Martin O'Malley, Antje Klemm (Eds.)
Cancer Research is a Social Endeavor

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An Interdisciplinary Introduction to Ethics in Cancer Research

Martin O'Malley,
Antje Klemm (Eds.)

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ta ethika

herausgegeben durch

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und
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Kleihues studied medicine in Munster, Hamburg, Munich and Pavia, and has held various academic positions in Cologne, Freiburg

and Zurich, researching in neuropathology and oncology. He has been a Professor for Neuropathology for the past eighteen years with a research focus on nervous system pathologies, the genesis of tumors in the nervous system, as well as cancer epidemiology. He was the director of the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) in Lyon (1994-2003) and the Founding Director of the Ludwig Heilmeyer Tumor Center of the Comprehensive Cancer Center (CCCF) of the University of Freiburg (2004). He held a fellowship at the Wissenschaftskolleg in Berlin (2005), was a visiting scholar of the Center for Cancer Research (CCR) of the National Cancer Institute (NIH/NCI) in the USA (2006-2007). He was the Founding Editor of the journal, *Brain Pathology,* and is presently a lead editor for *Clinical Cancer Research.*

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Knoepffler studied philosophy and theology in Würzburg and Rome (1981-1990) where the Gregorian University awarded him a Licentiate in Theology (1989), in Philosophy (1990), and a Doctorate in Philosophy (1992). He received his habilitation in 1998 and a further Doctorate in Political Science in 2004. He was a Fellow at the Institute for Technology, Theology and Natural Sciences (TTN) from 1996 to 2000 and was appointed Lecturer in Philosophy at the University of Munich in 1998. He then became Deputy Manager at TTN (2000-02) and received an appointment with the Commission for Bioethics with the Bavarian Government in 2001. In 2002, he was a Visiting Professor at Georgetown University, Washington DC. He was then appointed Professor of Applied Ethics at the Friedrich Schiller University of Jena (FSU), where he also leads the center of applied ethics, the EthikZentrum. He is the Vice President of the German Academy for Transplantation Medicine and since 2005 has served as Chair of the Ethic Commission of FSU's Department of Social and Humanistic Studies.

O'Malley, Martin J., PhD., Editor and Research Fellow at the EthikZentrum at the Friedrich Schiller University of Jena.

A graduate of Hamilton College, (BA 1988), he received an MA in Philosophy at St. Louis University (1993), after which he taught for two years in the history and philosophy departments at LeMoyne College, New York. Studying at the Weston Jesuit School of Theology in Cambridge, MA, he received a Masters of Divinity (1998) and a Licentiate in Moral Theology (2008). He received a Doctorate in Theological Ethics from Boston College (2007). Teaching positions include fellowships at Harvard University (1996, 1998) and Boston College (2004, 2005), and Instructor in Theology at Loyola College, Maryland (2004-2006). Research positions include visiting fellowships at The Woodstock Theological Center, Washington DC (1995, 1998), and at the Institut für Gesellschaftspolitik an der Hochschule für Philosophie, Munich (2003, 2005).

Schipanski, Prof. Dr-Ing. habil. Dagmar, President of German Cancer Aid *(Deutsche Krebshilfe e.V.).*

Studied applied physics in Magdeburg from 1962 to 1967 and earned her Engineering Diploma in 1967. She continued studies at the Institute for Semi-Conductors in 1972 at the Academy of Sciences in the Soviet Union in Novosibirsk, graduating in 1976. She received a professorial appointment in 1985, and in 1990 was appointed Professor for Solid State Devices. She was Dean of the TU in Ilmenau between 1990 and 1993, Rector of the TU Ilmenau from 1995 to 1996, and was Thuringian Minister for Science, Research and Art from 1999 to 2004. Since 2004, she has been the President of the Thuringian State Parliament. She was a member of the Science Council of the Federal Republic of Germany from 1992 to 1998 (Chair, 1996-1998), the Berlin-Brandenburg Academy of Science, as well as the UNESCO World Commission for Ethics in Science and Technology. Since 1998, she has been a member of COMEST, the German Academy of Natural Science Researchers, Leopoldina, in Halle, and has served on the International Advisory Board of the University of

the United Nations in Tokyo since 2001. She has been President of the German Cancer Aid since 1999.

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Studied medicine at the University of Freiburg where he received his doctorate in 1984, after which he spent three years of research at the University of San Diego and three years at the Institute of Pathology at the University of Zurich where he received his habilitation in 1990. He was appointed Director of the Institute for Neuropathology at the University of Bonn (1992-2003) and Director of the German Brain Tumor Reference Center as well as the Medical Business Manager of the LIFE & BRAIN GmbH (1992-2003). Since 2004 he has been Chair and Scientific Fellow of the Foundation Board of the German Cancer Research Center.

Winnacker, Prof. Dr. Ernst-Ludwig, General Secretary of the European Research Council

Studied chemistry in Zurich and received his doctorate from the University of California, Berkeley in 1968. From 1968 to 1970, he did a post-doctorate in Berkeley. He was then at the Medical Nobel Institute at the Karolinska Institute in Stockholm from 1970 to 1972. In 1974, he was an assistant at the Institute for Genetics at the University of Cologne, and during that same year he received his credentials to be a university professor. He has been Professor for Biochemistry at the University of Munich since 1980 and Director of the Laboratory for Molecular Biology – Gene Center at the University of Munich since 1984. He has also been a visiting professor at Harvard Medical School since 1990. He took over as President of the German Research Foundation (DFG) in 1998 and is also Vice President of the Alexander von Humboldt Foundation. He serves on many commissions and is a member of many foundations.

Preface

Martin J. O'Malley

The first Wartburg conference, dealing with human biotechnology, referred to the "social challenge" it posed. In translating the German subtitle *gesellschaftliche Herausforderung* for these papers from the second Wartburg conference, I prefer the phrase "social endeavor". Endeavor avoids the unintended notions of confrontation contained in the English word "challenge" as well as the notion that the work lies in the future. Endeavor conveys a sense of hope-filled, ongoing collective work, and determined striving for righteous goals. Those are the connotations that are most consistent with the works in this collection of papers on cancer research.

The papers reveal the excitement of potential discovery that presently exists among scientists who study cancer, and they reveal the many obstacles and struggles that stall progress in the prevention and treatment of the many manifestations of this terrible disease. What especially unites the collection is the point that a social commitment is required – that cancer is a risk not only for individuals, but also for communities. For communities to commit themselves to support and direct the research that is necessary to protect themselves, a number of things are necessary. Information about cancer must be available that is comprehensible to non-specialists. This information must present a realistic vision of what is possible and what is most effective for improving the actual lives of citizens. Cancer research requires more than great sums of public and private resources; it needs a structure that benefits from efficient and productive networks of scientists. There is also a requirement that is not so obvious, however. The community must trust that cancer research is guided by ethical ideals that are consistent with their own.

The doctor-patient relationship serves as an important analogy here. Patients, like most members of society, cannot be expected to completely understand their illnesses. Therefore, they must make

decisions based upon a trust that their doctor has their best interests in mind. Because the medical community has earned this trust over decades of faithful service, patients can make prudent decisions about their care based upon the expert advice of doctors. Similarly, society can make prudent decisions in the form of public policies regarding cancer research and treatment, despite the fact that few of us are experts. This is possible, however, only when we share a basic assurance that the research will benefit society and remain within generally accepted moral boundaries. Thus, the papers included in this collection benefit from the expertise of scientists from many different fields of study, but they all essentially function to inform a wide public about the nature of the problem that cancer poses for society, the guidelines that govern research, and the way that research can benefit society.

Just as patients need to engage their doctors regarding medical care, we too need to engage in a rational public discourse regarding cancer research. While we do not need to attain professional levels of expertise, there are several areas where we need to be well informed: We need to understand the basic biological, structural and ethical facets of the problem. We need to know what has been done in the past and what is being done presently. We need to know the questions of justice that are engaged in cancer research and treatment. We need to know the dangers that are posed by research – and also the dangers posed by forestalling research. We need to know how institutions are responding to the demands for research and treatment coordination. And, we need to know about the concrete steps that can be made by individuals, communities, institutions, universities and governments.

Dagmar Schipanski's opening paper builds upon the axiom that research is itself a social process. She played a central role in planning the series of conferences and here she conveys the original conceptions and goals. Having experience in both research and the political process, she sheds light upon the complex matrix of social cooperation necessary for success in dealing with a disease such as cancer. Within scientific research communities, the various disciplines depend upon one another to benefit from the great breath of research tak-

ing place in both the technical and humanistic fields. Structural networks aid this cooperation and foster young scientists as they earn their qualifications and, as peers, enrich the capacity for new insights. She emphasizes the responsibilities that scientists bear to society as a whole, and the communication that is an integral aspect of this responsibility. Cancer treatment benefits from individuals' insights, and leads to the treatment of individuals, but we cannot lose sight of the reality that it is an essentially social endeavor.

Otmar D. Wiestler provides us with a basic sense of the biological processes involved in cancer illness and the great potential benefit of genetic developments. Though we are still at an early state of understanding and thus utilizing genetic understanding for medical treatment, we have some examples that indicate the direction cancer research may take. It is an exciting time, Wiestler assures us, because scientists are beginning to unravel the mysteries of cancer developments in human cells. He sounds a common note by impressing upon us the need to build networks among scientists, but also between scientists and industry because industry is playing an ever more important role in developing medicines.

Paul Kleinhues' paper gathers the data to describe cancer's causes and prevention. Though his paper deals with the science involved, he uses the data from across the world to highlight successes and failures not of science in an isolated sense, but of the role of public policy and its relationship to science. Certainly, there are successes, but the glaring example of the delayed response to asbestos exposure serves as a warning. Kleinhues' outline of national responses to the now well-established dangers of tobacco smoking shows that we are still susceptible to ignoring such warnings. Not only tobacco use, but also lifestyle choices in general can be associated with cancer prevalence. This reinforces the sense that social actions are critically important to consider in reflections upon cancer illness.

Reiner Anselm's paper focuses much more closely upon the ethical issues involved in cancer research. He advocates a more transparent and less restricted use of medical information for the purposes of individual treatment and scientific research, yet he argues that this is

possible only when patients' privacy and wishes are totally protected. Research proceeds on the basis of often unintended consequences, and the availability of medical data is essential to this process, especially as genetic techniques become more refined and commonplace. Once patients can trust that their personal data and therefore privacy are protected and used only according to clear consent agreements, systems can be put into place to provide both better treatment options for particular cases, and better data for further science. This raises the interesting corollary that when people perceive that scientific research is acting independently of social norms, then opposition would likely be raised to the collection and use of personal information. Thus, distinct and understandable limits and boundaries for the use of data are actually more beneficial for scientific progress. With considerations that include personal privacy and the principle of solidarity, Anselm provides a useful set of ethical criteria to guide the way that data can be used for science.

Nikolaus Knoepffler's systematic approach to the ethics of cancer research takes a hard look at the profound inequalities that exist in the world for people in need of cancer treatment. Beginning with a commitment to principles of justice, human dignity, solidarity and universal equality, he sets forth a series of principles to guide cancer research. These principles essentially respect the freedom of particular nations to provide advanced care for their people, but those advances come with responsibilities. Utilizing the basically Kantian insights of John Rawls, Knoepffler insists that health systems must permit individuals' and communities' freedom to secure advanced health care unavailable to the poor, but that inequalities are only tolerated if they produce potential gains for the less fortunate. He pursues this line of argumentation in terms of the principles of subsidiarity and solidarity, and applies his models to the concrete situation in Germany.

Karl G. Blume outlines the structure of comprehensive cancer centers in the United States. The basic idea is to gather the most advanced experts of all aspects of cancer research and treatment together in one center as a way of accelerating progress. The centers are provided with the resources necessary for advanced research and

yet they are focused specifically upon the treatment of patients in associated clinical settings. These centers are enormously expensive, but they have proven to be effective and the model is being replicated in Germany.

Ernst-Ludwig Winnacker's paper fittingly concludes the selection of papers because it offers a view of the future of cancer research and therapy. He offers a sweeping history of cancer research in the 20th century, beginning with the insights of the biologist Boveri, as a way to provide some perspective regarding the potential for future progress. Leading us through basic principles of biology and gene science, Winnacker then tackles the processes by which protein molecules function as important conveyers of information in the cell. He does all this while adhering to the instructions set forth by Schipanski in the introduction that the papers must be understandable to lay people. In the case of cancer, he teaches, because these protein molecules play an essential role in the growth of tumors and other manifestations of illness, the ability to control these molecules gives scientists the key to developing cancer medicines. Research centers, building upon advances in genetic science, have opportunities for great progress. Cancer specialists know all of this, of course, but the rest of us require such basic understanding in order to be able to engage in discussions of ethics and public policy.

Introduction to the Wartburg Conference: Cancer Research Is a Social Endeavor

Dagmar Schipanski

Dear Ladies and Gentlemen, Professors, and dear Students,

I would like to cordially welcome you all to this conference on behalf of German Cancer Aid *(Deutsche Krebshilfe)*, the German Research Foundation *(Deutsche Forschungsgemeinschaft),* the German Center for Cancer Research *(Deutschen Krebsforschungszentrums)*, and the Center for Applied Ethics (EthikZentrum) of Jena's Friedrich Schiller University.

I am pleased to see that so many have responded to our invitation to Eisenach. And my hope is that our remarkably beautiful weather today is a good omen for an important and memorable conference. I also hope that the Wartburg Castle's charm and beauty are adequate compensation for your long journeys here. This is a place of ancient tradition – over one thousand years. Legend has it that the castle was established by Count Ludwig the 'Springer', a Thuringian landgrave and a member of one of the most influential noble families of the Holy Roman Empire. Speaking about the Wartburg's historical "highlights", the famous minstrels' contest *(Sängerkrieg)* in 1206 that inspired one of Wagner's operas is probably only legendary. However, we have good evidence from the papal archives that St. Elisabeth spent much of her exemplary life here in the early 13th century. The most important chapter of the Wartburg's long history is indisputably when Martin Luther resided here in 1521 and translated the New Testament from Greek into German. Luther's Room, here above in the Vogtei tower, is a continuing reminder of this achievement. Finally, the 1817 gathering of the early student fraternities had a decisive impact upon the 19th century movement for German liberty. For all these reasons and more, I can truly assure you that we, the people of Thuringia, love this castle. We cherish the buildings and the beautiful views that they provide of Thuringia's valleys and

From the Laboratory to the Clinic – The Present Status of Cancer Research

Otmar D. Wiestler

Cancer represents a great challenge for research, medicine, ethics, politics … and it goes without saying that those afflicted by cancer disease feel this most poignantly. This conference, which endeavors to bring together specialists from many different areas, is an ideal forum to bring to light the problems we face in fighting cancer in all its many facets.

The timing for this conference is especially favorable, because cancer research and cancer medicine are presently in an important and exciting phase. Cancer research has the duty to investigate the causes for the emergence of this illness, and we use this basic understanding to develop new methods for diagnosis and treatment. Over time, this has proven to be extraordinarily difficult. And yet the research has made amazing progress across many fields. The progress that has been achieved is due to many different branches of biomedical researchers working on varied aspects of the disease. Here we must emphasize, however, the cell and tumor biology and in particular the decoding of the human genome – it is the most valuable common inheritance that we humans all share. This success is also in great measure due to a change in cancer research's basic approach. For a long time, previously, we focused upon models of animal experimentation and individual cell research. But that focus has shifted more and more to actual cancer patients – and these patients are now the central focus of our research. The great task before us is the transfer of the important success we have achieved in the laboratory to treatments in the clinic.

How does the situation look for cancer medicine in the clinic? Today about one half of all patients with cancer can be successfully treated. The progress with individual forms of cancer is especially distinguished. Here, as examples, one can point to Hodgkin's disease

Cancer Causes and Cancer Prevention

Paul Kleinhues

The newest data regarding the global scope and the extent of cancer illness originates from the year 2002. Taken together in the year 2002, worldwide, eleven million people fell ill with malignant tumors and almost seven million of these patients died from those tumors. The present prevalence of people with tumors is estimated to be 25 million (Parkin/Bray/Ferlay/Pisani 2005). And this number will only rise. In the *World Cancer Report* that we published in 2003, we estimated that from this year until 2025, 15 million more people would be diagnosed per year (Kleihues/Stewart 2003). This is due, on the one hand, to the rising life expectancy and the fact that cancer is predominantly an illness of later years. On the other hand, it is due to increasingly unhealthy behaviors that are associated with higher cancer risk. Both of these trends are characteristic of developed nations. World wide, male patients tend to suffer predominantly from tumors of the lungs, the intestines (colorectal) as well as the prostate and liver. For women, likewise, colorectal tumors predominate, and to a lesser extent they suffer from tumors of the breast, the cervix (ovaries), the stomach, and the lungs. A closer view of the total number of the new illnesses, both in developed and developing nations, shows that some tumors exhibit very distinct regional differences (Parkin/Bray/Ferlay/Pisani 2005). On the pinnacle are lung tumors caused by smoking tobacco. This is a worldwide phenomenon. However, there are also tumor diseases that are more prevalent in developing nations, such as those that affect the stomach, the liver and the esophagus. In western industrial nations, the diseases that predominate affect the intestines, the prostate and breasts. In the following discussion, I would like to deal with the possible causes of these differences.

Is It Legitimate To Prefer Ignorance? Theological and Ethical Considerations Regarding The Responsible Use of Information in Predictive Medicine

Reiner Anselm

1. Introduction

How Much Knowledge Is Good for Us? Chances and Risks of Predictive Medicine. This is the title of a joint statement for the 1997 "Week for Life" by the committees of two major German churches, the Evangelical Church's Council (EKD) and the Roman Catholic Bishops' Conference. The document urged against the possible routine use of genetic testing procedures on the fetus during pregnancy, and advised only restrained use of such procedures. Otherwise, as the document warned, the possibility exists „that [such routine testing] would change the assessment of disease and disability, as well as the understanding of what constitutes 'normal'. And it could generate a creeping discrimination against persons with specific genetic characteristics" (Evangelische Kirche in Deutschland/Deutsche Bischofskonferenz).

Some argue that prenatal genetic diagnostics and the associated possibility for abortion pose a risk for discrimination of disabled people. This pressing question remains despite the fact that this argument regarding the level of care for the disabled has been rejected convincingly and objectively by Weyma/Lübbe. They argue instead that no rise of discrimination against disabled people has been determined despite the expansion of prenatal genetic tests (see Lübbe, W. 2006, 265-276). In the face of increasingly refined techniques of genetic diagnostics and more precise understanding of the correspondence between genes and the onset of diseases, there is a significant need to

Justice for Cancer Therapy

Nikolaus Knoepffler

1. Introduction

A four-year-old boy named John has acute lymphatic leukemia and he is doing well with a regimen of chemotherapy. He was affected by minimal side effects and after achieving an early stage of remission, he began a maintenance therapy of mercaptopurine, which he took orally. Because a genetic test showed that John has a gene mutation that limits his body's production of thiopurine S-methyltransferase, an enzyme that metabolizes mercaptopurine, his doctors prescribed a reduced dose of the drug. Without the possibility of this newly developed genetic test, patients with this gene mutation would not be able to survive a treatment of mercaptopurine. Because of this precautionary measure, John tolerated the maintenance therapy without setbacks and after several years achieved a complete remission.

This single case study shows just how much cancer therapy has benefitted from the achievements of research from many different fields of research, and it demonstrates the rich potential for further inter-disciplinary progress in treating medical disease. The following essay builds upon the presupposition that it is a moral imperative that medical research continues to develop more and better treatments for the treatment of cancer.

A critical challenge for ethical consideration is posed by the question of distributive justice regarding cancer therapy. From a global perspective, we can see the great disparity that exists between the availability of treatments for cancer patients in the west and for the much poorer cancer patients in developing countries. This reality poses the fundamental global and national challenge: How can we conceive of a just system of cancer therapy that can be concretely

Comprehensive Cancer Centers in the USA

Karl G. Blume

1. Introduction

In 1937, the National Cancer Institute (NCI) was established by the United States Government. The first Cancer Center, the Memorial Sloan-Kettering Cancer Research Center New York, was supported by funds form the NCI in 1966. In 1971, President Nixon signed the National Cancer Act and in 1975, the US Senate endorsed the establishment up to 35 Comprehensive Cancer Centers in USA. In 2006, the NCI is funding 61 Cancer Centers with a budget of $260 million, which is ~5% of the total NCI budget.

The NCI designation as a Cancer Center is a highly prestigious distinction for any center in the USA. There are three types of Cancer Centers, one which carries out exclusively *Basic* cancer research while at others the emphasis is mostly on *Clinical* cancer research; 22 such *Basic* or *Clinical* Cancer Centers are in existence. In addition, there are 39 *Comprehensive* Cancer Centers in the USA (current size of the total US population is 300 million). For comparison, the state of California with 36 million inhabitants has one Clinical Cancer Center, two Basic Cancer Centers and six Comprehensive Cancer Centers.

2. Definition:

To qualify for NCI designation as a *Comprehensive Cancer Center*, the institution must demonstrate reasonable depth and breadth of research activities in each of three major areas: basic, clinical, and prevention, control, behavioral and population-based research, and exhibit a strong body of interactive research that bridges these scientific areas. In order to receive recognition as an NCI designated

Cancer Biology and Therapy: Looking to the Future

Ernst-Ludwig Winnacker

As a way of contributing to the discussion, I would like to present some thoughts on the future of the cancer research and cancer therapies. To that end, I present the new systematic approaches, with special attention given to the amazing developments and progress in recent years in the area of pharmaceutical chemistry. For this effort, I own much thanks to Robert A. Weinberg's recently published book *The Biology of Cancer* (2006).

During the period 1960 to 1997, the mortality rate from heart attacks has been reduced by half from a rate of 300 per 100,000, whereas the average rate of cancer mortality remained effectively constant. This raises the important question, whether the successes that have been achieved for heart, circulatory and stroke diseases can also be achieved by cancer research and cancer therapies. To date, there has not been much to report on this point. Even the positive example of the significant reduction of stomach cancer in the last 75 years – by a factor of six – can be attributed not to better cancer therapies, but to improvements in food storage and advances in the treatment of helicobacter pylori bacteria infections. The number fatalities attributed to cervix cancer is likewise attributed to the so-called "pap smear" tests which offers the possibility for early diagnosis and treatment. Lung cancer, which had been increasingly prevalent in men, has been gradually stemmed by the prohibitions of smoking, and breast cancer mortality has been reduced by 15 percent by early recognition and the use of secondary (adjuvant) treatments such as chemotherapy. Altogether, it is possible to say that almost all the medical advances achieved in reducing and treating malignant cancers can be attributed to the prevention and early recognition of the diseases, and not to the discovery of genuine therapies.

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