about three times that of the USA. Interestingly, a recently completed study conducted by the George Soros Foundation has found that 88% of the patients in the USA are consistently undermedicated for pain relief.[8] Three observations emerge: (a) modern medicine has yet to reach a universally agreed upon, comprehensive definition of pain; (b) pain is a universal, human condition; and (c) the experience, perception and representation of pain is culturally determined.[9] My following remarks, since I am not a physician, will deal with aspects of the latter two observations.

1.1 Pain as Human Condition

Cultural anthropologists, ethnographers, physicians, public health experts and neuroscientists could but need not be adduced to support the claim that pain is a universal feature of the human condition.[10] In fact, prior to the nineteenth century, pain was such an unalterable condition of humanity that it had the force of a natural, indeed divine law. Unlike hunger, terror, or fear, pain, like death, was inevitable.[11] Likewise, all human beings everywhere sought to avoid and alleviate pain to the degree possible in a multitude of ways. Thus, to focus on Western examples, the authors of the *Hippocratic Corpus* knew and used opiate plants such as mandrake, henbane, nightshade and poppies. All ancient Greek and Latin medical authors proffer numerous different remedies for pain in accordance with their etiologies.[12] However, even though ancient medical writers, especially Aretaeus of Cappadocia and Galen of Pergamon, often described the various symptoms of pain very accurately, their remedies remained largely ineffectual.[13] Phrased differently, prior to the early nineteenth century and the widespread introduction of effective means to achieve complete and lasting insensitivity to pain, namely chloroform, ether, and morphine, lasting alleviation of most forms of pain had not been possible.[14] Only as a result of the path-breaking findings regarding the function of nerves and the discoveries

related to anesthetics as well as their subsequent widespread employment in the 1840s and later has it been possible, for the first time in human history, to alleviate and even avoid pain. The importance of that development cannot be overestimated and was evident at the time. In fact, the widespread introduction of ether, chloroform and morphine, especially during surgery and in childbirth, was hotly contested precisely because, according to its opponents, it violated natural laws (divine laws, such as the commandment of Genesis, "in pain and sorrow shall you bring forth thy children" were cited, but less frequently). One important argument against the use of complete anesthesia was precisely that it deprived the patient of the use of a tool considered essential for any cure and recovery: his or her "nature" or "energy" (or "valor" or "life force"), in short, his or her mind and free will.[15] That is, the fact that attempts at alleviation prior to the 1840s (including laudanum, opiates, "sweet vitriol," nightshade) remained insufficient to render someone completely insensitive to extreme pain was not seen as problematic, on the contrary. Since in accordance with Galenic medical principles the mind was thought to exert a profound influence on morbidity, a cure could also only be achieved through the active cooperation of a patient's conscious mind. Such active cooperation required the endurance of pain.[16] Therefore, the principal way to deal with pain was to find ways to endure, suffer and live with it, in the essential absence of ways to avoid and alleviate it. Hence, all societies sought to understand, express, and use pain and its endurance in numerous different ways.[17] And despite all medical advances from the 1840s onwards, it remains the case even today that the manner in which each individual lives with, endures, expresses, and evaluates pain, results from a complex set of historically specific cultural constructions – all of which, of course, affect a person's self-definition of health and healing, or as promised by a very successful Pain Clinic, one's "Freedom from Pain."[18]

1.2 Pain as Cultural Construct

Thus, from the perspective of the physician but also from that of the historian, pain occupies a very specific place: unlike almost any other facet of humanity it stands at the nexus between the individual, neurologically and anatomically determined experience of each and every human being, and the cultural constructs of their society.[19] Expressed differently, pain emerges not solely at the intersection of a violating agent and tissue damaged, and the history of its alleviation is not solely a story of biomedical progress, but pain and its experience emerge at the intersection of body, mind and culture.[20] Therefore, from the perspective of the historian, shifts in the manner in which pain is expressed, represented, used and valued can be highly significant indicators of larger societal changes. Such changes in turn affect the manner in which individuals perceive and endure pain. By the same token, the ways in which societies have historically expressed and represented pain, in particular prior to the fundamental shift of the 1840s, may also be of value to today's physicians engaged in palliative treatments. Precisely because of the immense

success of the biomedical/neurological/anatomical discoveries regarding pain and the tremendous advances in minimizing surgical invasion, the limits of these advances have also become clear. Especially, prolonged pain resistant to medication has emerged as an illness rather than a symptom. Pain clinics, now numbering well over 1,000 in the USA, though frequently differing in their approaches, all seek to deal with chronic pain in a comprehensive manner, which sees pain not only as a neurological sensation but also as the result of the patient's perception and representation, which in turn are shaped by his or her environment and its cultural constructs.[21] What is now re-emerging as significant are the multiple ways of "living with pain" known to earlier societies, i.e. an expansion of the treatment of pain solely through medication.[22] The social and cultural construction of pain and its expression, i.e. "pain narratives," and the particular moments in which such "pain narratives" appear to demonstrate shifts in the cultural matrix out of which they emerge have thus increasingly become the subject of scholarly investigations.[23]

2 Roman Pain and the Rise of Christianity

One such shift, it has been argued, occurred between the 1st century BCE until about the 2nd century CE in the emerging Roman Empire.[24] The reason for such an assumption becomes immediately obvious if we recall that this was the period that witnessed the rise of Christianity. Though I have implicitly argued in my previous observations that the discoveries of the 1840s represent the only fundamental shift in the understanding, expression and evaluation of pain in human history, because it had never before been possible to achieve real anesthesia, a powerful argument can be made that persons in the early Roman Empire expressed shifts in the cultural construction of pain with equally far-reaching consequences. These shifts, it is argued, were vital for the acceptance and the eventual rise of Christianity. This argument and some of its implications will be the subject of my following brief remarks.

Central to Christianity is a divine figure whose divinity is manifest through two intimately connected "events," theologically understood to have occurred both in a historic moment yet to be also eternal and hence universal. The significance of the principal event is obvious: Christ's resurrection. Through it, he, a God made human, overcame death and thus made manifest mankind's salvation from this unavoidable fate through the possibility of an afterlife. Perhaps less central today, post-1840s, is the significance of the second aspect, crucially linked to the first. Jesus' death was the result of Roman legal procedures: a specific form of execution reserved for non-citizens and persons of low social status, preceded by a standard form of due process, also calibrated to social status, namely torture.[25] Since Jesus' social status was low and the Roman legal system calibrated punishment more to the social status of the accused than to the crime, his torture and execution were designed to cause and to demonstrate publicly extreme and prolonged pain. Thus, for persons who had no means of alleviating pain, including those whose social status did not protect them against juridical torture, Jesus' extremely painful death

and subsequent resurrection provided a divinely inspired model of enduring and thereby alleviating pain by ways other than death, which already Cicero had considered the sole true analgesic.[26] The "pain narrative" of Jesus' death and resurrection promised his followers ultimate salvation understood as endurance and eventual alleviation of all pain in eternity.

Of course, for everyone alive at that time, the sources for constant and acute pain, both physical and psychological, were manifold, even if they never encountered the Roman legal system. For example, recent archaeological data and epidemiological studies combining the observations of ancient physicians with modern methodologies confirm, not surprisingly, that the city of Rome was the capital of the Roman Empire also with regard to infection and disease. Not only were the bodies of its residents battlegrounds for worms, amoebas, bacteria and viruses of all kinds, but Rome especially was also a breeding ground of all forms of malaria present in the Mediterranean with particular prevalence of the malignant tertian fever caused by *Plasmodium falciparum* and quartan fever (*P. malariae*).[27] Especially at risk were recently immigrated (male) adults, i.e. persons who were neither immunized through childhood exposure nor of a social status that permitted them to join the annual exodus of the wealthy to the hills and mountains from September to October, i.e. the peak malaria season. Aside from death through malaria itself, its widespread presence led to fatal interactions with other diseases present in the city, especially diarrhea, respiratory diseases both acute (pulmonary tuberculosis) and chronic, as well as typhoid, paratyphoid and amoebic dysentery. Given such interactions, comparative studies suggest a 60% mortality rate in adults between 20 and 50 years of age, a Crude Death Rate for the city of Rome of 60 per 1,000, which puts the mean life expectancy at birth below 20 years – a staggering imbalance between births and deaths, which could only be (and was) mitigated through correspondingly large-scale immigration.

Further, Rome's location at the crossroad of commerce and migration meant that every communicable disease was sure to enter it sooner or later. Leprosy, for example, had just arrived in Rome by the time of Galen, i.e. around 120 CE. At that point, Rome had had close ties to Alexandria and Egypt, the primary centers of leprosy in the ancient world, for over 150 years and many of Rome's Egyptian immigrants were carriers. However, the spread of leprosy in the city was slow, perhaps precisely because of the elevated body temperatures caused by the presence of tuberculosis and malaria, which may have inhibited the new bacterium. Nonetheless, many other deadly epidemics periodically ravaged the city, such as the "Antonine Plague" of 166, which may have conceivably cost the lives of up to a third of its population, about 300,000 people or several thousand a day, and a second severe plague in 189.[28] Such illnesses were, of course, mere additions to the normal sources of pain such as accidents, beatings, giving birth, rotting teeth, and so on.

The results of these recent epidemiological studies into early imperial Rome, pointing to the increasing stranglehold of malaria and the arrival of leprosy combined with two ferocious plagues during the latter part of the second century, could, upon first glance, support recent theories that argue that Christianity's rise was made possible because of a preceding general shift in the Roman cultural perceptions of the body in pain. Christianity, so goes the argument, won out, because its central

narrative of a divinity in pain, whose suffering overcomes death and promises alleviation and healing, was a better story than that of competing "pain narratives." The theory, influenced in large part by the works of Michel Foucault and other cultural theorists (like Julia Kristeva, Luce Irrigaray, and Gille Deleuze, as well as Elaine Scarry's seminal work on the body in pain), is a seductive one.[29]

Reflecting Foucault's arguments according to which narratives or discourses of "embodiment" express the way cultures "construct" the individual as a self and as a member of a community, scholars like Judith Perkins have linked the rise of Christianity to the emergence of exactly such a new self, this time the "suffering self." The "suffering self" takes hold on the "psyche" of the elites of the Greco-Roman world during the period of Rome's expansion into the early Empire, roughly between 100 BCE and 200 CE. This expansion led to an increasing dependence of the social elites on an imperial power located outside their immediate sphere of influence, namely, their city or *polis*. Because faraway Rome rather than one's native *polis*, or in Rome itself an omnipotent emperor rather than one's peers, were now the source of supreme power, old, communal structures "broke apart," while the new locus of power remained outside one's own control. In response, the elites turned away from the community of the *polis* (*politeia*) as locus of power and focused instead on their own bodies as a new site of control upon which to establish authority. However, so the argument of Perkins, the body upon which many writers during this period focused their attention was not the body as well-functioning organism, but the body in pain, illness and suffering.[30]

Indeed, many sources support this argument. For example, several major ancient medical figures flourished during this period, namely Galen, Rufus of Ephesus, Soranus, Aretaeus of Cappadocia, men who wrote a significant portion of the ancient Greco-Roman medical texts preserved. Scholars have also noted a marked interest in the descriptions of physical conditions in a number of personal letters. Thus, the rhetorician Fronto wrote to his friend, the emperor Marcus Aurelius, how he had been troubled at night "with widespread pains in my shoulder and elbow and knee and ankle" (so that he could not even write this letter with his own hand, *Ad Marcum Caesarem* 5.73). Apuleius of Maduara, a well-known author and public speaker, detailed how one of his performances was severely hampered by an ankle twisted so violently "that I almost tore the joint from my leg. … My body broke out in a profuse sweat and I caught a severe chill. This was followed by an agonizing pain in my bowels" (*Florida* 16). Detailed descriptions of physical pain also formed part of a hugely successful literary genre, which emerged during that period, the so-called romance novels, in which the hero and heroine endured terrible physical distress before being happily reunited.[31] Pain and its endurance, as is well known, were key tenets of the writings of several "neo"- Stoic philosophers, such as Seneca and Epictetus, whose teachings became "*the* idea system … of the ancient classics word," reaching its apogee during the early empire.[32] Seneca, Epictetus and other Stoics used physical disease, violence, and pain as examples for humanity's incapability to affect anything other than one's own response to such afflictions through endurance.[33] Equally interestingly, a variety of sources, both literary and archaeological, suggest that many persons of elite status turned their fiscal (and emotive)

attention away not only from the city, but also from the official gods of their city and instead focused more on household gods and gods whose religion centered on narratives of pain and suffering. One such immensely popular goddess was Isis and her brother and consort Osiris. Their annual festival reenacted and celebrated Osiris' brutal and painful dismemberment, which was alleviated and cured through his subsequent "reassembly" and resurrection at the hand of Isis. The equally popular religion of the great mother goddess Cybele and her consort Attis focused on Cybele's healing and salvation of Attis who had been at death's door due to castration.[34] Thus, it appears indeed as if physical pain, the suffering of the body and means to alleviate and endure it, played an increasingly central role in the first 200 years of the current era. Was there then a shift in the cultural construction of pain? If so, does this really reflect a different evaluation of the nature of pain? And if so, what role did Christianity play?

As mentioned above, the argument put forward by Perkins and others for the eventual dominance of the Christian narrative of pain is that it was the "better" narrative. But "better" in what way? Better because, so the argument goes, it gave a more eloquent voice to individual pain and hence made the individual sufferer culturally visible, thus giving pain a more human face?[35] Or better for entirely different reasons? On first glance, there is little difference between the story of a brutally tortured, dying and resurrected god-human called Jesus and the equally tortured and resurrected, human god called Osiris, except that one was condemned to death by a Roman judge in a Roman court, and the other murdered by a power-hungry brother in a cosmic family drama.

But here, one could argue, lies the crucial difference. One "narrative" focuses on immense physical pain within the context of internal power-struggles and their resolution within an elite, divine Egyptian family, while the other focuses instead on an individual who represents an entirely different community: the community of all those who had been made to suffer pain in public as a result of their encounter with the expansion of Rome as represented by its all-powerful legal system. And, as one can imagine, this was quite a formidable community. Both stories, that of Isis and that of Jesus, or more accurately, his Greek equivalent, Christ, were apparently of considerable attraction to the elites of the early Roman Empire. Indeed, contrary to a notion still widespread, Christianity was never the religion of the "poor and downtrodden." Instead, it was embraced and spread by members of a stratum that one might want to call "lesser elites." These were persons who had means at their disposal and who were educated, who had things to lose, and lived within communal structures whose potential break-up they had reason to fear, but who were not in any position of "real" power.[36] That is, though they played a significant role and enjoyed corresponding privileges in the context of their own local law, whenever they encountered the negative effects of Roman law their social status was not sufficiently elevated to counterbalance their ethnic affiliation to a degree that would have granted them the protection against tortures enjoyed by Roman citizens of corresponding status as well as the higher elites of their own ethnicity.[37] In short, early Christianity was most popular among the non-Roman inhabitants of the Roman Empire who were increasingly affected in their own sphere of influence by

the presence of Roman law, its encounters with the local legal systems, and all that both Roman law and such encounters stood for.[38]

Thus, Christian narratives of pain were not "better" because, as has frequently been argued, they gave adherents a new subjectivity as sufferers and constructed a new community of sufferers within which the poor, the mute or the paralytic found a new visibility as a result of shifts in the understanding of pain – at least not before the sixth or even the twelfth century.[39] Rather, early Christian narratives of pain offered their readers and hearers ways to negotiate, address and redress their position vis-à-vis a new imperial power, embodied in the divine emperor and his representatives, the provincial governors who were also the supreme judges. Or to say it differently, shifts in the composition and construction of "narratives of pain" need not at all represent shifts in the understanding of the nature of pain or attitudes to it. This is especially true, I think, prior to the 1840s when there was so relatively little that could be done to actually change the nature of pain that it by necessity retained its position as a natural, unavoidable human condition. The shifts in "pain narratives" represented by early Christianity, I would argue instead, represent not a new understanding of pain, but an entirely new set of scenarios where members of local elites now, as a result of the Roman expansion, needed to fear potentially arbitrary exposures to judicial cruelty from which they previously had been exempt and, hence, protected.[40] That the sudden realization of their own vulnerability could and did *à la très longue durée* led towards the greater humanization of physical affliction and the greater sensitivity to injustice for which Christianity justifiably stands, is not in doubt; what I doubt very much is the argumentation that Romans fundamentally changed their attitudes towards pain, either before or as a result of Christianity.

2.1 Christianity and Roman Legal Pain

To support that view, namely that Christianity gained purchase during the early empire not primarily because its narrative of pain corresponded to a "shift" in the nature and representation of pain *per se*, but because it offered a powerful set of exemplars as to how to negotiate the frequently painful effects of Roman rule as made manifest and visible through legal torture, I would like to conclude with two sets of examples, one from the period in question, i.e. the second century, and the other from a period when Christianity had in fact become the religion of the empire, i.e. the fourth century, when, if attitudes to pain had profoundly changed, we should expect to find significant proof.

2.2 Judicial Torture I: Martyrdom

The most frequently cited texts to argue for the greater persuasiveness of Christian narratives of pain are not, as one might expect, the gospels, but a specific literary genre that also emerged during the second century of the current era, namely the

accounts of martyrdom. A phenomenon hotly debated in scholarship, it is clear that few aspects of Christianity play as important a role in its perception as does martyrdom – indeed, for most the history of early Christianity is still synonymous with persecution and eventual triumph over the persecutors.[41] Though numerous studies have pointed to the sporadic nature of actual deaths, it is easy to see why the accounts of martyrdom continue to capture the imagination. They are highly constructed narratives that describe in vivid detail bodies in excruciating pain and the eventual torturous death of the sufferer. For the early martyr accounts dating from the second and early third centuries CE, two features are crucial. First, the hero or heroine suffers extreme pain publicly as the result of Roman legal procedures. Their pain results from the official, legal means of execution and the preceding *quaestio*, i.e. the investigation of the facts of the case, which included torture. The reason why Christians were executed was not because they were Christian, but because of their refusal to sacrifice to the gods, which according to Roman laws (*ius in sacris*) and religious understanding was the equivalent of recklessly endangering the public welfare.[42] For Christians, on the other hand, the painful public tortures and death of the martyr imitated the death of Christ and hence manifested his continuing divine power. This was so, second, because the "pain narratives" of the martyr stories represent the hero or heroine visibly enduring extreme tortures. Since public killings are traditional means to establish dominance, the victim's endurance represents a reversal of the power-dynamic.[43] Visibly empowered to endure extreme pain through Christ's divine might, his martyrs (which is the Greek for "witness" in a trial) overthrow Rome's might as represented by its legal apparatus. In the words Minucius Felix placed into the mouth of one of Christianity's defenders, "nay, our boys and tender women are so inspired to sufferance of pain that they laugh to scorn crosses and tortures, wild beast and all the paraphernalia of punishment" (*Octavius* 37.5). Other martyrs are represented as accomplishing similar feats. Thus, Polycarp, the leader of the Christian community at Smyrna, overcame through his death the power of the unjust proconsul, thereby winning "the incontestable prize."[44] The more extreme the torture and the pain, the greater, of course, are the corresponding victory of the martyr and the humiliation of Rome. In another famous description of martyrdom, preserved by the fourth-century Church Historian Eusebius, Sanctus after several days of torture, which had included the application of hot bronze tablets to the most tender parts of his body, "could not even bear the touch of a hand … but his body unbent and became straight under the subsequent tortures; he recovered his former appearance and the use of his limbs. Indeed, the second trial by the grace of Christ provided to be not a torture but a cure."[45]

2.3 Judicial Torture II: Late Antiquity

By the fourth century Rome and its legal system had become the purview of Christian emperors. Given the fact that these emperors now defended Christianity, and thus a religion to which a divinity who died a painfully torturous death as a result of his encounter with Roman might was central, one would now expect a lessening

of judicial cruelty and tortures, in particular, in light of the overwhelming impact of the "martyr narratives" – if indeed a shift in the understanding of the body in pain or even the nature of pain had occurred. Indeed, one of Constantine's earliest legal acts was to prohibit the branding of slaves and criminals in their face, since it was made in God's image. What remained explicitly permitted was the branding of any other part of the body.[46] And that sets the tone. The fourth century is marked, according to both pagan and Christian accounts, by what one scholar has called "judicial savagery."[47] We have an unprecedented number of texts describing the ruthlessness of judges and the sadism of legal torture, as in the scene evoked by Ammianus Marcellinus: "[T]he racks were tightened, the lead weights brought out, along with the cords and lashes, everywhere [could be heard] the brutal cries of torturers as they went about their work amidst the creaking of the chains – 'hold him steady, shut him in, tighten, release' " (Amm. Marc. 29.1.23). What caused such outbursts of indignation at the cruelty of tortures was not, however, a new consciousness of pain, but rather a progressive erosion of the legal exemptions to tortures which had previously been granted to the elites (in part as the result of attempts by successive emperors to hold their imperial administrators more accountable). That is, the fourth-century authors, both Christian and pagan, who now decried judicial tortures were outraged not because of the pain caused or by tortures *per se*, but because they now affected people they knew. And since these were people they knew since they were of the same class, they presumed the victims innocent, and hence tortured unjustly. Neither the fact of torture nor its essential legitimacy or the pain it caused was ever questioned. Thus, the same Church Historian Eusebius states that the torture inflicted on martyrs was evil not because it was painful but because they were innocent. In addition, it was the means through which the martyr was able to testify to the strength of his or her faith and had therefore occurred in accordance with divine will. Hence, what made torture evil was not pain but the potential innocence of the victim.[48] Augustine argued likewise. The more painful the torture, the sooner the sinner would confess and the earlier divine mercy could begin to take its effect. What mattered was the moral character of the victim, not the infliction of pain itself (*acrius investigatio*). Thus is the tenor even of one of the most comprehensive and eloquent criticisms of judicial torture, namely Augustine's *City of God* 19.6, where he argued that judges had no other option but to resort to torture, because as a result of the fall it was the human condition to remain in a state of essential ignorance as to the motives of another human. Therefore, since judges too were human and as such essentially ignorant as to the accused's innocence or guilt, they could only arrive at the truth through torture. What was bad about the method was solely the potential innocence of a victim: in that case and that case alone, torture was wrong because unjust. Nowhere in his long reflection on the potential injustice of torture in case of the victim's innocence does Augustine object to the infliction of pain as a matter of principle. Pain was never seen as an evil in itself; if torture were to affect always only the guilty it would always be justified. In short, pain was and continued to be accepted as inevitability – perhaps precisely because the central divinity was now a God who had died as a man suffering and enduring painful torture and execution. Pain continued

to be endured as a matter of course, whether from natural causes or justly inflicted upon deserving victims. And, in the absence of anesthetics, there was little else that could be done other than to school the human mind in extreme endurance, whether aided by human or divine example.

References

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2. *Hipppocratic Corpus: Epidemics V* and *Aphorism* II. 46; see also Celsus, *De Re Medicina;* Jacques Jouanna (1974) *Pour une archéologie de l'École de Cnide*. Paris: Belles Lettres; Rey, pp. 20–25. For further discussion of the *Hippocratic Corpus* see Oliver Primavesi in this volume.
3. Ariel Glucklich (2001) *Sacred Pain. Hurting the Body for the Sake of the Soul*. Oxford: Oxford University Press, p. 179.
4. David B. Morris (1991) *The Culture of Pain*. Berkeley, CA: University of California Press, pp. 9–18; Rey, p. 7.
5. Glucklich, p. 11; Morris, p. 1.
6. K. D. Keele (1962) "Some Historical Concepts of Pain," in C. A. Keele and Robert Smith (eds.) *The Assessment of Pain in Man and Animal*. London: Duckworth, pp. 12–27.
7. Morris, p. 19; Mary-Jo Delvecchio Good et al. (ed.) *Pain as Human Experience. An Anthropological Perspective*. Berkeley, CA: University of California Press, pp. 3–7.
8. Barry Stimmel (1983) *Pain, Analgesia, and Addiction: The Pharmacological Treatment of Pain*. New York: Raven Press; Soros Foundation study as part of the "Project on Death in America," http://www.soros.org with an excerpt of George Soros's inaugural speech, where he states that "doctors, nurses, and other health professionals need better training in the care of the dying, especially in the relief of pain. Health professionals also need training in alleviating the psychological, emotional, and existential suffering that may accompany dying. Physical pain is what people fear most about dying. A dying person in pain cannot think about anything else, leaving no room for coming to terms with death, for reviewing one's life, putting one's affairs in order, for saying good-bye. Therefore, pain relief must come first. Doctors often under medicate their dying patients for fear of turn in them into drug addicts."
9. Rey, pp. 331–337.
10. Good, pp. 1–3 with bibliography.
11. Rey, pp. 132–260; Glucklich, pp.179–198.
12. M. Moisan (1989) "Les plantes narcotiques dans le Corpus hippocratique," in P. Pottier, G. Maloney and J. Desautel (eds.) *La Malatie et les maladies dans la Collection hippocratique*. Quebec: Editions du Sphynx, pp. 381–392; see also Celsus, *De Re Medicina*, 4.13, 1–3; 1. 9 and 2. 7; Aretaeus of Cappadocia (1958), Carl Hude (ed.) *On the Causes and Indications of Acute and Chronic Disease* II 2 and 12. Berlin: Akademie Verlag; Galen, *On the Use of the Parts*, 8. 5–6; 5. 9; see Rosa Maria Moreno Rodrigez and Luis Garcia Ballester (1982) "El dolor en la teoria y la pratica medicas de Galeno," *Dynamis* 2: 3–24; Rey, pp. 30–37. Galen was reluctant to use opium, which was to have an effect on later Galenism, Rey, p. 83.
13. Rey, pp. 44–131, esp. pp. 85–88. Opium sponges used in Antiquity to induce sleep fell out of use during the Middle Ages, but in the sixteenth century external compresses consisting of "stupefacients and narcotics," such as henbane, hemlock, solanum, mandrake and opium,

were used. Though known as a substance, ether's ("sweet vitriol") anesthetic powers were not understood prior to the late eighteenth/early nineteenth century. See Niklaus Largier (2001) *Lob der Peitsche. Eine Kulturgeschichte der Erregung*. Munich: Beck, pp. 60–107, for medieval pain, especially in the context of flagellation and pp. 311–359 for the healing associated with that practice.

14. On laudanum and the first "Opium Wars" in seventeenth-century Europe see Rey, pp. 82–85 and pp. 125–129.
15. Glucklich, pp. 179–201; Rey, pp. 132–260. See also Stefan Willich in this volume. For an in-depth discussion of the debates surrounding the introduction of ether and chloroform see Martin S. Pernick (1985) *A Calculus of Suffering. Pain, Anesthesia, and Utilitarian Professionalism in Ninteenth Century American Medicine*. New York: Columbia University Press.
16. See also Ambrose Paré *Dix Livres de la Chirurgie, avec le magasin des intruments*, facsimile cited in Rey, 347 n. 29; also id., *Traité de la peste*, in Malgaigne (1840–1841) *Œvres completes*. Paris: J. B. Ballière, pp. 152–158, 172; Montaigne, *Essais*, 1. 14, pp. 56–59; Rey, pp. 50–70.
17. Elaine Scarry (1985) *The Body in Pain*. New York: Oxford University Press.
18. From an anthropological point of view the *locus classicus* are Mark Zborowski's studies (1952) "Cultural Components in the Response to Pain," *Journal of Social Issues* 8 (4): 16–31, and Zborowski (1969) *People in Pain*. San Francisco, CA: Jossey-Bass, in which he demonstrated that "old Yankees," Jews, Irish and Italian war veterans reacted differently to bodily pain. Though based on taxonomies today considered anachronistic, Zborowski's studies had enormous impact, because he opened the field to cultural comparisons.
19. H. Fabrega and S. Tyma's studies (1976) "Culture, language, and the shaping of illness; An illustration based on pain," *Journal of Psychosomatic Research* 20: 323–337, and Fabrega and Tyma (1976) "Language and cultural influence in the description of pain," *British Journal of Medical Psychology* 49: 349–371, illustrate the complex nexus of culture and pain through an overwhelming use of evidence ranging from neurobiology via psychosomatic medicine to philosophy.
20. "Despite its many individual, social, and cultural characteristics, pain is not an historical subject in the same sense as … hell, or purgatory. Pain is based on an anatomical and physiological foundation, and if there is one experience where the human condition's universality and the species' biological unity is manifest, pain is certainly it," Rey, p. 5. See for example studies that observe the absence of pain experienced by men wounded in battle, e.g. in Henry K. Beecher's study (1946) "Men wounded in Battle," *Bulletin of the US Army Medical Department* 5: 445–452 ; and Patrick D. Wall (1979) "On the relation of injury to pain," *Pain* 6: 253–264. Such phenomena were already described by Homer, *Iliad*, 6 and 20; Mirko D. Grmek (1989) *Diseases in the Ancient Greek World*. Transl. by M. Muellner. Baltimore, MD: Johns Hopkins University Press, pp. 27–33.
21. Morris, pp. 74–78; Byron J. Good, "A Body in Pain – The Making of a World of Chronic Pain, in Goode et al., *Pain as Human Experience*, pp. 29–48; Linda C. Garro: "Chronic Illness and the Construction of Narratives," ibid., pp. 100–137. Recent studies de-emphasize earlier correlations between chronic pain and low income levels (where persons supposedly somatize more), but it appears certain that chronic pain is germane to Western industrialized societies.
22. Glucklich, pp. 40–77; Morris, pp. 48–74, and pp. 164–168 on the "peripheralist" versus "centralist" debates between John J. Bonica and Benjamin L. Crue, both pioneering founders of pain clinics in the twentieth century. Today's pain clinics as well as the *McGill University Pain Questionnaire* published in 1975 and again in 1992 seek to evaluate pain in a more comprehensive manner, focusing on experiential categories like sensory, affective and evaluative responses to pain, and treating not only the damaged tissue but seeking to take a patient's entire lived world into consideration, Glucklich, pp. 44 and 209. See for example the self-description of the Stanford Pain Management Clinic or of the Marcus Pain Clinic.
23. Especially influenced by Elaine Scarry's work.
24. Though based on a different focus, the foundational work for this line of argument is Michel Foucault (1988) *The History of Sexuality*, vol. 3: *The Care of the Self*. Transl. by R. Hurley.

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30. Perkins p. 4–76.
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33. Hence, it was one principle aim of Stoic teachings to school the two principle virtues of any human being: *toleratio* and *continentia*, endurance and refrain (Aulus Gellius, *Noct. Att*. 17.19. According to Epictetus, the training of *prohairesis*, or the active, deliberate choice of the intellectual mind in its response to external factors was the essential task: "learning what is under our control and what is not, and the only thing under our control is *prohairesis* … but not under our control are the body, the parts of our body, possessions, parents, brothers, children, country (1.22.10). …" "Disease is an impediment to the body, but not to *prohairesis*, unless it [i.e. *prohairesis*] wills it. Lameness is an impediment to the leg, but not to *prohairesis*" (*Handbook* 9); Perkins, pp. 77–103; A. A. Long (2002) *Epictetus. A Stoics and Socratic Guide to Life*. Oxford: Clarendon.
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A Perfect Healing to All Our Wounds: Religion and Medicine in Judaism

John Efron

"I would like to dedicate this essay to Erich Gruen, my friend and colleague."

Throughout the deep and varied layers of human experience, one of the foundational elements that links, say, the hunter-gatherer with the astronaut, the medieval caravan trader plying the Silk Route and the contemporary foreign-currency trader on any European bourse, is that each of these individuals shares the impulse to alleviate pain and disease.[1] This characteristic exists not only at the personal level. There has never been a human community at any time or in any place that has not invested enormous intellectual, experiential and religious energy to bring about the absence of pain and disease.

The desire to be free of discomfort and spared from sickness is, along with hunger, thirst, bodily function and sexual urges, the most natural of human drives and can be said to be one of the shared attributes of all human communities.[2] But like the fulfillment of urges brought on by human desire and necessity, the need for healing, once removed from the instinctual to the practical level, enters into and is dominated by the realm of culture. In other words, how we heal depends on who we are.

While all cultures are occupied by healing, some civilizations are tangibly and immediately associated with medicine to a greater extent than others. Among them, the Jews occupy one of the most important and curiously anomalous positions in the history of medicine. From its very inception, Judaism, like other cultures, has engaged with healing but in a religion so organized around practical prohibitions, one of Judaism's first forms of engagement with medicine was to devote considerable thought to whether medical practice among Jews was even permissible. The rabbis were prompted by a number of questions: Does the practice of medicine impinge on Divine authority and judgment? Studying medicine means acquiring profane knowledge; is that permitted for Jews? Need a sick Jew even seek medical care, if "all is decreed in Heaven"? If he or she does, how does turning to the physician reflect on the individual's faith in God? What role, if any, do the rabbis assign to the larger community within the medical economy of Jewish society?

The relationship of Jews to medicine first invites consideration of Judaism's relationship to the body. According to Daniel Boyarin, the culture of rabbinic Jews, those residing in the Hebrew-Aramaic linguistic axis in Palestine and Babylonia,

S. Elm, S.N. Willich (eds.), *Quo Vadis Medical Healing,*

developed a significantly different attitude to the body than that expressed by Greek-speaking Jews and Gentiles, influenced as they were by Hellenism and Christianity. Boyarin's position is that rabbinic Jews were led to this *Weltanschauung* through their deliberate rejection of post-Pauline Christian dualist notions that "allegorized the reality of Israel quite out of corporeal existence." "For rabbinic Jews," he writes, "the human being was defined as the body … while for Hellenistic Jews … the essence of a human being is a soul housed in a body."[3] As it developed, rabbinic culture not only made the Jews the "people of the book," but as Howard Eilberg-Schwartz has argued, it also turned them into "the people of the body."[4] This then begs the question of Judaism's relationship to the body of knowledge that seeks to preserve human health – medicine. And it is here that we immediately encounter the question of anomaly, one that is central to any consideration of Jewish medical history.

The anomaly is striking. Despite the corporeal nature of Judaism, the prominence of Jews as physicians, and Judaism's elaborate consideration of various aspects of medical practice and bodily concerns, none of this ever led to the development of a specific system that can be termed "Jewish medicine." While the rabbis of the Talmud certainly pondered the nature of disease and its causes, medical discussions that took place were generally for the purposes of making a *halakhic*, or legalistic point of interpretation.[5] An independent Jewish medical tradition analogous to that possessed by the Greeks, the Arabs, the Chinese or the Indians, has simply never existed, and yet at least since the Middle Ages, Jews have been intimately linked to the practice of medicine.[6]

By around 1250, when Jews first became noticeably associated with medical practice, they constituted about 1% of European society, with slightly higher percentages in larger towns and cities. Thereafter, however, Jews accounted for as much as 50% of the physicians in a given locale. In fact, this situation existed until World War II, when at the start of which, 50% of Berlin's doctors, 50% of Budapest's and 60% of Vienna's physicians were Jewish. However, my aim in this chapter is not to examine the emergence of this medieval, and later modern, social praxis, but rather, the theological time and culture before it, to examine certain aspects of Judaism's attitude to medicine and the place the ancient rabbis assigned to it within Jewish culture.[7]

During the Talmudic Age, roughly 330 BCE to 500 CE, the engagement of Judaism with medicine tended towards the ethical and concomitant legal encounter between Jews and their physicians.[8] Keenly attuned to the hermeneutics of medicine, the rabbis devoted intense consideration to it as a subject within the field of moral economy. The first issue the rabbis had to deal with was whether medicine was permissible.

As if to underscore the notion that it is God who causes illness and it is only He who can remove it, the Jewish canon has, at various points, expressed its disapproval of the physician and medical practice in general. The Mishnah, the core text of the Talmudic tradition, quotes an unknown sage as saying, "the best of physicians are destined to go to hell."[9] Elsewhere, it is said that doctors are among the seven professions whose members will not enjoy eternal bliss, because they are so bold as to interfere with a decree of the Lord. Many sages, such as Rabbi Acha, believed that people do not have the right to heal. This view would appear to be

condoned by the deliberate omission of any mention of the physician's responsibilities in works such as the *Mishnah*, *Baraita*, and *Tosefta*. Given that, among other things, all three texts describe the duties and responsibilities of various communal officials, the failure to mention those of the physician indicates the superfluousness of his person to the authors. The translators of the Hebrew Bible into Greek would seem to follow suit when they exclude the physician from those to be resurrected. Moreover, believing in the sacrilegiousness of doctors, the Septuagint substitutes the word *rofim* (physicians) for *refa'im* (ghosts) and elsewhere translates *refa'im* with the word *aseveis*, meaning, disrespectful of God.[10]

Judaism's conception of God's nature, of His relationship to humanity, and in turn, relations between people, serves to complicate the religion's attitude to medicine. Multitudinous references to God's omnipotence in the Bible, and specifically His power over the human body, such as "I deal death and give life; I wounded and I will heal; None can deliver from My hand" (Deut. 32: 39) or, "He injures, but He binds up; He wounds, but His hands heal" (Job 5: 18), would tend to obviate the need for physicians. There is a certain fatalism inherent in all this. The people cannot possibly alter what has been decreed from on high. But that is not how Judaism conceived of illness and recovery.

Judaism does not regard the patient as helpless, devoid of agency on the road to his or her recovery. Within biblical religion one was not expected to sit passively by while being overtaken by sickness. Some of the earliest recorded prayers in the Bible are intended to heal the sick and serve as a means of therapy beyond recourse to the physician. Referring to his sister Miriam, who had been stricken with leprosy, "Moses cried out to the Lord, saying, O God, I beseech Thee, heal her!" (Num. 12: 13).[11] When the prophet Isaiah was sent by God to inform the ailing King Hezekiah to set his affairs in order "for you are going to die; you will not get well," Hezekiah "turned his face to the wall and prayed to the Lord." Thereupon, the Lord responded, saying, "I have heard your prayer, I have seen your tears. I hereby add fifteen years to your life" (Isaiah 38:1–5).[12] And as a measure of the perceived curative efficaciousness of prayer in Judaism, the Amidah, the central prayer of the thrice daily services, has as its eighth benediction, "Grant a perfect healing to all our wounds; for Thou, almighty King, art a faithful and merciful Physician. Blessed art Thou, O Lord, who healest the sick of Thy people Israel" [*barukh … rofeh kholei amo Yisrael*]. Finally, in the Middle Ages, it became customary to recite publicly in the synagogue, a *misheberakh* for a person who is ill, and for the speedy recovery of a woman who has recently given birth. The custom is maintained among all branches of Judaism to this day.[13]

The rabbis were specific about the nature of prayer and the mode of its issuance. Prayers are to be said with what is called in Hebrew, *kavanah*, or "proper concentration," just as the *mitzvot*, or commandments, are to be carried out with all due care and devotion. The right method of praying and living can, according to scripture and tradition, help sickness be avoided, or assist in the cure of someone already taken ill.[14]

In addition to prayer as a curative, there is also the performance of God's commandments, *mitzvot*. Of Judaism's 613 commandments, 213 refer either directly or

indirectly to health. In fact, according to the faithful, the fulfillment of God's laws can serve as a prophylactic therapy. "If you will heed the Lord your God diligently, doing what is upright in His sight, giving ear to his commandments and keeping all His laws, then I will not bring upon you any of the diseases that I brought upon the Egyptians, for I the Lord am your healer [*ki ani adonai rofekha*]" (Ex.15: 26).

There is in Judaism yet another means to bring about good health. Repentance after transgression of God's law can result in preventing a divinely sanctioned illness. Israelite religion held that even the Egyptians themselves were ripe for such remedial treatment. "The Lord will first afflict and then heal the Egyptians; when they turn back to the Lord, He will respond to their entreaties and heal them," said the prophet Isaiah (Isaiah 19: 22). In Judaism, one can also fast in order to promote the recovery of a sick person.[15]

The agency of the individual patient never obviated the dependence on the physician and in fact facilitated his presence because of the anti-fatalism of rabbinic culture. Help for the patients could thus come from many sources. Despite the potential challenge to divine authority posed by doctors, negative assessments of them and their art remained aberrative views – the isolated and sometimes cranky expressions of misguided piety and misanthropy. Instead, as it pertained to medicine, the cultural and social world of the Jewish people was dominated by a sense that the doctor was an asset to society, and a partner, not an adversary of God.

The following mishnaic passage illustrates the point:

> It is told of R. Ishmael and R. Akiva that, while they were walking through the streets of Jerusalem accompanied by a certain man, a sick person confronted them and said, "Masters, tell me, how shall I be healed?" They replied, "Take such-and-such until you are healed." The man accompanying the sages asked them, "Who smote him with sickness?" They replied, "The Holy One." The man: "And you bring yourselves into a matter that does not concern you? God smote, and you would heal?" The sages: "What is your work?" The man: "I work the soil. You see the sickle in my hand." The sages: "Who created the earth? Who created the vineyard?" The man: "The Holy One." The sages: "Then why do you bring yourself into a matter that does not concern you? God created it, and you eat the fruit from it!" The man: "Don't you see the sickle in my hand? If I did not go out and plow the vineyard, prune it, fertilize it, and weed it, it would have yielded nothing." The sages: "You are the biggest fool in the world! Have you not heard the verse 'As for man, his days are as grass' [Ps. 103: 15]? A tree, if it is not fertilized, weeded, and [the area around it] plowed, will not grow; and even if it does grow, if not given water to drink, it will die–will not live. So, too, the human body is a tree, the fertilizer is a healing potion, and the tiller of the soil is the physician."[16]

Contained in this parable are some of the most important features accounting for the pivotal role medicine has played within the social and religious life of the Jewish people. Moreover, it is a guide to understanding the great esteem Judaism has accorded the physician throughout its history.

The initial encounter itself between the sick man and the masters permits the author to establish rabbinical approval of the physician and the act of healing.[17] First, the rabbis advise the man that to cure his ailment, he must take an unnamed medication which they prescribe. More than this, the meeting provides the rabbis with an opportunity to explain why the man's visiting a physician was in keeping

with the fundamental tenets of Judaism, rather than being a sign of disrespect for the Divine organization of the universe.[18]

In challenging the right of the rabbis to advise the man on how best to be cured of his sickness, the onlooker sets before R. Ishmael and R. Akiva a most difficult problem. He asks, in effect, how they dare interfere with something God has done – in this case caused illness – for as it is written in the Talmud, "no man bruises his finger here on earth unless it was so decreed against him in heaven."[19] In explaining to the perplexed man that just as the physician tries to heal a body afflicted with a disease caused by God, so too does he, a farmer, interfere with God's work by preparing his field in order to maximize its yield. With this teaching of the rabbis, the man is made to understand the physicians' (and his own) role in society in light of Jewish ways of looking at the world, such as the complex and indeed intertwined and precarious balance between secular and profane acts.

The man comes to see that the doctor who tries to heal is not acting counter to God's wishes and intent. Like the vineyard, the human body is subject to potentially deleterious changes that if left untreated threaten the vitality of the organism. To enable the man to harvest the greatest amount of fruit possible, or, in other words, for any person to function to their optimum capacity in God's universe, sound health is required. But by Jewish definition, God's omniscience is the very means by which the opportunity is created for a physician to attempt to reverse the course of the illness. Performed with God's cognizance and countenance, the art of healing, rather than an act of sacrilege, is, according to the rabbis, a necessary and divinely sanctioned endeavor. The Talmud, quoting from the *Wisdom of Ben-Sira* (c. 170 BCE), also known as *Ecclesiasticus* says: "The Lord has created medicines from the earth, and a sensible man will not disparage them."[20]

Beyond *midrash*, there is law to validate the centrality of the physician in Jewish culture. Among other things, this takes the form of elaborate regulations governing compensation claims, medical malpractice and physician responsibility. For example, in cases where bodily injury has occurred, Judaism generally demands that restitution be made in the form of monetary compensation, of which there are five categories. These are *rip'ui*, healing costs to cover physician's fees and medications; *shevet*, sick leave benefits for those whose illness makes them unable to work; *tsa'ar*, monetary compensation for pain; *boshet*, damages for any shame or humiliation caused by the injury; and finally, *nezek*, or damages resulting in permanent disfigurement.[21] Healing costs, especially for a claimant who has had to miss work, are generally paid to the court in an advance lump sum. This was intended to curb the temptation by the injured party to drag out the period of recovery in order to increase the compensatory payment.[22]

For the physician specifically, the laws concerning damages are somewhat different than those applying to the average person. Certainly, the law sees him as responsible if he intentionally injures a patient. But, on the other hand, if a patient is injured as a result of physician error, then, unlike the ordinary person for whom liability law exists, the doctor is not held responsible. The basis for this ruling is what the rabbis call "for the public good."[23]

From this, however, it should not be construed that the physician was free to be negligent and irresponsible. Unlike ancient Greece where the law never held the doctor liable for either the premeditated killing or accidental death of a patient, Jewish law only granted exceptions from malpractice liability to a *rofeh uman*, an experienced or expert physician, one who was a duly licensed communal doctor.[24] By contrast, the non-licensed physician is subject to the general terms of compensation for damages in rabbinic law.

The social roots of physician responsibility in Judaism take us back to the idea that the doctor is an integral character in the life of a community, and that every community must have its physician. It is "for the public good." But in the ancient world, where cures were as much if not more a result of natural healing as physician intervention, and the mortality rate was extremely high, blaming the physician for every mishap would have severely reduced the number of individuals wishing to take up the occupation. And thus for both religious and social reasons, the rabbis held the absence of a communal doctor to be an unacceptable risk.

However, therapy for the sick is not entrusted to the doctor alone. Judaism does not see illness and the recovery therefrom as merely a private or semi-private episode in a person's life. To be sure, the principal players are God, the patient, the family, and the physician. But built into Jewish social life is the integral role the larger public is expected to play in the recovery of one of its ailing communal members. Principally, this takes the form of visiting the sick, *bikkur kholim*, an act of a highly regulated nature. It is an important social obligation with deep religious significance, and its performance is regarded as a holy act or charitable deed, *gemilat hesed*.

The religious custom of visiting the sick is, according to a midrashic interpretation, an emulation of the *mitzvah*, performed by God Himself, who is said to have visited Abraham who was recovering after his circumcision (Gen. 18: 1). The sages of the Talmud declared that visiting the sick was one of the six acts for which "a man enjoys the fruit of this world while the principal remains for him in the world to come."[25]

Because *bikkur kholim* is an act so essentially human, a rite of pure compassion, Jews are also enjoined to visit ailing non-Jews. In addition, neither does the socioeconomic status of the patient determine who the Jew visits. The Talmud states that the prominent person must visit the sick person of little means "even a hundred times a day," if necessary.[26] The religious duty of the individual, plus his social responsibility were succinctly enunciated by the twelfth-century Rhineland pietist, Judah ha-Hasid, who wrote in his collection of ethical and religious precepts, *Sefer Hasidim* (*Book of the Pious*), that: "Even the great should visit the humble. If a poor man and a rich man fall ill at the same time, and many go to the rich man to pay him honor, go thou to the poor man, even if the rich man is a scholar."[27]

Visitation alone is regarded as insufficient for the fulfillment of the holy precept of *bikkur kholim*. It is incumbent upon the visitor to say the requisite prayers for the sick, attend to their material needs, and be respectful and mindful of their delicate state. Thus Jewish law relates when the visitations should take place, who should be visited (not a person with a gastrointestinal ailment for fear that their frequent

trips to the toilet may cause them embarrassment), and what may and may not be discussed. In Jewish communities, *bikkur kholim* societies or associations were established to ensure and oversee this important social practice.

Thus far, the discussion has focused on Jewish attitudes towards healing, and the deep religious motives and theological justifications for seeing that people were both physically and mentally well. In the realm of illness, any hint of fatalism in Judaism or predetermination as a consequence of God's omnipotence was and is offset by the unshakable belief in the infinite value of human life, the Divine commandment to preserve it, and the role accorded the physician to help ensure this.

In Judaism, God's supreme act was that of human creation. God made men and women in His image (Gen. 1: 27), and for that reason, the rabbis, rather than deny the body, relish it, admire it, and above all, call for its protection. They believe that pleasure, enjoyment, and a tactile and cognitive engagement with God's creation leads to human happiness. The asceticism and monasticism of Christianity do not find their roots in the Jewish tradition. On the contrary, there has been a "carnal Israel."[28]

But Judaism not only celebrates the human body because it is the crowning glory of divine creation, and shares God's likeness. In Jewish teaching, human physicality is cherished not because of any integral fascination with corporeality, but primarily because it is expressive of human spirituality.[29] The deeply intertwined nature of both dimensions is made beautifully clear in the following midrash:

> The body of man is a microcosm, the whole world in miniature, and the world in turn is a reflex of man. The hair upon his head corresponds to the woods of the earth, his tears to a river, his mouth to the ocean. Also, the world resembles the ball of his eye: the ocean that encircles the earth is like unto the white of the eye, the dry land is the iris, Jerusalem the pupil, and the Temple the image mirrored in the pupil of the eye.

But man is more than a mere image of this world. He unites both heavenly and earthly qualities within himself. In four he resembles the angels, in four the beasts. His power of speech, his discriminating intellect, his upright walk, the glance of his eye – they all make an angel of him. But, on the other hand, he eats and drinks, secretes the waste matter in his body, propagates his kind, and dies, like the beast of the field.[30]

Animated by divine breath (Gen. 2: 7), the human body is the means by which God's ultimate purposes can be fulfilled. His laws and commandments can be followed, and exercising their God-granted freedom of moral choice, people can have dominion over the earth, for creation was called into being just for their sake.[31]

The rabbis of the Talmud recognized that the sine qua non of this scenario is good health. Going even further, they assumed that God leased humans their bodies for the duration of their lives. From this is derived the idea that since the body is on loan from God, the borrower (like anyone who rents any object), is obligated to take excellent care of it.[32]

Because of his expertise, the physician became an authority figure in Jewish society, his advice sometimes shaping and helping with the adaptation of Jewish law.[33] For example, the rabbis use the term *pikuakh nefesh*, "regard for human life," to describe

one's duty to save a human being whose existence is imperiled. The concept derives from the biblical injunction, "Neither shalt thou stand idly by the blood of thy neighbor" (Lev. 19: 16). The rabbis interpret this to mean that one must do all one can to medically assist someone in need. In fact, the Talmud goes further and states that in the execution of *pikuakh nefesh*, it is even permissible to violate the Sabbath if necessary.[34]

The rabbis read into the biblical verse, "The children of Israel shall keep the Sabbath to observe the Sabbath throughout their generations as a covenant for all time" (Ex. 31: 16), and thus it is permitted to violate the Sabbath in order to make sure the person recovers so as to be able to celebrate many more, and thereby partake in the perpetual covenant.[35] Moreover, it is written that even the performance of ritual observances need not be scrupulously performed if in so doing a life is put in jeopardy. The most obvious example is the special dispensation given pregnant women and the sick from fasting on specially designated days.[36] Similarly, even the dietary laws may be overridden when a physician's diagnosis maintains that a person's life would be endangered by adhering to them.[37]

In sum, instead of wishing that the doctor meet a fiery death, Jews endowed him with considerable power and were inclined to structure their communal life around the wisdom of another Talmudic dictum, namely, that "it is forbidden to live in a city without a physician."[38] Given that the Bible never actually uses the word *rofeh*, physician, except to derogatorily refer to foreign "healers" who used magic, the rule that Jews must only reside in places with a physician marks what one scholar has called a "major historical and philosophical development [in Judaism]."[39] For one, it suggests that the Hellenistic period signaled the beginnings of medicine as a profession among the Jews. And for another, the inspiration for Jewish doctors came from the Greeks, who, unlike healers before them who relied on pagan incantations and practices to affect cure, provided Jews with a "scientific" model of medical practice. Ostensibly shorn of religious overtones, it was a medical tradition that Jews could consider worthy of emulation and modification, with Judaism placing far less emphasis on the soul and more in the material worth of the body as a vehicle of God's creation and design. Yet even if the Greeks provided a new model of medical inspiration for Jews, this still does not mean there was a "Jewish medicine." Instead, there was a Jewish epistemology of medicine.

In the social sphere, the compatibility of Judaism and medicine became most manifest in the Middle Ages. With rabbis of the Talmudic age having passed laws that in essence recognized a preexistent social reality, the rabbis of the medieval and early modern periods came to actively encourage the study of medicine. This constituted a significant cognitive breakthrough in Jewish culture, for what was being promoted was nothing less than the acquisition of secular knowledge.

At the time when large numbers of Jews moved to Italy to study medicine, especially at the University of Padua, the sixteenth-century Italian rabbi, Gedalia ibn Yahya (1515–1578), issued one of the most cogent rabbinic justifications for the study of medicine. His view can be taken as representative: "[Medicine] is a precious and famous branch of wisdom, since it is a ladder standing on the earth, leading men to perceive the greatness of the Holy One and His wonderful deeds in the heavens and earth."[40]

For European Jewry, the granting of theological permission to study medicine and the incorporation and application of that belief into the body of the law, no matter how elaborate, does not necessarily mean that medicine was a "particularly Jewish" profession, or one that even attracted an especially large number of Jews. However, following the decline of Jewish life under medieval Islam in the mid-thirteenth century, prior to which Jews and Muslims together created a celebrated medical tradition, the focal point of Jewish medical activity shifted to Europe. This migration saw Jews continue their pursuit of medical study. Theoretically, the study of medicine remained a potential challenge to Divine (and rabbinic) authority. The practice, or at the very least, keen interest Jews showed in medicine occasioned rabbinic disquisition on the suitability or even permissibility of medical study among Jews, for the study of medicine meant the acquisition of profane knowledge.

In the main, Jews acquiring secular knowledge, especially in the form of medicine, however, was not considered a drawback. As an extraordinary expression of intellectual openness and a testament to the ability of medical knowledge to erase cultural and religious boundaries between Jews and non-Jews, the fifteenth-century Spanish rabbi and physician, Simeon ben Zemah Duran (1361–1444), declared that "if somebody will reproach me for having brought into the words of holiness words of the Gentiles, no guilt rests upon me, since it is unworthy of a scholar to omit words of truth by whomever they may have been uttered. Our sages have already said: 'Accept the truth from whomever it may come.' We do not rely upon this particular man but upon the truth."[41]

The most unequivocal Jewish estimation of medicine, one wherein the theological underpinning of it is made most clear, was made by Joseph Karo (1488–1575), the author of the *Shulkhan Arukh*, the authoritative code of Jewish law. There he writes: "The Torah gave permission to the physician to heal; moreover this is a religious precept and it is included in the category of saving life; and if he withholds his services, it is considered as shedding blood."[42]

One of the most cogent rabbinic justifications for the study of medicine, one that likewise stresses the universalism of scientific knowledge came from the sixteenth-century Italian rabbi, Gedalia ibn Yahia, who noted that "[medicine] is a precious and famous branch of wisdom, since it is a ladder standing on the earth, leading men to perceive the greatness of the Holy One and His wonderful deeds in the heavens and earth."[43]

This opinion became representative among the rabbis and we hear such views continuing to be echoed centuries later. Discussing the permissibility of Jews studying science, the distinguished eighteenth-century German rabbi, Jacob Emden (1697–1776), declared that "the study of nature is surely permitted and praiseworthy, and is needed for looking at the work of God … especially that part of it that is included in medicine, since it concerns the life of man, and the Torah approves of its existence and commands us to study it."[44]

As a consequence of such teachings, mainstream rabbinic Judaism ignored its own, sometimes highly critical, teachings and contemptuous evaluations of the doctor. It never, for example, concurred with the opposition to medical assistance

adopted by the Karaites, an eighth-century Jewish sect opposed to the Oral Law and the rabbinic interpretation of scripture. They believed that the only curative was prayer. Yet even they eventually abandoned their position. When the nineteenth-century Karaite scholar, Joseph Solomon Lutski, took ill on a visit to St. Petersburg, we are told in his biography that the doctor was unhesitatingly called for and his advice followed.[45]

While medieval and early modern Christian Bible scholars were also confronted, as were the rabbinic sages, with reconciling faith and medical intervention, the latter was sanctioned within Christian culture, despite a list of obloquies hurled at the doctor that resemble those made by some rabbis. In 1163, for example, Pope Alexander III maintained at the Council of Tours that the devil sought to seduce priests away from their sacred duties by exposing them to constant temptations. One such temptation was the study and practice of medicine. Clerics were, therefore, prohibited the study of medicine (and law) and faced excommunication if they were found to have breached Church rule on the matter. Similarly, in 1215, Pope Innocent III directed an anathema against surgery, forbidding any priest from performing operations involving the use of fire or instruments made of steel.[46]

Here Christianity differed from Judaism in that many of the latter's most illustrious religious authorities were themselves physicians. Yet, influenced by Judaism, Christian religious thinkers sanctioned medical education for the laity and praised the socially valuable role played by the physician.[47] Much later on and only among certain branches of Christianity, for example, Jehovah's Witnesses, Seventh Day Adventists, and Christian Scientists is there to be found the idea that recourse to medical assistance is irreconcilable with faith.[48]

But in Judaism, no serious sect of medical rejectionists ever developed, nor did theories of fatalism which precluded medicine ever strike root.[49] On the contrary, both in the realm of *halakha*, Jewish law, and social custom, it was (and is) incumbent upon Jews to seek medical attention. More than this, it is the moral and religious responsibility of those with the skill to provide it when necessary. Such an opinion was still being expressed by rabbinic authorities into the current era. In his magisterial *Lonely Man of Faith*, Joseph Soloveitchik opined that "the conquest of disease is the sacred duty of the man of majesty, and he must not shirk it."[50]

In conclusion, the link between the religious teachings of Judaism and the social practice of medicine was only strengthened throughout the medieval and early modern periods. During that time the rabbi-physician was a frequently sighted figure on the Jewish social landscape, and this further bolstered the prestige of the profession, making its more illustrious practitioners beloved among their communities. Making reference to the Islamic world, though it later became true of Southern European Jewish communities as well, Shlomo Dov Goitein observed that "an almost unbroken succession of medical men constituted both the actual and official leadership of one of the two minority groups in Egypt and the adjacent countries during the whole of the High Middle Ages and far beyond."[51] Moses Maimonides (1135–1204), the rabbinic authority, philosopher, and court physician was the most famous, but thus far only, character of this type.[52]

Socially, the Jewish physician came to enjoy pride of place among his co-religionists. The reason for this is that the rabbis, practical men, created a system of laws designed to serve God in the context of an organized and duly constituted social organism, the *kehillah*, or community. In its all-encompassing worldview, Judaism regards the physical and mental well being of its adherents as a sine qua non of a religiously fulfilled and fulfilling experience. To assist in the attainment of such, the sages saw the doctor as someone whose skill and assistance should and must be enlisted.

This had a decided effect on the culture and value-system of the Jews, for medicine was seen as a noble undertaking, its practice compatible with tradition. From early on, doctors became role models for Jews. As such, so many of them became doctors that despite the absence of a body of knowledge that can be designated as "Jewish medicine," a deep cognitive and cultural association of Jews with medicine, which persists down to our own time, was formed in the minds of Jews and Gentiles alike.

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20. Ben-Sira, 38: 4. The full passage in Ben-Sira reads: "Honor the doctor for his service, for the Lord created him. His skill comes from the Most High, and he is rewarded by kings. The doctor's knowledge gives him high standing and wins him the admiration of the great. The Almighty has created healing substances to grow from the earth, and the wise man knows their functions. Was it not a tree that sweetened water and so disclosed its properties? The Lord has imparted knowledge to men, that by their use of his marvels he may win praise; by using them the doctor relieves pain and from them the pharmacist makes up his mixture. There is no end to the works of the Lord, who spreads health over the whole world."
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34. BT Yoma 85 a.
35. BT Yoma 85 b.
36. BT Yoma 82 a–83 b. The rabbis instructed that the course to follow was one of incremental violation, in the hope that patient suffering could be alleviated without too much transgression of the law. Thus, the Gemara reads: "Our rabbis taught: If a woman with a child smelled the flesh of holy flesh, or of pork, we put for her a reed into the juice and place it upon her mouth. If thereupon she feels that her craving has been satisfied, it is well. If not, one feeds her with the juice itself. If thereupon her craving is satisfied it is well; if not one feeds her with the fat meat itself, for there is nothing that can stand before [the duty of] saving life."
37. BT Chullin 10 a. The ruling follows a discussion about the legal potability of water left standing covered, and then later discovered uncovered, and vice versa. The chance of contamination led the rabbis to decide the beverage should not be drunk and concluded that "regulations concerning danger to life are more stringent than ritual prohibitions."
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Part III
Chinese Medicine and Homeopathy

Part III further expands the theme of the cultural construction of health and healing. Paul Unschuld, a leading expert on the history of medicine in China, challenges the entire notion of *Traditional Chinese Medicine (TCM)*, to argue, based on the historical evolution of medicine in China, and the fact that most of that evolution is traceable only in handwritten, unpublished manuscripts, that there is no such thing as *TCM*, so popular amongst the advocates of complementary care. *TCM*, as he demonstrates, is an entirely modern, Maoist invention. Claudia Witt's cultural "other" is located in German medical history: Samuel Hahnemann and his development of homeopathic medicine. As Witt points out, strict scientific analyses of homoeopathic practices do show promising results in treating various conditions, even though homoeopathic medicine is based on an understanding of disease which stands in near diametric opposition to that found in modern, scientific medicine.

How Chinese Is 'Chinese Medicine'?

Paul U. Unschuld

Was Chinese medicine already familiar with the circulatory system before it was confronted with Western knowledge of physiology in the nineteenth century? We can safely assume so.

In handwritten Chinese medical texts from past centuries we find the notion that a 'bloodworm' is located in the body. The bloodworm has a head – a 'blood head'. Like a train, the bloodworm passes through the entire body. In the course of 12 two-hour periods it passes through a system of pathways – one could also say blood vessels – which are marked by 365 points, comparable to train stations. However, the bloodworm does not stop at these points voluntarily. Authorities on this theory know just where to find the blood head at any given point during the day or night. They also know that by gently touching the 'station' at which the blood head has just arrived, they can bring the bloodworm to a stop. They do not have to apply great pressure to this point – quite the opposite. A chopstick, a calligraphy brush or a feather will suffice. Once the bloodworm has come to a stop, then the body in which it was moving is also condemned to a standstill. At this point it is possible to kill the victim or to set it back in motion. This particular knowledge is thus used only in combat; martial arts specialists pass it on from generation to generation.

The concept of the bloodworm does not appear in printed books of Chinese medicine. Indeed, there is much that does not appear in these books – the knowledge of how to treat deafness, for example. Take a certain amount of the mineral magnetite and lay it on one of the patient's ears. Then take iron powder and put it on the other ear. Both packages are then bound firmly in place using a silk scarf, which is wrapped around the patient's head before he or she goes to sleep. Each day the magnetite and iron powder need to be replaced for the coming night. After 49 days the patient is cured of deafness. Or a third example: In China an acupuncture needle would occasionally break and leave its tip in the patient's body. What is the acupuncturist to do if the tip of the needle cannot be removed manually? He spoons out the brain of a living rat and rubs it on the point of insertion into which the tip of the needle has disappeared. The needle tip will then slide out on its own.

There are a great many books on acupuncture and Chinese traditional drug lore, both in China and the Western industrialized nations. However, none of these examples of theoretical knowledge, physical therapy or acupuncture expertise can be found in printed Chinese medical literature. Nor can they be found in literature

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written for a Western audience interested in ‘Chinese medicine’. I have taken all three examples from handwritten texts that reflect the knowledge and practices of perhaps 90–95% of the population in pre-modern China. However, these examples do not reflect the knowledge and practices that the social elite in pre-modern China regarded as appropriate to document in printed literature.

This should give us pause. I have chosen three examples that could also be quite useful for the Western world. Why, then, does literature on ‘Chinese medicine’ withhold this knowledge from us? And why has printed Chinese medical literature withheld this knowledge from its readers? These questions all touch on the fundamental issue of how Chinese medicine has been received in the West, especially over the past quarter century. What exactly has the Western audience been reading in these countless books in German, English, French, Italian, and other Western languages? It is no secret that, in the past 25 years, bestseller books on ‘Chinese medicine’ have been written by authors with little or no knowledge of the Chinese language. Many of them have been to China for only very brief visits, if at all. And yet, although these authors know hardly anything about the history of medicine in China, they have written quite successful books on ‘Chinese medicine’.

Clearly, there are still some questions here that need to be answered. There are deep divides between different segments of the population in China, each of which has different knowledge and practices. Clearly, there is also a great divide between China as a whole and the Western world – a divide which to this very day has prevented much of that which Chinese medicine has to offer from reaching us. The fundamental question is therefore: What is ‘Chinese medicine’? When we hear this term, are we to think of the knowledge and practices employed by the vast majority of Chinese – the 90–95% mentioned above – to prevent and treat disease? Or should we regard ‘Chinese medicine’ to be the knowledge and practices that were recorded in printed form by the 5% of the Chinese population we call the Chinese elite? When phrasing these questions in such a way, we take into consideration that the healing arts in China were specific to different societal strata. The formally educated Chinese upper-class possessed knowledge that was completely different from that of the vast majority of Chinese, who had a lower status in society and were less well-educated. Thus, we can distinguish between the development of both an elite medicine and the popular healing arts of the majority of Chinese. The three examples mentioned above are from the latter of the two. From a purely quantitative perspective, it is precisely the popular healing arts that should be given the name ‘Chinese medicine’, as they are representative of the largest section of the Chinese population. However, we are reluctant to make this type of definition because, in a strict sense, we cannot discern any ‘medicine’ in the popular healing arts.

What do I mean by this? Medicine is the art of healing that disregards the influence of supernatural powers (i.e. gods, ancestors, ghosts and demons). It aims to understand and explain the nature of sickness and health solely on the basis of science and, in doing so, to help sick patients become well again. Another task of medicine is to prevent healthy individuals from becoming ill in the first place. Defined narrowly in this manner, medicine is a sub-category of a broader range of healing arts. There are medical and non-medical healing arts. The latter are comprised

of all arts of healing that are based either solely on experience or the application of non-scientific theories, notions and insights. The popular healing arts are thus non-medical healing arts.

The advent of elite medicine in ancient China can be traced back to the second and first centuries BC when a segment of the Chinese elite began to use the new theories of natural science that propounded the correspondence of all things – today known as the Yin Yang and Five Agents Doctrines. They used these doctrines to explain and influence the normal and abnormal functioning of the human body according to the same natural laws that were presumed to govern the workings of the entire universe. From that point on, the popular healing arts in China coexisted with a medical art of healing. The former were primarily handed down orally and in manuscripts from generation to generation. The latter was also passed on from teacher to student, within the family or at formal institutions of learning; however, the transfer of knowledge from generation to generation took place primarily through the printed word. Today, it is only the latter that we call literature of Chinese traditional medicine.

It would be insufficient to describe Chinese medical culture as divided into the healing arts of the 'lower classes' and the 'Chinese medicine' of the elite. It is, in fact, hardly the case that all members of the formally educated Chinese elite turned their backs to the non-medical healing arts and devoted themselves to a new system of medicine. As I noted above, only a segment of the Chinese elite began to use the new theories of natural science that propounded the 'correspondence of all things' in order to explain how the human body functions, whether healthy or ill, and to influence it accordingly. We do not even know if it was the greater or smaller part of the elite at the time that made the decision for or against the inclusion of natural laws in medicine. The decision cannot have been easy. After all, knowledge from the popular healing arts in China had been used successfully since prehistoric times, and the invocation of gods, ghosts, demons and the spirits of ancestors, as well as the use of pharmaceutical substances, had, time and again, shown the desired effect – without Yin Yang and without the Five Agents Doctrine.

The emergence of a belief in the usefulness of science is a fascinating phenomenon. Why should someone have come to believe that one of the many new varieties of the Five Agents Theory could prove itself useful in understanding how the body and its diseases function? As always in the history of medicine, the belief in the usefulness of a new theory appears well in advance of the desired clinical success. First, a conviction is formed that a particular new theoretical approach will help advance medicine or the healing arts. Only on the basis of this conviction does the new approach achieve general acceptance. But where do such convictions originate? Nothing comes from nothing. What plants the seed of a new theory into someone's mind? How does it grow into a conviction? Elsewhere I have spoken of the plausibility or promise of truth that surrounds each new successful theory. Where does this plausibility originate? The answer to this question is closely related to the process by which a theory first comes into being.

In the China of classical antiquity, and time and again in the centuries since then, we can see the various steps in this process quite clearly. From reliable sources we know that a segment of the Chinese elite developed an awareness of the importance of laws and law-governed processes. This was the direct result of needing to effectively govern states that were becoming increasingly large, as was the case near the end of the era of the Warring States. The family ethic, which until then had regulated the relationship between the rulers of individual states, as well as the relationship between rulers and their subjects, was no longer suited to the new situation. It became clear that bureaucracies were necessary in order to implement government decisions in a large, anonymous population. Those members of the elite who were proponents of a large state also advocated running the state using a system of laws. By accepting the all-embracing presence of laws in people's social interactions, the awareness of the importance of laws in all of nature began to grow.[1]

One is tempted to say that the laws were suddenly 'seen'. If they really did exist, then they had always been there. It is simply that no one had seen them up until then. This changed, however, not because people had suddenly become more intelligent, but because an external catalyst – a profound change in social structures – had created a broad awareness of the necessity of laws in society and of the all-encompassing existence of laws everywhere in the universe. After this conviction had come into being, and after these laws had been postulated for the entire universe, the logical consequence was to see the existence of the individual human organism and its normal or abnormal functioning as subject to this system of laws. This development marked the beginning of Chinese medical history as a branch of the history of the Chinese healing arts.

Let us take another look at the ancient Chinese version of a natural science necessary for the creation of medical healing arts. The idea of natural laws found expression in the Yin Yang and Five Agents Doctrines. Together, we call these the teachings of the systematic correspondence of all things. It could, however, have been another type of natural science. In ancient Greece, for example, natural science was based on analysis – on the division of all things into elements. In contrast, natural science in ancient China focused on the entirety of things, and on the way in which individual elements interacted as part of this whole – an approach that would influence scientific thought in China for the next 2,000 years. To some extent, there was also a notion of systematic correspondence and an understanding of the relationship of things to each other in ancient Greece. But this notion remained rudimentary. Analytical, alphabetical thinking has been a typical feature of European science and medicine from the very start. In ancient China, the emphasis lay on the interaction of things, and this would not change for two millennia, until the encounter with Western science and logic in the nineteenth and twentieth centuries.

This distinction is one of the few truly profound differences between Western and Chinese medical traditions. When Western medicine was introduced to China in the nineteenth century, it did not seem particularly foreign to Chinese scholars. Indeed, with the exception of the fact that the intruders from the West believed that the truth could be found in the future and strove to reach this goal with the help of

scientific research, and their Chinese colleagues were of the opinion that all essential knowledge was already known during antiquity, the fundamental concepts of the new Western medicine were already present in Chinese traditional medicine.

In Europe, as in China, illness is seen above all as the result of two events. Either a foreign invader makes its way into the body, or people treat their bodies in ways that violate certain fundamental natural laws. In the former case, the foreign invader can be a microorganism, but it can also be an environmental factor, such as wind, cold or dampness. People can protect their health by guarding themselves against such invaders or, if the invader has already made its way into the body, by destroying it or driving it out. This fundamental concept is as important today in Western medicine as it has been for 2,000 years in China.

By subordinating the way they act with and treat their bodies to certain laws, people can remain healthy; or they can violate these rules and become ill. This aetiological concept is as familiar to Western medicine today as it is to Chinese traditional medicine. Today, we think of chemistry and physics when we speak of the laws that must be observed in order to remain healthy. In ancient China, people spoke of Yin Yang and the Five Agents. Just as we today are convinced that we can use chemistry and physics to understand natural laws that are valid both in the farthest corners of the universe and in the smallest cells of our body, so too were the ancient Chinese certain that the natural laws embodied by Yin and Yang and the Five Agents were universally applicable. In both cases, the goal of adapting to a system of natural laws is good health. Breaking these laws means acting against nature, and this has similar consequences for a person's body and well-being as does violating the laws of society.

Many other concepts that developed in both medical cultures in a parallel fashion could be named here. One last example is immunology – the idea that the body possesses defence mechanisms whose strength can determine whether a person remains healthy or becomes ill in response to a foreign invader. But in conclusion let us mention one important difference: the knowledge of the self-healing powers of the human body. Both the ancient Chinese and ancient Greeks observed that the body was able to recover from an illness without any treatment and recorded this observation in their writings. However, only in Europe did people keep asking themselves throughout the centuries what the cause of this might be. Only in Europe did the idea of self-healing powers, indeed of the body's self-interest in healing itself, a teleology of self-healing, as it were – emerge. In China, this concept never developed. This is hardly surprising when we compare the concept of an organism's powers of self-healing with the democratic institutions of ancient Greece – a state, a polis without kings or tyrants, to be governed and led through crises by its citizens. This way of thinking was never forgotten in Europe. In China, however, it was never present in even the most rudimentary form. To this very day, the Chinese as a whole have never believed that a social organism could govern itself without strong leadership. There has never been a democratic tradition in the European sense of the term. Thus, it is hardly surprising that, although the ancient Greeks and ancient Chinese observed the same phenomenon of self-healing, they came to different conclusions.

Before we go on to take a closer look at this 'Chinese medicine', we should direct our attention to the segment of the ancient Chinese elite that chose not to go along with these developments. Those who refused to accept progress were no less intelligent, and it was not a lack in formal education which made it impossible for them to believe in a system of natural laws. In fact, they had read the same literary canon as the other segment of the Chinese elite. Nevertheless, for reasons that can no longer be reconstructed today, these members of the Chinese elite could not bring themselves to approve of the growth of increasingly large states governed by an anonymous ruler and directed by an anonymous bureaucracy. These people – we can refer to them as Daoists – saw the ideal political unit, the ideal community, as the one described by Laozi in Chapter 80 of the *Daodejing*:

> Let there be a small land with few inhabitants: even if there were inventions that would reduce the amount of labour tenfold or one-hundredfold, the people would not use them. The people would rather die twice before they would depart from this place. Perhaps there would be boats and wagons, but no one would travel in them. Perhaps there would be weapons, but no one would practice with them. There would be no writing, except for knots in a rope. … The closest settlement might be so near that one could hear the rooster crow and the dogs bark. But the people would grow old and die without having gone there.[2]

Those who devoted themselves to such ideals of human communes must have been horrified by contemporary developments. And now we see where the rift in the elite of ancient China has its origin. The Confucians and Legalists were the moving force behind the actual, real-world developments. They supplied the new, large state with its civil servants. They educated those who could read and write, who also knew how to lead the military. They encouraged trade within the different parts of the kingdom, which had been united in the year 221 BC. All of this was alien to the Daoists, the followers of the way of life described by Laozi in Chapter 80 of the *Daodejing*. The Daoists could not see the sense in man-made laws. For them, nature was a source of herbs, minerals and animals – the raw materials they needed to feed themselves and combat disease. Confucian medicine gave birth to acupuncture, which represented the attempt to fend off sickness through the insertion of needles at special points on the body. Confucian medicine was not designed to treat manifest disease, but to prevent it by initiating treatment at the very first signs of illness. This was similar to Confucian politics in general, which concentrated on the prevention and early management of crises. In their healing arts, however, the Daoists always rejected acupuncture. They used the herbs, the minerals and the animals, just as they chased away demons and invoked spirits to heal manifest disease.

To summarize what we have written so far, we can say that ancient Chinese society was split into three parts. First, there was formally educated elite. This elite was, in its political views, by no means homogeneous. As a consequence of its split into primarily two groups with completely opposite views of how the ideal society should be structured and how to deal with crises, there developed completely opposite views of human physiology and how to treat diseases. Acupuncture treatment was based on the science of the systematic correspondence of all things, which stemmed from the Confucian school of thought. The continuation of the popular healing arts founded on demonology and an experience-based pharmaceutical

approach took place primarily in a Daoist context. Neither tradition influenced the other. The Confucians did not incorporate the pharmaceutical approach into their canon of medical knowledge, and the Daoists kept their distance from acupuncture, Yin Yang and the Five Agents Theory. This schism lasted for more than a thousand years, when outside influences caused both traditions to begin to merge in the twelfth and thirteenth centuries AD.

This belated amalgamation can be seen most clearly in the establishment of a pharmacology of systematic correspondences. This represented an attempt to explain how medicinal substances worked in the body using the Yin Yang and Five Agents Doctrines. Important to note is that none of the building blocks already present in these theories needed to be modified to create this new pharmacology. In fact, they had already existed for more than a thousand years. In 200 AD, at the same time as the Greek physician Galen in ancient Rome, Zhang Ji had suggested first steps to create just such a system. However, the time was not right, and it would take another 1,000 years before his ideas would fall on fertile soil.

In addition to both groups of the Chinese elite and the respective traditions of healing arts supported by each, there was still the majority of the population, which had it own ideas and practices. A certain degree of overlap can be discerned. Some medicinal substances that were sold by apothecaries for the upper-class were also used by the broad masses. The knowledge of the existence of demons and ghosts was also shared by the Daoists and the masses. Even acupuncture may have been familiar to those outside of elite circles, though nothing precise is known about this. The popular healing arts were, above all, based on an enormous repertoire of ready remedies. These could be instructions on how to use individual substances or more substantial mixtures thereof. The popular healing arts also consisted of a large number of physical therapeutic procedures that are mentioned only in the margins of printed literature, if at all. The same applies to popular medical ideas about how the body functions.

But let us return to the question posed at the beginning of this chapter: Which of these three health care areas constitutes 'Chinese medicine'? The Confucian-inspired health care? It is closest to the modules imported from China by the Western world and called Chinese medicine. Also, if we use the narrow definition of medicine described above, then Confucian medicine is the only 'real' medical tradition from that period. However, we must always keep in mind that Confucian medicine alone is by no means representative of Chinese society and culture as a whole, but only of the views and values of some members of a small elite.

In addition, all this talk of 'Chinese medicine' must not obscure the fact that this medicine, as is the case with the Chinese healing arts in general, was constantly subject to change. When someone states that he or she practices, or would like to learn, Chinese medicine, the question must be asked: 'Which Chinese medicine?' The original Chinese medicine of the Confucians from the Han Dynasty 2,000 years ago? That would be difficult, because at the time there was no homogeneous system of medical thought. Different authors of the period wrote substantial treatises on fundamental concepts of systematic correspondence and on vessel theory, but a practicable system that we in the West could simply adopt did not exist – and

has never existed – in China. Throughout the subsequent two millennia, countless authors wrote new texts in which they published their personal interpretations of antique theories based on their own experiences and observations.

At no point in time was there anything like a generally accepted 'school medicine' that remained static for a time or, being compulsory for the majority of doctors, would have been developed further. One has to imagine Chinese medicine as a big flower pot into which intelligent doctors and observers of nature continually fed new insights. Over time, these grew into an increasingly large inventory of often contradictory observations and conclusions. Doctors would then pluck ideas from the flower pot as they pleased – taking whatever especially appealed to them, and for whatever reason. There was no straightforward path toward more effective or 'better' practices. On the contrary, non-medical societal factors apparently influenced developments in medical theorization and treatment more strongly than did clinical insights. An example is the gradual rejection of heroic methods, including not only acupuncture, but also (and especially) effective pharmaceutical remedies. After the fourteenth and fifteenth centuries, a preference for milder procedures can be observed in China. It seems that doctors began to increasingly avoid any sort of risk. Why this is so has yet to be determined. Perhaps it was a result of increased competition among a growing number of doctors, none of whom wanted to gain a reputation for injuring his patients, much less for being responsible for a patient's death.

This was the state of affairs up until the nineteenth and twentieth centuries, when the encounter with Western culture created an entirely new situation. The decline of traditional Chinese culture as a whole resulted in Chinese medicine losing its conceptual legitimacy. This is a point that needs to be emphasized. The conceptual foundations of Chinese – or, rather, Confucian – medicine were not built on clinical observations, but were a result of the creation of an empire in 221 BC. With the decline of this empire and the Confucian system of government, it seems logical that this medical tradition also had to lose its legitimacy. There is nothing preventing Chinese traditional medicine from being practiced in the future. For many patients it has been, and will be, a successful means of therapy – at least from their own point of view. But this type of medicine will not progress any further, and will be increasingly out of place in Chinese society. Chinese students interested in learning about Chinese traditional medicine will, despite a certain linguistic familiarity with the material, experience it as an element from a foreign culture – just as students from the West do. The last of the old doctors who learned Chinese medicine before the People's Republic of China was founded will soon have passed away. Students who learn it now have all grown up in today's world. They are shaped by Western logic. They are familiar with the Internet, with physics and chemistry. They know about the real human organs and how they work from today's – or rather a Western – point of view. There will, then, no longer be an independent tradition of Chinese traditional medicine.

Since the 1950s, the People's Republic of China has actively encouraged this development. Early on, commissions were appointed to sift through China's extremely heterogeneous heritage of medical and non-medical medicine and create

a new medicine that would correspond to Mao Zedong's dictum that the new Chinese society be 'democratic and scientific'. As a result, only a fraction of the knowledge available from that large, 2,000-year-old flower pot has actually been harvested. These commissions took a small selection of ideas, treatment methods and remedies, and, based on Western logic and science combined them for the first time into a homogeneous system with the name 'traditional Chinese medicine'. This represents the first time in Chinese history that there has been a standard 'school medicine' that at least educators at public institutions are supposed to teach. This new system was created in a completely arbitrary manner. It is based on political directives and not on clinical insights.

This new system went through its initial formative phase in the mid-1970s, when the People's Republic of China opened up to the West. An astonished Western public learned of acupuncture and the intellectual world of Yin and Yang, which up until that point had been known to only a small group of outsiders. Western media, doctors and interested lay people who travelled to China were not confronted with the heterogeneous medical traditions of China as they had truly developed, but with an abridged version called 'Traditional Chinese Medicine'. And in a way, this is exactly what they wanted to see. It was somewhat exotic, but not too foreign to be threatening, because it was already based on Western thought and a Western system of logic that was free of contradictions.[3]

Since then, this 'Traditional Chinese Medicine' has achieved very broad general acceptance in the West. It has been successful, however, not because it is a historical, authentic medicinal tradition from China, but rather because it is a version easier to digest, that had already been adapted to Western ways of thinking. Even the modern form of 'Traditional Chinese Medicine' as it is taught and practiced in the People's Republic of China has not arrived unaltered in the West. The translation of technical terms from Chinese into Western languages, in itself, has led to new interpretations of these terms – interpretations that are tailored to Western expectations rather than historical Chinese ideas. The best example of this is the translation of the Chinese term 'qi' (the Chinese equivalent of the ancient Greek term 'pneuma') with the Western term 'energy'. At no point in Chinese history was the concept of 'qi' ever associated with a concept of energy. This association was first made by George Soulié de Morant at the beginning of the twentieth century, and was only familiar to a handful of esoterics. It was only after the energy crisis of the 1970s that the equation of qi with energy made its way to the centre of Western interpretations of traditional Chinese physiology and pathology. Translation into Western languages has also led to the disappearance of the martial terminology and metaphors so typical of Chinese traditional medicine. In fact, Chinese traditional medicine makes much stronger use of the terminology of warfare than does even modern Western immunology. Nevertheless, because 'Traditional Chinese Medicine' was supposed to be a 'gentle' alternative to the 'aggressive' medicine of the West, the aggressive metaphors inherent to it did not make it past the ideologically motivated filter of translation. Interestingly, in the early years of traditional Chinese medicine in the West, those who attempted to translate its terms and metaphors in a more direct fashion were denounced in polemic fashion as 'enemies of Chinese medicine'.

We began this chapter with the question: How Chinese is 'Chinese medicine'? Clearly, the answer to this question depends on what one means by the term 'Chinese medicine'. Both the 2,000-year-old tradition of Chinese traditional medicine and modern 'Traditional Chinese Medicine' in China could be called 'Chinese', as they were developed there as a reflection of their respective contemporary world views. The fact that there are many parallels to the European medical tradition does not contradict this in any way. This is, however, not the case with what we refer to in the West today as 'Traditional Chinese Medicine'. Here we are dealing with various reconstructions of elements imported from China and based on Western logic and Western sensibilities. The fact that the Western version of 'Traditional Chinese Medicine' developed in this manner is understandable, and it has had effects that have obviously brought relief to many. From the point of view of a historian, the only thing to criticize is that some advocates of this new artificial product do not promote it as a synthesis of Western and Eastern thought, but rather as 'traditional Chinese medicine' or 'classical Chinese medicine'. Then again, perhaps this little deception will also contribute to the success of this synthesis as an alternative art of healing.[4]

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Medicus Curat, Natura Sanat in Homeopathy

Claudia Witt

1 Introduction

In his *Organon of Medicine*[1] the founder of homeopathy, Samuel Hahnemann, writes that it is 'the physician's highest and only mission […] to restore the sick to health, to cure, as it is termed' (§1). 'The highest ideal of cure', Hahnemann adds, 'is rapid, gentle and permanent restoration of the health, or removal and annihilation of the disease in its whole extent, in the shortest, most reliable, and most harmless way, on easily comprehensible principles' (§2). At first glance, the fact that Hahnemann emphasizes here the physician's role in healing patients would seem to contradict the widely held naturopathic notion that 'the physician treats, nature heals', or 'medicus curat, natura sanat'.

A closer look at Hahnemann's writings, however, reveals that this is not the case. Hahnemann clearly also subscribed to the idea that 'nature' plays an important, if not essential, role in the healing process. In the *Pure Materia Medica* Hahnemann writes 'that nature hides within her cornucopia of medicinal substances an abundance of power that is almost unlimited if it is properly revealed and elaborated'.[2]

2 Homeopathy

Homeopathy is a therapeutic method that was developed at the beginning of the nineteenth century by the German physician Samuel Hahnemann (1755–1843). It is based on the observation that certain substances that cause disorders or symptoms in healthy individuals can be used in diluted form to stimulate healing in patients who have similar symptoms when ill.[3] This is referred to as the 'rule of similarity' and is one of the fundamental tenets of homeopathic practice.

The effects of such substances are found through a process called 'proving' a drug. Hahnemann described it in detail in §121–140. In these 'drug provings' healthy subjects take a homeopathic substance until symptoms occur. Hahnemann's methodology for 'drug provings' has since been adapted to modern standards of research including randomization and blinding.[4] The symptoms elicited in healthy

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subjects by a particular substance and the cure of the similar symptoms in an ill person after treatment with the same substance are referred to as the substances' 'remedy picture' (homeopathic drugs are more commonly referred to as 'remedies'). A collection of various remedy pictures is called a 'Materia Medica'.

Selecting remedies for treatment in this understanding relies on the match between the symptoms of disease in individuals who are ill and the known symptoms from the 'Materia Medica' in healthy persons to find the remedies of the highest similarity. If only a single homeopathic remedy is selected based on the total symptom picture of a patient, we have an example of what is called 'classical' homeopathy.[5]

Homeopathic drugs are produced through a process called 'potentization', which is a special combination of dilution and sucussion. They are made from many different substances. The pasqueflower, for example, is the source of the homeopathic remedy 'Pulsatilla'; bee venom the source of the remedy 'Apis'; and gold the source of the remedy 'Aurum metallicum'. Diseased tissue or the product(s) of disease can also be 'potentized'. For example, gonorrhoeal discharge is potentized into the remedy 'Medorrhinum'.

3 Defining Illness and Health

Different schools of medical thought approach the notions of 'illness' and 'health' in different ways. The World Health Organization (WHO) defines health in a particularly broad fashion as a 'state of complete physical, mental and social well-being' as opposed to the simple 'absence of disease or infirmity'.[6] The WHO definition thus sets a very high standard, which clearly cannot be reached by medicine alone. Nevertheless, in homeopathy, health is defined in a broad manner, but without explicitly taking into account the aspect of social well-being. Homeopathy holds the view that the body, mind and emotions are not separate and distinct entities, but fully integrated components of an individual. Thus, homeopathic physicians seek an individualized remedy that addresses the totality of a patient's physical and psychological symptoms and complaints.

In the *Organon of Medicine** (§9–10), the notion of 'health' is described as follows: 'In the healthy condition of man, the spiritual* vital force (autocracy), the dynamis that animate the material body (organism), rule with unbounded way, and retain all the parts of the organism in admirable, harmonious, vital operation. … The material organism, without the vital force, is capable of no sensation, no function, no self-preservation.'

In this model, the body possesses innate mechanisms of self-regulation – what Hahnemann refers to as a 'vital force'. Maintaining or restoring the harmony of these self-regulating mechanisms is thus key to good health, and disease, on the other hand, is a 'derangement', or disruption of these self-regulating mechanisms:

*The traditional translation of 'geistartig' into 'spiritual' is somewhat misleading, as 'Geist' is both 'mind' and 'spirit'. Hahnemann uses this word to denote independency from a therapeutically active material substance.

'When a person falls ill, it is only this spiritual, self acting (automatic) vital force, everywhere present in his organism, that is primarily deranged by the dynamic influence upon it of a morbific agent inimical to life; it is only the vital force, deranged to such an abnormal state, that can furnish the organism with its disagreeable sensations, and incline it to the irregular processes which we call disease; for, as a power invisible in itself, and only cognizable by its effects on the organism, its morbid derangement only makes itself known by the manifestation of disease in the sensations and functions of those parts of the organism exposed to the senses of the observer and physician, that is, by morbid symptoms, and in no other way can it make itself known' (§11). Hahnemann was also aware of the fact that not every organism reacts to a pathogenic agent with illness: 'The inimical forces, partly psychical, partly physical, to which our terrestrial existence is exposed, which are termed morbific noxious agents, do not possess the power of morbidly deranging the health of man unconditionally; but we are made ill by them only when our organism is sufficiently disposed and susceptible to attack of the morbific cause that may be present, and to be altered in its health, deranged and made to undergo abnormal sensations and functions – hence they do not produce disease in every one nor at all times' (§31). The theoretical foundations of Hahnemann's homeopathy vis-à-vis conventional medicine appears to exhibit some similarity to the debate between natural philosophy and physician's practice as described by Primavesi in this volume.

A disruption in the harmony of the body's self-regulating mechanisms, which can be termed 'disease' (§17), manifests itself only through symptoms. This means that symptoms are the only indications of illness (§12). Through the use of homeopathic remedies, the harmony of the body's self-regulating mechanisms can be restored (§16). The goal of homeopathy is thus not to eliminate or suppress symptoms, but rather to discover and treat their underlying cause. If, in response to this treatment, the signs of illness (i.e. symptoms) disappear, then it is no longer possible to speak of disease and a cure or healing has been achieved.

A significant difference between homeopathy and conventional medicine is the way in which a physician observes and examines his or her patients. This is the foundation for making a diagnosis and thus choosing an appropriate therapy. In conventional medicine, details of the pathology are of great diagnostic value. Homeopathy demands instead that the physician focuses on symptoms and observes the patient as a whole person, including body, mind and emotional state. Only then can the appropriate remedy be prescribed – the remedy picture itself being the homeopathic diagnosis. Hahnemann, who observed the course of chronic illnesses in his patients over many years, extended this concept along the course of time. He said 'that a homeopath, faced with this kind of chronic illness, indeed with all chronic distempers, is concerned not only with the disease which he sees before him, must not regard it and treat it just as a self-contained illness, … but instead regard it as an isolated part of a deep-seated primal derangement, which displays itself from time to time in new symptoms'.[7]

As a result, in classical homeopathy remedies must be customized to match the individual. Even if two patients have the same conventional diagnosis, they may require completely different homeopathic remedies. In such a case, conventional medicine would see two different patients with identical diagnoses. In contrast,

homeopathy sees also two patients with a conventional disease that can manifest itself differently in each individual and is represented by different symptoms. This also applies to incidental factors like changes in mood, thirst, appetite, reaction to temperature, and other physiological functions.[8] However, even according to conventional medicine the pattern of clinical symptoms almost always differs in some details from person to person, but the treatment is often the same.

4 Research on Homeopathy

Although great strides have been made in the natural sciences and modern conventional medicine, an increase in the number of patients who take advantage of homeopathic treatment methods has been observed. A survey in the United States[9] has shown that between 1990 and 1997 there was a marked rise in the use of complementary and alternative medicine (CAM), including homeopathy. In 1990, only 1% of the population used homeopathy. Seven years later, this had increased fourfold. In Germany around 15% of the population (10% of men and 20% of women) used homeopathic remedies within 12 months.[10]

Despite the increasing demand for homeopathic treatment, there are a number of issues that need to be addressed. This applies not only to questions of basic research (i.e. the kind of information and its transfer to the human organism are unknown), but also to clinical questions. For example, it is important to determine who is treated homeopathically for what kinds of diseases and with what degree of success. Also important are questions of treatment expense and the overall costs of illness. In the following, I will concentrate primarily on clinical questions from the area of usual care rather than basic research.

A key question[5,11] among physicians and patients alike is the efficacy of homeopathic remedies based on generally accepted, 'objective' scientific criteria. A number of studies have already addressed this issue and compared homeopathic remedies with a placebo and are summarized in various meta-analyses. However, conclusions of the two most important meta-analyses were contradictory.[5,12] Basic information about the spectrum of diagnoses and therapies were scarce. Over the last year two studies were conducted by our team.

The first study was a prospective observation of the spectrum of diagnoses and therapies seen in 103 doctors' practices in Germany.[13] Our findings show that, among women, migraines and other types of headaches were the illnesses most often treated homeopathically. Among men, allergic rhinitis and hypertension were the most common diagnoses. In children of both genders the most frequently diagnosis was atopic eczema. In total, 95% of the illnesses diagnosed were chronic, with a median duration of 9 years for adults and 4 years for children. Among the patients who received treatment, the number of women (70% among adults) and the number of patients with a German high school diploma (60%) was markedly higher than in the general population. After an observational period of 24 months and an average treatment duration of 14 months, the patients' symptoms improved, both

according to the assessment of treating physicians and patient self-assessment.[14] Similar improvements were observed in quality of life, which was measured in adults using the SF-36 questionnaire.

In a second study,[15] patients who presented at either homeopathic or conventional doctors' practices were included in the investigation. The course of disease in both groups was then compared. According to patient self-assessment and physician evaluation, therapeutic success was similar in both groups. In addition the study showed that a segment of patients used homeopathic treatment in addition to conventional therapy. Importantly, their use of conventional therapy decreased during the study in comparison to the pre-study period.

However, it was a non-randomized study and self-selection of patients that resulted in differences in the baseline characteristics. Adjusted analysis was performed to reduce hidden bias to a minimum. On the other hand, the chosen design closely reflects normal clinical practice, so that outcome and cost measurements provide a more realistic picture than can be expected in a randomized trial.

The results of both studies indicate that the great majority of patients seeking medical care from a physician practicing classical homeopathy suffer from long-term ailments and improve under this care. Its individual and holistic approach is one reason why homeopathy has become an integral part of outpatient medical care in Germany. Studies in usual care are helpful for decision-making. However, these studies cannot answer the question if a homeopathic remedy is more efficacious than a placebo. It seems that those aspects which are normally summarized under the term 'placebo' play a relevant role in homeopathy. Nevertheless, further research on homeopathy and multi-layered research concepts are necessary to determine the benefits and cost-effectiveness, and to provide more details of those placebo aspects.

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Part IV
Acute Health Care and Social Medicine

With Part IV we shift towards today's medical practice. Stefan Willich's analysis of the focus of modern medicine on acute care demonstrates both the strength and success of this approach as well as its drawbacks, particularly with regard to the often painful, chronic, nonfatal conditions resulting from aggressive, life-saving acute care, which frequently compromise quality of life. As a direct consequence, therefore, Dieter Koch-Weser, former chairman of the Department of Preventive Medicine at Harvard Medical School, postulates the urgent need to place greater emphasis on the role of today's physicians in social and preventive medicine. His chapter, which also has a historical slant, illustrates the crucial importance of social factors such as working and living conditions to health and to the emergence of "public health" as a field.

Healing In Acute Medical Therapy: Opportunities and Limitations

Stefan N. Willich

1 Introduction

The evolution of effective acute medical therapy has depended on a number of major historical developments. In addition to the identification of causal factors behind diseases, pathophysiological insight into their underlying mechanisms expanded rapidly in the nineteenth and twentieth centuries, paving the way for the development of targeted therapeutic interventions. Following Robert Koch's landmark discoveries, pathogenic microorganisms affecting human tissues began to be identified systematically, which opened the door to treatment with appropriate medication. The development of diagnostic tools has, in turn, allowed acute therapy to be applied more effectively. Indeed, highly targeted treatment is now possible owing to modern laboratory testing and the ability to visualize affected tissues by radiological, sonographic and other means. The introduction of anaesthesia and asepsis was also of the utmost importance in the development of modern surgery. Finally, the advent of modern-day hospitals in the eighteenth century and, more recently, of mobile emergency units as their present-day extensions was another prerequisite for developing and delivering effective acute therapy.

Thanks to this substantial progress in the understanding and treatment of disease, the notion of healing in medicine can now be based on modern scientific grounds. The outlook for controlling disease, healing patients, and extending longevity does indeed appear promising. At the same time, however, the limitations of acute therapies are becoming more apparent as medical outcomes frequently fall short of the expected results. There is also a growing appreciation for the risks of acute therapies. Medicine is inherently linked to potential side effects, which can affect a patient's quality of life or even lead to life-threatening complications. In this chapter, we will discuss several important aspects that might foster a more balanced perspective on the opportunities, limitations, and risks of acute medical therapy.

S. Elm, S.N. Willich (eds.), *Quo Vadis Medical Healing,*

2 Defining Healing

Healing is a somewhat vague notion in modern medicine, despite the major advances that have been made in the diagnosis and treatment of serious acute and chronic disorders; for even if 'sickness' essentially means a lack of health, 'disease' is still much easier to define. The World Health Organization, for example, describes health as physical, mental, and social well-being.[1] According to such a definition, achieving health would be a political task far beyond the capacities of medicine. Disease, however, can be regarded in general as any condition associated with a reduction in life expectancy, physical or psychological abilities, or quality of life.

There is no universally accepted notion of health in modern medicine. Until several decades ago, healing was seen as the elimination, or at least attenuation, of biological deviance (e.g. pathogenic bacteria or tumour tissue). Today, however, there is growing consensus that healing should be regarded as the restoration of quality of life and normal or near normal life expectancy.

Defining the term 'normality' poses additional challenges. Conceptually, it is important to keep in mind that disease progression is often sub-clinical, with the disease remaining latent for days, months, or even years. It is usually only after symptoms appear that patients seek medical attention and therapy is initiated. However, when a disease is suppressed below the symptom threshold, conventional medicine regards this outcome as a sign of health, even though the predisposition to the disease or its sub-clinical progression may not have been adequately addressed (Fig. 1). It is precisely here that the more holistic approach to health and healing often seen in complementary and alternative medicine comes to the fore (see also the chapters by Unschuld and Witt). According to this approach, healing is regarded as an overall enhanced state of health following the process of learning and personal growth that can result from a patient's experience with disease.

In short, the concept of healing appears difficult to define in the context of modern-day medicine. If healing is considered the elimination of abnormal and pathological

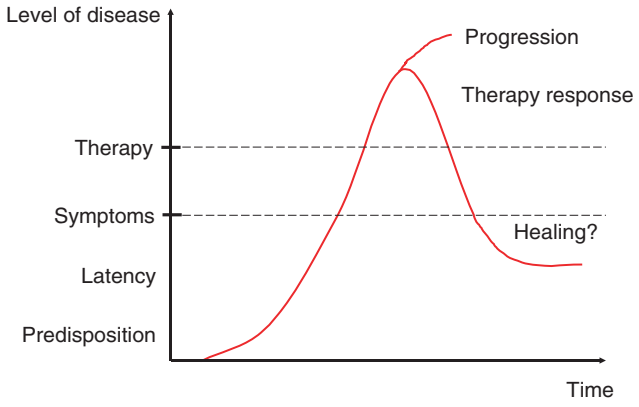

Fig. 1 Concept of disease progression or healing in acute medical therapy (see text for details)

states, modern medicine has been a success. However, if healing is measured in terms of quality of life based on patient-reported outcomes, then it is safe to say that modern medicine lacks a more holistic approach including elements from the disciplines of medicine, psychology and sociology.

3 Epidemiological Challenges in Medicine

When seeking to identify opportunities for healing in modern acute medicine, analysing the frequency and importance of different disorders is a good start. Among the leading causes of death today, atherothrombotic diseases are the number one killer, accounting for approximately 15 million deaths per year worldwide, followed by infectious diseases, pulmonary disease, cancer and deaths caused by violence[2] (Fig. 2). Interestingly, although the fight against infectious diseases is considered one of the major success stories in modern medicine, these are still among the leading causes of death, even though a number of important infections have been effectively controlled or even eradicated.

Whereas mortality has traditionally been considered the main indicator of medical success, morbidity and quality of life are often more important from the patient's perspective. In a widely publicized World Health Organization study on global burden of disease measured in disability-adjusted life years, groups of disorders other than those at the top of the mortality statistics turned out to play a more central role in determining a population's overall health status[2] (Fig. 3). The study showed that

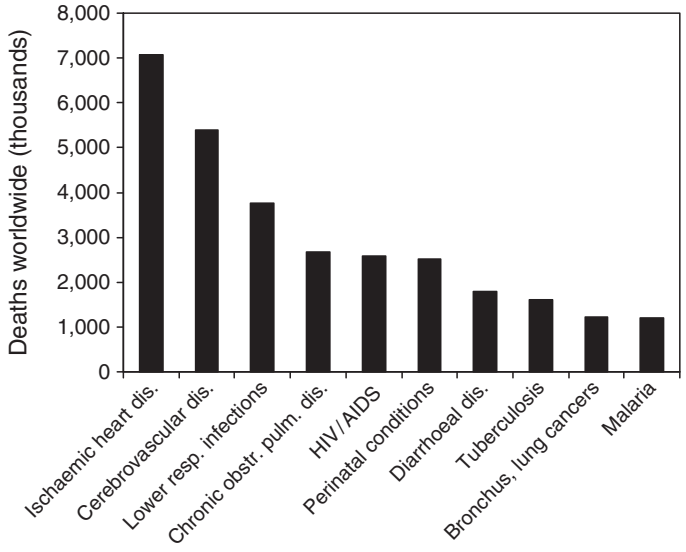

Fig. 2 Leading causes of death worldwide (adopted from the WHO Global Burden of Disease study) (Lopez et al.[2])

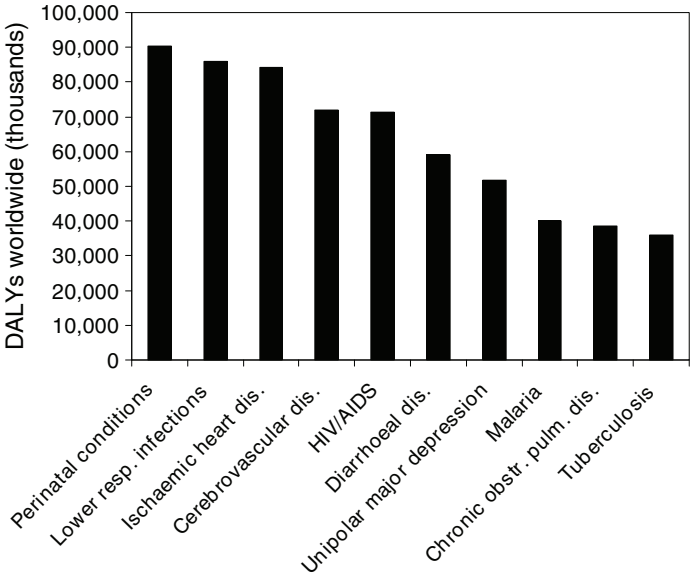

Fig. 3 Leading causes of disability worldwide (adopted from the WHO Global Burden of Disease study) (Lopez et al.[2])

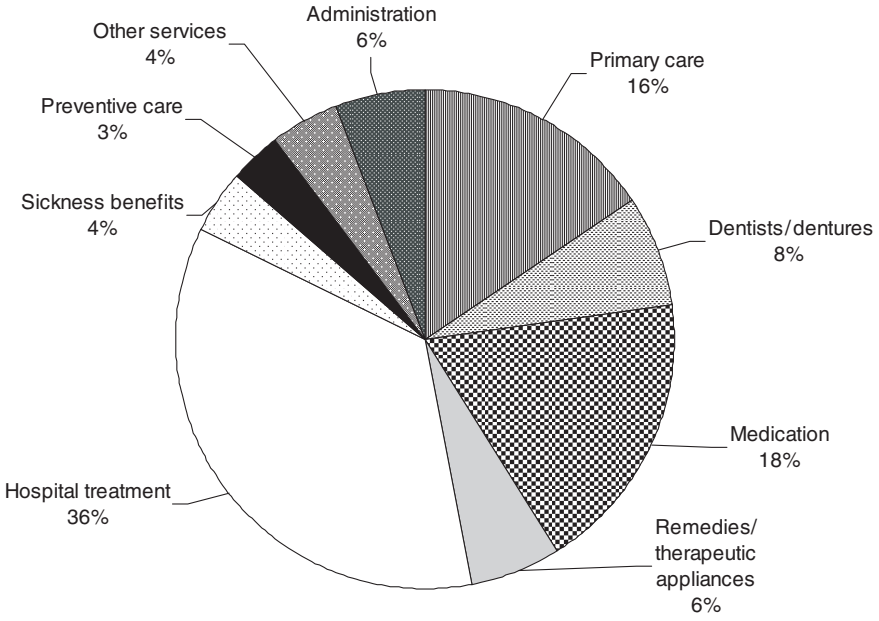

Fig. 4 Health care expenditures in Germany (2005 data from statutory health insurance funds, Federal Ministry of Health 2008)

neurological and psychiatric disorders, including depression, alcohol abuse, dementia and schizophrenia, have been greatly underestimated in their contribution to global burden of disease. In fact, most of the disorders that cause considerable burden in terms of reduced quality of life and lost productivity are actually chronic conditions.

The success of modern medicine in focusing on acute and life-threatening disease appears to be associated with the emerging importance of chronic disorders. Clearly, modern medicine has limitations in dealing effectively with these disorders and does not provide adequate means of prevention.

Looking more closely at health care expenditures in developed societies reveals the high priority that is currently placed on acute therapy (Fig. 4). In the German health care system, approximately 32% of total health expenditures are attributable to in-hospital treatment, compared to 16% for primary care and only 3% for preventive care. This differential allocation of resources has allowed developed societies to focus on mortality, morbidity and 'softer' endpoints, such as quality of life or even lifestyle. But has it really led to increased life expectancy?

4 Medical Therapy and Longevity

Historical trends in life expectancy in the United States show that although major progress was made between the years 1900 and 1950, life expectancy appeared to reach a plateau between 1950 and 2000 (Fig. 5). It would therefore seem premature to conclude that the large financial resources allocated to modern acute therapy, are directly associated with improved health and increased longevity in our societies.

Furthermore, vastly increased health spending over the past several decades has not led to the desired results. Compared to earlier periods in modern medicine, there is – at the current level of life expectancy – relatively little clinical benefit to be gained from increasing spending on modern acute therapy. This phenomenon may be due to natural upper limits in human life expectancy and/or to characteristics specific to today's major life-limiting diseases.

It is illuminating to take a closer look at the history of mortality rates for infectious diseases, since advances in the treatment of the latter are widely regarded as one of the major success stories in acute medical therapy. Taking the example of tuberculosis, we see that deaths already declined markedly during the period following the identification of the tubercle bacillus and the development of diagnostic tests. Compared to this decline, the additional progress seen after the advent of effective antibiotic therapy is surprisingly small[3] (Fig. 6). In other words, developing effective preventive measures based on knowledge gained about infection patterns and risk factors led to reductions in disease burden that were much more significant than those observed following the introduction of acute medical therapy.

These examples indicate that the correlation between the resources allocated to acute medical therapy, on the one hand, and life expectancy, on the other, is weak or at least smaller than generally assumed.

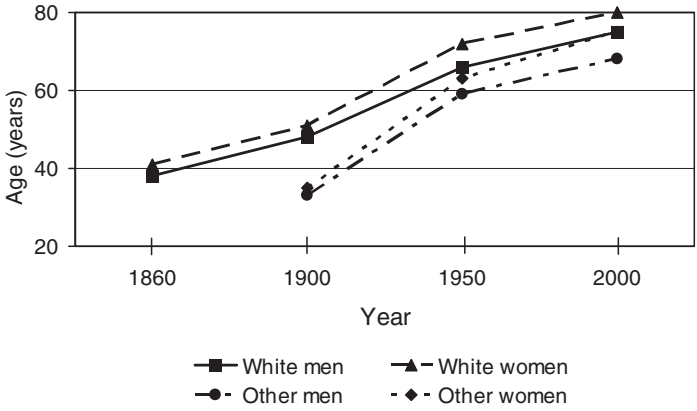

Fig. 5 Trends in life expectancy in the United States (adapted from the National Vital Statistics System, US Dept. of Health and Human Services, Centers for Disease Control and Prevention)

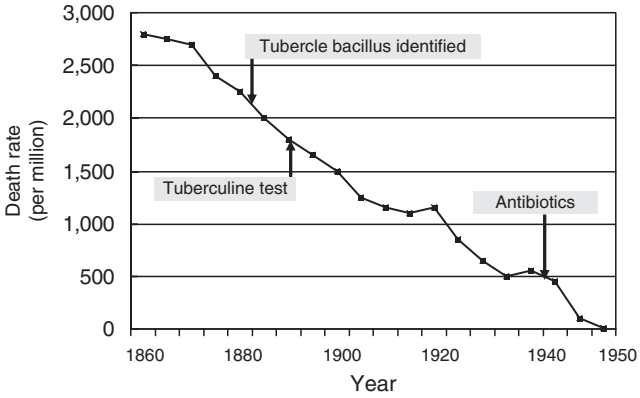

Fig. 6 Association between mortality from respiratory tuberculosis in Great Britain and Wales and general medical progress (Adapted from McKeown et al.[3])

5 Medical Therapy and Morbidity

Modern strategies in acute medical therapy have led to striking improvements in morbidity for many patient groups. Particularly in the area of cardiovascular disease – the leading disease group in terms of worldwide mortality (Fig. 2) – the development of pharmacological interventions (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors, and lipid-lowering drugs), invasive and surgical procedures (e.g. catheterization and coronary bypass surgery), and emergency care (e.g. resuscitation and defibrillation techniques) has been responsible for improved outcomes, as demonstrated in numerous controlled studies.

However, even in the case of cardiovascular disease, the use of acute therapy is not necessarily directly correlated with outcome. For example, when patient populations in different countries or regions with varying frequencies of invasive procedures were compared, the prognostic outcome following acute cardiovascular events turned out to be similar.[4] Furthermore, just because a therapeutic option is available does not necessarily mean that it is being used appropriately. Patient compliance with pharmacological therapy, for example, has been identified as a key problem in modern medicine. Studies on the long-term use of prognostically relevant medication in patients with cardiac disease demonstrate that insufficient pharmacotherapy following hospital discharge is associated with a worsening of cardiac risk factors[5] (see Fig. 7). The reasons for such underutilization may include patient fears of long-term side effects or a failure within the patient–physician relationship to cooperate or provide clear instructions.

Controlled clinical trials have produced disappointing results regarding the benefits expected of many medical procedures. In a surprising study, patients with osteoarthritis of the knee were randomly assigned to receive arthroscopic surgery or placebo surgery with skin incisions, but no actual knee joint involvement.[6] Patients and assessors were blinded to the treatment. Surprisingly, placebo patients tended to have improved overall clinical outcome in terms of pain and knee function during the first months following the procedure compared to patients who actually

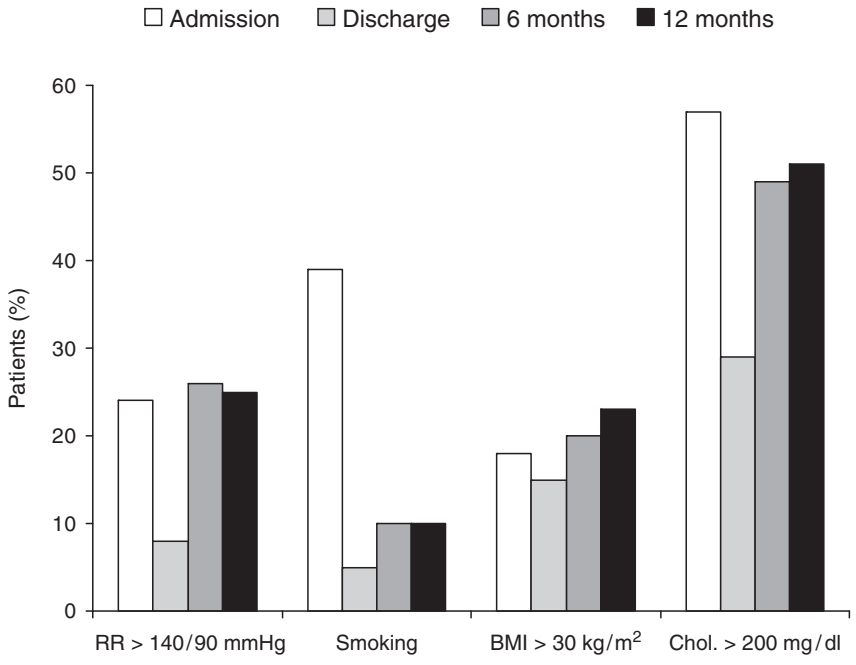

Fig. 7 Development of cardiac risk factors in patients during the 12 months following an acute cardiac event (Willich et al.[5])

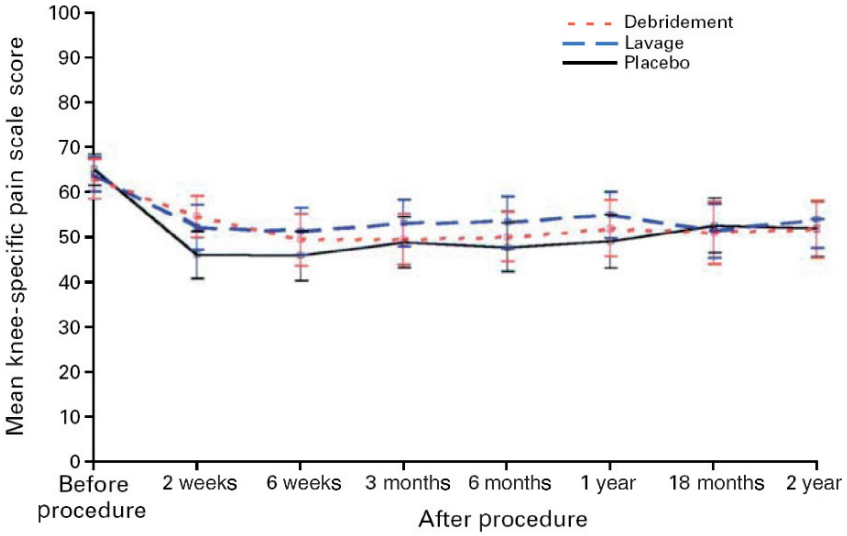

Fig. 8 Efficacy of treatments for osteoarthritis of the knee (Moseley et al.[6])

underwent surgery. Moreover, both groups demonstrated similar long-term results (see Fig. 8).

Findings like these indicate that the assumed benefits of modern medicine should be viewed with caution. Even medical approaches that appear intuitively reasonable should be rigorously tested in controlled trials before being introduced into routine care. Doing so will help avoid wasteful or even harmful medical procedures.

6 Medical Error

Medicine is notoriously associated with risks. Everyday clinical experience has taught us that side effects are to be expected, particularly after invasive medical interventions. However, although the risk of medical error is likely one of the main drawbacks of acute therapy, this area has yet to be explored in sufficient detail, whether with regard to the frequency of medical error, its underlying causes, or its prevention. Physicians, patients, and the public often fail to recognize the tremendous medical and economic burden imposed by medical error in acute therapy.

Medical error most often involves incorrect diagnosis or erroneous medication. For patients with complex syndromes, in particular, a diagnosis or treatment may simply be inadequate, leading to additional, unnecessary risks. In many cases, surgical interventions are performed unnecessarily (see example above) or, conversely, avoided in situations where they are indeed necessary.

The medication administration chain is complex. It begins with a physician's order and is followed by administrative procedures performed by nurses, the delivery or distribution of the medication by the pharmacist, and the intake of the medication by the patient. Good collaboration between these different parties, leading to adequate pharmacological treatment, is the prerequisite for compliance – yet another area of research that has received too little attention to date.

A meta-analysis of 39 prospective studies on fatal adverse drug reactions in hospital patients estimated that between 50,000 and 100,000 deaths, and approximately 1 million new disorders per year, are attributable to medical error in the United States alone.[7] This means that 3–5% of total mortality in the population is caused by adverse drug reactions, placing this category roughly between the fourth and sixth leading cause of death. Preliminary estimates indicate that medical error in acute therapy is also a considerable problem in Germany.[8]

With these figures in mind, it is surprising that interventions for systematically reducing medical error have only rarely been explored. A recent overview identified a total of 13 randomized studies evaluating methods for reducing medical errors, including medication, prescription and diagnostic errors.[9,10] Medical errors were frequent in these studies, sometimes arising in more than half of the cases where an opportunity for error existed. Relatively simple interventions, such as computerized reminders of corollary orders, leaflets, automated bedside dispensing, team intervention and self-medication programmes, were able to achieve large reductions in error rates. However, more studies are needed to provide better insight into the mechanisms behind medical errors and effective ways to prevent them.

7 Underlying Concept of the Physician's Role

Rapid changes in the health care systems of developed societies, including the evolution of new technologies and opportunities in the delivery of medical care (see also the chapter by Paul), are presenting dramatic challenges to – or even threatening – the professional concept of the physician's role. It has been suggested that current conditions of medical practice are increasingly tempting physicians to abandon their commitment to the primacy of patient welfare in the face of market forces, societal pressures, and administrative exigencies.[11,12] In order to mitigate these hazards, the Medical Professionalism Project proposed a physician charter that set forth three fundamental principles[11]:

1. The primacy of patient welfare, which is based on a dedication to serving the interest of the patient – something that has been at the core of the patient–physician relationship since ancient times
2. Patient autonomy, which requires the physician to serve as an adviser to patients in matters related to quality of life in the home and the workplace
3. Social justice, which requires the physician to promote the fair distribution of health care resources

This set of principles, arguably one of several conceivable configurations, implies a range of professional responsibilities, such as a commitment to quality care, to honesty, to confidentiality, and to improving access to health care (see also the chapter by Koch-Weser on the social responsibilities of physicians).

In light of the delicate balance between the opportunities and risks of modern-day medicine, establishing a clear set of philosophical and moral principles would seem necessary to provide health care professionals with a firm basis for making decisions and delivering effective care. This would seem especially important if we consider current controversies surrounding abortion and artificial life support, as well as future challenges related to genetic diagnosis and therapy (see also chapter by Paul). As part of a code of medical ethics, Pellegrino and Thomasma[13] have summarized physician obligations similar to the principles described above and complemented these with a list of patient obligations, including trust in the competence of the physician, respect for his or her moral agency, telling the truth about one's illness, trying not to ask more of medicine than it can provide, and participating, at least to a limited extent, in medical research.

8 Conclusions

Acute medical therapy has contributed to our achieving higher life expectancies than would have been possible in previous centuries. However, this success is closely related to developments in social medicine and is not based only on progress in acute treatment. Of course, acute medicine has clear strengths in the areas of acute infection, surgical procedures, and life-threatening emergencies. But it also has obvious weaknesses in providing effective care for patients with chronic disorders – and it is precisely these disorders that play a major role in contributing to the global burden of disease.[2]

Side-effects, adverse drug reactions, and medical error are major limitations of acute medical therapy. They have been greatly underestimated to date and should be addressed in future research. From a medical and public health perspective, acute medical therapy needs to be followed by assessments of long-term outcome, which should be based on close coordination between acute therapy, subsequent rehabilitation (if indicated), long-term ambulatory care, and preventive medicine. We clearly need better technology and tools to reduce the frequency and consequences of medical error.

Finally, the dramatic changes in modern health care systems associated with current and future treatment options require that we develop, evaluate, and implement new frameworks for supplying health care providers with a professional and ethical basis for making decisions and delivering the best possible care.

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The Historical Development of Social Medicine as a Responsibility of the Physician

Dieter Koch-Weser

In our contemporary Western society, the essential role of the physician is generally considered to be one of healer of the sick. Therefore the education and training of the future physician is primarily directed towards the goal of curing the physically or mentally diseased person and returning the same to a healthy state. It has, however, been more and more accepted that to avoid such physical and mental dysfunction, preventive measures must be taken which also must include attention to social factors. This was recognized by the World Health Organization, which defined health as "not only the absence of disease, but the complete state of physical, mental, and social well-being." Critics say that with this definition the physician would assume a dominant role in all aspects of human life and behavior and would become, so to speak, the high priest of society. And indeed, in antiquity and frequently in the Middle Ages, the healers were also the priests and chieftains. How then, through the centuries, has the question of the physician's responsibility and competence for dealing not only with physical and mental diseases, but also with the underlying social causes, been answered?

In ancient Greece, the god of health, Asklepios, had two competing and quarreling daughters, Hygeia and Panakeia. Hygeia was given the role of maintaining health through sound living and "prophylaxis" (hygiene, preventive medicine) while Panakeia was responsible for healing and curing illness (panaceas, curative medicine).[1] Originally meant to be equals, visits to her temple, sacrifices for and prayers to Panakeia appear much more frequently in our sources than those for Hygeia, indicating a greater demand by the people for assistance in healing their illnesses than willingness to change their lifestyles or social behavior aimed at avoiding the same. As described by Rosen[2]: "Health problems have always been intimately related to the political, economic and social conditions of particular groups of people; but in earlier periods these relationships were not the subject of systematic investigation. … Nonetheless, sporadic observations linking social and cultural factors or situations with the health of the members of a community were recorded in antiquity and in medieval times." However, the imbalance between preventive and curative care persisted, and the healing of illness remained at the center of the physician's activity.

Only in the eighteenth century, largely through the fundamental work of Johann Peter Frank,[3] was widespread attention paid to the influence that poor lifestyle and

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social conditions exerted on health. Frank called "poverty the mother of disease."[4] His analysis of the economically disadvantaged populations is still valid today, and his ideas about the social implications of health and illness exerted a stronger influence in neighboring countries than in feudal Germany itself. He described in nine volumes a "system of a complete medical policy," a forerunner of "public health," proposing that the government should take measures to protect individual and group health. It covered such wide-ranging topics as maternal and child health, sewage disposal, food, clothing, recreation, housing, welfare of school children, and supervision of educational institutions.[5] While in most European countries, due to reactionary political pressure, only fragments of the proposals of the "Medical Policy" were enacted, in revolutionary and post-revolutionary France, they were further developed.[6] Urbanization and industrialization created stresses and strains on the fabric of society, including rapidly deteriorating health conditions of the working class. Not only physicians, but also politicians, economists, and even poets became concerned and asked for action. Charles Baudelaire wrote about factory workers:

> How can anyone, whatever party one may belong to and whatever prejudices one may have been brought up on, fail to be touched at the sight of this sickly multitude breathing the dust off the factories, swallowing cotton floss, their systems saturated with white lead, mercury, and all the poisons …, sleeping amid vermin in quarters where the greatest and simplest of human virtues nestle by the side of the most hardened vices and the vomit of the penitentiary?[7]

The development in these years of sophisticated epidemiological and statistical methods allowed numerous demonstrations of the social causes of disease, such as a comparison of the mortality of the rich and the poor in different quarters of Paris.[8]

During the revolutionary years of 1847 and 1848, Jules Guerain, in describing the link between such social and health conditions, wrote:

> We had already had occasion to indicate the numerous relations which exist between medicine and public affairs. … Instead of those half-hearted and uncoordinated approaches, we have tended to include under such rubrics medical policy, public health, and forensic medicine. The time has come to collect these separate parts into an organized whole and to raise them to their highest potential under the designation of "Social Medicine," which better expresses their purpose.[9]

In Germany, Rudolph Virchow became an eloquent advocate of these ideas. Virchow was a highly respected leader of the traditional medical establishment in Berlin, a successful pathologist and investigator. In 1847, he was commissioned to investigate an epidemic of typhus in Silesia, and wrote extensively about that experience, concluding that the local social conditions were responsible for the epidemic and that poor nutrition and miserable housing had increased its severity.[10] Virchow also wrote these often quoted sentences: "Medicine is a social science and politics nothing but medicine on a grand scale." And, "If medicine is really to accomplish its great task, it must intervene in political and social life." And, "Physicans are the natural advocates of the poor, and social problems belong, to a considerable degree, in their jurisdiction."[11] Virchow continued his brilliant career as a pathologist and scientist, but his and other reformers' ideas were considered too radical and idealistic and led (after the defeat of the liberal and democratic

revolution of 1848) only to minor changes that were acceptable to the reactionary political decision-makers.

Actually, the writings of Guerain, Virchow, and other reformers, pointing out the dismal health conditions of the lower class, were a confirmation of an earlier publication in 1845 by a young German industrialist who was managing his rich father's textile factory in Manchester, England. The writer, Friedrich Engels, in a certain way, led two lives.[12] He was a "business man by day and a revolutionary at night."[13] He wrote a scathing description of the unsanitary and dangerous conditions of the workplace and living quarters of the laborers, who were mostly children. In his book entitled "The Conditions of the Working Class in England,"[14] he described

> a pretty list of diseases engendered purely by the hateful greed of the manufacturers: Women made unfit for childbearing, children deformed, men enfeebled, limbs crushed, whole generations wrecked, afflicted with disease and infirmity, purely to fill the purses of the bourgeoisie. How can one be otherwise than filled with wrath and resentment against a class, which boasts of philanthropy and self-sacrifice, while its object is to fill its purse, a "tous prix".

One can understand that the extreme hate expressed in this book prevented its publication in monarchistic England for more than 20 years, until 1886, while it was published in Germany in 1845, before the social upheaval. Engels continued to be successful as a businessman and industrialist, supporting with his inherited and acquired wealth what was to become the communist movement. He was also the co-author with Karl Marx of the "communist manifest" in 1845, and assumed, after Marx's death in 1883, the leadership of international communism.

In European countries, with the defeat of political socialism in 1848, the interest in social medicine, by then mostly called social hygiene, also declined and was generally considered to be not relevant in the prevailing political climate. Also, the great scientific discoveries, principally in bacteriology and pharmacology, promised a cure for the prevalent infectious diseases, so that the great German scientist Emil Behring could write that "the study of infectious diseases could now be pursued unswervingly, without being sidetracked by social considerations and reflections on social policy."[15] Nevertheless, after the turn of the century, due to the increasing dissatisfaction with the health care, particularly of the underprivileged segment of the population, more writers pointed at the social conditions as the cause. Among them, in Austria, Ferdinand Hoeppe declared that "Hygiene is a social art which has developed in response to social need; consequently it must and will always be social hygiene, or it will not exist at all."[16] And Emile Duclaux in France pointed out that the spread, severity, and duration of communicable diseases depended not only on the infectious agents, but on a number of other factors such as nutrition, working and living conditions, education and income.[17] In Germany, Alfred Grotjahn, with his teaching and writing, was very influential in the preparation for the social changes which took place with the revolution of 1918. His book on "social pathology"[18] emphasized the etiological relationship between social condition and disease, and it advanced, even beyond the borders of Germany, the understanding and acceptance of social medicine as relevant for the practice of medicine. This understanding increased throughout the twentieth century with the

publication of numerous books and articles in Europe[19–20] and the United States.[21–22] What one could still hope for is a greater emphasis on the teaching and training of physicians and other health care providers in this field. And finally, as a responsibility, physicians should demand and accept a leading role in the analysis and treatment of those critical, emerging, and controversial topics which are both social and medical. They include among others: universal and egalitarian health care, cloning, active and passive euthanasia, rationing of health care, abortion, genetic manipulation, and violence. There can be no question that physicians have the responsibility to participate in solving these problems of social medicine.

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Part V
Business Concepts

Economic factors as a crucial precondition for health are also at the heart of today's medicine and biomedical research, seen in Part V from a different perspective, namely from the point of view of *Business Concepts*. Wolfgang Meyer-Sabellek's contribution highlights the challenges faced by large multinational pharmaceutical companies in attempting to address urgent medical needs, especially in developing countries (tuberculosis, malaria, AIDS), yet also to meet budgetary requirements demanded both by the skyrocketing costs of the R&D for new drugs and by shareholder value. Herbert Schuster focuses on the new biotechnology sector. In his chapter he proposes a "new systems approach," based on our increasingly sophisticated understanding of comprehensive biological processes, including their molecular basis. In his view, health is often threatened much earlier than can currently be detected. His proposed "new systems approaches," which include new testing methods, thus tie in with Koch-Weser's demands for greater prevention in order to preserve health rather than to treat illness.

Unmet Medical Needs and the Role of Pharmaceutical Companies

Wolfgang Meyer-Sabellek

1 Introduction

Rising health care costs have been prioritized in the budget planning of all Western countries. Rising R&D costs of up to $800 million per marketed new pharmaceutical have dramatically reduced the approval of new chemical entities (NCEs). Globalization of diseases like AIDS and SARS has had a definite impact on the economic situation not only in the Western world, but also in developing countries, especially for AIDS in Africa and SARS in Asia. The World Health Organization (WHO) is calling for free anti-tuberculosis (TB) drugs to be made available to people living with human immunodeficiency virus (HIV). The spread between unmet medical need in large indications (e.g. Alzheimer's disease) and in niche indications (e.g. Huntington disease) and the economic burden to create a blockbuster ($1 billion sales within one year after launch) has created a marketing-driven clinical development of new chemical entities. A paradigm shift has occurred by which developing a new innovative drug by documenting short-term efficacy, quality and safety rather than long-term efficacy and emphasizing pharmacovilliglance including considerations of health economy within the medical environment a shift that has fundamentally changed and challenged the pharmaceutical industry.

2 Challenge I: Globalization and Costs

Health costs in the Western world range as low as 6.9% of the gross domestic product in the UK to 13.1% in the USA followed by Germany with 12.3% with rising trends. In developing countries (especially in Africa) with almost no capital, health costs remain in the one-digit range and are almost negligible for medical care or prevention. Expenditures out of total health costs ranked number 3 in most countries and for medication range from as low as 11% in the USA to 13.3% in Germany to 16.3% out of the total health costs, demonstrating different policies and health environmental systems.

Unmet medical needs are a universal problem, affecting however different areas differently. While tuberculosis plays an increasing role in Asia (the number two cause of death in Indonesia) still cardiovascular diseases play a primary role in the civilized world though were overtaken by cancer in 2005.

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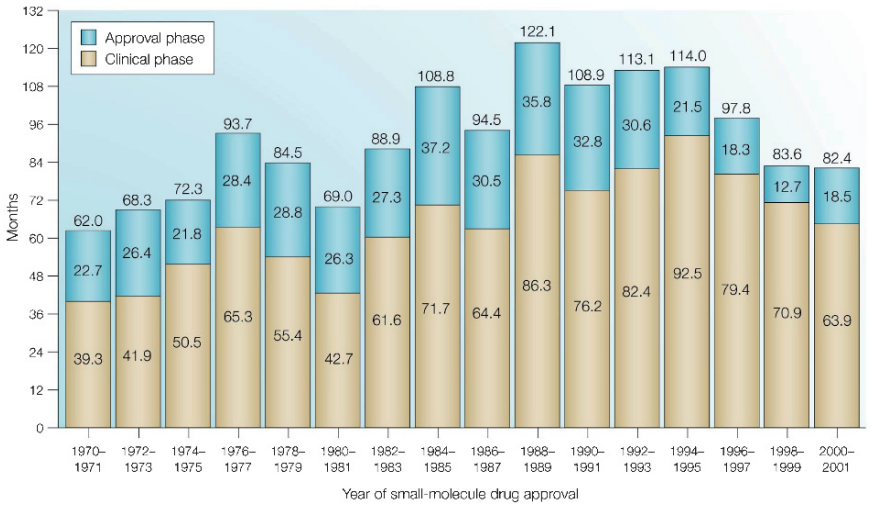

Fig. 1 Mean clinical and approval phase lengths for small-molecule drugs approved in the USA during 1970–2001 (Reichert 2003[12])

The share of the registered pharmaceutical world market demonstrated that more than 60% contribute to North America (especially the USA), 25% to Europe and more than 16% to Japan. The USA, therefore, is the main driver in pharmaceutical development.

In 1996, R&D costs were $16.9 billion, in 2002 at $32 billion; however, new chemical entities (NCEs) declined from annual $53 billion to $17 billion in the same time period. The mean clinical and approval phase lengths for small-molecular drugs approved have not changed in 30 years and will take – including preclinical development from CD (candidate drug) to NDA – approximately 12 years (Fig. 1).

3 Challenge II: Demographics and Patients

Demographics are changing due to life expectancy and GDP in different parts of the world (Fig. 2).

Africa, Asia and Australia, even growing by a two-digit percentage on the pharmaceutical market, contribute far less than 10% to the world market. Population-wise China with 1.3 billion people and a GDP of $4.8 billion contributes increasingly by volume not by value, but may be a main driver for new untreated population (e.g. approximately 40 million untreated asthmatic patients) and a growing pharmaceutical market, due to rising prosperity.

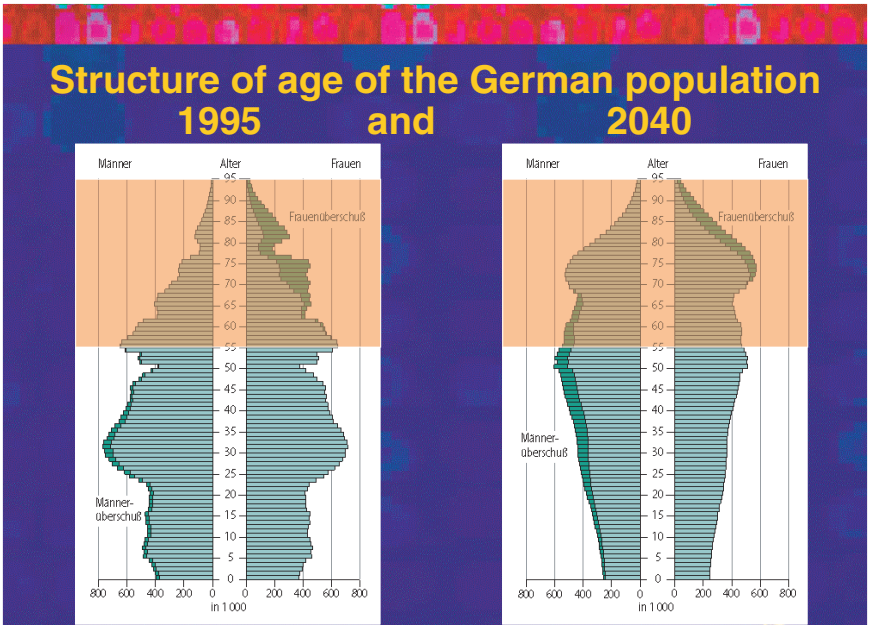

Fig. 2 Predicted demographic change in Germany

Demographic changes due to increasing life expectancy have altered the 'target population'. The unmet medical need for a population has broadened and shifted, e.g. for antibiotics for infectious diseases like syphilis, pneumonia, etc., to cardiovascular diseases at the end of the last century, whereas the most primary focus today relates to oncology, neuroscience and infection.

Pharmaceutical development has focused on the male population (due to the risk for women of childbearing potential) and on a target group of 20–60 years. Children and the growing elderly population have only poorly been investigated and off-label use is common.[1]

In the elderly population the most common neurodegenerative disease, Alzheimer's disease constitutes about two thirds of cases of dementia overall with vascular causes and other neurodegenerative diseases such as Pick's disease and diffuse Lewy-body dementia. Alzheimer's disease is a progressive neurological disease that results in the irreversible loss of neurons, particularly in the cortex and hippocampus and the clinical hallmarks are progressive impairment in memory, judgement, decision-making, orientation to physical surroundings, and language. Alzheimer's disease has a prevalence of approximately 1% among those 65–69 years of age and increases with age to 40–50% among persons 95 years of age and over.[2]

Parkinson's disease, the second most common neurodegenerative disorder after Alzheimer's disease, is clinically characterized by resting tremor, bradykinesia, rigidity

and postural instability, and pathologically by the loss of neurons mainly in the substantia nigra in association with the presence of ubiquinated protein deposits in the cytoplasma of neurons (Lewy bodies) and threadlike proteinaceous inclusions within neuritis (Lewy neuritis). Parkinson's disease has a prevalence of approximately 1% among persons 65–69 years of age, rising to 3% among persons 80 years of age and older.[3]

These diseases are predominantly idiopathic disorders of unknown pathogenesis. However, the genetic mapping and gene-isolation tools created by the Human Genome Project over the past decade have greatly accelerated the rate of identification of genes involved in the rare inherited forms of these diseases.

The Western world has changed its lifestyle; the estimated lifetime risk according to a recent US trial of developing diabetes for individuals born in 2000 is 32.8% for males and 38.5% for females. Females have higher residual lifetime risks at all ages. The highest estimated lifetime risk for diabetes is among US Hispanics (males, 45.4% and females, 52.5%). Individuals diagnosed as having diabetes have large reductions in life expectancy. A recent trial demonstrates that an individual diagnosed at age 40 will lose 11.6 life-years and 18.6 quality-adjusted life-years whereas women will even lose 14.3 life-years and 22.0 quality-adjusted life-years.[4]

On the other hand, the current statistics and outcome trials on cardiovascular diseases including acute myocardial infarction and ischemic heart disease have dropped continuously throughout the last decade due to better diagnostics, identifying risk factors and new medication including anti-hypertensives, anti-diabetics and thrombolytics.

4 Challenge III: Information and Education

Health data and literacy are a prerequisite for guided clinical development and the appropriate use of medication (81.5% of the total population in China compared to 52% in India) and have a huge impact on life expectancy (71.4 years in China and 62.5 years in India). The worldwide highest rate is currently in Japan with over 81 years for women and more than 75 years for men, which is comparable to the Western world.

Currently far more than 30% of patients in the USA first consult the internet before visiting a doctor and learn about web-based guidelines, trials and recommendations about the possible outcome of a disease.

The growing population of affluent older people may have greater expectations of medical care, fuelled by advertising and communication (older people are likely to demand cures for wrinkles, baldness, yellow teeth and relief from symptoms of menopause or andropause).

Botulinum toxin has been developed for the treatment of wrinkles, minoxidil for male pattern baldness (primarily developed as a vasodilating hypotensive drug), hormone replacement therapy, currently under heavy discussion for women, and Viagra for impotence developed as an anti-hypertensive drug. The limits to demand for health care have been widely discussed in the literature. The controversial results of the Women's Health Initiative Trial on post-menopausal hormonal treat-

ment (HRT) also published in the lay press have led to a 50% decrease according to a recently published observation in New Zealand.

The intrinsic prosperities of an 'ideal' drug cannot by themselves ensure appropriate utilization. An ideal treatment may enhance physician and patient comfort by providing maximum efficacy and safety in the most convenient formulation. This would entail once-daily administration of a single treatment not influenced by meals or time of day with no adverse event or monitoring required, no adjustment for age, weight or race. Therefore comprehensive leaflets or programmes of effective communication and educational tools are necessary. Huge armies of representatives distribute such information, but have been heavily criticized for the only minutes-lasting information given to the doctor. However, in general licensed doctors do not have to update their knowledge on pharmacotherapy on an obligatory basis and rely on the information and education provided by the pharmaceutical industry.

5 Challenge IV: Evidence-Based Medicine and Medical Marketing

Almost all of the ten biggest pharmaceutical companies in the world have at least two cardiovascular drugs in their pipeline or in their portfolio. Anti-hypertensives like beta blockers, angiotensin II antagonists and calcium antagonists sales have been rising throughout the years, since better diagnostic tool awareness and communication of risk factors documented by international megatrials and huge prospective outcome studies have been communicated via lay press and internet within and without the industrialized world.

6 Challenge V: Diagnostics and Prognostics

Simple screening diagnostic tools like blood pressure measurements and blood sugar cholesterol have changed and have been included in the guidelines for medication. New individual or conventional prognostic factors may even build up a different understanding in the pathogenesis of a disease and may ameliorate standard treatment to be documented in outcome trials. More than 50% of patients with coronary heart disease (CHD) lack any conventional risk factors (cigarette smoking, diabetes, hyperlipidemia and/or hypertension).[5]

Among patients with CHD at least 1 of 4 conventional risk factors was present in 84.6% of women and 80.6% of men. Other non-traditional factors and genetic causes have to be evaluated. Although C-reactive protein (CRP), lipoprotein (A), fibrinogen and homocysteine are associated with vascular risk, their optional use in routine screening and risk stratification remains to be demonstrated.[6]

The introduction of CAD risk equivalent categories within the American ATP III Guidelines substantially increases the number of patients eligible for LDL-cholesterol

reduction to less than 100 mg/dl from approximately 5 or 6 million to approximately 20 million. More intensive lipid modifying treatment is thus also clearly needed to provide the additional reduction LDL-cholesterol methods for achieving optimal levels in patients with more challenging LDL-cholesterol goals. Prospective observational studies identified low HDL cholesterol as an important independent coronary risk factor. Some rare inborn errors of HDL metabolism cause low HDL cholesterol and premature atherosclerosis. In large, controlled intervention studies, statin and fibrate treatment of patients with increased HDL cholesterol reduced the incidence of coronary events, and in some of these trials, the increase in HDL cholesterol correlated significantly with the decrease of event rates. HDL-associated proteins and lipids exert several potentially anti-atherosclerotic activities. Transgenic over-expression of human apoA-I or ABCA1 genes was shown to inhibit the development or even induce regression of atherosclerosis in atherosclerosis-susceptible animal models.

Six controlled and perspective landmark studies (>50,000 patients >5 years) demonstrated that lowering of LDL cholesterol with HMA-CoA reductase inhibitors (= statins) or fibric acid derivatives (= fibrates) therapy reduces coronary event rates by 30% (fatal and non-fatal MI, as well as coronary intervention).[6–7] LDL is currently considered a causal factor (and main diagnostic tool) in atherosclerosis, but may be just the tip of the iceberg, whereas the pleiotropic effects of statins may also cover other effects, e.g. anti-inflammatory and antifibrotic potencies.

7 Challenge VI: Drug Design and Individual Therapy

Traditional progress to cancer treatment relies on the combination of surgery, radiotherapy and chemotherapy. Current cancer drugs which are mostly lethal for cells (cytotoxics) either affect DNS synthesis and the process of cell division or cause chromosomal damage. Identifying a candidate drug (DC) via computer, chemical or biotechnical models followed by *in vitro/in vivo* proof of concept will lead to a new chemical entity (NCE). Biotechnical engineering in the production of new drugs plays an increasing and important role (e.g. STH, insulin, TPA), the role of gene therapy is yet limited to well-defined niche indications and will not revolutionize the pharmaceutical world but will affect approximately 20% of the diseases within the next two decades. Which population will be targeted and who can pay for it or provide reimbursement will have a major impact on the success of individualized or gene therapy in the near future.

8 Challenge VII: Patent and Generics

The life cycle of a new pharmaceutical has a great impact on investment for the pharmaceutical industry. An innovation of changing salicylate into acetylsalicylate has been developed in the early last century, but the pathophysiological pathways have only been evaluated within the last decades including anti-thrombotic effects, stroke prevention and even anticancer potentials. Nevertheless, aspirin is out-of-patent

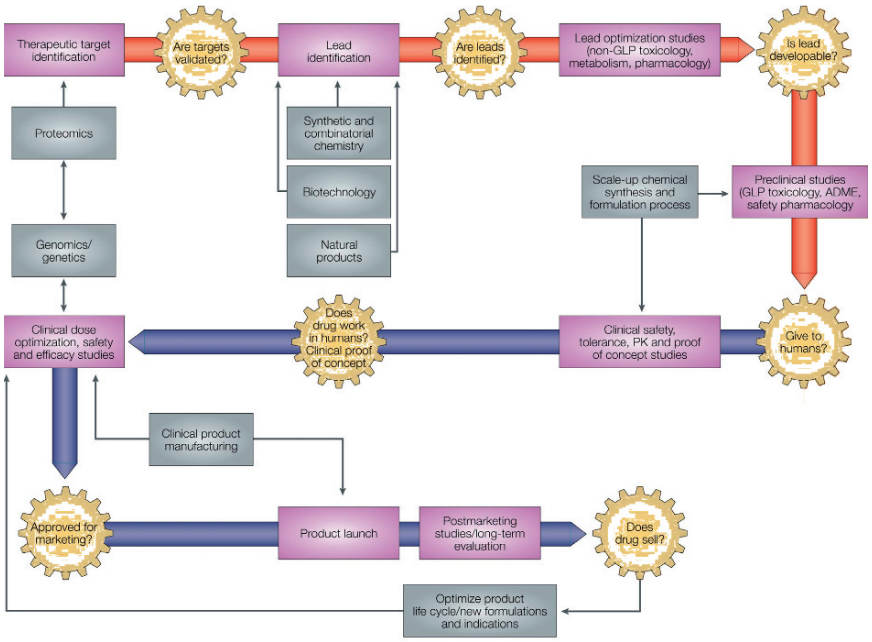

Fig. 3 Process of drug development (Pritchard et al. 2003[13])

for decades and only different formulations may protect the originator from overrun by generics or even OTC (over-the-counter) medication. The patent situation in different countries might be the key to success or a nightmare for a pharmaceutical company because development times reach up to 10–12 years before being approved by the authorities or even marketed. Despite improving clinical development but due to the increasing prerequisites guidelines to develop a new pharmaceutical, it has left normally only a couple of years for new pharmaceuticals to pay back the huge development costs of approximately $500–800 million. Different national laws allow different patent interpretations, whereas molecule patent or manufacturing patents are differently interpreted, indication patents are almost not valid outside the USA.

Today the biggest market of more than $21 billion in 2002 are the statins, which have been proven to prevent coronary heart disease (CHD).[6–8] The situation that statins were claimed to have hypothetically an anti-osteoporotic effect and being patented by an American company has led to a reduced interest in the pharmaceutical industry to develop this indication because royalties would have to be paid to the appropriate patent holder and outcome trials demonstrating superiority will last more than 5 years with 10,000 patients in different populations and a high risk of failure.

Generics are quite necessary to reduce costs and stimulate innovations. The current situation, however, demonstrates an increasing share of generics, especially in countries

like Germany or Denmark which face a generic market of more than 50%, whereas in the USA (currently heavy discussion about import from outside especially Canada and Mexico), the UK and France this market is yet in the range of 10%. The existence of generics on the one hand has built up a whole new industry with two-digit growth taking market share and volume with no money spent on innovation or any clinical development. The pharmaceutical companies on the other hand spend up to 20% of their sales on R&D development. The different legislations within the different countries in Europe also have built up parallel trade to undermine the bright politics earning in the range of billions for a parallel trader who just repacks, refills and sends it to different countries.

9 Challenge VIII: Health Care and Lifestyle Medicine

The development of sildenafil for erectile dysfunction, orlistat for obesity and minoxidil for male pattern baldness have been classified as "lifestyle drugs" in the popular imagination.[9] It is difficult to define what we mean by the term lifestyle drug since the perception of what is illness and what is within the sphere of personal responsibility rather than health care may depend on whether one is a potential patient or potential payer, thus problems at the margins of health and well-being.[10]

10 Conclusions

The pharmaceutical industry is an important economic tool in the Western world. The increasing costs of health care systems in any country in the world have recently changed the paradigm from developing a new, efficacious and safe high-quality drug for unmet medical need to identifying either potential blockbusters or individual biotechnically driven, highly specialized individual therapies. The main cost drivers are still the treatments of the most common diseases like cardiovascular, oncological or infectious diseases.

In the early 1990s, the Australian government introduced formulary submission guidelines[11] and since then such guidelines have been applied in many major markets. The need to demonstrate cost-effectiveness, affordability and the benefit–risk ratio to the health system of a preferred formulary position as opposed to a restricted indication, where the product is targeted at subpopulation of patients is leading into off-label use.

The efforts to develop an innovative drug to be competitive, well-tolerated and reimbursed by the different health insurance systems have become as costly as a more than $500-million jigsaw puzzle which may pay off in the case of statins and proton pump inhibitors.

The failure or safety issue may delete or seriously effect a worldwide operating company as seen 30 years ago in the case of Grünenthal (thalidomide) or recently for Bayer (cerivastatin: Lipobay).

The probabilities for success or forecasting are not real science but have made development of medication a risky business case for any unmet medical need.

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A Revolution in Research and Development – The Impact of Biotechnology

Herbert Schuster

As the biotechnology industry has evolved over the past decade, so too has our definition of biotechnology. High-tech industrialization has increased the efficiency of certain activities to levels that would have been difficult to imagine only ten years ago. Instead of assigning individual scientists to work manually on small-scale experiments, industrial and academic researchers now invoke automation and parallel processing to conduct experiments of much greater scope and complexity, and at a much faster pace. The data that result are correspondingly of immensely greater value, both in terms of quantity, as well as quality. Enormous databases now afford views of biological processes of a comprehensiveness so far without precedent. As a result, researchers are increasingly able to understand the properties of biological systems rather than simply of individual parts. This ability to understand complex processes in their entirety has allowed researchers to shift their focus from observation and description to the development of overarching theories and models. This new view of biology is called "systems approach."

System biology is not concerned with investigating individual genes or proteins one at a time, but rather with investigating the behaviour and relationship of all elements in a particular biological system while this system is functioning. The Human Genome Project was one of the first modern biological endeavours to practice biology systematically. System biology differs from hypothesis-driven science, which creates hypotheses and attempts to distinguish between them experimentally. Integrating these two approaches – discovery-based and hypothesis-driven science – is one of the mandates of systems biology.

One of the most important off-shoots of biotechnology is molecular medicine. Currently, diseases are diagnosed by studying signs and symptoms observed in patients with established diseases. Treatment then often follows something of a trial-and-error format, whereby a physician prescribes one drug and then another if the first fails to work, and so on. This trail-and-error approach is becoming increasingly unsatisfactory because of the growing antibiotic resistance and, perhaps most importantly, the relatively high frequency of adverse drug reactions. For the patient, the advantage of molecular medicine is obvious – personalized medicine and more efficacious treatment. The concept relies on the capability to diagnose the disease on the basis of its molecular makeup, not its symptoms, and to treat it with molecularly targeted therapy that is tailored to the patient's personal drug response profile.

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Clinical signs and symptoms are almost always ambiguous. Quite often, a definitive diagnosis cannot be made before the late stage of a disease has been reached. Today, current therapy can, in many cases, only relieve the signs and symptoms of a disease but not cure the underlying illness. Thus, despite the enormous costs of such interventional and palliative care, the overall prognosis and final outcome of a disease often remain unchanged vis-à-vis less intensive treatment methods. Because today's health care systems focus primarily on intervention, the underlying causes of disease remain, for the most part, unclear. Preventative care still plays a minor role.

The hope for the future lies within the analysis of the human genome and the development of molecular medicine, which will change the face of medical care. A new and more detailed understanding of disease mechanisms will allow physicians to identify risk factors for diseases and to initiate preventative programmes before an illness has reached a point of development and destruction that precludes the restoration of complete health – and perhaps even before clinical signs and symptoms appear at all.[1] A new and better understanding of disease aetiology and pathogenesis will also provide new insights into the complex interactions of heredity and environment. In addition, this new knowledge will invariably lead to the discovery and identification of new points of intervention for promoting health and preventing diseases before they even occur.[2] The overall objective of molecular medicine is thus to intervene as early as possible to protect individual well-being and maintain active participation in society. In this respect, preventive medicine is very different from palliative and interventional care (Fig. 1).

In principle, modern health care systems cannot function without preventative care. First, in many cases, disease progression occurs within minutes, with sudden death as the first clinical sign of disease. Second, many complications of common diseases such as stroke are untreatable. Therefore, a lack of preventive care not only

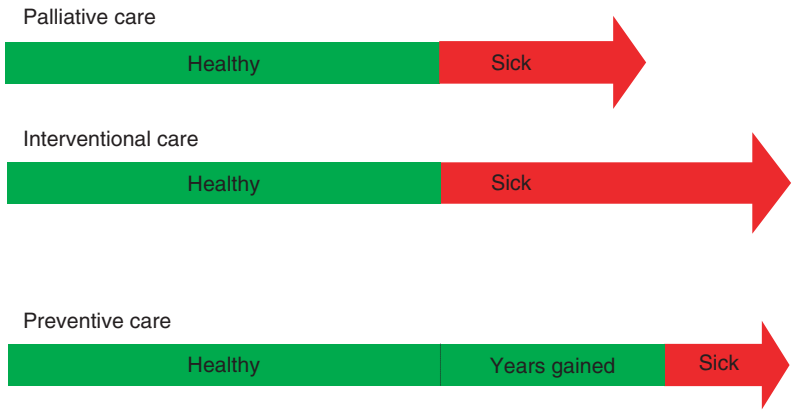

Fig. 1 Segments in health care systems

places enormous financial burdens on a society, but also prevents individuals from systematically benefiting from new achievements in molecular medicine.

The potential of preventative options has been widely underestimated, despite the fact that for almost every epidemiologically important disease there are enormous opportunities for prevention. This is particularly true for cardiovascular diseases. Lifestyle changes, especially those directed towards diet and physical activity in combination with sophisticated new therapeutics, significantly improve morbidity and mortality rates.

In order to further improve health promotion measures and preventative care, it is essential to stop focusing entirely on symptomatic disease. Policy makers and key players in the health care industry need to develop strategies that target, in their entirety, the processes by which health can deteriorate, including functional limitations in physical and mental fitness and the resulting de-socialization with all its consequences. We must no longer interpret disease as a definite status, but rather as the final stage in a biological process.

Because diseases vary widely with regard to their clinical presentation and outcome, estimating disease risk represents a major challenge for physicians (see Heinemann in this volume). Indeed, disease risk is determined by a large number of interrelated biological and environmental factors. As a result, it is impossible to estimate disease risk without using proper equations and statistics. Risk estimates are extremely misleading if they are based only on individual experiences. Usually, we humans tend towards the mean of the distribution, overestimating low risk and underestimating high risk. This is particularly true for disease risk estimates.

A common result of such misclassification is the improper allocation of resources, which in the case of low-risk individuals can lead to a waste of resources and in the case of high-risk individuals can have fatal consequences. Strangely, for some individuals the risks of side effects are higher than the disease risk without treatment, leading to a high risk/benefit ratio.

The misallocation of resources in the German health care system is well documented for many areas of clinical practice and reinforced by the disintegration of preserved structures which were once adequate to match palliative and interventional medicine in end stage disease.[3] Without individual risk assessment strategies, preventative care will always remain unfocused and ineffective at the population level and ultimately fail as a result of financial restrictions and non-compliance at the patient level.

In order to make effective use of the increasing amount of medical knowledge, structural changes are needed in our health care systems that will allow for the delivery of preventative services. Currently, our health care systems are optimized for interventional medicine and palliative care (Table 1). Interventional care aims primarily at freeing patients with established disease from the signs and symptoms of disease. Signs and symptoms also represent the basic driving force behind patients' use of health care services. Patients and physicians are rewarded by immediate response to their actions. This phenomenon is most obvious in surgery, intensive care and first aid. The entire process of intervention occurs over a relatively short

Table 1 Characteristic differences between interventional and preventative care

Intervention	Prevention
Signs and symptoms	Knowledge and care
Disease status	Disease risk
Active physician	Active consumer
Closely outcome-related	Poorly outcome-related
Provided through medical centre	Provided through medical network
Short-term very costly	Long-term cost favourable
Cost-oriented	Benefit-oriented
Spectacular public interest	Low public interest

period of time within the same service unit, and physicians and patients can monitor outcome variables simultaneously. With regard to economic concerns, costs and benefits are closely related.

In contrast, health promotion and preventative care aim to lower disease risk and maintain physical and mental fitness over a prolonged period. Whereas patients with symptomatic disease actively seek help, asymptomatic individuals lack the driving force provided by the signs and symptoms of disease. They need to be made aware of potentially harmful behaviours as well as of the services and products available to them already at an asymptomatic state before they can take advantage of them. Our reliance on the signs and symptoms of disease needs to be replaced by educational and informational measures that emphasize the importance of proactively caring for our own health as well as that of relatives and others early on. Because the benefits of preventative measures are not immediately visible, our health care systems need to provide secondary benefits, such as bonus programmes that reward behaviour that promotes good health. Preventative care will only succeed if individuals are active consumers rather than indulgent patients. In addition to cost considerations, prevention must integrate the benefit of remaining healthy so that cost/benefit ratios can be estimated on a macroeconomic level. Because cost and benefit occur in different segments of a health care system, which is offered by different providers at different times, preventative care presumes integrated systems in which cost and benefit elements are monitored continuously along individual consumer-patient histories in a manner similar to that used in case management programmes for very costly patients.

Additionally, all concepts aimed at promoting health or at prevention must take into account the fact that common diseases are multifactorial in aetiology. Cardiovascular diseases may serve as a paradigm in this respect. A typical aspect of cardiovascular disease is comorbidity. Several disease entities defined at the metabolic level occur simultaneously although they may start at different time points and meet in different phases of disease progression. Therefore, preventative care very often needs to be integrated into interventional care (Fig. 2). Individualized disease risk assessment is the prerequisite of an effective prevention with regard to cost–benefit. In light of the limited options to cure most diseases and restore complete

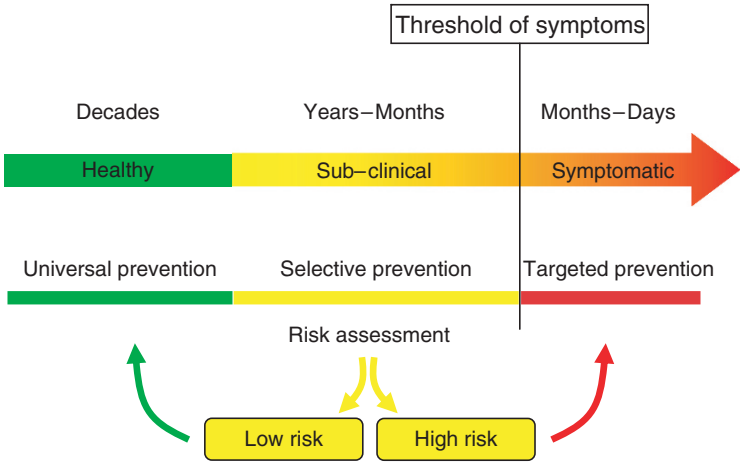

Fig. 2 Risk-dependent prevention model

physical and mental fitness, prevention needs to be initiated when a disease is still sub-clinical. In the case of cardiovascular disease, this would be when there are signs of hypertension, impaired lipid or glucose metabolism, or even earlier when the first tendencies towards the upper limits of 'normal' levels in biochemical or physical markers are observed.

Clinical studies with therapeutic agents that aim to receive approval from regulatory authorities are usually divided into primary and secondary prevention. This classification is not suitable for clinical decision-making, however. Today, therapeutic decisions need to be based on absolute risk. Therefore, selective prevention is a much better term for the transfer of evidence-based knowledge to patients.[4] In current recommendations and guidelines for the prevention of cardiovascular disease this concept has been implemented by defining risk-dependent treatment goals for biomedical variables such as cholesterol levels or blood pressure.[5,6]

Effective cost–benefit and health promoting programmes aim to identify the deterioration of physical and mental fitness as early as possible in order to reduce the number of costly diagnostic and therapeutic procedures. This can be achieved only by considering the interaction between hereditary and environmental factors. The key success factor is the availability of sufficient information for both physicians and the population at large. Information, however, does not equal knowledge, and knowledge alone neither prevents disease nor maintains health. Information needs to be individualized and combined with services and products to gain the lasting trust of consumers. Lack of compliance is the major limitation of preventative care and an issue that still needs to be addressed adequately. During the past century, disease prevention changed largely from focusing on reducing environmental exposures over which the individual had little personal control, such as providing potable water, to emphasizing behaviours such as avoiding tobacco, fatty foods and a sedentary lifestyle. Although individuals have a choice in these matters, such

individual responsibility for health can only be fully effective if there is easy access to the necessary information, education and professional services. If integrated into a multilevel approach, genome-based research offers enormous promise for improving the promotion of health.

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Part VI
New Approaches in Medicine and Their Constitutional Ramification

In conclusion, Part VI addresses the potential and limitations of the newly emerging molecular medicine, especially with regard to genetics. Martin Paul, a leading genetic researcher, illustrates the possibility of actually achieving cures, or even healing affected tissues, through gene and cell therapies, many of which are still in the preliminary research phases. As he points out, despite significant technological and pharmacological advances, today many of the great "killer" diseases, such as cardiovascular disease or diabetes, can be controlled but rarely if ever cured. Through a number of gene- or cell-based interventions, actual "remodeling" of affected areas could be achieved, but promising early results require much more intense and widespread testing prior to their clinical applications. Here, public perception, ethical and legal issues can be a barrier quite uncalled for at times. Therefore, outreach and concerted efforts to inform the public and the legislators should form part and parcel of these avenues of medical research, which are not as "new" as many think. Martin Nettesheim, finally, discusses the legal ramifications of genetic research, in particular with regard to some of our most foundational notions, namely human rights and the manner in which their protection and guarantee are expressed in our constitutions. Though his focus is on the manner in which the German Constitution has reified the inviolability of human rights and human dignity – in particular, in response to National Socialism – he makes it clear that new approaches to health and healing, procreation and aging, resulting from genetic and molecular research also push the constitutional envelope: common presuppositions as to the nature of human dignity, even of what it means to be human, no longer hold. Genetic research thus leads to profound challenges and into uncharted territories, not only for scientists, ethicists, and theologians, but also for legal theorists.

Healing By Gene Therapy – Hype or Hope?

Martin Paul

> All we know is still infinitely less than all that remains unknown.
>
> William Harvey

1 Introduction

The ultimate goal of medicine is to heal patients and develop concepts and treatment strategies to improve the outcome of a patient's illness. Over the past centuries, physicians and medical researchers have made this drive for improvement their primary mission – with remarkable success. This is illustrated by numerous milestones in the history of medicine, such as the introduction of antisepsis in obstetrics and surgery, the advancement of anesthesia, the discovery of bacteria as a cause of infectious diseases and the introduction of antibiotic therapy for their treatment. These and other remarkable success stories of modern medicine have resulted in a significant increase in life expectancy in the Western world over the past 100 years. On the other side of the coin, this development also led to an increase in noncurative treatments, which actually are not aids that lead to "healing," but extend and improve the quality of life in patients who suffer from diseases that are mostly incurable. One example is *Diabetes Mellitus*, which before the use of insulin invariably led to a patient's death. Today, diabetic patients can live normal lives if treated properly, despite the fact that their disease is not cured. The dilemma of modern medicine, therefore, is that it has to confront the fact that doctors today are in most cases not actually healing their patients, but rather contributing to an increase in life expectancy and quality of life. In this context, the concept of palliative medicine deserves special consideration.

There are still many diseases that are deadly and incurable, including many forms of cancer. Despite significant efforts to find new treatments, there is still a marked discrepancy between the buildups of medical technology and the continuing inability to cure many diseases.

This dilemma is interestingly causing two developments that, at first glance, are contradictory. On the one hand, there is the drive for an ever-faster pace of new developments and technologies, and on the other hand, there is a movement searching for "alternative" therapies, which are typically based on traditional ethnic approaches, such as traditional Chinese medicine (TCM; but see Unschuld in this volume), homeopathy, anthroposophy and other practices defined as "alternative" (see also Becker-Witt in this volume). Although these two

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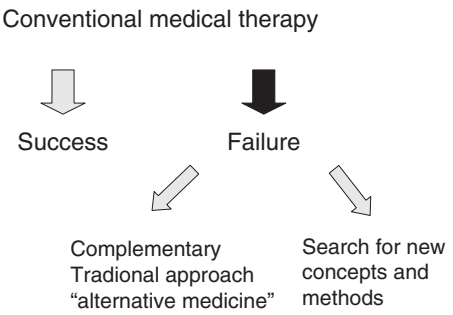

Fig. 1 Molecular medicine versus traditional therapies: same goal, different strategy

approaches use different, if not opposing, methodologies and methods, their common drive is the underachievement of the available medical technologies to improve a patient's health (Fig. 1). The aim of this chapter is to define the contributions of molecular medicine in the context of healing with a particular emphasis on the role of gene therapy.

2 What Is New About Molecular Medicine?

The term “molecular medicine” combines the methodological approaches of molecular biology and genetics and applies them to the diagnosis and treatment of diseases. Unbeknownst to most observers and even practitioners, these technologies have already been integrated into the methodological arsenal of modern medicine for many years. This is particularly true of diagnostic approaches. One example of this is the genetic diagnosis of trisomy 21 and a large number of monogenic diseases, or the genetic analysis of tumor markers in oncology. In this respect, “molecular medicine” is a logical consequence of the technological development of medicine where the diagnostic and therapeutic potential is directly related to the possibilities of the “level of resolution” to recognize pathogenic mechanisms (Fig. 2). For hundreds of years, the medical profession was restricted to diagnosing and treating disease based on external signs, such as skin color or changes seen in body fluids, such as urine. Advancements in the field of anatomy allowed us to obtain knowledge about disease pathology at the organ level and ultimately to link changes in organ structure to functional alterations.

The anatomist William Harvey, who graduated from the university of Padua in Italy in 1602, was one of the first to link the description of organs to function, as is evident from his statements: “I profess both to learn and to teach anatomy, not from books but from dissections, not from the positions of philosophers but from the fabric of nature.” The “fabric of nature” (i.e., the definition of normal and abnormal organ structure and their link to alterations in organ function) laid the groundwork

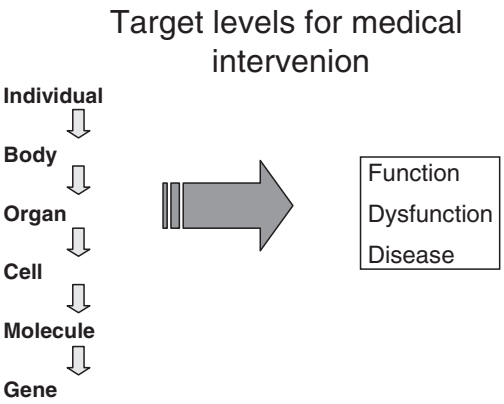

Fig. 2 Resolution levels for medical treatment

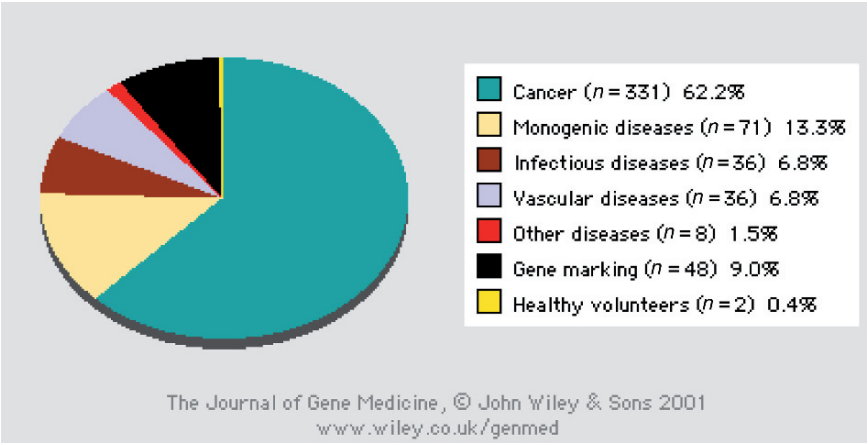

Fig. 3 Molecular medicine as a clinical reality: science and fiction

for establishing the basis for pathology and pathophysiology. Further developments, such as the discovery by Pasteur and others that microorganisms can cause disease, as well as the introduction of the concept of "cellular pathology" by Rudolf Virchow have directed the attention of medical science to the cellular and, consequently, molecular level. Combined with the discovery of hormonal regulation and biochemistry, the resulting concepts have revolutionized medicine. Finally (at least for now), the discovery of DNA as the carrier of biological information by Watson and Crick almost exactly 50 years ago has again refined the possibilities for investigating pathological changes at the molecular level as the basis for disease. Based on this discovery, genetic research has become a stronghold in medical science. The sequencing of the complete human genome some years ago has finally provided the basis for linking new genes to disease mechanisms.

Interestingly, public awareness of molecular medicine has focused on its more spectacular techniques, such as cloning, which is for many reasons far removed from medical reality today. It is often forgotten that many diagnostic procedures are based on genetic targets; in this context, at least, we are no longer at the beginning, but rather in the middle of a new era. The next big step will be the inclusion of gene therapy in the medical repertoire (Fig. 3).

3 Gene Therapy

One of the most fascinating components of molecular medicine is gene therapy, since it is directly linked to genes known as the basis of a disease. The term "gene therapy" describes all therapeutic approaches used to transfer genes into cells or tissues. Somatic gene therapy is based on gene transfer into non-germline cells, in contrast to germline gene therapy, which is currently banned because of ethical concerns. Most current research focuses on somatic gene transfer to treat diseases of different origins (Fig. 4). Here, we will use *cardiovascular* gene therapy as an example to illustrate the problems and opportunities of this approach.

Among all diseases, cardiovascular diseases are still the number one killer in the Western industrialized world, despite the widespread use of pharmacological treatments. Nonetheless, they are still less frequently the focus of gene therapy research than is, for example, cancer. However, efforts to apply this technology to the cardiovascular system have increased recently, as the heart and blood vessels are comparatively easy to reach by interventional methods, such as catheter-based applications.

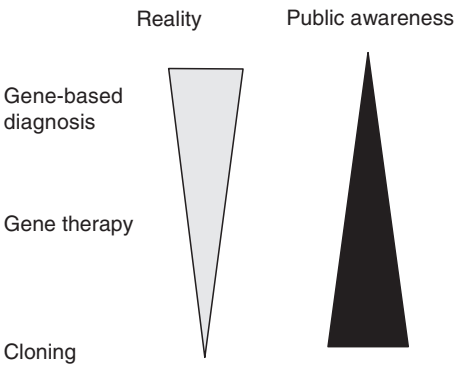

Fig. 4 Target disease groups for gene therapeutic strategies in approved clinical trials

4 Cardiovascular Gene Therapy

Two approaches are most commonly used, first an *ex vivo* approach in which a patient's cells are isolated, genetically altered by integrating specific genes, and then reinfused into the patient. This can be applied, for example, to endothelial cells that are transfected with genes to counteract atherosclerotic mechanisms. After transfection in cell culture, the genetically modified cells are then returned to the patient, for example via a balloon catheter inserted into a diseased blood vessel. The balloon blocks blood flow, allowing the genetic material to be applied through a small opening in the catheter tip. The second *in vivo* approach of gene therapy involves applying genes directly to the diseased organ or tissue, so that this organ or tissue can express genes that counteract disease mechanisms. The latter approach requires efficient transfer and application systems to deliver the genes to the target areas, which are less accessible than blood vessels. Gene constructs, also called "vectors," are typically used to allow expression of a therapeutic gene in a target tissue, such as the liver or heart.[1]

4.1 Viral and Nonviral Vectors

The injection of pure ("naked") DNA into skeletal or heart muscle can already lead to the expression of a gene that has been applied to the tissue by gene transfer. This approach is hampered, however, by inefficient expression, which is typically restricted to only a very limited number of target cells (usually significantly less than 10%). Despite these encouraging results, it is generally accepted that DNA will be degraded inside the cell and that naked DNA is not an optimal way for achieving long-term results. On the positive side, there are almost no limitations to the size of the DNA fragment being transferred and very few side effects, which is an advantage over viral carriers. The efficiency of this approach can be significantly enhanced by combining naked DNA gene transfer with lipid complexes, which improve the uptake and internalization of the sequences through the cell membrane which consists of a lipid bilayer.[2]

The efficiency of transferring naked DNA appears to be considerably higher when short DNA sequences are used. For example, remarkable results have been obtained with a single injection of short sequences encoding for so-called antisense oligonucleotides (sequences that are designed to inhibit the transcription of genes) against components that are known as vasoconstrictors and candidates for high blood pressure (hypertension), leading to consistent lowering of blood pressure over days.[3]

Other oligonucleotides can bind to proteins involved in mediating the transcription of genes into mRNA; these "decoy" oligonucleotides compete with endogenous DNA for binding, which can affect the overall transcriptional activity. Yet another approach is the use of specific RNA molecules that inhibit the binding of endogenous RNA to its intracellular target proteins. Combining the use of these short

DNA or RNA sequences with specific application techniques, remarkable results can be achieved. For example, high pressure and specific catheter systems can be used for vascular gene transfer, resulting in a transfection efficiency of up to 90%. Nevertheless, these success rates appear to be related to the nature of the (short) molecules used and specific routes of administration; in many cases the transfer of naked DNA is not sufficient to achieve adequate transfection efficiency or long-lasting expression. This often requires the use of viral vectors.

To date, the most common virus used for cardiovascular gene therapy is the adenovirus, which is efficient for gene transfer into post-mitotic cells (i.e., cells that are not dividing). Adenovirus has the advantage that large DNA sequences (up to 37,000 bases) can be integrated in the viral genome. Gene transfer is efficient, but the adenovirus causes a strong cellular and humoral immune response, which can lead to the elimination of transfected cells and determine a narrow time frame for expression of the transgene (i.e., the transferred "therapeutic" gene sequence). This requires repeated application, the effectiveness of which can be compromised by the immune response.

Longer-lasting expression is achieved by other viral vectors, specifically retroviruses and adeno-associated viruses, which lead to an integration of the transgene into the genome. This can lead to insertion effects, such as the integration of the transgene at a location in the genome where other gene sequences are destroyed or activated, which can be harmful. Another problem is that retroviruses can only transfect cells undergoing cell-division, and adeno-associated viruses can only transfect specific cell types.

In sum, there is currently no ideal viral system for gene transfer, and the specific advantages and disadvantages of each transfection system have to be considered before a viral vector for gene transfer can be chosen. The combination of vector system and innovative application technologies such as double balloon catheters[4] can help to improve the efficiency of viral systems.

5 Angiogenic Gene Therapy

A significant percentage of cardiovascular diseases are vascular in origin. Ischemia due to an insufficient supply of oxygen by diseased blood vessels as seen in coronary heart disease, myocardial infarction and peripheral artery disease create considerable health problems. The concept of angiogenic gene therapy, therefore, is to induce new vessel growth by transferring specific gene sequences and to increase the supply of blood, oxygen and nutrients to the affected area. It specifically targets genes that are known to play a role in the generation of the blood vessel system during the prenatal development. Here, several mechanisms act together: *angiogenesis* targets endothelial cells and leads to the formation of capillaries; arteriogenesis includes endothelial cells, vascular smooth muscle cells and other cells; and *vasculogenesis* reflects the formation of complete intact blood vessels during development.

Many factors can modulate angiogenesis, but few of these initiate angiogenesis *in vivo* and *in vitro*. Two of these are *vascular endothelial growth factors* (VEGF) and *fibroblast growth factors* (FGF), both of which appear to play an important primary role in the angiogenic process and are currently being tested in many clinical trials of vascular gene therapy worldwide.

Several positive reports showing an improved clinical outcome of vascular gene therapy have been published.[5–6] However, these should be interpreted with caution, as the studies in question did not enroll the large numbers of patients typically required in clinical trials, and several critical parameters still need to be addressed. These include insufficient knowledge about the possible risks of angiogenic therapy, such as effects on the enhanced vascularization of tumors, inflammatory reactions, and risk of thromboembolic events, among others. Furthermore, control groups are typically missing in these studies, making it difficult to critically evaluate the true clinical outcome and its statistical significance. In addition, the exact knowledge of the need for interaction and co-application of specific angiogenic factors is still missing.

Angiogenic therapy focuses not only on the use of naked DNA, viral and liposomal systems, but also involves the use of recombinant proteins. It has been suggested that the longer time frame and local targeting of expression seen after gene transfer could offer benefits over the short-term benefits of pharmacological treatment.

5.1 Gene Therapy of Peripheral Artery Disease and Ischemic Heart Disease

In Germany alone, more than 30,000 partial or complete amputations of legs are performed due to chronic ischemia of the peripheral arteries, which is caused by atherosclerosis and is often associated with diabetes or smoking. Conventional means to avoid this include bypass surgery, angioplasty and stent implantation. Angiogenic therapy is considered an additional option and is currently being evaluated in clinical trials. Animal studies have demonstrated improved perfusion of ischemic limbs after injection of VEGF DNA into the skeletal muscle surrounding the ischemic area,[7] and a phase I study in nine patients[8] with peripheral artery disease showed maximal transgene expression after 1–2 weeks, resulting in improved formation of collateral blood vessels. This resulted in better blood flow in some patients, reduction of the clinical symptoms of ischemia, healing of ischemic leg ulcers and avoidance of amputation. Plasma levels of VEGF were elevated, showing that the gene was processed into the therapeutic protein.

Neurological evaluation showed improvement of ischemic neuropathy.[9] To finally determine the clinical efficiency of this form of gene therapy, there is a need for larger studies that address the potential risk of side effects and have longer observation periods.

Therapeutic angiogenesis is also a goal for the therapy of myocardial ischemia. After initial pilot studies using intramyocardial injection of genes,[10] a phase I study was recently published that involved the catheter-based application of VEGF.[11] After successful gene transfer, six randomized patients showed a reduction in the incidence of angina and ischemic symptoms, as well as a decreased use of nitrates, and in this group, as well as in 19 additional patients who were included in a follow-up study, no serious side effects could be detected.

In contrast to the previously discussed methodological approaches, a catheter-based myocardial gene transfer is noninvasive and more practical for clinical use.[12,13] It should be noted, however, that the above-mentioned studies were limited in size and their outcome must still be validated in larger investigations. These studies should not only focus on the verification of significant effects and the absence of side effects, but also on statistically significant effects on morbidity and mortality as well as quality of life after the intervention. Lastly, the costs and benefits of this approach must be put into perspective.

6 Gene Therapy for the Treatment of Heart Failure

Heart failure is defined as the compromised capability of the heart to sufficiently perfuse the peripheral organs. In more advanced stages according to the classification of the New York Heart Association (NYHA) the one-year lethality of this disease is 9–17% (NYHA III) and 36% (NYHA IV). Pharmacological therapy is available but cannot heal the disease. Therefore, gene therapy has been considered as a possible approach to improve the long-term treatment situation of this disorder.

There are several possible routes for gene delivery into the heart (Fig. 5). Vector and perfusion-based systems are applied to transfer genes that modulate the con-

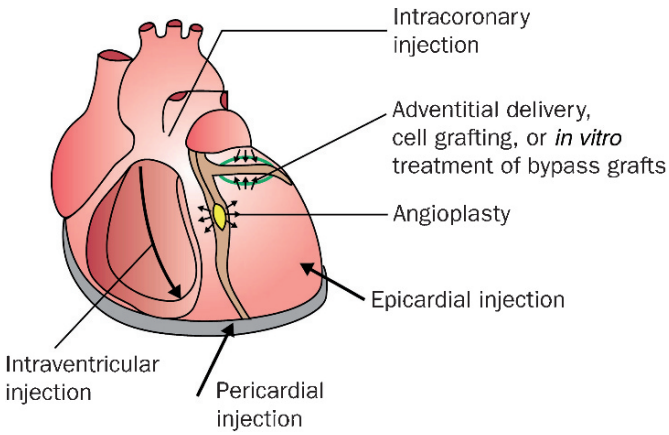

Fig. 5 Strategies for intracardiac gene transfer

tractile apparatus of the heart. Gene targets for this approach are, for example, the sarcoplasmatic calcium ATPase type 2 (SERCA 2) and phopholamban, which regulate intracellular calcium homeostasis. This is a primary factor influencing myocardial contractility, which is compromised in heart failure. Other targets include receptor genes of the adrenergic system. Myocardial beta-adrenergic receptors are downregulated in chronic heart disease. In addition, a beta-adrenergic receptor kinase (βARK1) is upregulated in chronic heart failure, leading to a reduction of beta-adrenergic effects. Antisense-driven inhibition of βARK in the heart by viral gene transfer has been shown to lead to a slower progression of heart failure[14] and an improved left ventricular function in experimental heart failure.[15] Also, intracoronary gene transfer of the β2-adrenoreceptor gene improved hemodynamic function. These data are supported by results from transgenic animals with permanent overexpression of these genes leading to similar phenotypes.[16]

More recently, embryonic stem cells have been used to treat heart failure and have gained immense popularity. Although this is not a gene-based, but rather a cell-based, therapeutic approach, it should be discussed in this context. Cardiomyocytes have been considered as terminally differentiated cells, meaning that myocardial cell death is irreversible and there are no cardiomyocytes generated in postnatal life, leading to replacement of cardiomyocytes by non-contractile cells such as fibroblasts which are a component of connective tissue without the contractile capabilities that the heart requires to function properly as a "blood pump." This process, termed *cardiac remodeling*, is the pathophysiological basis of myocardial insufficiency. The concept of embryonic cell transfer in cardiac disease is based on the idea that embryonic stem cells applied into the myocardium could then locally differentiate into myocytes, ensuring functional repair of the heart. This approach has led to remarkable success in animal experiments, and also some initial clinical studies have shown improvement in functional parameters such as left ventricular end-diastolic function (a good clinical marker for heart failure). Larger clinical trials are ongoing.

7 Therapy of Vascular Proliferative Disease

In cardiology, the problem of restenosis after interventional cardiac catheterization and after coronary bypass surgery remains one of the biggest clinical problems. After balloon angioplasty during coronary catheterization, the blood vessels lose their lumen by restenosis in about 30% of all cases. The implantation of stents to maintain the lumen still leads to a restenosis rate of 20%. This process is slower in blood vessels used for coronary bypass surgery; 50% of these artery segments become clogged up after 5 years.[17] The common problem in these conditions is the uninhibited proliferation of vascular smooth muscle cells from the vascular wall into the lumen, leading to stenosis. Gene therapeutic approaches, therefore, focus on the application of genes that have antiproliferative effects. In animal models, this approach has been very successful, and a number of target genes such as genes encoding for molecules involved in vasodilatation, for example the gene for nitric

oxide (NO), or genes encoding for cell cycle inhibitors which reduce the capability of cells to divide were identified.

Global gene expression studies are currently adding to our already extensive knowledge about the coordinated action of endothelial cells, vascular smooth muscle cells and adventitial fibroblasts in response to pathophysiological stimuli. Indeed, these studies may lead to the identification of new therapeutic targets. Despite positive pre-clinical data in this area of research, however, only a few validated clinical studies have been conducted to date. One of these studies will be discussed in more detail below as an example.

Published in *The Lancet* in 1999, the single-center PREVENT (Program in *ex vivo* vein graft engineering via transfection) study involved the intraoperative, *ex vivo* transfection of human bypass veins with E2F decoy oligonucleotides.[18] As an intracellular protein responsible for the induction of multiple cell cycle-dependent genes and subsequent proliferation of vascular smooth muscle cells, the transcription factor E2F represents an ideal target for gene therapy. Animal studies have already shown a significant reduction in neointima formation following the administration of double-stranded DNA fragments specific to the E2F binding site.

In the PREVENT study, 41 patients were randomized into three groups: in 16 patients the bypass veins were left untreated; 17 patients were treated with E2F decoys, and 8 patients were treated with unspecific decoys in order to exclude methodological variation. The successful application of DNA fragments (with an average transfection efficiency of 89%) was achieved without the use of liposomal or viral gene delivery systems, relying instead on an improved, pressure-mediated DNA transfection technology. After 12 months, there was a lower incidence of high-grade stenosis and graft occlusions in the group treated with E2F decoys. In addition, the *ex vivo* administration of the decoys avoids the potential side effects of *in vivo* therapy and can thus be classified as relatively safe.

Of course, this therapeutic strategy will have to be examined in studies with much larger patient populations. In addition to the above-mentioned short-term results, the long-term functionality of the bypass grafts will be of special interest to determine the clinical applicability of this procedure in the chronic context of the underlying disease. Following fast-track approval by the US Food and Drug Administration (FDA), a number of studies have begun to examine precisely this issue. In addition, the preliminary results from a study on the use of E2F decoys in coronary bypass procedures (Phase IIb CABG Trial) will soon be available.

In addition to the concept of influencing transcription factors such as E2F, NF-κB, Gax and GATA-6, many other gene therapy strategies are in development, especially for the treatment of coronary restenosis. These include gene transfer of cytotoxic agents, the modulation of cyclins, cyclin-dependent kinases and retinoblastoma proteins, the administration of cytokines and growth factors, and strategies for influencing signal transduction cascades.[19] In the future, these will compete with pharmacological treatment methods in terms of efficiency, safety and cost.

7.1 Gene Therapy of Atherosclerosis and Hypercholesterolemia

The pathogenesis of atherosclerosis offers a large number of potential therapeutic targets. Among other strategies, modulating lipoprotein metabolism and receptor density has shown promising results in animal studies. By transferring genes coded for the appropriate receptors, it is possible to lower cholesterol levels significantly and to markedly reduce the LDL/HDL ratio.[20] Somatic gene transfer of human apoA-I has been shown to prevent the progression of atherosclerosis in various mouse models.[21] In addition to helping researchers develop new therapeutic strategies, these studies provide us with a great deal of new information on the pathogenesis of atherosclerosis.

In the mid-1990s, Grossman and others showed in a pilot study that, in principal, it is possible to treat familial hypercholesterolemia by harvesting hepatocytes from study participants and exposing them *ex vivo* to retroviruses capable of transferring a functional LDL receptor gene.[22] However, although LDL levels were successfully reduced in three of the five patients, no subsequent studies were conducted. As a result, it is still unclear whether this area of research will produce clinically relevant results in the short term.

7.2 The In Vivo Production of Blood-Clotting Factors in the Treatment of Hemophilia

Hemophilia is currently treated using regular infusions of the missing blood-clotting factor (VIII or IX). The continual, endogenous production of the deficient factors would be the equivalent of a cure and is thus an attractive goal for gene therapy.

On the basis of the viral vectors discussed above, a large number of animal and preclinical studies of treatments for hemophilia A and B have been conducted, all of which are characterized by the above-mentioned limitations of these vectors.[23–24] Recently, however, the therapeutic efficiency of a nonviral delivery system was demonstrated.[25]

Dermal fibroblasts were obtained from six patients by skin biopsy and transfected in cell culture with plasmids containing sequences of the gene that encodes factor VIII. Cells that produced factor VIII were then successfully selected and administered to the patients by laparoscopic injection into the omentum. In four of the six patients, the blood-clotting factor was produced *in vivo* for the first time and for a maximum period of 10 months. This led to a decrease in bleeding and a reduction in the need for exogenous factor VIII. No severe side effects were observed.

7.3 Long-Term Control of Systemic and Pulmonary Hypertension

Systemic hypertension is one of the main risk factors for cardiac and vascular disease, including cardiac insufficiency, occlusive arterial disease, stroke and chronic kidney

failure. Whereas there are already numerous treatment strategies for the pharmacological treatment of this condition, there are still no effective treatments for the different forms of *pulmonary* hypertension, and the prognosis for affected patients is poor. The expectations placed in new forms of therapy are correspondingly high.

Genes whose products function as vasodilatory or vasoconstrictive mediators represent interesting targets for antihypertensive therapies. In animal models, for example, Chao and coworkers showed an efficient lowering of blood pressure and reduction in secondary damage after gene transfer of vasodilatory substances such as adrenomedullin, atrial natriuretic peptide, human kallikrein, kallistatin, and NO-synthase.[26–27] A different approach involves the antisense-mediated inhibition of vasoconstrictors. Most research in this area has focused on the already well-understood renin-angiotensin system and β-adrenergic receptors. A good example of this concept, and for the temporal effect of different transfer methods, is the use of antisense gene therapy that targets the angiotensin II type 1 receptor.[28] Whereas in one study the systemic administration of oligonucleotides led to a reduction in blood pressure that lasted for one week, the use of an adeno-associated viral vector in adult spontaneously hypertensive rats (SHRs – an animal model for primary hypertension) resulted in a 9-week-long reduction of 23 +/– 2 mm Hg.[33] Retroviral treatment strategies prevented hypertension for half a year when administered on day 5 after birth and reduced existing hypertension for one month in adult SHRs.[29]

The examples cited above show that, for certain forms of hypertension, it is possible to achieve a significantly longer-lasting reduction in blood pressure with gene therapy than with pharmacological treatment. However, it is still unclear to what extent the results from these animal studies can be applied to human forms of high blood pressure, and whether the benefits of a long-term reduction in blood pressure justifies an invasive procedure that employs, in part, viral antisense constructs as opposed to well-established pharmacological alternatives.

In contrast, gene therapy of pulmonary hypertension may be able to offer patients possibly curative treatment options, since this disease can currently only be treated with palliative approaches. Current research is focusing on the overexpression of vasodilators, such as eNOS, prepro-calcitonin gene-related protein (CGRP), and prostaglandin-I synthase (PGIS). Adenovirus-mediated gene transfer of constitutive and inductive NO-synthase via aerosols has led, for example, to a reduction in rats with induced pulmonary hypertension.[30,31]

8 Summary

There are now many "proof of concept" studies that show the feasibility of gene therapeutic strategies for clinical use in cardiovascular medicine. Among these is stimulation with growth factors of angiogenesis in ischemic tissues, or the reduction of restenosis via E2F decoys. Though promising, the preliminary results of the phase I studies described above must nevertheless be verified in larger, double-blinded randomized studies. Both these and future cardiovascular gene therapies will have

to measure up against other forms of treatment, such as pharmacotherapy and improved drug delivery techniques, brachytherapy or stem-cell therapy in terms of therapeutic benefit, safety and costs.

With regard to applicability and safety, there is currently a trend toward the use of nonviral vectors that, in certain cases, may even be administered *ex vivo*. Improved virus-mediated delivery systems may reverse this trend in the long term. Certainly, however, much more research needs to be conducted in order to help define new therapeutic targets, improve efficiency and achieve more exact dosing of cardiovascular gene treatments. In order for Europe to become more competitive in this area of research, national and European institutions as well as industry will need to invest significantly more financial resources. At the same time, clinicians – namely the people who will be applying these technologies in the future – must receive sound scientific training in the new techniques. And last, but not least, the public needs to be informed of both the benefits and the drawbacks of these types of treatment.

The first successful "proof of concept" studies described above make clear the great potential and progress of the dynamic field of cardiovascular gene therapy. Nevertheless, the next step will be to design clinical studies with larger and better-defined patient populations in order to validate these new treatment methods. The era of observational studies is over. The clinical studies of the future must fulfill the same stringent criteria that apply to investigations of new conventional treatments. In the end, it will be necessary to prove that gene therapeutic strategies are better than, or noninferior to, the pharmacological treatments that have been validated many times over in the field of cardiovascular medicine. As long as this evidence is lacking, there is no reason to abandon the tried and true treatment strategies that have been successfully employed to date.

In conclusion, it should be noted that gene therapy, despite the methodological progress that has been made, is still not able to provide a cure for cardiovascular disease.

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Biotechnology and the Guarantee of Human Dignity

Martin Nettesheim

1 Biotechnology as a Challenge to the "Classical Reading" of Art. 1 Par. 1 GG[a] regarding Human Dignity

The astonishing and breathtaking future prospects of biotechnology have become clearer and clearer in recent years. The possibilities opened by interventions into the genome, the genetic cultivation of tissues and organs, and the biotechnical optimization of the human body alter contexts which hitherto seemed unalterable to constitutional law. The genetic endowment of human beings, even the continuity from one generation to the next, loses the certainty and organic quality which used to determine the unexamined and self-evident background of our constitutional theory and our conception of ourselves. The soon to be available possibility of the self-optimization of the human race shakes the self-evidence of elementary background assumptions – both of an ethical and legal nature – which until now have never been subject to attack. Distinctions which until a few years ago seemed simply unalterable and insurmountable are threatening to become slippery. Categorical distinctions and demarcations, which the constitution could assume to be invariant and "natural" or "God-given" are suddenly becoming undifferentiated.[1] In the realm of ethics,[2] but also in the domain of constitutional theory and constitutional law, the developments in biological science lead into *terra incognita*.

In Germany, the future of biotechnology has provoked a heated and challenging discussion of the content of the guarantee of human dignity.[3] Article 1 par. 1 of the German Basis Law (Grundgesetz) sets forth: "Human dignity is inviolable" ("Die Würde des Menschen ist unantastbar"). This article does not only mark the beginning of the constitutional text; it is considered to be the cornerstone of the Grundgesetz and the prism through which all other provisions must be understood and interpreted. At the same time, the provision is, by virtue of Art. 79 of the Grundgesetz, also inalterable. Recent years have seen a constant flow of law review articles and journal contributions which attempted to show how the constitutional guarantee of human dignity confined the use of modern biotechnology. Most of these articles shared common features: they relied on the assumption that the traditional doctrinal approach to Art. 1 of the Grundgesetz would stand the test of time in light of the biotechnological challenge, and they claimed that the constitution

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itself imposed strict and invariable limitations on the use of biotechnology. These contributions also shared the view that the biotechnological challenge can be met by confronting political options with the supposed trump card of a violation of Art. 1 par. 1 GG – a trump card that cannot be taken even by lawmakers changing the law. Of course, the battle cry that this or that is incompatible with "human dignity"[4] allowed one to play the "highest card" – but at the price of rendering impossible any methodically proper discussion, which weighs goals, interests, and results against one another in a rational and reasoned fashion. Sometimes it seemed that here the roles of the citizen, engaged in the political fight for public opinion, and of the constitutional scholar had not been sufficiently differentiated.[5] It was merely one price of this strategy (and this should fill constitutional theorists with dismay) that lately many politicians regarded any appeal to Art. 1 par. 1 GG as a mere rhetorical gesture. Hypocritical compromises like those of the law on stem cells[6] made the rule's loss of meaning all too obvious. Those capable of examining Art. 1 par. 1 GG not with the heated passion of the political fighter but with scientific coolness had to admit not only that there is considerable uncertainty as to the concrete meaning of Art. 1 par. 1 GG, but in addition, one had further to admit that this provision cannot be understood as a little *Vademecum*, which can answer any challenges from biological science if approached with enough skill in interpretation.

In reaction and as a result, the value of the traditional approach was lately questioned by some authors. This challenge culminated late last year when the Bonn professor of constitutional law Matthias Herdegen published a new interpretation of Art. 1 par. 1 of the Grundgesetz in what is probably the most influential commentary on the Basic Law, that of Theodor Maunz and Günter Dürig, brought out by the C.H. Beck publishing house. Probably the most important thesis of this new commentary holds that interpretation of this passage should start by "considering the protection of dignity as a process, with the strength of an existing claim to respect and protection depending on a process of development."[7] According to this theory, the guarantee of human dignity constitutes an entrenched constitutional guarantee whose concrete content is situationally determined and must be decided by the balancing of colliding interests protected by law.[8]

Ernst-Wolfgang Böckenförde, professor of constitutional law at Freiburg and former justice of the Federal Constitutional Court, subjected this new commentary to a long critique in the *Frankfurter Allgemeine Zeitung* which was even signaled by a notice on the first page. Böckenförde's criticism culminated in the reproach that this new commentary represented a turning point and a historical rupture: for Böckenförde, it threw into question a consensus of constitutional interpreters which had lasted for over 50 years, according to which the provision in Art. 1 par. 1 GG was not a constitutional guarantee which required the balancing of competing values or interests and which in a particular case might give way to other considerations. Unlike any other provision in the basic law, Art. 1 of the Grundgesetz was considered to be the immovable foundation of the state's legal system, on the basis of which the inner teleology, interpretation, and content of the other provisions could be elaborated. Böckenförde complained that following Herdegen's interpretation, after 50 years of stability "the categorical foundation of state and legal order,

which in 1949 had erected inalienable foundations for the future based on memories of the National Socialist period" was becoming "blurry," becoming permeated by "prevailing trends," and beginning to "crumble."[9]

If this reproach were indeed true, not only should the public sphere take note, but there would be cause for deep concern in the realm of constitutional theory. Particularly in a period when the emerging possibilities in biological science present the legal system with a challenge which threatens to throw its basic values and structures into question, for constitutional law to destroy its own foundations and open itself to the possibility of the arbitrary balancing of "the provisions of the Basic Law as commonplaces" would have to be seen as a suicidal act. In fact, Ernst-Wolfgang Böckenförde's critique includes the reproach that a younger generation of constitutional law professors – here Böckenförde certainly meant to include Wüerzburg University Professor of Law Horst Dreier[10] – is destroying and talking away traditional and proven theoretical elements and dogmas which seemed, if not tried and tested, at least suitable for the task of holding biological science on the path of human dignity.[11] For Böckenförde this seemed to be happening either from a lack of understanding of the importance and fundamentality of Art. 1 of the Basic Law or from the desire to remove limits which got in the way of the development of biological science, an approach which these younger professors held to be right for their own subjective reasons. Böckenförde's answer to this development is his assertion that the challenge from biology can be met simply by invoking and applying the traditional interpretation of Art. 1 par. 1 GG, which is assumed to allow the constitutional law jurist to determine whether this or that specific technique (e.g. the production of embryos for research purposes, the production of and experimentation on stem cells, planting the nucleus of one cell into another cell for research, therapeutic,[12] or reproductive purposes, and positive or negative eugenics) remains inside or outside of the limits prescribed by the Basic Law.

2 The Dominant Doctrinal Approach

The authors of the German constitution, as is well known, passed Art. 1 par. 1 GG on to the jurisdiction of the Constitutional Court and to scholarship as an "uninterpreted thesis" to be made more concrete in the future. Asserting that constitutional theory has had difficulties with this inheritance is unlikely to spark contradictions. The Federal Constitutional Court has indeed emphasized that the guarantee of human dignity is central to the strength of the constitution – functioning for example as the unimpeachable supreme value ("Wert")[13] and the highest principle of the Constitutional Court,[14] as the fundamental structural principle of the constitution,[15] or as the "foundation of all the basic rights."[16] Others even speak of the "most central principle"[17] or of the "perhaps highest guiding idea."[18] It is certainly true that the theories of constitutional law of the early Federal Republic were able to develop an impressive approach to the philosophy of values[19] and to introduce these into constitutional law via Art. 1 par. 1 GG. It is certainly also true that this construction influenced the *constitutional identity* of the

Federal Republic in a powerful way. Yet the construction was always problematic: from the viewpoint of *legal philosophy* it was always clear that the idea of a "system of values" standing behind the law, and which supposedly guides constitutional interpretation, was hardly convincing in terms of content and, if taken literally in its philosophical implications, would become entangled in contradictions. From the viewpoint of *constitutional theory* this approach posed the question of whether human dignity could really function as the Archimedean point in the constitutional structure, which could be used to understand and develop the relationship between legal sovereignty and human being. Would not the attractive ideal of being a person in autonomy and freedom be a much more appropriate perspective for understanding constitutional theory?[20] This question was obviously justified once the guarantee of human dignity in Art. 1 par. 1 GG was drawn on by constitutional interpreters to forbid people behaving in ways which they chose, but which are undesirable ("unworthy") from the point of view of society – if not much sooner. And from a *doctrinal* viewpoint, it was always clear that not every construction which was successful in terms of the politics of constitutional identity also demonstrates those doctrinal qualities, which are needed to distinguish right from wrong in the face of new challenges.

Yet the construction was so successful (and the challenges luckily so slight) that the efforts over the last 50 years to develop a conceptual apparatus and an accompanying doctrine adequate for interpreting the constitution could be carried on in a fairly half-hearted fashion. This was all the more true since it was feared that defining humanity and human dignity in the sense of the Basic Law might lead to consciously or unconsciously excluding particular people. Over and over it was cautioned that the idea that someone might be capable of deciding who the bearer of human dignity is and – consequently – the subject of human rights is incompatible with the very idea of human rights. No one must be allowed to become the judge of someone else's humanity. The act of determining the meaning of human dignity more precisely, it was claimed, would inevitably lead to the legal isolation of people lacking the given attributes or possessing them incompletely and to their being deprived of legal protection. From this perspective, the theory, voiced quite early, that one should regard the concept of human dignity as "indefinable" is still justified.[21]

Even those who do not believe that such definitions are forbidden will agree that constitutional theory and doctrine have not progressed very far in the last 50 years. Even a cursory reading of treatises and commentaries on Art. 1 par. 1 GG makes clear that no stratification has arisen in the handling of this article such as the Federal Constitutional Court has produced in dealing with the other basic rights by taking up its power to interpret and approving of the development of scholarship oriented towards a positivist interpretation of the constitution. Furthermore – especially in comparison with the interpretation of the other basic rights set out in the first part of the Basic Law – the treatment of Art. 1 par. 1 GG is remarkably peculiar and odd. No other provision in the section on basic rights has remained so indeterminate and vague in terms of what it is supposed to protect. So far, constitutional theory and doctrine have not been able to develop the beginnings of a consensus around a concept of human dignity. Some have recourse to commonplaces; some attempt to promulgate some formula of consensus. In this way the normativity of the most

basic provision of Art. 1 par. 1 GG is lost: there is no threat to be found in the places where there is a consensus on what is adverse to human dignity. One must agree with Peter Häberle that so far "no adequate handy formula can be ascertained"[22] which would allow cases to be subsumed under this article. Sometimes human dignity is defined as "the intrinsic value and independence, the fundamental character and nature of the human being as such"[23]; others speak of the "core of human personality,"[24] or of human beings "in their specific and most fundamental sense."[25] In yet other articles human dignity is treated as solidarity between humans. In part dignity is also defined as the expression of social recognition: "Dignity is constituted … in social recognition by the positive assessment of social claims to respect."[26]

If the currently dominant approach involves such attempts at definition, at least it does not maintain that they have a doctrinal quality. Instead, it is assumed that "a positive definition of the object Art. 1 par. 1 GG aims to protect is impossible."[27] This leads to the practice of developing the constitutional provision "based on examples of its violation."[28] Of course, in a context where the object of protection is not defined, making the concept of infringement more concrete is hardly easy. Here two approaches coexist.[29]

The *technique of exemplary rules*, on the one hand, emphasizes the means used by the state, and according to it particular types of infringement ("defamation, discrimination, humiliation, stigmatization, persecution, ostracism and cruel punishments"[30]) must count as violations of human dignity. The technique of exemplary rules is reliable where obvious cases derived from historical experience are concerned[31]; it can also serve as an orientation point in situations where there is danger of gradually slipping standards. But with sudden advances into entirely new areas, this technique of grouping individual cases into categories is of little help. At the same time, the technique of exemplary rules has difficulties with the indeterminacy and vagueness of many exemplary rules.

The *object formula* ("Objektformel"), on the other hand, starts from the motivation and goals of the state's actions, and according to it, a human dignity is infringed "whenever a concrete person is degraded to an object, a mere means, to a fungible element" ("vertretbare Größe").[32] The BVerfG has often had recourse to this formulation.[33] The object formula suffers much more severely from the drawback that it can place limits on the state's actions only where the agent has simply not taken proper account of the personality, the interests, and the well-being of those affected in choosing among various possible actions. The object formula is based entirely on the subjective decision processes of the agent.[34] In fact, the BVerfG objectifies the formula by also examining whether the interests of those affected have played a sufficiently large role in the processes of decision; thus a sort of proportionality test takes place.

3 The Weakness of Dominant Approach

Even the BVerfG admits that this doctrinal approach is laden with problems and defects. Aside from the problem of coping with the challenges of biotechnology, any approach based on the object formula[35] leaves many reasons for perplexity and dissatisfaction – or leaves room for arbitrary interpretations:

1. This is the only area in the legal doctrine of German constitutional law where the objective or good protected by a fundamental state norm or norm of the basic law remains undefined.[36] Approaching the regulatory content of Art. 1 par. 1 GG not via the domain protected, but on the basis of the object formula, renders it impossible to make safeguarded pronouncements about the holder of the guarantee of human dignity. The BVerfG may well decide (or, according to some observers, decree) that even "unborn life" has human dignity.[37] Without defining the concept of human dignity, there can be no rational discussion of whether or not this determination is tenable.[38] In such a context, deciding whether such protection begins with the union of egg and sperm cells, with implantation, or later is entirely arbitrary. In the mean time, some have called for the protection to begin even earlier, including even gametes. As the difference between totipotent stem cells,[39] pluripotent stem cells, and somatic cells becomes more and more tenuous, the last limits preventing the guarantee of human dignity from encompassing all the cells of the body are erased as well. The temporal extension of protection to embryos and possibly to totipotent stem cells, however, might provoke the objection that basic constitutional concepts like "human dignity" and "human rights" not only become blurry, but lose their normative potential when they are extended to such counterintuitive and questionable cases.

But there is also a noticeable lack of clarity in the project of judging how the state's actions violate human dignity. On the one hand it is assumed that "human dignity" allows for no balancing at all, not even implicitly, in judging the quality of infringement of an action by the state.[40] Without regarding the immediate or mediate goals of the state's actions, it is claimed only the action itself may be taken into account.[41] According to this theory, torture is always forbidden, no matter what goals it is designed to serve,[42] and so is the killing of embryos. In protecting human lives endowed with dignity any sort of differentiation is invalid – with the result that the embryo must be protected from violation just like the human who is already born (including the "protection of human dignity which continues to be in effect after death," which must be respected in doing research on stem cells obtained by killing embryos[43]).

According to the theory that seems currently to predominate, any sort of appreciation and balancing of values ("Abwägung") is forbidden.[44] On the other hand, existing law also shows that the concept of "treatment contrary to human dignity" can have different meanings depending on the context. It is obvious that prisoners may be treated in ways that would not be permissible for free people. It is also obvious that the state's educational role allows it to intrude in the lives of children in ways which would not be accepted in the case of adults. In the case of people who lie in a coma without any hope of regaining consciousness, "humane treatment" can include the cessation of treatment; here, too, discriminations are made. If the protections of Art. 1 par. 1 GG are to be extended to unborn lives then differentiations of protection are necessary and normal in the context of diverse tensions and interests: the regulations for abortion illustrate this point clearly. The same situation

will have to apply in protecting unborn human lives *in vitro*. Many articles on this subject, however, imply that "human dignity" (and it is noticeable that many authors elide the important semantic difference between dignity and the protection of dignity) can be stuck onto human life like a sticker, thereby making it "inviolable" because any *differentiation of the objects protected* supposedly also relativizes *the protection* itself. But this need not be granted – the case, assumed, presupposed.

2. In the context of the object formula, Art. 1 par. 1 GG is also violated whenever in the development of biology the government makes a decision which affects the interests of the holder of dignity but in which the interests and well-being of the holder of dignity have not been given the proper weight. In this context one often hears the opinion that this sort of "objectification" occurs especially in cases where embryos are created to be used for research purposes and then discarded. Even if one thinks that embryos enjoy the guarantee of human dignity, this conclusion is not obvious: those who maintain that the interests of research (measured by its importance, the likelihood of success, and the availability of alternatives, for example) outweigh the interests of embryos *in vitro* cannot immediately be charged with making the embryo into an object. The situation in constitutional law changes only if one undertakes to adjudicate the balance of interests and postulates that human life should only be brought into being when it is not done for the sake of research which benefits others. But to make this judgment is already a process of appreciation and balancing. In abortion law such a process of balancing is recognized as admissible: here it is precisely the advocates of the traditional notion of human dignity who allow for the balancing between the duty to protect the human dignity of the embryo and the interests of the mother, which favors the mother in cases where there is a threat of death. Methodologically it is only consistent to allow such balancing in the domain of biological science as well: thus in all consistency there can be no objection to the position of H.H. Klein, who holds that research which consumes "surplus" embryos should be allowed, since such embryos would have no chance of life anyway. In any case the object formula cannot be used to prevent pre-implantation diagnostics: those who know that an embryo will come into the world severely handicapped, and decide on an abortion after having carefully adjudicated the factors influencing the quality of life, do not thereby turn the embryo into a mere object.
3. It is a basic axiom of the modern constitutional state that law and ethics cannot be forced into conformity without further ado. Constitutional norms – particularly the norms of the basic rights – are not the pure expression of ethical principles. In a pluralistic society they could never be that, because the constitutional state cannot undertake to make a particular ethics universally binding. Despite this fact, the normative weakness of Art. 1 par. 1 GG almost invites us to use particular theological[45] or philosophical ideas as a guide in interpreting it.[46] Suggestions in this line have been quite varied. On one side stand authors who see implanted in Art. 1 par. 1 GG a conception of humanity shaped by Christianity which has metaphysical roots: "Human beings are not understood

only in terms of their life in this world" ("Der Mensch wird nicht allein innerweltlich verstanden"). In this way, they claim, the constitution rejects "any claim to absoluteness by the world," "even for the law regulating the relationships among human beings."[47] On the other side, an important role is played in contemporary discussions by the idea that Kant's[48] notion of human dignity has found its expression in Art. 1 par. 1 GG. Thus it has been suggested that Art. 1 par. 1 GG should be understood as a "principle of constituting the state" whose presuppositions must be elaborated in the light of "Kant's philosophy." "It was the background of his ideas," we are told, that "influenced the members of the parliamentary council – along with ideas of natural law – in creating Art. 1 par. 1 GG."[49] This leads to the strange and unique situation where interpreters of Art. 1 par. 1 GG abruptly and directly cite from the Bible or works of philosophy. Thus, Art. 1 par. 1 GG has become a gateway for particular ethical tendencies and views. In general, one can say that the dominant interpretation does not succeed in giving Art. 1 par. 1 GG a genuine constitutional content that would keep the law of a constitutional state and ethics appropriately separate.

But there is another downside to this approach. Whoever relies on an ethos of "good living" ("Wohlleben") – which surely defines our society today, and which was described by Arnold Gehlen over 30 years ago[50] – as the foundation of an ethics based on "contentment" ("Lebensglück") will not be able to avoid the conclusion that we should use the possibilities for self-optimization provided by biological science. According to this ethics, for example, not life itself but rather the quality of life to be expected must inform the decision of whether unborn life is to be protected or not. And the goal of fighting against and healing diseases justifies almost any means: "our right to the highest possible quantity of health"[51] wins out over moral qualms. The ethos on which this viewpoint is based has already made huge inroads into law – not only in the realms of abortion law, the law of social help, or even the law of damages ("damages for a child"[52]). Constitutional theory must ask itself critically if it has truly adequate answers to the clearly visible social expectation that this ethos should be made the guiding principle in interpreting Art. 1 par. 1 GG and that biological science should be evaluated in terms of how much happiness (of researchers and beneficiaries) it can provide.[53] Answering this expectation with the formulaic recitation of fragments of decisions by the Federal Constitutional Court, or by doctrinal insistence that some particular ethical approach (e.g., one based on the preservation of a particular species) is binding on everyone, will not be very convincing; given that "mass eudaimonism" is very influential in society and has long been acknowledged as a force in law, it smacks of contradiction. This may be one reason why the constitutional censures "derived" by constitutional lawyers from Art. 1 par. 1 GG are met (in the purest sense of the word) with sheer incomprehension among wide sections of society.[54]

4. Special problems are caused by understanding Art. 1 par. 1 GG as a way of steering the development of ethical propositions when these are to be made binding on third parties via the doctrine of the "duty to protect."[55] The unproblematic equation of particular values and generally significant, specially protected legal

constructions poses large threats to the constitution as a *guarantor of freedom*.[56]

5. The normative weakness of the object formula leads directly to an instrumental use (and misuse) of the constitutional norm. It is absolutely inviting to apply the constitutional norm where the constitution itself has holes, actual or apparent. Thus Christian Starck[57] supports his demand to extend the protection of human dignity to unfertilized gametes with the consideration that this is the only practical way to prevent the manipulation of gametes. If one agrees with the principle that Art. 1 par. 1 GG is the foundation of all legal order and illuminates all of its domains, this is a consistent approach. Given the activism of the BVerfG in the area of basic law and the idea that Art. 1 par. 1 GG illuminates all of law the idea that the constitution might not provide any answers to the most important challenges in human development in particular seems to be unthinkable for many constitutional jurists. But the price of this approach is quite high. The constitution loses its function as a limiting framework. In addition, this approach overworks Art. 1 par. 1 GG, causing this constitutional provision to lose even more of its normative potential. Positions like those of Matthias Herdegen, who bases his thesis of the graduated protection afforded by the guarantee of human dignity by claiming that it saves the constitutional community "from continually setting up and abandoning taboos and from the trauma of breaking them,"[58] should give one pause. Dissolving the normativity of Art. 1 par. 1 GG in this way raises the question of whether it is time to examine the dominant understanding of Art. 1 par. 1 GG.

In sum the traditional interpretation of Art. 1 GG, as conjured up by Ernst-Wolfgang Böckenförde, proves incapable of meeting the challenges of biological science in an effective way. On a closer view, the apparently solid foundation he evokes proves to be a fragile scaffolding which is too vague and open in its judicial-interpretative content to establish clear interpretative guidelines. In light of the currently predominant doctrinal approach, Art. 1 par. 1 GG does constitute a direct hinge between the world of ethics and juridical conclusion. It thus allows for the legal justification of positions one already holds to be morally correct. This approach proves functional and valuable in areas in which there is an ethical consensus among the interpretative community. It loses its usefulness where there is no longer or not yet any ethical consensus among reasonable members of the political community. In areas in which the consensus disappears – such as modern biotechnics where different kinds of philosophical ethics provide different answers to the bioethical questions (e.g., the questions of when life begins, of research with embryos, or of euthanasia) the approach fails to produce a juridically rational application of Art. 1 par. 1 GG. It is obvious that an ethics based on freedom and self-determination will reach entirely different conclusions how to treat unborn life than a utilitarian ethics or an ethics which holds every human life to be made in God's image (Gen. 1: 27) as soon as the egg cell is fertilized. In other words, the traditional and prevailing understanding of Art. 1 par. 1 GG does not sufficiently confine or control the introduction of ethical judgments into the system of law, in a meaningful way. In an area where no

common viewpoints have developed yet and where ethical uncertainty exists, the constitution's provision does not provide any instructions for deciding between them. Thus, Art. 1 par. 1 GG fails precisely in areas of new challenges where the formation of established opinions has not yet been possible.

4 A Constitutional Law Concept of Human Dignity

4.1 Human Dignity as a Transcendental Quality?

According to the clearly dominant concept, human dignity is a quality with which human beings are transcendentally endowed. In this view, dignity is the essence of the human being.[59] Dignity is regarded as a concept in an ontological metaphysics which sees being made in God's image,[60] in the faculty of reason, or in other capabilities a special transcendental quality which separates humans from other living things. In Günter Dürig's formulation, human dignity is a "fact of being, which 'is' independent of time and space and which 'should' be realized with legal means."[61] The human quality of dignity is regarded as an absolute value which is not subject to balancing and which cannot be compensated for, a value which people owe it to one another to recognize and respect, necessarily and unconditionally. For understanding this conception of dignity it is important to realize that it attempts to define the concept of human dignity un-empirically and with transcendental logic: dignity is not a quality whose presence depends on the specific capabilities of concrete people. Anyone who belongs to the group of humans is entitled to dignity, irrespective of their concrete ability to exercise autonomy. According to this theory, cloned people also have human dignity, and – with the premise that it too is already made in God's image or is (potentially) destined to be rational – prenatal human life as well. The point of reference of these theories of human dignity is the human organism, which must be treated as an individual by the mere fact of its difference from its environment and from other humans. In this context it is quite consistent to equate the origin of human life with the origin of an *individual* genome.

For constitutional theory, the positions developed above are both strong and weak. Their strength lies in the fact that human dignity conceived as transcendental and empirically empty cannot be harmed, cannot, as it is put in Art. 1 par. 1, be "violated." Someone's destiny to be rational cannot be taken from them, any more than their being made in God's image. But if something is inviolable in any case, the question aimed at in Art. 1 par. 1 GG of how to prevent the state from damaging this right need not be raised at all. Cynics use this fact to combine verbiage about the highest idealization of human beings with "pragmatically" relativized implementations of the domain to be safeguarded.

Relegating the protected domain of Art. 1 par. 1 GG – the dignity protected by constitutional law – to the transcendental level is not to be recommended, if only on the grounds that any transcendental protection based on constitutional law would be pointless. The attempt to turn the concept of human dignity into an absolute and

basic norm of law by appealing to a universally binding final cause merely *devalues* Art. 1 par. 1 GG. The "hermetically sealed idealization"[62] which makes Art. 1 par. 1 GG refer to "the essence of the human"[63] "creates fatal dangers through creating mental taboos."[64]. It would be a mistake to assume that a constitutional provision like Art. 1 par. 1 GG can be so raised up and immunized that it is removed from the conflict of pluralistic interpretations, yet manages to retain its practical use as a binding norm of secular positive law. In a central area like Art. 1 par. 1 GG, constitutional law must not endorse an approach which is so clearly impregnated with a particular worldview that any criticism would require constitutional law to take sides in an area which modern societies have quite sensibly left as an arena of controversy. Unless the *legal content* of Art. 1 par. 1 GG is purified of transcendental assumptions, those of natural law,[65] or religion,[66] in particular, there is always the danger that the norm will be crushed by the religious conflicts of the interpreters. This very purification allows the interpreters the freedom to explain using their own *ideas of what defines the human being*, just *why* human beings and their dignity are given such an important place in constitutional law. In this way, the ideal pluralism which exists on a level above constitutional law is not expressed directly in interpretations, and is – at least in part – immunized. And for this very reason, a conception of human dignity which respects the claims of Art. 1 par. 1 GG must not try to make a priori or transcendental determinations possible "by freeing the concept from all practical and empirical notions of humanity."[67] Instead, it recognizes that Art. 1 par. 1 GG is reacting to actual threats to a dignity which can be attacked. We must make a distinction between the *reasons* for recognizing and protecting human dignity and the actual *object* protected by Art. 1 par. 1 GG. The dignity described by Art. 1 par. 1 GG can only be a quality which is subject to empirically demonstrable dangers in the actual workings of the constitution.

4.2 Human Dignity as Social Attribution?

Article 1 par. 1 GG was written in reaction to dangers that were experienced historically and which demonstrated empirically that human dignity *is* violable. Unless it was violable, it would not need the normative protection of Art. 1 par. 1 GG. With this understanding Niklas Luhmann and Hasso Hofmann have developed concepts of human dignity which start from empirical facts. According to Luhmann's theory, human dignity is a product of a concrete human being. It should be seen as an achievement of human subjectivity. For Luhmann, human beings gain their dignity by successfully creating identities through actions they have chosen to carry out.[68] To claim, as is occasionally done in inaccurate depictions of this theory, that it regards human dignity as an expression of social worth or social position is incorrect. The problem with this theory is not that it postulates a sort of human dignity which varies according to social position. Its problem is rather that it sees human dignity as the *result* of a process of identity formation. Now the state cannot judge whether or not someone's personality (and this is the crucial aspect here) has developed well or not. Rather, the state's

constitutional order has the general duty to protect the process of developing a personality. Protecting only the result and expression of personality formation would be dereliction of this duty. Under Art. 1 par. 1 GG, one cannot equate human dignity with a successfully developed personality.

Similar objects can also be made to the relational concept of human dignity developed by Hofmann: "Dignity is constituted… in social recognition when attempts to gain social respect are positively valued."[69] Here dignity must be understood as a category of the individual's social life: "Dignity means reciprocal recognition of others in their own individually and particularity, with everything they contribute as a part of the whole." Hofmann's approach results in seeing human dignity as the product and the expression of social recognition by third parties – and therefore as the product of something attributed to the individual by third parties: human dignity as a "promise" which provides the foundation of the national sense of solidarity.[70] This raises the objection that there may be a normative duty of third parties to recognize the dignity of others, but that dignity itself does not result from recognition by others. In Art. 7 par. 1 sec. 2 of the constitution of Brandenburg, this duty is vividly expressed: "Everyone owes everyone else recognition of their dignity." One can debate about the sense of putting such provisions into a constitution; at least they make clear that dignity is not a product but a precondition and point of reference for social relations.[71] Human dignity is not based on social recognition – which can be and obviously has been denied. Should the state force fellow citizens to yield up social recognition?

Of course, it is above all in the debates around biological science and constitutional law that one can find arguments and positions which are trapped in a scientific naturalism – for example, positions which hold that human life with dignity must begin with the fusion of gametes, or with implantation, or with birth, because it is at that particular point in development which particular natural qualities appear. Political importance in this area has been achieved by Horst Dreier, in particular, whose theory claims that prenatal life cannot be said to have human dignity because it lacks "all the preconditions (self-consciousness, reason, and the capacity for self-determination) which constitute human dignity." A detailed discussion of such viewpoints is not necessary here, if only because they have not yet been developed into a comprehensive theory of human dignity according to Art. 1 par. 1 GG. The same is true for theories which approach the problem through conceptual analysis, for example, through artificial explanations of the difference between "the development into a human being" and "development as a human being."[72]

4.3 Dignity as the Aptitude and Destiny to Develop a Personality

If the constitutionally protected object of Art. 1 par. 1 GG is not to dissolve into the transcendental, and if it refers only to that which has already been accomplished, it must lie in those basic qualities of human beings which are empirically

and anthropologically demonstrable. In this sense, dignity is the expression of humans' unique and special ability *to develop into a person* and to *be a person*. Every human life has the *destiny to have a personality* – even unwanted human lives.[73] This is what distinguishes humans from non-human life-forms and from things. It is not the developed personality,[74] or the content of a personality,[75] but the fact that human beings are " 'persons' in their very way of being" that gives humans their dignity. This is true of all people, children, handicapped people, criminals, and those on the point of death.[76] The individual situation and the level of development play no role, what matters is solely being part of the species.[77] Thus the question of the chances of life or survival, which often) plays a central role in discussions about human dignity (e.g., with respect to zygotes and embryos), cannot be the *decisive* factor, because the crucial normative thing is to determine how much the chances for development should be protected.[78] But it should be remarked in passing that dead people have no human dignity in the sense of Art. 1 par. 1 GG.[79] Here one can only consider to what degree the bereaved have a right to respect and to what degree lawmakers can impose particular cultural notions about how the dead people should be treated.

In this context, if one asks to what degree one should also attribute human dignity to unborn life, cautious analysis is necessary if only because the problem has not been solved in advance by the specious "natural analysis of concepts" ("the development into a human being" versus "development as a human being") or by "biologistic" inevitability. On the contrary, the problem requires a normative agreement by the community of constitutional interpreters – an agreement which must occur in the light of our notion of what a human being is.[80] In fact, there are good reasons for ascribing human dignity even to the fertilized egg cell *in vitro*.[81]

It is not clear why protection of the *potential personality* inherent in the embryo should be dependent on whether it is developing inside or outside of the mother's body. Although it is correct to distinguish between potential and actual *human life*,[82] it is impossible to discover a point in the course of human development which marks a qualitative leap in terms of potential personality.[83] As soon as a human life can be developed to the point of birth in an artificial uterus, as will soon be possible, the "point of implantation," so important until now, will lose its meaning: why does the theory of Art. 1 par. 1 GG ignore these approaching developments and insist on arguing only about the here and now?

But this also means that constitutional arguments which revolve around the point at which egg and sperm cells are fertilized[84] are becoming precarious. Insofar as other types of cells prove to be totipotent stem cells,[85] the attribution of human dignity should be expanded – but, as we shall see, this does not mean that the same protection should be afforded to every type of cell and for every stage of development. From this point of view, the protection of dignity and the protection of life should in principle (not in their content, but as regards the object protected by law) run in parallel; developments can be seen which will force the theory of constitutional law to regard the protection of dignity as prior to the protection of life.

5 Art. 1 par. 1 GG as a Multidimensional Constitutional Guarantee

In recent years, criticism of the dominant understanding of Art. 1 par. 1 GG has become stronger in the area of constitutional theory, and rightly so.[86] It is time to reflect on the function of Art. 1 par. 1 GG as a *setting of limits*, which provides the outermost and inviolable limits to the power of the state, but thereby opens up a space of freedom in which the political process – while heeding the more particular basic rights – can play out. Article 1 par. 1 GG can be understood not as the source of the basic rights (or the entire constitutional order)[87], but as the norm of protection which formulates the inviolable content ("Wesensgehalt") of the more particular basic rights[88] and sets ultimate limits in cases where these other basic rights do not provide any protection.[89] Viewed as a limiting rule which sets outermost and inviolable limits to the power of the state,[90] Art. 1 par. 1 GG (or so we will argue) can set limits only in a few cases, which reach deep into the very notion of the constitutional state as envisaged by the basic law. Anything beyond that must be decided by political conflicts among free and equal citizen. Too much is being asked of Art. 1 par. 1 GG when the rule is understood as the foundation and starting point of a "system of values and claims"[91] which represents itself as "comprehensive," and which claims that its individual value judgments have the inexorability of absolute limits, hostile to balancing and heedless of all consequences.[92] In this context, calls to return[93] to the interpretative roots[94] of Art. 1 par. 1 GG give cause for skepticism.

In this context, it appears impossible to avoid a new way of thinking about the doctrinal content of Art. 1 par. 1 GG. In so doing, the following premises must be kept in mind: it should at least be consistent with the jurisprudence of the German Constitutional Court; within its outlines the decisions of the BVerfG should be able to find room as far as is possible. It should provide for coherence; in particular, its determinations on biological science and abortion should not include the contradictions such as those which have been accepted occasionally in connection with the "object formula."[95] It should remain aware of the limited ability of the norms of positive constitutional law to settle disputes: there is little point in making transcendence the protected object of a constitutional provision. Finally, the constitutional norm which declares human dignity to be inviolable should not be reduced to a mere point of view for balancing. But neither is there any point in postulating limits which are apparently unalterable and unchangeable across time: those who have studied the history of the guarantee of human dignity know only too well that what it protects depends on prevailing circumstances and can undergo changes. The BVerfG admits this explicitly.[96] And in international discussions of human rights it is now recognized that although the demand to protect human dignity must claim to be universally valid, the protected domains may depend on temporal, geographical, and cultural circumstances.

In this context, the interpretation of Art. 1 par. 1 GG cannot revolve around the abstract and transcendental quest for the essence of humanity, instead it is a matter of how humans use their abilities.[97] The object protected by Art. 1 par. 1 GG lies in

the area of tension between humans' various attempts to define themselves, between scientific discoveries and sociocultural opinions ("the concept of the human being").[98] What does Art. 1 par. 1 GG demand in terms of precautions and protections? According to the dominant view, the constitutional provision should be understood as a commandment (and today also as a basic right) which establishes the duty to protect individuals from objectifying treatment by state agencies or third parties. This protection should apply to every human life; any differentiation according to the level of development is supposedly forbidden.[99] According to the theory developed here, this approach misunderstands the object protected by Art. 1 par. 1 GG: the dominant doctrine, which understands Art. 1 par. 1 GG as a unified structural principle (and, according to controversial theories, as a unified basic right) overlooks the fact that the constitutional provisions involve three strictly different approaches to protecting the human capacity for personality. The doctrine of Art. 1 par. 1 GG thus includes three different dimensions. Article 1 par. 1 GG includes three different guarantees which protect different objects. The task of limiting humans' ability to use biotechnology in remaking themselves requires all three dimensions.

5.1 Art. 1 Par. 1 GG as a Principle of State Ethics

If one takes the trouble to reread the commentary by Günter Dürig, now almost half-a-century old, it is obvious that Dürig was interested above all in formulating a basic principle of *state ethics*. The state depicted in the Basic Law should be forbidden to make the individual into an object, to a mere means to an end, to a fungible element or justifiable cost. In this way Dürig picked up on the formula which had already appeared in Art. 1 par. 1 of the Herrenchiemsee constitutional draft: the state exists for the sake of people. In forbidding the objectification of people, Dürig was formulating a rule in state ethics which was to be binding on every person carrying out state power: when making a decision using the powers entrusted to him or her, everyone who holds office under the Basic Law must take into account not just the interests of the general public or of third parties, but also and always the interests of the person affected by their decisions. Decisions involving the use of state powers must always revolve around the individual person affected ("grounds to suppose that the results will be favorable to human beings"[100]); they must never fail to consider him or her. The constitutional norm expresses a notion of the common good which starts from, is guided by, and has as its absolute goal the well-being of the individual. The criteria for "contempt" or "arbitrariness" occasionally adduced by the BVerfG indicate a violation of this dimension of Art. 1 par. 1 GG regarding the common good, but they are not a necessary precondition for violation. In terms of this dimension – elaborated by Wolfgang Graf Vitzthum in important works[101] – Art. 1 par. 1 GG is not merely a state institution; it is an official duty.[102]

It is characteristic of this dimension of Art. 1 par. 1 GG that it is binding on every *action by the state*. To hold that this state ethics of the common good centering on

the individual holds only for important or particularly far-reaching decisions would be to misunderstand Art. 1 par. 1 GG completely. Of course, it is obvious that deciding to imprison someone for life is only permissible if the individual circumstances of the accused are taken into consideration and if the sentence is carried out while keeping the good of the condemned in view. Objectification of the individual, however, is forbidden as well even in trivial decisions, even in decisions which have barely any affect or are carried out with good intentions.[103] How the various interests must be taken into account in decisions by the state depends on the extent and intensity of their effects: the more intensely the state's decision intervenes into the sphere of the individual, the more the individual's interests must be taken into account with regard to the particular case. The fact that *every* action by the state must conform to the principles of state ethics in Art. 1 par. 1 GG also explains why no protection needs to be defined, and why no definition can be constructed by starting from the actions which violate the principles.[104]

In this dimension, the constitutional provision does not provide any hard-and-fast or unalterable limits. Admittedly the duty to respect the standards of state ethics in the state's process of making decisions is unconditional: it is simply unimaginable for any state power to be exercised under the Basic Law which would not be obliged to consider the well-being of the individuals affected. For this reason it is true that the no-restriction of Art. 1 par. 1 GG could be *justified*. In this sense the current approach, according to which the concrete content of the guarantee of human dignity can be defined only with regard to the concrete historical, political, social, and societal circumstances of the particular case, misses out on this first dimension of the guarantee of human dignity: the constitutional provision always structures the procedure for decision in the same way and always fixes the same goal for the decision. But in the dimension of state power being discussed at present, it does not set any limits regarding the object or the substance. How the decision will come out in a concrete individual case is not determined by Art. 1 par. 1 GG. Even imprisonment for life can be reconciled with the idea of well-being centered on the individual laid down by Art. 1 par. 1 GG if some person is so dangerous that it is not reasonable to expect his or her fellow-citizens to allow him or her to live in freedom. The same thing is true for the "final death sentence." From this it can be seen clearly that the guarantee of human dignity and the principle of proportionality lie on different levels. The conclusion that disproportionate actions by the state violate the dimension of state ethics in the guarantee of human dignity is inadmissible. Both principles of the constitution are violated simultaneously by any state action in which an official empowered by state office does not make his or her decision revolve around the affected individual (state ethics) *and* imposes inappropriate burdens (the relationship of means to ends).

Against the background which has just been sketched it is correct to regard the dimension of common well-being as one of the most important fundamental norms as well as a foundational legal requirement of the state, which can claim to be binding for the interpretation of all other norms in the Basic Law and in addition, for implementation of all other norms beneath the constitutional level. In particular, any interpretation of the basic rights must take into account that state powers

regarding the basic rights can only subsist under the Basic Law if they satisfy Art. 1 par. 1 GG's stipulations on state ethics. At the same time, this context makes clear why the dimension of guarantee in Art. 1 par. 1 GG can have no *subjective-legal* quality as a fundamental norm of the state: there can be no claim on the part of any individual to make state agencies structure their decisions in a particular way. Such structures are not an object of law which can be demanded by an individual in a subjective-legal fashion before a court – even by lodging a constitutional appeal; these structures can only be inspected implicitly when some established legal right – for example, freedom, property, body, or life – has been infringed. It is certainly insufficiently understood that these facts do not necessarily hold for the other protected dimensions of Art. 1 par. 1 GG.

The point of reference for a state ethics which forbids those who hold power from the state to objectify individuals is obviously primarily and fundamentally the (born) human being. It is certainly established in this ethics that it commits the state to respect and honor life in the process of coming into being. Those who hold power from the state would be neglecting their duty if they were indifferent to prenatal life. The same would be true if they did not assume responsibility for the fate of "orphaned embryos" and did not clarify their chances for life – for instance, by introducing some sort of adoption regulation.[105] State power under the Basic Law must also attend to the well-being of potential life. In contrast to the approach of the traditional doctrine of Art. 1 par. 1 GG, this duty does not arise only when new life comes into being, that is, at the time when egg and sperm cells unite. The respect demanded by state ethics extends as well to germ cells. On the other hand – and here too there is a contrast with the traditional doctrine – a reading of Art. 1 par. 1 GG in terms of state ethics does not require from the state a *particular* position towards life in the process of coming into being. Adjudicating solutions, like those found in existing abortion law, are allowable – also regarding life coming into being *in vitro* – as long as sufficient attention is given to the intrinsic value of this life.[106]

The substance of the free constitutional state is threatened if the content of state ethics in Art. 1 par. 1 GG is imposed onto private persons via the doctrine of the duty to protect. This threat is not always taken seriously enough. All too often the idea that the state may not make the individual into a mere object is transformed into the idea that the state must prevent individuals in a private legal relationship from making each other into objects. Sometimes Art. 1 par. 1 GG is even made out to be the source of a duty on the part of everyone to respect the dignity of everyone else.[107] For instance, it is used to justify a constitutional duty to forbid private experimentation on embryos. From the perspective of constitutional theory it can be objected that a duty of state ethics can never be made binding on private individuals. Those who use the object formulation to judge the actions of private individuals (e.g., private researchers) on constitutional grounds abandon the fundamental distinction between a state committed to the common good and free citizens, and thereby destroy those limitations which constitute the political unit under the Basic Law. The state is forbidden to demand that private citizens obey the principles of state ethics; it can only demand that citizens follow the law. In that sense, people who make use of third parties in private relationships without taking their personality

and individuality into account do not violate the constitution or the law. Here the law of the state (e.g., the law on work) can set outer limits, but cannot compel any sort of personal views. Obeying the laws of Kantian ethics cannot be made into a duty by invoking Art. 1 par. 1 GG.

The state ethics described above can be seen as an expression of the principle of dignity – human dignity as the *destiny to have a personality* – because the realization of this dignity (as opposed to dignity which is transcendental or obtained by one's own efforts) would be endangered if the citizen were transformed into a desubjectivized slave. In this sense Art. 1 par. 1 GG protects the individual from an *abstract danger* even where the freedom to develop a personality has not been harmed concretely.

5.2 Art. 1 Par. 1 GG as a Protection of Personal Freedom

The constitutional content of Art. 1 par. 1 GG does more than establishing the fundamental commandments of state ethics. Along with the dimension of state ethics it introduces the dimension of fundamental liberal rights, whose goal is to fend off concrete harm to human dignity. What Art. 1 par. 1 GG guarantees and protects in its dimension of fundamental liberal rights is the *freedom of the individuals to put into practice their aptitude and destiny to develop a personality*. Article 1 par. 1 GG forbids the state from allowing humans to be treated in ways that make it impossible for them to lead lives in which this aptitude and destiny can be put into practice. The state respects and protects human dignity by ensuring the freedom to actually make use of the *destiny to develop a personality*. This is not a matter of "guaranteeing human dignity" (for no one's human dignity can be taken from them) but of guaranteeing the right to make use of one's own autonomy and thus giving expression to one's dignity; this freedom can be violated. It is characteristic of the constitutional state established by the Basic Law that it fundamentally refuses to assess how human beings come to terms with their dignity. The constitution makes no judgment on whether a human being uses or squanders this opportunity. The constitution – and the state agencies it establishes – is not entitled to judge whether people use their autonomy, freedom, and aptitudes properly or not. In this respect, the fundamental liberal protective dimension of Art. 1 par. 1 GG makes a double guarantee: first, the constitutional norm protects and safeguards the *necessary conditions* of freedom – such as the state's guarantee of the minimal existence necessary for survival. In addition, Art. 1 par. 1 GG protects freedom: it protects the freedom of the individuals to decide on how to conduct their own. Regarding the freedoms guaranteed by special basic rights, Art. 1 par. 1 GG functions as a final and insurmountable defense; in this respect it complements and supports the freedoms guaranteed by the special basic rights. Insofar as some threat has not been subsumed by the special basic rights, Art. 1 par. 1 GG serves as a primary and exclusive guarantee.[108]

The liberal protective dimension of Art. 1 par. 1 GG (unlike the dimension of state ethics treated above) demonstrates a *protected domain* to be outlined by the

interpretation of the constitution. The question of which external and internal preconditions are so crucial to someone's ability to conduct their own lives that the constitutional state of the Basic Law must take responsibility for them cannot be resolved simply. It is also necessary to resolve which actions are so elemental in constituting a personality and conducting one's life that the state may not subject them to any sort of external compulsion. To begin with, individuals must be granted the primary *right to define themselves*; this right, however, is limited, insofar as only those rights to self-determination can be protected by the constitution which society regards as crucial to the formation and continuation of a personality: the compulsion to stop when a traffic light is red does not harm the personality; the same goes for changing in the title of an office[109] or the omitting of diacritical marks in someone's name on a telephone bill.[110] Here freedom of conscience as defined in Art. 4 par. 1 GG serves to "trump" societal opinions – thus Art. 4 par. 1 GG is one of the most important building blocks in the Basic Law's edifice of protections of dignity.[111]

In addition, Art. 1 par. 1 GG protects *individuals' freedom to conduct their lives and make their own decisions*. The BVerfG has developed ample precedents in marking the state's limitations in this area.[112] In this tradition it is recognized that personality consists in the "freedom of self-portrayal" ["Freiheit zur Selbstdarstellung"] but also in the "freedom of self-determination" ["Freiheit zur Selbstbestimmung"] (e.g., to decide on the circulation of basic data, the existence of property rights, etc.). In the course of development of the social state it has been recognized that, in addition, the provisions of Art. 1 par. 1 GG not only protect freedom, but also guarantee the minimal material conditions necessary to make use of this freedom.

Such freedoms are always violated when the state's actions interfere disproportionately with individuals' freedom to define themselves, conduct their lives, or make their own decisions: it is obvious, for example, that humiliating measures which deprive individuals of their self respect violate this freedom. The BVerfG has rightly based individuals' freedom to make their own decisions to include the right to decide on how and to what extent information and media exposure about them can be spread by others or by the state.

If one understands the freedom to define oneself and make one's own decisions as the domain protected by the liberal dimension of Art. 1 par. 1 GG, this norm fits seamlessly into the Basic Law's section on basic rights. In this way – contrary to its role in its dimension of state ethics – Art. 1 par. 1 GG establishes subjective rights and can be called upon by individuals who have been harmed in the sphere of their personal rights. Only natural persons can be said to have these basic rights. One can, however, claim there is a duty to protect unborn life in reference to its ability to have a personality. It is clear that the liberal content of Art. 1 par. 1 GG allows for balancing between competing interests protected by law: in terms of this content, Art. 1 par. 1 GG – contrary to its content in the domain of state ethics – is not an absolute right, but – like the other basic liberal rights – envisages a distinction between its prima facie content and its definitive content. Such deliberations are in fact common in applying Art. 1 par. 1 GG, but until now they have been hidden behind the "object formula." In the light of the duty to avoid disproportionate

actions, this results in differentiated, gradual protection. In developing the dimension of Art. 1 par. 1 GG dealing with basic liberal rights, the object formula has no place. This is not a matter of the abstract dangers of "objectification" but of concretely protecting the freedom to define oneself, conduct one's own life, and make one's own decisions.

5.3 The Guarantee of Human Dignity and the Protection of the Human Species ("Gattungsschutz")?

The above reflections clearly show that the concrete applications made until now often give no answers to the challenges of biological science. Anyone who tries to deal with current problems must admit that neither the "object formula" nor the technique of exemplary rules allows for a consistent and coherent response to these challenges. To give only three examples: Manipulation of the germline of living consenting humans cannot be prevented by the object formula, nor will the technique of exemplary rules be of any use. The dominant doctrine also leads to a dead end in cases of manipulations which bypass the union of egg and sperm cell. Further difficulties arise in deciding what to do with clones which have been illegally produced: §6 par. 1 of the Law for the Protection of Embryos [EschG] demands punishment of anyone who transfers an illegally cloned embryo into a woman's body. This provision establishes a duty to kill which is protected from punishment, which seems unconstitutional against the background of the "object formula."[113] And yet one can give reasons for this rule: should these have no force in constitutional law? It is surely no contradiction to claim that a cloned human being, once born, has the same legal status as any other person – so why should there be a commandment to kill embryos?

These examples also show that these challenges to species ethics cannot be met either with the approach of state ethics, or by recourse to liberal principles – except by allowing that constitutional law can put no limits on technological developments. *Ethicists*, too, have recognized that traditional concepts and approaches are no match for developments in which human beings move towards self-optimization. In particular, key ethical concepts like self-determination and freedom can no longer be used to derive convincing limits to what is possible. Furthermore: today they are used to defend the ethos of a "mass eudaimonism"[114] according to which only the good of the greatest number could be the basis for moral actions. The self-optimization of human beings promised by the biological sciences represents merely the final touch of this ethicization of well-being, after the basic rights and the social state have met the needs of its immaterial and material aspects. There is no place left in this vision for responsibility to one's self, which has recently been rediscovered by constitutional theorists as the necessary complement to freedom.[115]

In this context it must be asked whether it is not time to develop a third additional dimension to Art. 1 par. 1 GG, namely one which would provide limits to human beings' abilities to dispose of themselves. This question is raised above all

because it is high time to comprehend the developments of biological science as a whole from the perspective of constitutional theory and constitutional doctrine – and to react to them from this perspective. Current discussions of whether this or that biotechnological practice is allowable or not under the constitution cannot take us any further. The possibilities which are now arising pose the question of to what degree constitutional law should oppose the development of a social situation in which people no longer regard decisions about their genetic disposition or that of their descendants as things laid down by God, nature, or chance, but see them as opportunities. That would be a situation in which human beings' power to act could be directed against themselves and their own genetic foundations. Humans would define their genetic makeup – and that of their descendants – in terms of their own interests, and in consequence, they would bear responsibility for them in that light. Utilitarian considerations – possibly dominated by the boundless excessiveness with which we are already familiar in today's dealings with nature and the environment – would determine how people dealt with the genetic foundations of humanity. This situation would certainly lead to the reformulation and reconstruction of the concept of the human which underlies the constitution. This problem is no more or less than the question of whether the Basic Law allows us to initiate or accept developments which would inevitably lead to the invention of a new concept of the human species. The provision in § 6 of the German Law on the Protection of Embryos clearly shows that *lawmakers* have already begun the process of making provisions for the legal protection of the species.[116]

In this situation constitutional law can provide protection and guidance only by giving Art. 1 par. 1 GG a further protective dimension. Yet the object of a possible protection of the species according to Art. 1 par. 1 GG cannot depend on some arbitrary notion of humanity based on the subjective ethical or social norms of the observer (or of the members of the Constitutional Court). Subjective convictions forbidding particular sorts of breeding or suppressing certain sorts of research do not justify writing the protection of the human species into Art. 1 par. 1 GG. An arbitrary species ethic cannot just be read into the constitution and made binding on everyone. In today's situation, where the competition between classical, religious concepts of humanity bearing the stamp of metaphysics, and naturalistic ones based on physics, evolutionary biology, or neurology has once again become lively, it is crucial to understand that only those concepts of humanity can be defended using Art. 1 par. 1 GG which correspond on the one hand to the insights held to be true by the natural sciences (Darwin, etc.), but also take up the normative self-conception of human beings as autonomous subjects capable of language and action, subjects with moral responsibility (persons).[117] Any attempt at scientific evasion could thus be rejected along with attempts to get around it via constructivism.[118] This constitutional provision is not a norm which could be used to introduce particular conceptions of the good into the law and make them binding even for lawmakers. This should be emphasized especially because everyone who calls on ethical arguments must recognize that such arguments have been formulated against the backdrop of implied systems of varied ethical thought. But who

would dare to suggest that Art. 1 par. 1 GG establishes a particular ethic as binding for the state for constitutional reasons?

It cannot be stressed enough that "attaching" legal doctrines which protect the species onto Art. 1 par. 1 GG turns it in an anti-individualistic direction. If Art. 1 par. 1 GG is read in the light of Enlightenment tradition there is little call to attribute to this provision content which might limit the autonomy and self-determination of human beings – even with regard to their self-optimization. But if one understands Art. 1 par. 1 GG as a provision which protects the constitution itself from erosion, then meanings which protect the species can be attached to it. Article 1 par. 1 GG allows – or so I am arguing here – for the prevention of technological developments which would affect that normative self-understanding of the nature of human beings which underlies the Basic Law. This is the conception of human beings as autonomous and free, self-determining and responsibly acting persons. This conception is not only written into the constitution, but can also be thematized and protected via Art. 1 par. 1 GG. If it turned out that technological developments called into question the possibility of maintaining the modern constitutional state which places autonomous and free human beings living in a society, then an intervention using Art. 1 par. 1 GG would be in order. Any developments which would endanger the concept of "living beings which are ethically free, morally equal, and oriented to norms and reasons"[119] should not be tolerated by lawmakers in the context of Art. 1 par. 1 GG.

Where these limits lie is difficult to determine in the context of societal views which are in the process of change. Such a point of danger would certainly be arrived at if biotechnological developments led to forms of life which blurred the boundaries between humans and animals. The concept of human beings protected by Art. 1 par. 1 GG is based on the idea that individuals are unique, not "available for the use of others," and of a particular species. The exploitation of humans – for example, permitting research on people who are unable to give their consent and who would not be benefited by the research – certainly raises doubts in this context.[120] In addition, the "breeding" of human beings with the goal of producing life which could be exploited without legal recourse[121] is to be forbidden on constitutional grounds. On the other hand, research which consumes embryos certainly does not constitute an attack on the very concept of humanity. Such research can be considered good or bad; but it certainly does not infringe the concept of living things which are ethically free, morally equal, and oriented to norms and reasons. In the same way, the attempt to fight certain serious diseases using pre-implantation treatments can also not be seen as a constitutional impermissible infringement of the concept of the human species as enshrined in constitutional law; and this is true despite the fact that important limits are violated by such procedures.[122] In the context of Art. 1 par. 1 GG's function as a legal framework, one cannot simply assume that constitutional limits have been overstepped even if such interventions served hedonistic goals of optimization ("perfect people"[123]). In the light of the liberal protected domain of Art. 1 par. 1 GG, to which anyone who wishes to optimize themselves or their descendants can appeal, the over-hasty setting of limits in this domain are not permissible: the human utopia

of self-realization and self-improvement is not unconstitutional as such. One can use Art. 1 par. 1 GG to set legal limits only in cases where the preconditions for the free constitutional state are threatened with destruction because the process of self-optimization is likely to damage its underlying equality. There is much to say for the viewpoint that even cloning for research purposes does not collide with Art. 1 par. 1 GG.[124]

The development of an additional third protective dimension would certainly be admissible from the viewpoint of constitutional theory; the BVerfG would certainly not be exceeding its competency to give the provisions of the constitution concrete form. Even the protective content of Art. 1 par. 1 GG which is recognized today (the principle of state ethics, the protection of human autonomy) is the result of judicial activity in giving concrete expression to a constitutional norm which is semantically open. There is no reason to assert that the BVerfG may not continue this process of interpretation in the context of new social problems. The BVerfG would certainly be called upon to protect the content of Art. 1 par. 1 GG which protects the species as sketched above if it were to be threatened. Of course, in the light of uncertainty about exactly when the point is reached when the "scientific degradation of human beings"[125] must be prevented, and given that the limits discussed here are not only hard to define but likely to be made slippery by developments abroad, lawmakers are called upon for the moment to take up their prerogative to set limits. The objection that in a pluralistic constitutional state, the duty of lawmakers necessarily includes setting limits to what is permissible in the domain of biological science loses its force in cases where it is sufficiently clear that there is a danger to the concept of human beings as autonomous and free, self-determining and responsibly acting persons. According to the conception of the Basic Law, this domain is beyond the freedom of lawmakers; here the BVerfG must take up its role as a guardian. Here – and only here – the BVerfG must oppose even the political realm. But in so doing, the BVerfG must not underestimate the danger that the notion of human beings might be slowly undermined. It is not huge leaps into the unknown, such as occur in science fiction films, which represent the real threat, but the quiet, technological, gradual endangering of the foundations of the constitutional state. The timely imposition of limits capable of halting developments in this direction is urgently needed. The last – and not, as the excited discussion of the last two years might suggest, the first – word belongs to the constitution.[126]

References

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2. Here see: M. Düwell, K. Steigleder (eds.) (2003) *Bioethik. Eine Einführung*; V. Gerhardt (2001) *Der Mensch wird geboren. Kleine Apologie der Humanität*.
3. For the state of the discussion, see for instance, E. Benda, Gefährdungen der Menschenwürde (edn. Rheinisch-Westfälische Akademie der Wissenschaften), Vorträge G 198, p. 7 ff.; Chr.

Starck (1981) Menschenwürde als Verfassungsgarantie im modernen Staat, *JZ* p. 457; W. Graf Vitzthum (1985) Menschenwürde als Verfassungsbegriff, *JZ* p. 201; Chr. Enders (1986) Die Menschenwürde und ihr Schutz vor gentechnologischer Gefährdung, *EuGRZ* p. 241; T. Geddert-Steinacher (1990) *Menschenwürde als Verfassungsbegriff*; H. Hofmann (1993) Die versprochene Menschenwürde, *AöR* 118, p. 353; P. Häberle (1995) Die Menschenwürde als Grundlage der staatlichen Gemeinschaft, in: J. Isensee/P. Kirchhof (eds.), *Handbuch des Staatsrechts*. Bd. I, 2. Aufl. 1995, p. 815; Chr. Enders (1997) Die Menschenwürde in der Verfassungsordnung; E. Picker (1998) Menschenwürde und Menschenleben, in: Festgabe für W. Flume zum 90. Geburtstag, p. 155; W. Höfling (2001) Verfassungsrechtliche Aspekte der Verfügung über menschliche Embryonen und "humanbiologisches Material." Gutachten für die Enquete-Kommission des Deutschen Bundestages "Recht und Ethik der modernen Medizin," Mai 2001; E. Picker (2002) *Menschenwürde und Menschenleben*; O. Höffe (ed.) (2002) *Gentechnik und Menschenwürde*; R. Merkel (2002) *Forschungssubjekt Embryo*; J. Nida-Rümelin (ed.) (2002) *Ethische Essays*; B. Schlink (2002) *Aktuelle Fragen des pränatalen Schutzes*; C. Starck (2002) Verfassungsrechtliche Grenzen der Biowissenschaft und Fortpflanzungsmedizin, *JZ* p. 1065; H.-D. Dederer (2003) Verfassungskonkretisierung im Verfassungsneuland: Das Stammzellgesetz, *JZ* p. 986.

4. The frequent semantic arbitrariness in connection with concepts like "human dignity," "the protection of human dignity," etc., can be seen as the expression of their lack of clarity.
5. In this regard, see also U. Volkmann, Nachricht vom Ende der Gewißheit, *FAZ* vom 24.11.2003, p. 8.
6. Discussion and criticism in H.-G. Dederer (2003) Verfassungskonkretisierung im Verfassungsneuland: Das Stammzellgesetz, *JZ* p. 986; M. Ronellenfisch (2002) Stammzellgesetz. Einleitung, in: W. Eberbach/P. Lange/M. Ronellenfisch (eds.), *Recht der Gentechnik und der Biomedizin*. Bd. 4. Teil II, C. III.
7. M. Herdegen (2003) in: Th. Maunz/G. Dürig, Grundgesetz. Kommentar, Loseblattsammlung, February 2003, art. 1 par. 1 Rdnr. 56 ff. Cf. previously: M. Herdegen (2001) Die Menschenwürde im Fluß des bioethischen Diskurses, *JZ* p. 773 (774 f.): "In certain forms of human life (hard to imagine today), recourse to human dignity would be out of place at least in the earliest stages (for instance, in the case of an egg cell modified according to the 'Dolly' procedure or a stem cell reprogrammed to be totipotent)."
8. M. Herdegen (2001) (see n. 7 above), *JZ* p. 773 (774).
9. E.-W. Böckenförde (2003) Die Würde des Menschen war unantastbar, *FAZ* vom 3. September 2003, Nr. 204, p. 33 (35). For the implications for biological science: E.-W. Böckenförde (2003) Menschenwürde als normatives Prinzip, *JZ* p. 809.
10. H. Dreier (1996) in: Dreier (ed.), *Grundgesetz. Kommentar*. Bd. I, art. 1 Rdnr. 32 ff.; cf. also: H. Dreier (2001) Große Würde, kleine Münze. "Unantastbar": Die zwei widersprüchlichen Interpretationslinien des ersten Grundgesetzartikels, *FAZ* vom 5.7. 2001, p. 8.
13. U. di Fabio (2004) Grundrechte als Werteordnung, *JZ* p. 1 (5), even speaks of human dignity as the "highest principle of world law."
14. BVerfGE 32, 98 (101); 50, 166 (175); 54, 341 (357).
15. BVerfGE 87, 209 (228).
16. BVerfG, NJW 2003, 1303 (1304).
17. J. M Wintrich (1957) *Zur Problematik der Grundrechte*, p. 14.
18. W. Wertenbruch (1958) *Grundgesetz und Menschenwürde*, p. 33.
19. On the criticism, see: H. Goerlich (1973) *Wertordnung und Grundgesetz*; R. Alexy (1985) *Theorie der Grundrechte*, p. 136 ff. More generally: J. Petersen (2001) *Von der Interessenjurisprudenz zur Wertungsjurisprudenz.*
20. It is noticeable that other goods, such as life, have also already been designated as the "highest value": BVerfGE 49, p. 24 (53).
21. Cf. also E. Forsthoff (1969) Der Staat 18, p. 524: Human dignity is a "general empirical" under which "nothing can be subsumed."

22. P. Häberle (see n. 3 above), § 20 Rdnr. 46.
23. H.C. Nipperdey (1954) Die Würde des Menschen, in: Franz L. Neumann/H.C. Nipperdey/Ulrich Scheuner (eds.), *Die Grundrechte*. Bd. II, p. 1 ff.
24. BayVerfGH, BayVBl. 1975, 646.
25. H. Wernecke, in: H. von Mangoldt/F. Klein (eds.), Bonner Kommentar, Erstbearbeitung, art. 1 Anm. II 1a.
26. H. Hofmann (1993) Die versprochene Menschenwürde, *AöR* 118, p. 353 (364).
27. Ph. Kunig (2000) in: I. von Münch/Ph. Kunig, *Grundgesetzkommentar*, 5. Aufl. 2000, art. 1 Rdnr. 22.
28. G. Dürig (2002) in: Th. Maunz/G. Dürig (eds.), Grundgesetz, Loseblatt, Stand 2002, art. 1 par. 1 Rdnr. 28; W. Graf Vitzthum (1985) (n. 3 above), *JZ* p. 201 (202).
29. See the overview by K. Stern, Staatsrecht, Bd. III/1, p. 24 f.
30. BayVerfGH, BayVBl. 1982, 47 (50).
31. Cf. for instance U. di Fabio (2004) (n. 13 above), *JZ* p. 5: "Human dignity is the remembrance of fundamental crimes which humiliate humans and their own worth as individuals, made binding on all."
32. G. Dürig (2002) in: Th. Maunz/G. Dürig (eds.), Grundgesetz, Loseblatt, Stand 2002, art. 1 par. 1 Rdnr. 28; cf. previously G. Dürig (1952) Die Menschenauffassung des Grundgesetzes, *JR* p. 259; G. Dürig (1956) Der Grundrechtssatz von der Menschenwürde. Entwurf eines praktikablen Wertsystems der Grundrechte aus art. 1 par. I in Verbindung mit art. 19 par. II des Grundgesetzes, *AöR* 81, p. 117.
33. BVerfGE 9, 89 (95: "It contradicts human dignity to make human beings into mere objects in the state"; 27, 1 (6); 45, 187 (228); 50, 166 (175); 72, 105 (116).
34. In this context, the formulation in BVerfGE 30, 1 (26) has rightly undergone strong criticism, according to which violations of human dignity must involve "arbitrary ill-treatment" or "contemptuous actions." This is irrelevant to the object formula.
35. The technique of exemplary rules fails in any case because there are no historical experiences which could be used as the basis of societal consent on which particular manipulations are unacceptable and exceed the limitations to legitimate action by the state.
36. Definitions are explicitly renounced, e.g., by Chr. Starck (1999) in: H. von Mangoldt/F. Klein/Chr. Starck (eds.), *Das Bonner Grundgesetz*. Kommentar, 4. Aufl. 1999, art. 1 par. 1 Rdnr. 16: "Es wird hier davon abgesehen, die Menschenwürde in eine Formel zu fassen."
37. BVerfGE 39, 1 (41); building on this BVerfGE 88, 203.
38. Rightly critical, e.g., H. Hofmann (1986) Biotechnik, Gentherapie, Genmanipulation – Wissenschaft im rechtsfreien Raum? *JZ* p. 258.
39. According to § 8 par. 1 2. HS ESchG every "totipotent cell taken from an embryo" counts as an embryo.
40. M. Herdegen (n. 7 above), art. 1 par. 1 Rdnr. 90 (understanding of the concept of intervention is "purely modal").
41. H.-D. Dederer (2003) (n. 3 above), *JZ* p. 988, fn. 20.
42. However doubts are now raised by W. Brugger (1996) Darf der Staat ausnahmsweise foltern? Der Staat 1996, p. 67.
43. Discussion of this protective dimension in H.-D. Dederer (2003) (n. 3 above), *JZ* p. 986 (992 f.).
44. Clearly discussed by Chr. Enders (n. 3 above), p. 101 ff.
45. See, e.g., E. Schockenhoff, Die Würde ist immer die Würde das anderen. Der Schöpfungsglaube hat einen rationalen Gehalt, der in der Debatte um die Biopolitik konsequent entfaltet werden sollte, *FAZ* vom 23.1.2002, p. 44; R. Anselm et al., Pluralismus als Markenzeichen. Eine Stellungnahme evangelischer Ethiker zur Debatte um die Embryonenforschung, *FAZ* vom 23.1.2002, p. 8.
46. The difficulties are shown by the occasional remark that the interpreter has to deal with "two and a half thousand years of the history of philosophy" and the corresponding "burden of theory."

47. Christian Starck (n. 36 above), art. 1 par. 1 Rdnr. 6.
48. Hierzu J. Schwartländer (1968) *Der Mensch ist Person. Kants Lehre vom Menschen.*; H. Wagner (1992) *Die Würde des Menschen.*
49. Ute Sacksowsky (2001) Der verfassungsrechtliche Status des Embryos in vitro. Gutachten für die Enquete-Kommission des Deutschen Bundestages "Recht und Ethik in der modernen Medizin", September 2001, p. 56.
50. A. Gehlen (1969) *Moral und Hypermoral.*
51. R. Wolfrum (2001) Unser Recht auf ein Höchstmaß an Gesundheit. Wenn die Risiken in Grenzen zu halten sind, darf das Streben nach Erkenntniserweiterung nicht behindert werden, *FAZ* vom 29. Mai 2001, p. 53.
52. BGHZ 86, 240 (248); BGHZ 124 (128); approved by BVerfG NJW 1998, 519. See E. Picker (1995) Schadensersatz für das unerwünschte eigene Leben – "Wrongful Life."
53. Clearly formulated, e.g., by: H. Markl, Von Caesar lernen heißt forschen lernen. Die Menschenwürde gebietet, dem Rubikon ständig ein neues Bett zu bahnen. *FAZ* vom 25.6.2001, p. 52. Markl clearly demolishes the moral and scholarly understanding of the last 50 years.
54. It should be remarked in passing that the economization of social relationships is causing developments in which a prima facie argument could be made for biotechnological developments or interventions into human life justified on cost-savings.
55. G. Hermes (1987) Das Grundrecht auf Schutz von Leben und Gesundheit.
56. This would also be an objection to ideas based in natural law which call upon a natural order of the human species which could be "blasphemously" violated.
57. Chr. Starck, Gutachten zum 56. DJT, A 17.
58. Herdegen (2001) (n. 7 above), *JZ* p. 773.
59. Thus, e.g., Hans Carl Nipperdey (n. 4), p. 1 ff.; cf. also Chr. Enders (n. 3 above), p. 170: Human dignity designates "that which constitutes human beings in their essence and thus also that which has found expression in its special relationship to the Divine. This, however, is that which cannot be expressed, the truth itself."
60. Cf., e.g., W. Leisner (1977) Das Ebenbild Gottes im Menschen – Würde und Freiheit, in: Staatsethik (ed.) ibid., p. 81; J. Isensee (1987) Die katholische Kritik an den Menschenrechten. Der liberale Freiheitsentwurf in der Sicht der Päpste des 19. Jahrhunderts, in: E.-W. Böckenförde/R. Spaemann (eds.), *Menschenrechte und Menschenwürde* p. 138.
61. G. Dürig (n. 32 above), *AöR* 81 (1956), p. 117 (125).
62. E. Picker (n. 3 above), FS Flume, p. 191.
63. W. Höfling (2003) in: M. Sachs (ed.), *Grundgesetz*. Kommentar, 3. Aufl. 2003, art. 1 Rdnr. 23.
64. E. Picker (n. 3 above), FS Flume, p. 191.
65. Thus A. Verdross (1977) Die Würde des Menschen als Grundlage der Menschenrechte, *EuGRZ* p. 207.
66. See, e.g., R. Spaemann (2003) Freiheit der Forschung oder Schutz der Embryos? Die Zeit, 20. November 2003, p. 39.
67. T. Geddert-Steinacher (n. 3 above), p. 39.
68. N. Luhmann (1965) *Grundrechte als Institution*, p. 53 ff.
69. H. Hofmann (1993) (n. 3 above), *AöR* 118, p. 364.
70. H. Hofmann (1993) (n. 3 above), *AöR* 118, p. 374.
71. On the close links between Hofmann's viewpoint and the theory of the social contract, see H. Hofmann (1993) (n. 3 above), *AöR* 118, p. 371.
72. H.-G. Dederer (2002) Menschenwürde des Embryo in vitro? *AöR* 127, p. 1 (6 ff.).
73. On the dignity of the embryo, see, e.g., R. Spaemann (2003) Freiheit der Forschung oder Schutz des Embryos? Die Zeit vom 20.11.2003, p. 39.
74. More narrowly, e.g., G. Dürig: "Würde haben heißt Persönlichkeit sein" (n. 32 above), JR 1952, 259 (261)); similarly F. Münch (1951) Die Menschenwürde als Grundforderung unserer Verfassung, p. 8; H. Peters (1953) Die freie Entfaltung der Persönlichkeit als Verfassungsziel, in: Festschrift für Rudolf Laun, p. 669 (674); in diese Richtung auch BVerfGE 5, 84 (204); 45, 187 (228); 79, 256 (268).

75. Th. Maunz (1951) Würde ist, "was den Inhalt der Persönlichkeit ausmacht" (Th. Maunz, Deutsches Staatsrecht, 1. Aufl., 1951, p. 84).
76. It is characteristic that the BVerfG says elsewhere that the "moral, personal and social recognition which a people have achieved by their own efforts" (BVerfG 1. Kammer des Ersten Senats), *NJW* 2001, 2957 (2959) should be protected.
77. H. Markl, Eine Raupe ist noch lange kein Schmetterling, *FAZ* vom 27.11.2001, p. 49.
78. Now also Justice Minister B. Zypries, Rede am 29.10.2003: Since the fertilized egg cell "has only a chance" of developing "the basic attributes of human dignity," there is no call for a "recognition of human dignity."
79. But for another perspective see BVerfGE 30, 173 (194).
80. Similarly R. Zippelius (1995) in: R. Dolzer/K. Vogel (eds.), Bonner Kommentar, art. 1 par. 1 und 2 Rdnr. 51.
81. Similarly also Chr. Starck (n. 43), art. 1 par. 1 Rdnr. 17 f., 86, 89 f.; W. Höfling (n. 63), art. 1 par. 1 Rdnr. 21, 51 f.; M. Herdegen (n. 7), *JZ* 2001, p. 773 (774 ff.); G. Robbers, in: D.C. Umbach/T. Clemens (eds.), Grundgesetz, Bd. I, 2002, art. 1 Rdnr. 21; 70; J. Taupitz (n. 12), p. 3438; ablehnend etwa H. Dreier (n. 10), art. 1 I Rdnr. 51, 59; A. Podlech, in: E. Denninger/W. Hoffmann-Riem/H.-P. Scheider/E. Stein (eds.), AK-GG, 3. Aufl. 2001, art. 1 par. 1 Rdnr. 52b, 57.
82. B. Schlink (2002) *Aktuelle Fragen des pränatalen Lebensschutzes*,p. 10–13.
83. In detail J. Wisser (2001) Einzigartig und komplett, in: Chr. Geyer (ed.), *Biopolitik*, p. 221; Chr. Stark (2002) (n. 3 above), *JZ* p. 1065 (1068 f.); E.-W. Böckenförde (2003) (n. 9), *JZ* p. 812 (Grenzziehungen würden "ein Loch in die Entwicklung des einzelnen individuellen Menschen" reißen).
84. See, e.g., E.-W. Böckenförde (2003) (n. 9), *JZ* p. 812.
85. V. Stollorz (2003) Die Abschaffung der Keimbahn, Frankfurter Allgemeine Sonntagszeitung vom 4.5.2003, p. 55.
86. Cf., e.g., E. Hilgendorf (1999) Die mißbrauchte Menschenwürde. Probleme des Menschenwürdetopos am Beispiel der bioethischen Diskussion, in: Jahrbuch für Recht und Ethik 7 (1999), p. 137; ibid.., Klonverbot und Menschenwürde, in: M.-E. Geis/D. Lorenz (eds.), Festschrift für Hartmut Maurer vom 70. Geburtstag, 2001, p. 1147.
87. Cf., e.g., art. 14 par. 2 der Verfassung des Freistaats Sachsen: "The inviolability of human dignity is the source of all basic rights."
88. In this sense, it is unnecessary to subjectivize the constitutional provisions.
89. In this function art. 1 par. 1 GG must have the subjective quality of a basic right.
90. The appeal by W. Graf Vitzthum (n. 3 above) is similar; MS p. 5: "Here recourse to the guarantee of the inviolability of human dignity must be restricted to cases where the fundamental consensus of the constitution itself is called into question."
91. G. Dürig (n. 32 above), *AöR* 81 (1956), p. 117 (122).
92. On the acceptance of this idea in constitutional law: BVerfGE 7, 198 (205) ("Lüth"); criticism in E. Friesenhahn (1974) Der Wandel des Grundrechtsverständnisses, 50. DJT, G 1; E.-W. Böckenförde (1989) Zur Lage der Grundrechtsdogmatik nach 40 Jahren Grundgesetz, p. 24 ff.
93. W. Graf Vitzthum, Zurück zu Kant. Ein Zwischenruf in der Debatte um Klonen und Menschenwürde, in: R. Wolfrum (ed.), Klonen. Heidelberger Tagungsband, to be published 2004.
94. In this connection see esp. W. Graf Vitzthum (1985) (n. 3 above), *JZ* p. 201.
95. It is certainly odd to see it emphasized over and over that the guarantee of human dignity allows for no exceptions, and simultaneously see the treatment of embryos in existing abortion law justified by the "existential conflict in the situation of the mother-to-be." The position of the BverfG shows inconsistencies insofar as it postulates on the one hand that in applying the guarantee of human dignity any differentiation of its bearers is inadmissible, yet it allows for a situation in abortion which makes much use of differences in the developmental stage of the embryo and the situation of the mother. In this regard see, e.g., R. Merkel (2001) Die Abtreibungsfalle, Die Zeit vom 13.6.2001, p. 42; J. Ipsen (2004) Zur Zukunft der Embryonenforschung, *NJW* p. 268; J. Ipsen (2001) Der "verfassungsrechtliche Status" des Embryos in vitro, *JZ* p. 989 (992); W. Heun (2002) Embryonenforschung und Verfassung – Lebensrecht und Menschenwürde des Embryos, *JZ* p. 517 (518 f.).

96. BVerfGE 30, 1 (25) ("only ever with respect to the concrete case"); OVG Berlin, NJW 1980, 2484 (2485: "change").
97. On the significance of anthropology: J. Wintrich (n. 17), p. 5; ibid..; Fp. Apelt, p. 1; P. Häberle (n. 3 above), § 20 Rdnr. 56; W. Höfling (n. 63), art. 1 Rdnr. 43. cf. also W. Höfling (2001) Zyote – Mensch – Person. Zum Status des frühen Embryo aus verfassungsrechtlicher Sicht, *FAZ* vom 10.7.2001, p. 8.
98. Part of personality is also "human beings' own understanding of themselves in the trio of space, time, and the public (and private) sphere" discussed by P. Häberle (n. 3 above), p. 423).
99. See above under IV 3.
100. G. Dürig (n. 32), art. 1 par. 1 GG, Rdnr. 15, referring to R. Marcic (1957) Vom Gesetzesstaat zum Richterstaat, p. 319.
101. N. 9 above.
102. Art. 1 par. 1 GG thus allows for the possibility of taking reflections on the theory of the state, such as those made by E.-W. Böckenförde over 25 years ago (E.-W. Böckenförde (1978) Der Staat als sittlicher Staat) into the realm of constitutional theory.
103. Dissenting Opinion in BVerfGE 30, 1 (33, 40).
104. Thus G. Dürig (n. 32), art. 1 Rdnr. 28; W. Graf Vitzthum (1985) (n. 3 above), *JZ p*. 202 f.
105. Even the attempts by Christian Starck to allow "orphaned embryos" to be used for research purposes (Chr. Starck (2001) Hört auf, unser Grundgesetz zerreden zu wollen, *FAZ* vom 30. Mai 2001, p. 55) lie within the domains opened up by art. 1 par. 1 GG for the evaluation of norms via lawmaking.
106. On the discussion of this point see: N. Hoerster (2001) Hat der Embryo wirklich ein Interesse am Leben? *FAZ* vom 23. Juli 2001, p. 44.
107. T. Geddert-Steinacher (n. 3 above), p. 36.
108. With regard to constitutional doctrine, the viewpoint adopted here allows for criticism of the fact that the right to personality instantiated by the BVerfG has shifted an important protected domain of art. 1 par. 1 GG into a basic right on its own. In so doing, it has devalued art. 1 par. 1 GG – along with its particular protective strengths. It would be advisable to return this area, with its important meanings for human autonomy, to the jurisdiction of art. 1 par. 1 GG.
109. BVerfGE 38, 1 (21).
110. BVerwGE 31, 236 (237 f.).
111. BVerfGE 12, 45 (53 f.); 28, 243 (264); 48, 127 (163); 69, 1 (22).
112. Overview available in W. Höfling (n. 63), art. 1 Rdnr. 19 ff.
113. Cf. H.-L. Günther (1992) in: R. Keller/H.-L. Günther/P. Kaiser, *Embryonenschutzgesetz* § 6 Rn. 11. Günther justifies this provision by claiming that "the protection of the dignity of the human being (in all of its stages of development)… whose identity is being copied" takes precedence in the conflict over the right to life of the embryo. Cf. also E. Hilgendorf (2001) (n. 86), *FS* für H. Maurer, 1147.
114. A. Gehlen (1969) *Moral und Hypermoral*.
115. U. di Fabio (2004) *JZ* n. 17, p. 1 (7) ("freedom for restraints").
116. There has long been a discussion in constitutional law of whether people can be protected from themselves (e.g., Chr. Hillgruber (1992) *Der Schutz des Menschen vor sich selbst*).
117. Commandment to recognize autonomy, the duty to respect others equally, and the duty to take others into account out of solidarity.
118. J. Habermas (1999), Wahrheit und Rechtfertigung, 1999. Cf. in addition the contributions on the theme of naturalism and natural history in: *Deutsche Zeitschrift für Philosophie* 49 (2001), p. 857–927.
119. J. Habermas (2001) Die Zukunft der menschlichen Natur. Auf dem Weg zu einer liberalen Eugenik? p. 74.
120. E. Picker (2000) Menschenrettung durch Menschennutzung? *JZ*, p. 693.

121. Whether one agrees with it or not: the process of the *exploitation* of our life cannot be held in check anymore (cf. W. Lipp , Das verwertete Leben, FAZ vom 16.7.2001, p. 39).
122. In this regard, see the ethical perspective of R. Schröder, Was dürfen, was sollen wir tun? Fragen eines Philosophen zu den Fortschritten in der Biomedizin, *FAZ* vom 21.7.2001, p. 8.
123. Thus the title of an article by J. Limbach, *FAZ* vom 25.2.2002, p. 51.
124. See for example, G. Roellecke, Es wäre unbedingt ein Leben mit mehr Sinn. … Das Klonen ist nicht unsittlich, *FAZ* vom 1.3.2002, p. 46. Going too far and extending art. 1 par. 1 too far in a liberal direction: E. Hilgendorf, Therapie muß erlaubt sein. Ein vollständiges Klonverbot verstößt gegen die Menschenwürde, *FAZ* vom 13.2.2003, p. 42.
125. E.-W. Böckenförde/R. Spaemann (1987) *Menschenrechte und Menschenwürde*, p. 295 (312).
126. P. Glotz (2001) Die neue Scholastik, Der Spiegel 24/2001, p. 42, is properly critical.