



Consumer Medicine

Edited by Aaro Tupasela

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Foreword

The Nordic Committee on Bioethics (NCBio) was founded in 1989 with the aim to promote Nordic cooperation and exchange of information between scientists, parliamentarians, opinion leaders and public officials in the area of bioethics. NCBio works by organizing workshops, conferences and by publishing reports or other publications to promote Nordic and international debate on bioethics. NCBio has two members from each of the five Nordic countries. Members are appointed by the Nordic Council of Ministers from the nominations of the Nordic countries. The committee is funded by the Nordic Council of Ministers.

In this edited volume we present some of the viewpoints from the invited speakers at two of our conferences in 2009. The first was held in January in Århus, Denmark, on Genetic self-testing, and examined the development of genetic tests that are sold over the internet to consumers. The second conference was held in May in Sigtuna, Sweden, on medical tourism. Both of these subjects touch upon a broader theme that we have called *consumer medicine*. The topics map and explore recent changes that have been taking place in relation to the production and sale of medical goods and services to patients transnationally. These patients, however, are increasingly being seen as consumers of these goods and services. The traditional view of the patient as being a passive receiver of health services has, during the last decade, gradually changed towards that of the active consumer taking a stronger responsibility in the management of his/her medical treatment. This paradigmatic change brings with it, however, a number of challenges and issues which need to be critically explored.

With a growing number of new goods and services on the open market, the need to investigate their consequences on individuals, selected groups and the entire society increase. The two conferences on genetic

self-testing and medical tourism identified several, important challenges. This demonstrates that it is important to investigate the consequences of consumer medicine further.

The Nordic Committee on Bioethics hopes that this volume will serve as an important resource to people who are interested in the development and consequences of consumer medicine, in particular by identifying some of the key issues involved and the challenges that lay ahead in its governance.

January 2010

Ole Johan Borge

Chair

Nordic Committee on Bioethics

Forord

Nordisk ministerråds komité for bioetikk (NCBio) ble etablert i 1989 for å fremme nordisk samarbeid og utveksling av informasjon om bioetikk mellom forskere, politikere, opinionsledere og myndighetene. NCBio arrangerer arbeidsmøter, konferanser og gir ut rapporter eller andre publikasjoner for å stimulere nordisk og internasjonal debatt om bioetikk. NCBio har to medlemmer fra hvert av de fem nordiske landene. Medlemmene blir oppnevnt av Nordisk Ministerråd etter å ha blitt nominert av de nordiske landene. Komitéen finansieres av Nordisk Ministerråd.

I denne redigerte boken presenterer vi synspunkter fra flere av de inviterede foredragsholderne på to av konferansene våre i 2009. Den første konferansen ble avholdt i januar i Århus, Danmark. Den omhandlet genetisk selvtesting og fokuserte på utviklingen av genetiske tester som selges på internett og sendes direkte til forbrukerne. Den andre konferansen ble avholdt i mai i Sigtuna, Sverige, og den omhandlet medisinsk turisme. Begge konferansene har til felles at de fokuserer på det vi har kalt "consumer medicine" eller på norsk "forbrukermedisin". På hvert sitt område utforsket konferansene produksjon og salg av medisinske varer og tjenester som tilbys pasienter over hele verden. Disse pasientene blir imidlertid i stadig større grad sett på som forbrukere av disse varene og tjenestene. Det tradisjonelle synet på pasienter som passive mottakere av helsetjenester har i løpet av det siste tiåret gradvis blitt endret mot at pasienter er aktive forbrukere som tar et sterkere ansvar for behandling og oppfølging av egen sykdom. Dette drastiske skiftet bringer imidlertid med seg en rekke utfordringer som det er behov for å utforske nærmere.

Med stadig flere nye produkter og tjenester på det åpne markedet, øker behovet for å se nøye på hvilke konsekvenser dette får for enkeltindivider, bestemte grupper og samfunnet som helhet. De to konferansene om genetisk selvtesting og helseturisme identifiserte flere viktige utfordring-

er. Dette viser at det er behov for å se nærmere på konsekvensene av denne utviklingen.

NCBio håper at denne boken blir en viktig ressurs for dere som er interessert i utviklingen og konsekvensene av forbrukermedisin. Spesielt håper vi at boken kan bidra til å synliggjøre noen av de mest sentrale temaene og utfordringene knyttet til styringen av denne utviklingen.

Januar 2010

Ole Johan Borge

Leder

Nordisk ministerråds komité for bioetikk

Introduction: Consumer Medicine – From Passive Patients to Active Consumers

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The chapters in this book all address an important area relating to the delivery of medical services, namely the development of consumer medicine. The chapters have come about from presentations that have taken place in two separate meetings; one on genetic self-testing, and the other on “medical tourism” or cross-border medical treatment. These topics, although somewhat different, can be grouped under the rubric of consumer medicine in that increasingly the relationship between the patient and various products and services is mediated through market mechanisms relating to consumption and advertisement, as opposed to the physician alone. This shift in power relations and roles between actors has brought about not only new opportunities for companies seeking to market and sell their new products, but also ethical challenges in the way these activities and some of their consequences can, and should, be governed and regulated. This is not an easy task since the markets for many medical products and services have become transnational, challenging the traditional notion that governments operate in relation to geographical boundaries and have increasingly become preoccupied with “zones formed through the circulation of technical practices and devices” (Barry 2001, 3). This is by no means a new trend, but a number of new features can be identified which have increased the effectiveness of marketing products to consumers, as well as made their consumption easier and more attractive. In this introductory chapter, I would like to highlight

some of the important strands and themes which have emerged out of our meetings, discussions and the subsequent texts in relation to genetic self-testing and cross-border medical treatment.

Consumers and the market for health

The notion of consumer medicine may appear as a recent phenomenon, but from an historical perspective the roots of advertising to consumers goes back at least three-hundred years. In many ways the notion of consumer medicine is related to the acceleration of the movements of goods, services and patients across various borders and territories, which have been traditionally understood in political terms. Increasingly, however, new technologies, such as the internet, help to transcend such boundaries creating new areas of operation that are more challenging to govern and regulate. This movement of materiality requires, however, various systems through which information is disseminated about products and services and thus makes them visible to the consumer. At the same time, increased interest has focussed on the “creation” of the “expert” or “informed” patient whose autonomy and independence has been seen as an important development in the transition from what some have called paternalistic progressivism towards medical modernization (Brown and Zavestoski 2004; Fox et al. 2006).

Although the internet has accelerated and provided new opportunities for advertising products and services, this phenomenon is by no means new. For example, in 1708 the first advertisement for a medication appeared in an American newspaper (Young 1967), starting a trend that has refused to abate, but rather has increased in its scope and volume. This advertisement can be seen to mark the beginning of what Wilkes et al. (2000, 112) have described as the development of a “symbiotic relationship” between the drug industry and the press; starting in the 1800s the drug industry began to spend larger and larger sums of money for advertising, and newspapers received an increasing amount of their income from these ads. Young notes, however, that it was not until 1908 that the US Pure Food and Drug Act was put to use in prosecuting the producer of “Cuforhedake Brane-Fude” remedy for making false claims in their advertisement (Young 1967, 3). A century later, the relationship between

consumers and the producers of medical services and products remains mediated to a large extent through different forms of media, such as the internet, and the claims that companies and researchers make concerning their products and innovations also remain the focus of contention, as well as trouble for consumers and regulators alike.

Advertising has, however, focused for a long time on health care professionals, in that it was through physicians, for example, that pharmaceutical companies were able to sell their drugs. It was not until the 1980s that drug companies also began to target the public through advertising in an attempt to better “educate” the lay consumer (Wilkes et al. 2000, 113). Some commentators have also noted that many governments, such as India and Cuba, have made concerted efforts to bolster their foreign tourism by supporting medical tourism within their national borders. In Malaysia, for example, the government has even gone as far as making medical tourism an official government policy (García-Altés 2004, 264). These activities can be seen within a broader political framework where the provision of national health care services to foreign nationals is developed within national economic policy frameworks. Many countries, especially in Asia, have worked to develop local or regional medical hubs that cater specifically to patients travelling from abroad to receive various forms of medical treatment (Choo 2002, 1004). This reflects a movement which is not just industry driven, but supported by national economic policies as well.

Despite the introduction of restrictive legislation both in the US and the EU, the use of advertising, educational material and different forms of media, such as the internet, continue to play an increasingly important role in the development of consumer medicine. In the US, the pharmaceutical industry is seen to wield a great deal of influence over policy making and some have argued that the increasingly high costs associated with the pharmaceutical industry are more related to lobbying than investments into research and development of new drugs (Angell 2005). At the same time, the interest to attract patients to different parts of the world to receive medical treatments and procedures has helped create a market for human tissue in various forms. Nelkin and Andrews (1998) note that cord blood can be used in shampoos, cosmetics and skin care products, which make it of great value commercially. Long hair can also be collected during haircuts for use in wigs for cancer patients who have lost their hair during treatment. The

market for human body parts used in medical treatments goes, unfortunately, much further, creating space and opportunity for illegal and ethically questionable activities, such as a global traffic in human organs (Scheper-Hughes 2000), which is directly linked to the demand for such products by wealthy patients. As Andrews and Nelkin (2001, 27) have noted “[t]he market mania encourages actions that violate body integrity, exploit powerless people, intrude on community values, distort research agendas, and weaken public trust in scientists and clinicians.”

Whether or not “the market” is to blame for questionable activities related to commercial healthcare services or the lack of regulation is difficult to gauge. Some commentators have argued that when the possibility of *selling* blood, for example, is added to the voluntary systems of blood donation, one is merely expanding the range of choices made available to the individual (Arrow 1972, 350). It is clear, however, that the role that choice has come to play in these developments serves as an important undercurrent fuelling the challenges faced by patients and regulators alike.

If advertising new products and services can be seen as one important driver of this industry then the increasingly important role that patients and patient organizations are taking in the provisions of services, care, as well as research can be seen to form another important component as well. Recent trends within healthcare to strengthen the role and autonomy of patients can be seen as an important change within the patient-physician relationship, in that increasingly the patient is expected and encouraged to be active in assuming responsibility over ones health and care. Some commentators have argued, for example, that biomedical discoveries related to the genetic causes of disease gives rise to new forms of sociality, where ones genetic conditions help to define ones associations with certain groups (Novas and Rose 2000). At the same time patient organizations are playing an increasingly important role in mobilizing resources for research, as well as the formulation of national and supranational policies (Novas 2007). The information and support provided by patient organizations can be seen as an increasingly important avenue through which patients and their family members receive information and support for their conditions. At the same time numerous companies are offering services to people through which they can receive information on their genetic make-up and possible risk factors.

These changes direct our attention also to the information that is made available to patients and who can be seen as the legitimate producer and disseminator of such information. Various information sources – besides patient organizations – which provide information over the internet, for example, are an important avenue through which various companies are providing “educational” information to potential customers. It remains difficult, however, for many patients of serious illnesses and diseases to be able to evaluate the “neutrality” of this information and to what extent it is based on existing evidence. This places patients and their family members at a disadvantage when searching for information on their condition.

Biotechnology policy and healthcare

Supranational and national policies can also be seen as another important element in the development of consumer medicine in that increasingly the products and services related to biotechnology are expected to form the basis for future economic development. As the European Commission has noted in a recent document:

“Life sciences and biotechnology are widely recognized to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies.” (European Commission 2002, 7)

It is not surprising then that policy labels such as the knowledge-based bio-economy (KBBE) (European Commission 2005) have more recently been put forward as a new policy rubric under which the economic, social and environmental potential can be reached through a more focused policy agenda. At the same time, however, the goals of scientific knowledge production are becoming increasingly intertwined with the knowledge-based bio-economy policies associated with biomedical research. As Häyrinen-Alestalo (2007; 2006) has noted, this represents an increased penetration of political expectations into theoretical explanations associated with scientific knowledge production and its perceived role in society and economic growth.

These economic policies, however, reflect a tension between the commercial expectations that are associated with biotechnology and its various applications and the role of the nation-state and supranational

organizations have in the regulation of such activities, as well as the provision of healthcare services to its citizens. On the one hand states are increasingly emphasizing the role of the private sector in providing goods and services in healthcare, but on the other hand they are also trying to govern and regulate the use and applications of new technologies, as well as maintain sovereignty and control of costs within public health-care infrastructures. This is particularly apparent in the Nordic welfare states. The development of common markets and its implications to national healthcare services are not clear cut in that policies dictate that there should be free movement of goods and services.

At the same time, however, states are faced with the situation that not all practices across these national borders meet the same criteria or standards in any given country. This tends to result in inequalities and differences between countries as to what is offered, at what cost and under what legal jurisdiction. This tension is evident in many of the recent problems that governments and local officials in the Nordic countries face in trying to develop policies through which they are able to manage and regulate various activities related to the provision of healthcare goods and services. The movement of patients across borders to receive services is just one example related to this. The tension between public and private is not just a matter of international movement of patients, but can also be witnessed within countries in the tensions that emerge when patients receive treatments from private clinics and then go to public hospitals to deal with any possible resulting complications. The question of who is responsible for these costs (the patient, the private clinic or the tax payer) emerges as an important question in how to govern new technologies and their provision to consumers. Indeed, many new technologies, such as genetic self-testing challenge the traditional authority of the nation-state in that such services can be purchased over the internet.

The application of policies which encourage the development and application of new technologies is certainly going to continue, but the tools with which the ethical issues related to their consequences remain under development. Some authors have argued that the logic associated with care operates under very different mechanisms as opposed to the logics associated with markets and that the notion that the emancipation of the patient leads to equality is in effect misleading (Mol 2008). As noted earlier, the notion of the patient as a consumer is not a new one in that

medical services and cures have been targeting patients for a very long time. One could argue, however, that what has emerged as an interesting development in the relationship between consumers/patients and the producers of various products is the degree to which such developments are linked to a positive view in the relationship between consumption and one's own health. Health and healthcare is to a lesser extent being mediated through the physician and to a greater degree through a private industry that creates images of good health and continually constructs and develops the individual's notion of what is and should be good health (cf. Helén 2004).

Patient expectations/political expectations

An important driver in this recent development is related to expectations and hope. Expectations and hope can be seen to operate at two levels; the political and the personal. On the political level expectations derive from the economic and scientific potential that research and development are expected to produce. The significance of science and technology policies in driving expectations cannot be underestimated as policies play an important part in structuring actions. At the personal level, the need and desperation to find a cure or treatment for a life threatening or serious condition is also very powerful. As noted above, the role of patient organizations has come to play an important role in structuring and formalizing patient activities.

The notion of expectations and hope has come to be studied under the rubric of sociology of expectations (see Brown and Kraft 2006). According to Borup *et al.* (2006: 285–286), “expectations can be seen to be fundamentally ‘generative’, they guide activities, provide structure and legitimation, attract interest and foster investment. They give definition to roles, clarify duties, offer some shared shape of what to expect and how to prepare for opportunities and risks.” In this sense the development of national policies to attract medical tourism and the need to find ways of curing or treating serious illness are related through the common thread of hope and expectations.

The emerging configurations through which R&D funding and medical services are mobilized and provided is increasingly premised on what

can be described as a commercial paradigm that is generated through the creation of hope and expectations in science and technology policies, as well as the way in which the private healthcare sector is seen to take over many of the traditional responsibilities attached to the Nordic welfare state (Tupasela 2007; Tupasela 2006; Helén 2004; Brown, 2003). The problem remains, however, in the evaluation of what goods and services have some type of validity in relation to their ability to improve the health of people. The move towards market-driven healthcare appears in some senses to undermine the efficacy of public healthcare policies. This question can be asked in relation to genetic self-testing: what type of new information will I gain on myself, how will this improve my understanding of my health, and will it have a significant impact on people's health in general?

From genetic self-testing to “medical tourism”

The chapters in this volume cover a host of issues in relation to genetic self-testing and “medical tourism”. The volume is divided into two sections which deal with these issues, respectively. The first section covers four presentations which dealt with ethical issues relating to genetic self-testing.

In the first chapter Ástríður Stefánsdóttir focuses on five problems she sees associated with the sale of genetic information. Most notably she raises concerns over the uncertainties related to the accuracy of tests and whether they meet international standards associated with providing health information. She also questions the negative effect the tests might have on the public healthcare system, as well as the lack of supervision by a physician.

Anders Nordgren looks at the rhetoric that consumer genomics companies use in advertising their tests. According to Nordgren, genomics companies appeal to two general areas in their advertising; personal identity and personal empowerment. He argues, however, that information on one's own genetic makeup provides only a limited picture to personal identity and empowerment and that further work must be done to reduce the risk of inadequate information which may lead to misunderstanding.

Robin Engelhart's approach to genetic self-testing is more personal and hands-on. By taking a test himself, Engelhart is able to identify a number of ethical problems that people may be faced with if they take such tests. An important critique that Engelhart raises relates to the way the risk figures change over time, as new data becomes available on the role that different genes play in the probability of certain conditions and diseases. The fluctuations in risk figures over time raise a number of concerns as to the accuracy and significance of risk estimates and the role of association in predicting onset.

The final chapter in the first section by Frances Flinter describes how the UK's Human Genetics Commission (HGC) has reacted to the selling of genetic self-tests. Although not a regulatory body, the HGC plays an important part in the UK by providing guidance and advice to decision makers and acts as a sounding board to various stakeholders and the public. Some of the concern of the HGC relate to the quality controls that are adhered, the need to have a physician involved in all predictive testing, to as well as the clinical validity of these tests.

Together these chapters identify a number of problems associated with genetic self-testing as it relates to the notion of consumer medicine. The idea that commercially offered services, in some way, empower people is problematic in light of the validity and significance of the information that they provide. At the same time, however, genetic tests have the potential to provide important information to patients given that the information derived from them is valid and the process by which people receive it is also supported in some way by a healthcare professional.

The chapters in the second section are comprised of papers based on presentations which covered the topic of medical tourism – a term which people felt was misleading in that most often the reason to travel has very little to do with tourism, but rather with necessity.

In his chapter Niklas Juth explores the question of health care using the notion of justice. He begins this process by asking according to what principle(s) should health care be distributed and what types of problems may arise from medical tourism in relation to the notion of justice. He concludes that medical tourism can give rise to three types of problems: undermining the quality of health care for those in worse off countries, the loss of health care professions and finally those seeking medical

treatment abroad receive treatment that is not legal or allowed in their own country.

Villy O. Christensen provides an important view-point to the discussion on medical tourism, namely that of the patient who is in need of treatment. Christensen asks a simple yet poignant question: wouldn't you do the same if you were facing such a situation? He points out that few patients travel abroad with tourism in mind. Christensen argues that the unwillingness of national authorities to reimburse patients for receiving treatments – that are proven and legal abroad – is in many cases problematic and places patients in difficult situations.

Guido Pennings and Heidi Mertes examine the question of cross-border medical treatment in relation to infertility patients seeking treatment abroad, or “reproductive tourism”. They note that there are several reasons why patients travel abroad: treatment cost, treatment quality and the availability of treatment. They argue that countries that have restrictive legislation should not intervene when patient's seek treatment abroad since this raises a number of practical problems which are difficult to resolve.

Iipo Helén looks at the issue of cross-border medical care from two perspectives. First, he looks at changes in public health care in relation to the “neoliberal turn” arguing that movements such as the New Public management have contributed to the changes that we are witnessing in public health care. Second, in order to understand mobility we need to see it in a broader context where there has been an increase in the movement of a multitude of various aspects related to medical care: knowledge, personnel and technology.

The final chapter by Sirpa Soini looks at these issues from a legal stand point. In the first part of her contributions Soini examines the challenges associated with regulating genetic self-testing, noting that such tests are both a service and a product at the same time. She points out that there are examples, however, whereby countries are able to limit and regulate the purchase and delivery of such products using customs services as a barrier if needed. In the second part of her chapter Soini looks at the regulatory problems associated with cross-border medical treatments, where national health care and social security systems must deal with the complications that patients may come by as a result of receiving treatment abroad.

All the chapters provide important perspectives on the challenges which face decision makers, consumers, patients, as well as companies in trying to manage and understand the trajectories involved in consumer medicine. Both genetic self-testing and cross-border medical treatment offer a number of opportunities, both for producers and consumers of goods and services. At the same time, however, a number of important questions arise as to the limits and regulations that should be in place to protect consumers and assure that the products and services that are being offered are of good quality and do not offer false or misleading information as to their efficacy or significance in helping patients and consumers.

The role of the state and supra-national organizations is by no means self-evident within this changing environment in that on the one hand, this process has been supported by these same authorities, and on the other hand, they are also trying to control and limit the extent to which it develops and undermines their sovereignty. This dual role has created tensions between the development of consumer medicine and the consequences that authorities must deal with as a result of this development.

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Part 1:
Genetic self-testing

1. The Sale of Genetic Information: Ethical Aspects of Genetic Analysis

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In professional periodicals, there has been considerable discussion in recent years of the type of a direct-to-consumer service whereby the consumer himself obtains and dispatches a DNA specimen and receives an analysis of his genome directly from a Genetic company. The service in question is generally marketed and offered via the Internet and conducted without any intermediary. The analysis that the consumer receives supposedly gives him information about the genetic risk of developing a number of diseases in the future. This procedure is described by Hunter et al in an article in the *New England Journal of Medicine* that appeared in January 2008:

As of November 2007, two companies have made available direct-to-consumer “personal genome services” (www.23andme.com) or “gene profiles” (www.decode.me.com) that rely on the same arrays of 500,000 to 1 million SNPs used in genomewide association studies. A third company (www.navigenics.com) has announced that it will offer similar services later this year. Essentially, a client sends a DNA sample to one of these firms, which analyzes the sample by means of SNP array; the data are stored in an online private account, the results are compared with allele–phenotype databases maintained and updated by the company, and the customer receives a readout of his or her levels of risk for specific conditions. ¹

¹ Hunter DJ, Khoury MJ, Drazen JM. Letting the genome out of the bottle; will we get our wish? *N Engl J Med.* 2008; 358(2): 105

The supporters of these tests claim that what is at issue here is an exciting innovation whereby the consumer or individual can himself decide whether to purchase a particular service, and that this service consequently increases the freedom of the individual. Furthermore it is claimed that the test enhances his self-awareness as he is given the opportunity to become better acquainted with himself and to know about his origins and even, to some extent, his future. It has also been suggested that an access to this service is a good thing in itself, that the risk of others' acquiring the information in question is minimal. In any event, it is claimed that it is easier to defend the privacy of anyone purchasing and conducting a test in this way than when the person procuring such a service takes advantage of the professional guidance of a health worker, because here there is no intermediary.²

In this article I will elaborate on some of the ethical concerns that have been identified regarding these services. I will focus on five main ethical issues. The first concern is that the interpretation of these tests is governed by numerous uncertainties and it is highly unlikely that the results of these tests give an accurate impression of the actual likelihood that the individual will develop a particular illness. The second concern I wish to point out is that many if not most of those purchasing this service consider it to be health service which provides health information. It is not clear that the client realizes that the product meets neither the formal standards nor the ethical standards agreed upon by the international community for health service. The third concern that I will elaborate on here is the negative effect that this new service could have on the public health system. The fourth concern I wish to address is that the individual receives the results of the test without obtaining a professional interpretation or appropriate advice suited to him personally.³ This raises the concern that the information could harm the individual. Finally, I will mention the possible effect that increased commercialism and consumerism in health care can have on the doctor-patient relationship.

² Kathy Hudson et al., ASHG Statement on direct-to-consumer genetic testing in the United States, *The American Journal of Human Genetics*, 81/3 (September 2007): 635

³ This is discussed in all the articles cited above but see in particular the discussion in Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): 284–293.

1.1. First concern: Uncertain result

First and foremost among the concerns that have been voiced about this new service is that the interpretation of these tests is governed by numerous uncertainties and it is not clear whether the result of the test gives an accurate impression of the actual likelihood that the individual will develop a particular illness in his or her lifetime or whether that individual will benefit in any way from the result of the test. To explain this in more detail it is necessary to look at how genetic tests for clinical application are evaluated.

The evaluation is done on three levels: It is possible to look at analytical validity, clinical validity and clinical utility. The analytical validity is the test's ability to accurately and reliably measure the genotype of interest.⁴ Analytical validity depends, for example, on the technical procedures at the lab and on appropriate handling of the sample. What might undermine the analytical validity of these tests is the fact that the samples are not taken and handled under certified conditions. These concerns have been discussed by Wasson et al. in the *Journal Ethics and medicine*, in 2006 where they say:

At present, both the testing processes and the results from DTC genetic tests leave room for inaccuracy and misunderstanding. Collecting biological samples at home might or might not maximize the reliability of results, as individuals may not follow the protocols sufficiently closely. In addition, it would be difficult to verify to whom the sample belongs and there could be a danger that an individual would send in another person's biological sample, for example, that of a child or spouse (with or without that person's knowledge of the genetic testing). The laboratories themselves may or may not be certified under the Clinical Laboratory Improvement Amendments (CLIA), which strengthened federal oversight to assure the reliability and accuracy of test results, and the processes used to conduct the genetic analyses and glean results are not transparent, making assessment of reliability and validity difficult. Standards of sample collection and their processing may vary and lead to misinformation or mal-information, which could be harmful in itself and/or if people act on it.⁵

When the handling of the samples is not according to usual standards and in cases where quality control monitoring is not transparent it is hard to

⁴ Hunter DJ, Khoury MJ, Drazen JM. Letting the genome out of the bottle; will we get our wish? *N Engl J Med*. 2008; 358(2): 105–107.

⁵ Katherine Wasson et al., Direct-to-consumer online genetic testing and the four principles: an analysis of the ethical issues, *Ethics & Medicine*, 22/2 (Summer 2006): p.84

ascertain the analytical validity of the direct-to-consumer tests. We can at best say that it might be high.

Secondly, when a genetic test is valued it is necessary to consider clinical validity. Clinical validity refers to the strength of the relationship between the test result and a particular disease. In other words: “How likely is it that you have got the disease, or that you are going to develop the disease if the test indicates that you’ve got the genotype that is associated with the disease? And how likely is it that you will go free, if the test indicates that you don’t have that genotype?” (Stefán Hjörleifsson 2008, 5). Clinical validity of these tests have been questioned by many authors⁶ and we can say that the relation between a particular gene variant being at place and the likelihood of developing a certain disease is not an accurate science at present. Hunter, Khoury and Drazen say, for example, in an article in the *New England Journal of Medicine* in January 2008:

“Most of the diseases listed by the direct-to-consumer testing companies (e.g., diabetes, various cancers, and heart disease) are so-called complex diseases thought to be caused by multiple gene variants, interactions among these variants, and interactions between variants and environmental factors. Thus, a full accounting of disease susceptibility awaits the identification of these multiple variants and their interactions in well-designed studies. What we have now is recognition of a limited number of variants associated with relative risks of diseases on the order of 1.5 or lower. Risk factors with this level of relative risk clearly do a poor job of distinguishing people who will develop these diseases from those who will not.”⁷

A general concern regarding both analytical and clinical utility is also voiced in the ASHG (American Society on Human Genetics)⁸ Statement on DTC testing in the US where they say that currently, the federal government exercises limited oversight of the analytical validity of genetic

⁶ Same source and Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): 284–293.

⁷ Hunter DJ, Khoury MJ, Drazen JM. Letting the genome out of the bottle; will we get our wish? *N Engl J Med*. 2008

⁸ The American Society of Human Genetics (ASHG), founded in 1948, is the primary professional membership organization for human genetics specialists worldwide. The Society’s nearly 8,000 members include researchers, academicians, clinicians, laboratory practice professionals, genetic counselors, nurses and others who have a special interest in the field of human genetics. <http://www.ashg.org/> (28.12.08)

tests and virtually no oversight of their clinical validity.⁹ It seems here that in both these articles the relationship between the genetic information and the development of the disease in the individual is much more complicated than is acknowledged when these tests are marketed and as for now we have limited scientific knowledge to draw conclusions from DTC genetic tests on the clients health in the future.

That leads us to the third consideration when a genetic test is valued, that is to say clinical utility. Clinical utility refers to the effectiveness of interventions based upon a test result. This is evaluated by balancing risks against benefits in a clinical setting.¹⁰ It can also be said that clinical utility is the bottom line in the evaluation of whether to use a test or not; it states what is most important: Is there a net benefit for the individual of using the test, and is there a net benefit for society?¹¹ Little seems to be known on clinical utility regarding DTC tests. Christopher Wade and Benjamin S. Wilfond state in their article: *Ethical and clinical practice considerations for genetic counsellors related to direct-to-consumer marketing of genetic tests*, in the *American Journal of Medical Genetics* (2006) that the clinical utility of most of these tests has not been well established. They take heart diseases as an example and say:

Many DTC companies offer genetic testing for the purposes of dietary management (Afman and Muller 2006) and may include a report of recommended health behaviours to decrease risk for heart disease. However, there is little evidence for the hypothesis that genetic susceptibility information will result in significant behaviour change (Audrian et al. 1997; McBride et al. 2002; Lipkus et al. 2004). As importantly, the behaviour recommendations that companies are promoting to reduce risk of cardiovascular diseases are general recommendations for those at increased risk for any reason (diet, family history, medical history) and are not clearly related to the genetic test result per se. Therefore, the preventive health recommendations would likely be the same, and possibly just as useful, in the absence of a genetic test. Finally, the test result may add little to the risk information that

⁹ Kathy Hudson et al., ASHG Statement on direct-to-consumer genetic testing in the United States, *The American Journal of Human Genetics*, 81/3 (September 2007):p.636.

¹⁰ Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): 284–293.

¹¹ Stefán Hjörleifsson. From “know thyself” to 2deCODeme “- how does genetic risk information relate to autonomy of man?” unpublished manuscript (doctorate lecture 2.12.2008).

other well-established risk assessment tools such as age, smoking habits, weight, blood pressure, and lipid profiles provide. (Sheridan et al. 2003)¹²

According to the literature cited above there is reason to have doubt about these tests, especially their clinical validity and clinical utility.

1.2. Second concern: Health information?

The DTC tests are advertised as a mean of “health promotion” a way of being “empowered” to take better control of one’s health, be able to prevent diseases, and reference is made to doctors who advocate this new method. Further, those who buy the tests are even encouraged to take the results to their physician where they are supposed to get help in interpreting the results and make plans for the future and to be able to prevent diseases. Thus, there is no doubt that, in the minds of most people purchasing the service, what is at issue is a way to enhance one’s understanding of one’s own health, with a view to being able to enjoy better health and to have a better life. Most people will see this service as prevention and even as a way to an early cure. If the results of these tests are regarded as health information – as there is much to suggest that they should be – then the company is providing health service. If the companies are in this position then their ethical role changes fundamentally.

When marketing an ordinary product you can normally say it is the consumers’ responsibility whether he buys it or not and how it is used (caveat emptor). It would be paternalistic to intervene and say: “You should not buy this product, it is not for your own good”. It is though always a fair claim that the buyer gets sufficient information to make an informed choice. Even if we look at the product this way the genetic companies have been criticized for not giving clear account of the significance or reliability of the information given to the buyer.¹³ But if on the other hand we take the standpoint that the genetic companies are not sim-

¹² Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): p.287

¹³ “The Report of the Ethical Council of the Icelandic Medical Association” (ECIMA), January 2008. <http://www.lis.is/Items/Default.aspx?b=2726>, (29.12. 08)

See also Kathy Hudson et al., ASHG Statement on direct-to-consumer genetic testing in the United States, *The American Journal of Human Genetics*, 81/3 (September 2007):p.636.

ply selling “any product” but instead offering health service on the market there is a shift in responsibility. By offering health service the company is putting itself in the position of a health service provider or “doctor” examining and informing a patient of the latter’s state of health. It should, therefore, assume a responsibility to its customers similar to that assumed by doctors with respect to their clients. In performing work of that art there are international ethical regulations in place on how the health service provider or the doctor should act. The ethical regulations are there for a reason. They are put in place to ensure the security of patients and to maintain the credibility of the medical profession and health services. We can for example take the Ethical Codex for Icelandic doctors¹⁴, which share the same value base as the ethical codex of doctors in other countries, and use them to look at the marketing of these products. There it is clearly stated that doctors are supposed to base their advice to patients and their treatment on sound scientific results and accepted experience (clause 6). It is further claimed that in the relationship between the doctor and the patient it is the doctor that bears the responsibility for the medical advice and for the recommended treatment (clause 8). However, since the scientific base for the clinical validity and the clinical utility of this information remains uncertain, the use of it in health services conflicts with these statements. There is also the danger that the assessments in question may be apt to cause needless and unjustifiable fear of illness and does therefore not sit well with the requirements of clause 19 where it is stated that:” Doctors must also avoid discussion that might cause either needless or unjustifiable fear of illness or an unfounded lack of confidence in the medical profession.”

Given that the scientific bases for the clinical validity and for the clinical utility is, uncertain, there is much to suggest that the values set forth in the Codex Ethicus for doctors in general are not respected in the discussion and marketing of genetic information. It is therefore important to demand that it will be settled once and for all whether or not what is at issue here is health information and a part of the available health service. If there is no health service given, there is conceivably no cause to abide by the values here raised. The companies then only bear responsibility in informing the client correctly so he or she can make an informed choice, since they are only selling a commodity not giving health service. It also

¹⁴ Codex Ethicus for Icelandic Doctors: <http://www.lis.is/Items/Default.aspx?b=12> (08.01.09)

follows from this, however, that such information is of no consequence within the health service and doctors and patients should not regard it as anything more than-at best-an interesting parlour game. If, on the other hand, the genetic companies wish to be taken seriously and for the information here in question to be regarded as health information and knowledge with some importance and worth for the individual and his health, the responsibility and framework surrounding such information and the acquisition thereof must be changed. It is not possible both to have the cake and eat it.

1.3. Third concern: Effect on the health system

As has been explained above the genetic companies seem to be marketing an ambiguous product. They market it as “health promotion” and then as something that enhances your health, promising the client a service similar to health service but instead of taking responsibility accordingly they work from the assumption that this is not a service given to the patient but more like selling a commodity where they take no actual responsibility for the result on the client of the service. Just as a store that sells milk or alcohol. When there is this ambiguity in the meaning of what is sold we have a third concern regarding the sale of genetic information. The eventual use of the information can have negative effects on the public health system. One can expect that, if genetic tests like these become commonplace, the burden on general practitioners will increase as people’s health concerns increase. Let’s remember here that the clinical utility of this information is not known. In a recent article by McGuire and Burke in *JAMA* where this possible burden on the health system is discussed the authors say:

To establish clinical utility, promoters of these genomic tests will need to provide convincing evidence that the test meets established standards for screening, such as reliable identification of asymptomatic individuals, improvement in health outcome with early treatment, and acceptability of the testing and treatment program. Over time, evidence for clinical utility is likely to emerge for some test uses and not others.¹⁵

¹⁵ McGuire AL, Burke W. An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing; Raiding the Medical Commons (commentary). *JAMA*, December 10, 2008- Vol 300, No.22 p. 2670.

No outside evaluation on the clinical effect of these tests seems to be in place so the research necessary to gain this information mentioned above has not been done and is not in progress. In the meantime physicians experience the pressure due to patients' fears of possible illness based on DTC. This might prompt doctors to refer people for research which no reliable scientific knowledge shows to be justifiable. This would increase the burden on our public health service and might cause the limited funds within the service to be prioritised in an arbitrary way. Further, it would cause preventive measures to lose focus and to fail to deliver the benefits anticipated. Here, then, there might come to be increased expense to the public health service and it is unlikely that this would deliver results in terms of better health for the individual.

1.4. Fourth concern: Gaining health information without health professionals

The fourth concern I wish to address is that the individual receives the results of the test without obtaining a professional interpretation or appropriate advice suited to him personally.¹⁶ The results of DTC tests can indicate the possibility of an increased risk of illness in the future on the part of the individual. For laymen not in a position to interpret the information, such information can prove to be a burden, e.g. by causing uncertainty with regard to the risks of particular illnesses. It is also possible that the individual has an increased risk for a certain disease in the future which the test does not reveal. In that case the client might feel overconfident and fail to take general precautions to prevent the disease. It is, therefore, recommended that individuals should be offered personal assistance from a specialist with knowledge in this area both in choosing the relevant tests, interpreting and drawing conclusions from them. It must be assessed and explained how reliable it is, what it means in the case in point and whether it is right to resort to preventive procedure. Hence, it is important that professional interpretation or appropriate advice suited to

¹⁶ This is discussed in all the articles cited above but see in particular the discussion in Christopher H. Wade and Benjamin S. Wilfond, Ethical and clinical practice considerations for genetic counselors related to direct-to-consumer marketing of genetic tests, *American Journal of Medical Genetics, Part C (Seminars in Medical Genetics)*, 142/4 (2006): 284–293.

the individual personally is offered. This is pointed out in the conclusion of the ASHG (American Society of Human Genetics) Statement on DTC Genetic testing where they say:

In the current environment, consumers are at risk of harm from DTC testing if testing is performed by laboratories that are not of high quality, if tests lack adequate analytic or clinical validity, if claims made about tests are false or misleading, and if inadequate information and counselling are provided to permit the consumer to make an informed decision about whether testing is appropriate and about what actions to take on the basis of test results.¹⁷

In their statement they stress the importance of making it clear to those taking the tests on what scientific basis they are made and that they are not promised more than they get. It is important that the client realizes that the results of the tests are by no means certain. As has been stated in the above quotes there is a danger that the tests give both misleading information and wrong information on the clients prospects in life. This can harm or affect the individual. It can lead people to make choices on false basis. Instead of being empowered by knowing themselves better the risk is at hand that people are given wrong information.

Fifth concern: Consumerism and Commercialism

If Direct-To-Consumer work processes will in the future become common as a way to know more about oneself and ones health, then it opens up new concerns about the relationship between doctors and patients. The responsibility which has hitherto been borne by professionals in their relationship with patients is not in evidence when the individual purchases the company's service. He becomes a health service consumer instead of being a patient and a health service recipient. He alone has to bear the responsibility for his life and health. The company which takes the place of the doctor is not a person and therefore approaches the matter in an impersonal and impartial way and appears to be able, under cover of this, to distance itself from the responsibility of what happens. This is an exaggerated manifestation of the tendency to regard health services as a product purchased on consumer terms and professional assessment plays

¹⁷ Kathy Hudson et al., ASHG Statement on direct-to-consumer genetic testing in the United States, *The American Journal of Human Genetics*, 81/3 (September 2007):p.637.

no part in this. Instead of talking about patients, one talks about consumers, and instead of health information, one refers to a product whereby a particular service need is fulfilled. However, the connection between gene information on one hand and health services and the health of the individual on the other is unambiguous. The notion of professionalism and the vision of health services afforded exclusively to those who need them, on the grounds of professional assessment, must here give way to ideas of health services afforded to those who want them, on the basis of the desires and wishes of the individual patient—the consumer. In such an environment, the position of the doctor is changed, and instead of being a professional who accepts responsibility in his relationship with the patient, he becomes an observer without responsibility who first and foremost satisfies the wishes of those who turn to him.

As access to this service is without any limitation, the individual is rendered entirely responsible for his health, his wellbeing and even his medical treatment. Although the freedom and responsibility of individuals in their own lives are for the better in most cases, the disadvantage of this approach is that here the patient does not receive the support often necessary and the education and the vision of professionalism that might serve the interests of the patient himself will not be in evidence. If no action is taken this will at length, change the position of medicine. The role of the doctor and the doctor-patient relationship can lose its meaning. That I believe is important to prevent. To stress my point I will conclude with a quote from a report¹⁸ from the Canadian Medical Association on Professionalism in Medicine where threats to professionalism are discussed:

“It is important, indeed imperative, for doctors to recognize that what they have is not just a market relationship or a trade union deal with the rest of society, but a very special moral contract. If this contract is blemished or broken, not only is public confidence in, and common esteem for, the medical profession sapped, but it will also infect and consume the self-esteem and moral habitus of the practitioners themselves.”¹⁹

¹⁸ “Professionalism in Medicine” (CMA Series of Health Care Discussion Papers). Canadian Medical Association Publications, Ottawa ON, 2001. http://www.cma.ca/multimedia/staticContent/HTML/N0/12/discussion_papers/professionalism/pdf/professionalism.pdf (02.01.09)

¹⁹ Hernes G. The medical profession and health care reform- friend or foe? (editorial) *Soc Sci Med* 2001; 52: 175–7.

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2. Personal Genomics: Consumer Genomics Companies and their Rhetoric

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2.1. Introduction

During the past 10 years we have seen an interesting development in “personal genomics”. More than a hundred companies have emerged that offer personal DNA information via the Internet “direct-to-consumer”. The most recently started “consumer genomics companies” use genome-wide scanning technologies in order to provide “personalised” genetic profiles. Some of these companies – the “me-companies” – emphasise the personalised nature of their genetic services by including first person pronouns in their company names: deCODEme (2009), 23andMe (2009), Knome (2009), and Mygenome (2009) (Nordgren & Juengst 2009). In this paper, I will analyse some aspects of the rhetoric of these “me-companies” and some other consumer genomics companies.

2.2. Genetic services

The genetic services of the consumer genomics companies vary. Some offer health-related DNA information, others non-health-related DNA information. A third category offers both types of information. In practical terms, the customer is invited to swab the inside of her cheek and send

her samples to the company. After a few weeks she gets the result on a confidential place on the company website accessible through a personal password. The prices vary substantially, from about 200 US dollars to 70,000 dollars. Most of the companies are based in the US, followed by the UK. Of particular interest in the Nordic context is deCODEme based in Iceland. Sweden got its first consumer genomics company in 2008, “DNA-guide” (2009).

The health-related DNA information may be of various types. The information may concern relative genetic disease risk, i.e., the risk compared with someone of the same age or gender in the general population, or absolute genetic disease risk, i.e., the risk to develop the disease over lifetime. The information may also be pharmacogenetic, indicating drug response. Some companies provide nutrigenetic information about nutritional needs and “DNA fitness”.

The non-health-related DNA information may concern traits like bitter taste perception or baldness. More commonly, the companies offer genetic ancestry tracing. Two main methods are used in order to find particular mutations that have occurred at different points of time during human history. One method focuses on the mitochondrial DNA, the other on Y chromosome DNA. The mutations define certain populational “haplogroups”. In addition to these tests, there are autosomal marker tests used in ethnicity analysis to estimate the probability of biogeographical ancestry.

2.3. Rhetoric

In the rhetoric of the consumer genomics companies, as it appears on their websites, two major appeals can be found. The first appeal is to personal identity: DNA information direct-to-consumer provides knowledge pertinent to personal identity (cf. Nordgren & Juengst 2009). The second appeal is to personal empowerment: DNA information direct-to-consumer empowers the consumer). Both appeals illustrate the personalised character of the companies’ genetic services. Let us take a closer look at these two appeals, beginning with the appeal to personal identity.

2.4. The appeal to personal identity

Narratives of personal identity try to answer the question: who am I? On the websites of many consumer genomics companies, it is stated that DNA information can give at least partial answers to this question. Let me give a few examples. DNA Worldwide maintains:

For thousands of years mankind has always wanted to know; who are we? Where do we come from? And what makes us unique? Now thanks to advances in DNA and genetics we can start to answer some of these questions (DNA Worldwide 2009).

The company “Knome” alludes to the Delphian dictum:

Know Thyself! (Knome 2009)

In addition to the company name itself, we find the following imperatives on the website of the Icelandic company deCODEme, which indicate that decoding the genetic code may provide important self-knowledge:

deCODE your health
/.../
deCODE your ancestry (deCODEme 2009).

Finally, 23andMe states:

By tapping into advances in DNA analysis and offering education, tools, and expertise, we at 23andMe want to help others take a bold, informed step toward self-knowledge (23andMe 2009).

The issue of personal identity is a very complex one and the relation of genetics and personal identity perhaps even more so (see Nordgren 2008). DNA information can be used to support both individualistic and communitarian visions of personal identity, and we see examples of both tendencies on the websites. Individualistic accounts may refer to the fact that everyone has a unique DNA fingerprint (this fingerprint can be used in, for example, forensic investigations). Everyone has also a unique set of properties that are at least partly genetically determined (as discovered in testing for diseases or traits). However, individuals are also part of a very long chain that lasts thousands of years back in time – which is the focus of genetic ances-

try tracing – and individuals share their basic genetically determined features with many others (as established in testing for diseases or traits). These genetic facts may be stressed in communitarian accounts of personal identity. The communitarian tendency on some websites is further indicated by the fact customers are encouraged to discuss their DNA information with other people as a social-networking tool.

Personal identity can be health-related as well as non-health-related, and the companies offer DNA information that can be relevant to both aspects. For example, genetic disease risk testing may provide input to health-related identity, leading to a new self-understanding: “I am a person at risk of developing the disease x”. Similarly, DNA information may be relevant to non-health-related identity: “I am the father of A” (based on paternity testing), or “I am an African-American” (based on ethnicity analysis).

Now, how important is DNA considered to be for personal identity? The company names and the content of their websites indicate that the appeal to personal identity is in fact an appeal to “genetic essentialism”. This is the view that our genomes define our personal identities, as secular substitutes for the “soul” in religious accounts (Nordgren & Juengst 2009). This appeal to genetic essentialism might seem surprising, for two reasons. The first is that one of the lessons from the last two decades of research into the ethical and social implications of genomics is the need for not investing too much personal meaning in genetic information. The second reason is that most companies also stress gene/environment interaction and “genes in context”. However, the appeal to genetic essentialism is probably an important factor behind the companies’ business success. Three cultural currents appear to be at work:

- a pre-modern interest in a naturalistic account of personal identity,
- a modern passion for science, and
- a post-modern emphasis on radical individual self-determination and an attitude of amused self-objectification “online” (see Nordgren & Juengst 2009).

The first current is a search for personal identity in terms of something naturally given that can be discovered rather than something socially constructed. Personal identity is to be discovered in the genes. The second cultural current is the belief that science rather than religion reveals iden-

tity. The naturally given identity is discovered by genetics. One aspect of the third current is radical individualism. This individualism makes people explore the genetic background of their health and identity on their own on the Internet rather than turning to the established health care system and its experts. Another aspect of the third current is amused self-exposure, for example on the Internet. Well-known tools are Facebook and Myspace. Such self-objectification may engage people in playful sharing of personal DNA profiles as a way of building new social networks.

Different customers may be attracted to different aspects of the rhetoric. Some seek a firm foundation for their personal identity in a pluralistic world. Others are driven by an enthusiasm for science. A third category is critical to experts and the established society and leads radically individualistic lives, in part and increasingly, online. Certainly, all three tendencies may also be present in one and the same person.

This is not the place for arguing extensively for this explanatory proposal. It is a hypothesis only (Nordgren & Juengst 2009). More investigation by sociologists and others is certainly needed.

2.5. The appeal to personal empowerment

Let us turn to the second appeal that can be found in the rhetoric of the consumer genomics companies. This is the appeal to personal empowerment.

This is how Navigenics puts it:

Navigenics is the leading personalized genetic testing company. We use the latest science and technology to give you a view into your DNA, revealing your genetic predisposition for important health conditions and empowering you with knowledge to help you take control of your health future (Navigenics 2009)

deCODEme stresses:

Getting to know your personal genome will empower you and provide you with a road map to improve your health (deCODEme 2009).

A third example is from 23andMe:

23andMe was founded to empower individuals and develop ways of accelerating research (23andMe 2009).

Now, what is empowerment? A clarifying analysis of this elusive concept can be found in Tengland (2007). Tengland differentiates between empowerment as a goal and as a process or approach. Empowerment as a goal is a matter of control (gaining mastery of one's own health or life) or internal resources (obtaining knowledge, becoming more autonomous, changing one's self-image). Empowerment as a process or approach means involving people in decision-making and action in a way that makes the experts having to withdraw some of their power (Tengland 2007).

On the websites we find examples – explicitly or implicitly – of both aspects. Empowerment as a goal may be attained by health-related DNA information direct-to-consumer about disease risks (because this may lead consumers to start taking certain helpful drugs or change lifestyle), about drug response (because this may lead the consumers to take certain drugs but avoid others), and about nutritional needs (because this may lead consumers to make certain changes concerning diet and lifestyle).

Moreover, empowerment as a process or approach may be accomplished by the provision of DNA information direct-to-consumer, because there are very few genetic counsellors and medical geneticists available, with the consequence that most people don't have access to genetic testing and its benefits.

The companies do not explicitly refer to empowerment with regard to non-health-related DNA information. However, it is fairly easy and not too far-fetched to reconstruct such arguments. Empowerment as a goal may be attained by non-health-related DNA information direct-to-consumer that supports the consumer's self-image and subjectively experienced social identity ("I am the father of A", "My ethnic roots are in Nigeria") or that changes his self-image in a way that is experienced as positive ("I'm glad to discover that I am the father of A, although I didn't believe so", "I'm happy to see that my ethnic roots are in Nigeria, although I didn't believe so"). These insights might have profound practical consequences and are not merely a matter of subjective experience (or recreation). In a country like the US, for example, the results may influence how people report their "race" on governmental forms, college applications, job applications and medical questionnaires. Moreover, tests have led African-Americans to financially support African communities to which they feel associated (Bolnick et al. 2007).

Furthermore, empowerment as a process or approach may be accomplished by non-health-related DNA information direct-to-consumer, because earlier there was no possibility to get to know these things even through genetics experts; the consumer gets involved in something that he/she could never be involved in before, for example, genetic ancestry tracing.

Why do the consumer genomics companies appeal to personal empowerment? This is probably due to the combination of the concept's ambiguity and positive connotation. This makes it a very useful rhetoric tool. Moreover, the appeal to empowerment is in line with the post-modern cultural current mentioned above with its individualism and critique of the established society and its experts.

2.6. Criticism of the two appeals

How well founded is the rhetoric of the consumer genomics companies? Several critical points can be made.

First, the information may be less informative than advertised. An example is given in a Report from the US Government Accounting Office. Fourteen "different" DNA samples, which actually came from only two individuals (two from a male (48 years old) and 12 from a female (9 months old)), were sent to four companies providing nutrigenetic testing. The recommendations from three of the companies simply mirrored the fictitious additional information that was given: those who were smokers were told to quit smoking etc. The companies asserted that the results would not contain any medical predictions, but all 14 results did contain predictions that might be interpreted as diagnoses. The Report concluded that the results lack scientific support (US Government Accounting Office 2006). Another example of the rather limited information offered can be found in genetic ancestry tracing. Membership in a particular haplogroup says very little about the individual's genealogy in detail. Both the mitochondrial method and the Y chromosome method provide information about only one line of descent (i.e., one ancestor per generation) of all that have contributed (Shriver & Kittles 2004).

Second, the tests may be premature, non-validated, or suffer from severe statistical limitations, and may therefore provide information that is

not quite adequate or reliable. The nutrigenetic tests investigated in the Report from US Government Accounting Office seem to be examples of premature science. The tests were not yet sufficiently validated. Moreover, in genetic ancestry testing we find examples of statistical limitations. A problem with the autosomal marker tests used to estimate the probability of biogeographical ancestry is that in cases of admixture many potential patterns may be compatible with a particular result (Shriver & Kittles 2004).

Third, there is a risk for misinterpretation of information. The consumer may not understand the limitations or premature nature of some of the tests. In health-related testing, the risk and severity of a disease may be exaggerated as well as underestimated (Hudson et al. 2007). As a result, the customer may get a false sense of security, worry unnecessarily, or neglect taking preventative action (Kaye 2008). In genetic ancestry tracing, the statistical limitations can easily be misinterpreted by the customer. Moreover, the companies commonly don't explain that DNA information is not the only source for ethnic identity. An individual may belong to a particular ethnic group even if her deep genetic ancestors were not members of the parental population associated with this ethnic group. The feeling of social belonging may carry more weight than genetics (Bolnick et al. 2007; Nordgren 2008; Nordgren & Juengst 2009).

Fourth, with a few exceptions the consumer genomics companies do not provide genetic counselling. This is serious, in particular with regard to health-related DNA information. 23andMe and deCODEme merely recommend the customer to seek advice from her physician or other qualified healthcare professional (23andMe 2009; deCODEme 2009). This is hardly sufficient. Good examples are Navigenics and DNA Direct, which include genetic counselling in their service packages (Navigenics 2009; DNA Direct 2009). Inadequate information or misinterpretation of information may distort personal identity (Nordgren & Juengst 2009) or disempower the consumer rather than the other way around. Without genetic counselling this may have serious medical, psychological, or social consequences for the customers.

2.7. The need for regulation

Given this criticism, it is obvious that the activities of the consumer genomics companies are in great need of regulation. The home of most consumer genomics companies – the US – lacks national regulation, but some states in the US have such regulation. These states do not permit their residents to obtain certain information about genetic risk unless a qualified health provider is involved in the ordering and the delivery of the results (Kaye 2008). In Europe, one step towards regulation can be seen in the *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes* recently issued by the Council of Europe (2008). As the title indicates, this is an addition to the *European Convention on Human Rights and Biomedicine* (Council of Europe 1997). This means that it will only affect countries that have signed the *Convention*. The UK, for example, has not signed it. Even for those European countries that have signed it, it still needs to be implemented into national legal regulation for full effect (Kaye 2008).

The global nature of the Internet creates special problems. A customer in one country can easily order genetic services from a consumer genomics company based in another country. The companies therefore emphasise that the customer must follow the laws of his own country. This is what deCODEme states:

This Website is controlled by deCODE genetics, Inc. from its offices in Reykjavik, Iceland. deCODE makes no representations that materials in this Website are appropriate or available for use in other locations and those who choose to access this Website from other locations are solely responsible for compliance with any and all local laws to the extent local laws apply (deCODEme 2009).

On the deCODEme website, we also see an explicit example of how the company respects the laws of other countries or parts of countries, in this case the laws of some US states:

Some states have laws that do not permit their residents to obtain certain information regarding genetic risk provided by the Genetic Scans, unless a qualified health care professional is involved in the ordering and the delivery of results. (As of the date of publication of this Service Agreement those states are AZ, CA, CT, GA, MD, MI, NJ, NY, PA, RI and WY. NY, MD & PA fur-

ther require that laboratories providing measurements of genetic risk obtain a laboratory license issued by that state. To date deCODEme does not have such MD, NY & PA licenses) Therefore, unless the Genetic Scan is ordered under the supervision of a physician who provides appropriate counseling, the deCODEme service may omit certain genetic risk information to residents of states where providing such information is restricted (not available in MD, NY & PA) (deCODEme 2009).

The problem is, however, that the activities of the consumer genomics companies are not regulated in most states in the US and in most countries worldwide, for example in Europe.

Let us see how the *Additional Protocol* would affect deCODEme and other consumer genomics companies if this protocol would have normative status in Europe. Article 5 from this *Additional Protocol* (Council of Europe 2008) stresses the need for scientific and clinical validity of the genetic tests:

Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that:

- genetic tests meet generally accepted criteria of scientific validity and clinical validity...

Article 6 points out the necessity of clinical utility:

Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.

Article 7 stresses individualised supervision by a physician:

A genetic test for health purposes may only be performed under individualised medical supervision.

Article 8:2 emphasises genetic counselling:

For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

- tests predictive of a monogenic disease,
- tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
- tests serving to identify the subject as a healthy carrier of a gene responsible for a disease (Council of Europe 2008).

To what extent does this new regulation apply to the services of the consumer genomics companies? It does not explicitly mention these companies, but the regulation concerns public as well as private genetic testing. So, in this regard it is applicable to these companies. However, it concerns only health-related testing, not non-health-related, and we have seen that a substantial part of the tests of the companies are non-health-related. Moreover, the regulation might not be applicable to all types of health-related testing provided by the companies. deCODEme states:

The Genetic Scan product is for informational purposes only, is not medical advice, and is not a substitute for professional medical advice, genetic counseling, diagnosis, or treatment. You must seek the advice of your physician or other qualified health provider with any questions you may have regarding the genetic aspects of a medical matter and you must not disregard professional medical advice or delay in seeking it because of the results of your Genetic Scan or anything you have read on the deCODEme Site.

This disclaimer can be compared with a similar one by 23andMe:

The genetic information provided by 23andMe is for research and educational use only... The Services Content is not to be used, and is not intended to be used, by you or any other person to diagnose, cure, treat, mitigate, or prevent a disease or other impairment or condition, or to ascertain your health (23andMe 2009).

These disclaimers indicate that deCODEme and 23andMe do not consider themselves as providing medical disease testing, only health-related education. This suggests that, according to these companies, the *Additional Protocol* would not be applicable to the kind of genetic services they provide. This does not exclude the possibility that it is in fact applicable despite these disclaimers. As far as I can see, the applicability seems to be an open question.

To the extent the *Additional Protocol* is applicable to the services of the consumer genomics companies, it might have vast practical implications. For example, some nutrigenetic tests appear to be scientifically premature. They do not live up to the standards of scientific validation and clinical utility. Moreover, the requirements of individualised supervision and genetic counselling would certainly affect the activities of many companies.

Conclusion

Can the consumer genomics companies tell me who I am? Can the consumer genomics companies empower me? The answer to these questions will likely be: yes, but only to some extent and only on certain conditions. First, the DNA information can only provide limited input to personal identity and empowerment. Genetics is only part of the picture. Second, the risk for inadequate information or misinterpretation must be reduced. Only on these conditions can the information from the companies truly tell us – at least in part – who we are and empower us. In order to satisfy these conditions, national and international regulation is certainly needed, although the companies themselves must also take their own corporate social responsibility seriously.

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3. Me, My Genes and Us – Personal Experiences With Gene Tests, and Some Sociological Observations

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3.1. Introduction

This article discusses my personal experiences with genetic tests. As a journalist, I got the opportunity to take a personal genetic test from the decodeme website in order to write about this new service for Danish newspapers. So, although I am a theoretical biologist by training, my task will be to take the perspective of the consumer and to convey some of the thoughts and feelings people may have when deciding to take one of these personal genetic tests offered by different companies. Some of the questions I want to try to answer are: What do these tests tell us right now? What do they do to us? And what kind of social expectations might be created around this brave new world of genomics?

The main points I want to put forward are threefold: First, the genetic tests on the internet are currently not very useful, neither for the consumer, nor for the health care system. Second, the perceived usefulness of genetic tests will also in the future continue to be low for the consumer, mainly because of the counterintuitive concepts of probability on personal health. Third: The coming social and governmental changes will be much bigger than the changes in health care and prevention. One of the consequences, for instance, will be an alliance between researchers and pa-

tients/consumers, whom will build up strong pressures on the health care system, which itself will lag behind the scientific developments.

3.2. Ordering and understanding a genetic test

A small scraping from my mouth was enough. I sent the sample to Iceland, and after two weeks, I could log into a website and read about my DNA, my ancestry, my appearance and my genetic mutations. I could also download a 30MB file with more than one million number plate-like codes, called SNP's, listing my most common DNA variations. They show what makes me genetically unique, and tell, where I have inherited what from my parents, and how my DNA is different from other people's DNA.

It was like being scared and reassured at the same time. But most of all, it was a fascinating experience. The ability to check my genes online and keep up with the latest research, linking disease with SNP's, is almost addictive. When I drank milk, smoked or had a pain in the knee – immediately I checked what my SNP's says: And yes, I have the mutation that makes me break down lactose and I can therefore digest milk. And no, I have no particular tendency to become nicotine dependent, and I even have a reduced risk of lung cancer (This is good, a little devil inside me thinks, because then I can continue to smoke). And yes, the arthritis my grandmother had might also become part of my future.

It turns out that my risk of getting cancer, asthma or sclerosis is lower than in general, but I will have to prepare myself to the possibility of getting old mans diabetes (rs7903146 – TT), Alzheimer's disease (rs4420638 – AG) or become blind (rs1329428 – GG), but most probably I will die from a heart attack (rs10116277 – TT). I can also see that my SNP rs7495174 has the initials AA, and that the SNP rs12913832 has GG. The vast majority of people with this combination have, like me, blue eyes. I can also compare my DNA to other peoples DNA. I compare with Bantu people, with Bedouins and Mayans. But I have clearly most in common with the French and Scots.

3.3. Where the difficulties start

But then the problems started. When looking at my gene profile, what struck me most about the results was that they were so boring. All numbers fluctuate around a relative genetic risk of 1.0 – which is defined as the average of the population in question. So the first lesson was the following: *SNP's don't seem to say much*. Whether I had a probability of 0.92 or 1.14 – the usefulness of such numbers seemed close to nil.

It is as if there is a paradox here: Everybody says that physical and psychological traits are to a high degree heritable – but my individual genes are not very informative. What does it mean that my relative risk of getting lung cancer is 0.82? And getting arthritis 1.43? Either I'll get it, or I won't. The probability of a single event is a meaningless concept for me. The problem is the following: It might very well be that genes can cause diseases, but SNP's just associate you with them. *Lesson: Association is not causation*.

The next question was: Which numbers should I ignore? Which ones should I worry about? And which ones could I be sure would manifest themselves at one point? Again: not easy. Although the absolute risk might seem more relevant, it also is not very useful. What does it mean that my risk of getting Alzheimer is increased from six percent to 10.5 percent? That I just can ignore it? That I should get checked? That I'll have to shoot myself in the head when I get 60? *Lesson: There is a real danger of getting hung up on numbers, even though they mean nothing*.

My family history is definitely more useful. I know that my grandmother had arthritis and my other grandmother got type 2 diabetes. For these two diseases there are elevated risks for me too, and suddenly these numbers make more sense. Although the absolute lifetime risk of arthritis is only 1.4 percent, I feel – because of my family history – that my risk of getting arthritis is much higher than, say, Alzheimer, of which there is a much higher absolute risk but no family history! *Lesson: The value of a genetic scan means less than knowing the disease history of your family. Wrong or only premature?*

The gene profile from the decodeme website clearly states that not all risk factors are included. This is important, because science is far from having found all the genetic associations for any of the investigated diseases. Take a look at the following table:

Trait	Relative genetic risk (May 2008)	Relative genetic risk (December 2008)	Relative genetic risk (October 2009)
Age-related Macular Degeneration	1.35	0.53	1.57
Celiac Disease	0.34	0.32	0.32
Colorectal Cancer	0.98	0.87	0.90
Crohn's Disease	0.92	0.88	1.44
Obesity	1.05	0.77	0.77
Prostate Cancer	0.85	0.64	0.81
Psoriasis	0.69	0.79	0.70
Restless Legs	1.38	1.26	1.26
Type 2 Diabetes	1.20	1.25	1.25

The table shows the time-dependency of the risks which have changed because of new evidence of associations. They are clearly changing the risk estimates in unpredictable ways. And probably this will continue for some years to come. What does it mean? Clearly consumers of the tests won't say, that they get healthier when their relative risk numbers decrease, but they will be fair to say, that the numbers are premature, if not utterly wrong.

According to statistician John Ioannidis (2005) from Tufts University, the first association studies usually show great effects. But soon after, when other researchers verify the results and new SNP's get included into the calculation, the strength of the associations is diminished. Often to such a degree that the effect becomes minimal and can be neglected. Even worse, Ioannidis believes that the vast majority of results are plainly wrong (ref 1). Rather than measuring an effect, the tests measure a bias, e.g. a distortion of data due to lack of information from what is not yet included. One has to remember that only 1 million SNP's are investigated, which means that we know nothing about 2,999 million SNP's waiting to be analyzed. *Lesson: Incomplete genetic data can lead to wrong conclusions about your health status.*

Also, the more SNP's you will find in the long run, there is a chance that the numbers will get closer and closer to the average relative risk of 1.0. Thus, the only way to verify the claims of the utility of the genome scans are to make large randomized studies, where participants not only get scanned all of their DNA, but also are followed through their life, so that you can correlate the genetic data with their behaviour, eating habits and lifestyle. The data would also have to be correlated with environmental and social factors. Only then it will be possible to achieve a safe separation between genetic and non-genetic factors underlying the devel-

opment of diseases. (As James Watson said at a recent conference, where researchers investigated his genome: “We’ll see if any of it adds five minutes to my life span,”) *Lesson: Genetic data, isolated from lifestyle and environmental data, is not very informative.*

3.4. What will other people do with this information?

Will other people be more sensible than I in interpreting their genes? Let’s hope so. At one point last summer I lured my half-brother to take the same test at decodeme. When I asked him what he had learned from the results, he said “nothing”. He felt cheated. When I told him about this conference he said “tell Kari that I want my money back”.

Why so? Let’s take an example: His results said that he might be bald as well (77%) – even though we both have the same mother. But he is NOT bald. His conclusion was that the test must be wrong! He wasn’t quite able to accept the difference between a statement about probability, and a prediction about himself: When reading that he is lactose intolerant, he said “but I drink milk and I digest it. So the test must be wrong!” And when reading that he has a less probability of restless legs than I have, he said “but I have more restless legs than you. The test must be wrong!” This is an important reason why personal genomics might have some problems of finding a broad audience. Causation is easy to understand and to make useful. Association is not.

Even I have started stupidly to speculate about, what’s in it for me. I like to brag about my Churchill gene when smoking a big cigar in a bar here in Denmark (It is still allowed to smoke in some public places in DK), because my genes (wrongly) suggest to me that I’ll not get lung cancer. But there are many other ways in which people can use this type of information for their own benefit. They can use it to improve doping results, to make decisions about their offspring (positive and negative eugenics) or deny moral responsibility (“blame not me, but my genes”). *Lesson: People will make an equal amount of wrong and right conclusion with regard to their genetic profile.*

3.5. Social concerns

Most public concerns have dealt with the question of unpleasant knowledge: What if I learned I was likely to die young? Or what if I have passed on a rogue gene to my daughter? Many have also questioned the potential abuse from governments, insurance companies and employers, who could use such information against them in the future. But probably the opposite situation will be even more common: People will go to their employer or their university and say: Hey, look at my Sioux gene; I am three percent Native American, so please give me my scholarship, and my casino money! Or they'll say, hey, I am seven percent Jew, please let me get Israeli citizenship (for what ever reason that is). In general, they will try to take advantage for their own benefit.

Also, with genetic test results in hand, parents may feel tempted to wave it in the child's face and say, "Your destiny is here. You have the Usain Bolt gene! Two copies of the ACTN3 gene! You have to go to sports training, not to these stupid drama lessons!" And too many children might have to fight the burden of hopeful parents, and run away, or commit suicide. In conclusion: As long as genetic tests are as tentative as they are right now, they become modern horoscopes. And horoscopes tend to be abused.

Lesson: The number of social abuses could very well be equal the number of social benefits.

Other important social concerns on the emergence of genetic testing are the following:

- *Self-knowledge implies knowledge about kin.*
An example: I am a carrier of the hemochromatosis allele (having the combination A;G in the SNP rs1800562) which is found in 5–10 percent of Caucasian populations. (A;A) homozygotes have a 85 percent risk of developing hemochromatosis, a disorder whose symptoms include cirrhosis of the liver, diabetes, hypermelanotic pigmentation of the skin, and heart failure. Me having one A means that there is no small risk that one of my family members are homozygote, and since this disease is easy to treat but difficult to diagnose (and since some of them seem to have skin problems), I

have told them that they should get a blood test for hemochromatosis. But this is not always a prudent thing to do. They might not want to know. They might not want me to know. They might just be plainly annoyed by me bothering them or knowing something about them.

Lesson: Knowing your own genes creates a non-trivial responsibility towards your family members.

- *Segmentation, social tagging and discrimination vs. health, pension, and insurance governance*

From a governmental point of view, population genetic profiling will be very useful. Health, insurance, and pension authorities will be able to make targeted preventive regulations against detrimental traits and, conversely, create proper incentives in order to harvest beneficial traits. But this only applies for benevolent democracies. Recently though, we have learned how fragile democracies and their institutions can be. In most cases politicians on this planet give a higher priority to the protection of the nation-state rather than to individual and human rights. It is therefore not clear, whether protective laws (like the Genetic Information Non-discrimination Act, GINA, in the U.S.) in all situations will hinder abuses of segmentation, genetic tagging and discrimination.

Lesson: Exposed genomes need stronger legal rights, extending beyond national borders.

- *Multiculturalism vs. social norms*

The manipulation and selection of genetic profiles will magnify social inequality. Even strong regulations won't hinder this in the long run. It will lead to an even more segmented civil society. The dangers are obvious: We will have to accept that some social norms apply only to some of us. Others have the right to marry their cat, to have children with their mutants, have special rights and treat each other in a way we sometimes think is inhumane. It could undermine civil cohesion and create new types of human groups who no longer want to share the community's future. Equal rights could risk being replaced by cultural clans with odd customs, inequality before the law and unequal opportunities.

Lesson: The possible disruption of civil coherence needs to be checked with plenty of education and information.

But you could also imagine a more positive scenario: a scenario where we learn to understand the difference between diversity and inequality, the difference between identity and the norm. A clarification of the limits of personal rights and social demands could also have the advantage that we start to think about an extension of the Universal Declaration of Human Rights, so that it becomes really universal and includes all possible variants of our species and their relatives.

Lesson: Whether the ongoing DNA revolution will result in greater tolerance, or whether it will result in greater bigotry and intolerance, is still an open question.

Conclusion

Let's try to review the lessons pushed forward in this talk:

- SNP's don't seem to say much.
- Association is not causation.
- There is a real danger of getting hung up on numbers, even though they mean nothing.
- The value of a genetic scan means less than knowing the disease history of your family.
- Incomplete genetic data can lead to wrong conclusions about your health status.
- Genetic data, isolated from lifestyle and environmental data, is not very informative.
- People will make an equal amount of wrong and right conclusion with regard to their genetic profile.
- The number of social abuses could very well be equal the number of social benefits.
- Knowing your own genes creates a non-trivial responsibility towards your family members.
- Exposed genomes probably need stronger legal rights, extending beyond national borders.
- The possible disruption of civil coherence needs to be checked with plenty of education and information.

- Whether the ongoing genome revolution will result in greater tolerance, or whether it will result in greater bigotry and intolerance, is still an open question.

It is clear, that many of the negative ramifications of genetic testing stem from a lack of knowledge and unclear consequences. Therefore, the way ahead should have a primary focus on education, rather than on regulation. People who have grown up with the democratization of information will not tolerate paternalistic regulations that keep them from their own genomes, and early adopters will explore how this new information can best be used to manage our health. A good example in this direction is the PGP-consortium (www.personalgenomes.org/) which is a group of volunteers from the general public working together with researchers to advance personal genomics.

A cry for regulation might be as premature as the tests themselves. In addition, the health care system, as mentioned before, is experiencing a power grab from the general public. In many medical areas there is a new alliance between researchers and patients. This emerging alliance tries to push forward the quality of the health care system, which itself very often is unaware of new insights, and which is lagging behind the implementation of new treatments. This will be even more pronounced in the case of personal genomics. Most doctors only have had a single course in genetics, and the increasing speed of new insights and new technologies put a huge demand on the training of health care personnel.

In such a situation, every hand is needed. Instead of holding back and trying to keep the academic authority, medical professionals will have to become coaches of people, who themselves will be the experts of their disease. This requires a maximum of educational effort and a minimal but sufficient amount of governmental regulation, which in turn will have to extend beyond national borders and apply globally.

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4. The Work of the UK's Human Genetics Commission on Genetic Tests Sold Direct to the Public.

Frances Flinter, HGC commissioner

4.1. Introduction

This report describes work that has been done by the Human Genetics Commission of the United Kingdom to ensure effective oversight of genetic tests supplied directly to the public. It summarises the conclusions of two published reports, *Genes Direct* (March 2003) and *More Genes Direct* (December 2007) and outlines further work that the Commission plans in this area.

4.2. Human Genetics Commission

The Human Genetics Commission is the UK government's advisory body on new developments in human genetics and their impact on individual lives. It was set up in 1999 and gives the government advice on human genetics with a particular focus on the social, ethical and legal issues. One of its key roles is to promote debate and to listen to what the public and its stakeholders have to say. It is committed to openness and transparency: plenary meetings are held in public and pod casts can be downloaded from the internet.

The Commission is made up of twenty-two members including experts in genetics, ethics, law and consumer affairs. The acting Chair is Professor Sir John Sulston. The HGC also has a consultative panel of

people with direct experience of living with genetic disorders, who act as a sounding board for its reports and recommendations. More information, minutes of meetings, a diary of future events and copies of all the reports that have been published can be found at www.hgc.gov.uk.

4.2.1. Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public (1)

In February 2002 the HGC was asked by UK government ministers to conduct a review of genetic testing services supplied directly to the public. The main conclusions in the report were as follows:

- The HGC recommended strict controls on genetic testing, but did not believe that there should be a statutory prohibition of some or all direct genetic tests.
- The HGC felt that there should be a well funded National Health Service genetic service supported by a genetically literate primary care force which could properly manage and allow access to new predictive tests that were being developed.

The HGC is not a formally constituted regulatory body and most of its conclusions and recommendations were intended as a framework to guide regulatory bodies (government, professional and industry). It did not set out to create precise recommendations for regulating genetic testing, but felt that instead the best way of protecting the public was through a combination of legal controls on the sale of tests and professional self-regulation of those who supply tests. The HGC defined direct genetic testing as “any test to detect differences in DNA, genes or a chromosome that is not provided as part of a medical consultation”. The Commission found overall support for regulating such tests and whilst some stakeholders consulted would have preferred to prevent direct to consumer genetic testing altogether, the general consensus was that a mixture of statutory and voluntary controls was more appropriate. The Commission accepted the right of individuals to obtain information about themselves and felt that the State should not intervene unless there was a risk of harm, particularly to vulnerable people like children. Two possible broad forms of harm were identified: the risk of misinterpreted or erroneous

predictive health information, which could cause anxiety, lead to delays in seeking proper medical advice, or encourage expensive or unproven lifestyle changes; and the possibility that people may obtain genetic tests on children or other adults without proper consent.

The HGC advised that most genetic tests providing predictive health information should not be offered as direct genetic tests, and that if a company wished to provide a genetic test then it should have to convince a regulator that the test was suitable and that anyone involved in providing the test had the right training and expertise to give good quality advice to the consumer. There were particular concerns about predictive tests done at home because of the problems of providing full information so that the implications of the test can be properly understood, together with a danger that children could be tested without lawful consent. The HGC acknowledged that whilst there were a number of bodies who could play a role in regulation, including the Medicines and Health care products Regulatory Agency, the UK Genetic Testing Network, the Human Tissue Authority and the Office of Fair Trading as well as the Advertising Standards Authority, it acknowledged that it was not easy to control or regulate the provision of genetic tests via the internet. In 2003 there were very few commercial genetic services being offered in the UK and the HGC noted an intention to monitor progress in this area as well as a review of arrangements covering paternity testing.

4.2.2. More Genes Direct: A report on developments in the availability, marketing and regulation of genetic tests applied directly to the public (2)

In 2007 the follow up report “More Genes Direct” was produced. This report was published after a meeting that reviewed the original recommendations, with the intention of identifying regulatory gaps and making realistic and practical proposals for the HGC to take to government and also to European bodies. There was particular concern about the levels of scientific evidence given by manufacturers in support of their genetic tests, the quality assurance process of genetic providers and the lack of independent-to-consumer information available. The agreed recommendations fell into three areas:

- **Pre-market review.** The HGC felt that firstly the recommendation in Genes Direct that certain genetic tests should only be offered by a suitable qualified health professional should be implemented. Secondly, medical genetic tests, which are covered by the in-vitro diagnostic devices (IVDD) directive, were noted to be classified by the relevant authorities in the UK as “low risk” and therefore exempt from independent pre-market reviews. HGC recommended that this classification should be reviewed urgently. Thirdly, for those genetic tests that fall outside the IVDD directive, such as so called lifestyle tests, an alternative regulatory mechanism was felt to be required to provide reliable oversight.
- **Quality Assurance.** The HGC recommended that a code of practice relating to genetic testing services should be developed to take account of the guidelines published by the Organisation for Economic Co-operation and Development (OECD) and other relevant international standards such as EuroGen test. Secondly, the development of a code of practice and its implementation should involve relevant stakeholders including government bodies, public bodies, charities and industry. Thirdly, the HGC felt the UK should engage with the Council of Europe and offered to participate in its work in this area.
- **Advice and Advertising.** HGC recommended firstly that advertising for tests that are available only via medical consultation should be restricted to medical practitioners (i.e. no direct to public advertising). Secondly, the Advertising Standards Authority (ASA) and the Office of Fair Trading (OFT) should consider enhancing the codes of practice for tests that may be marketed directly to the public. Thirdly, existing web based information sources should be used as a means of providing comprehensive and independent information for consumers. Test developers/providers should be encouraged to facilitate consumer access to this information.

In June 2008, the HGC held a seminar to explore the possible development of the code of practice to cover direct to consumer genetic testing further. Among the issues discussed were the scope of such a code of

practice and who should develop, maintain and oversee compliance with such a code. Industry representatives from the UK, continental Europe, Iceland and North America plus representatives from government, charities, professional and public bodies attended the seminar. There was overwhelming support for a code of practice for predictive genetic tests sold directly to the public. It was clear that there would need to be an effective mechanism to deter companies from working outside the code. It was agreed by delegates that tests should be stratified with the critical factor being the level of risk associated with the interpretation of the tests. Certain standards such as signed consent, confidentiality and quality assurance were not controversial; further standards such as involvement of the physician and proof of the clinical validity of tests were felt to be required only when the test information could have a greater impact on the life of an individual.

The topics of clinical validity and utility produced extensive debate. It was agreed that it is important to ensure that a certain level of gene disease association can be demonstrated, but presenting this sort of information in an intelligible way to the non-expert is not always easy. The suggestion was made that all genetic testing companies should put their background research into gene disease association into the public domain in order to build up an evidence base and also that the doctors or scientists who interpreted the results of these tests should be responsible for ensuring that the tests meet defined levels of clinical validity. These professionals would ultimately be regulated by their own professional bodies.

It was agreed that predictive genetic tests should only be carried out in laboratories that have quality assurance procedures in place and also that a physician should be involved in all predictive tests. There was confusion, however, over the exact role of the physician and how much direct contact they needed to have with the customer. All industry representatives confirmed that they obtained signed consent before undertaking genetic tests; however concerns about the testing of children were highlighted as the availability of tests on-line utilising biological samples sent through the post means that it is impossible to guarantee the origin of a specific sample.

The Advertising Standards Authority, the established regulatory body covering the advertising of genetic tests direct to consumers in the UK, believes that the advertising codes as they stand are sufficient to protect

consumers. The MRHA claims that there is currently no legislation specifically covering the advertising of medical devices.

There were discussions about who should develop and maintain a code of practice. The HGC, Department of Health, Royal College of Pathologists and BIVDA were all cited as possible candidates. It was evident from the seminar that a code of practice developed for the UK should be done in collaboration with international counterparts.

The overriding factor emerging from this seminar was that this is an international issue with the internet making it easy for consumers to buy genetic tests from abroad; therefore an international approach is indicated. Writing a code of practice for the UK would not necessarily be directly helpful in other countries and a better solution was felt to be to create a high level overarching document which could be applicable in many different countries and jurisdictions.

At a Plenary Meeting in September HGC Commissioners considered the proposal that the HGC should lead the development of a common framework of principles for direct genetic testing, which would be a high level document that could be applied universally in different jurisdictions. This document would be supported by additional guidance for each country so that the principles could be given effect through existing local mechanisms and highlight any regulatory gaps for that country. Within the UK it is anticipated that the development of a common framework of principles would be followed by a UK code of practice and the Department of Health and the MRHA were both supportive of this approach. A detailed report of the elements to be included in this proposal is attached at Annexe A.

Within the UK there has been a steadily increasing awareness amongst the general public of the emerging availability of direct-to-consumer genetic tests, with several programmes on the television, radio and detailed articles in a number of national newspapers. These have served to raise general awareness of the sort of tests that are emerging, as well as concerns about their limited value and the difficulty in interpreting the results. One of the concerns identified by people working within the National Health Service genetics clinics is that they will become increasingly involved in trying to explain to patients the results of tests that have been organised independently, as this is not something that general practitioners are necessarily able to do. Tests provided by the Regional Genetics Centres go through a very detailed approval process, with evidence of

their clinical validity and utility being more easily available, but it is sometimes much harder to identify the evidence to support the sorts of tests that are offered commercially.

Barbara Prainsack and colleagues (3) have noted that existing regulatory frameworks may be ill suited to the task of protecting the customer and raised concerns that premature regulation could have unintended negative effect. They conclude that research is needed to address the question of how people will use such data and this will only be possible if over-the-counter genetic tests are not outlawed altogether. Collaboration across different jurisdictions in undertaking this research could be a fruitful area for future work.

Annex A

The following have been highlighted as important issues that should be incorporated into the framework of principles for direct genetic testing.

- a) Clarification – It is essential to address exactly which tests will fall under this framework of principles. Throughout the seminar on the 30 June 2008, tests were classified as predictive and pre-dispositional, lifestyle and health test, direct- to- consumer, direct- to- public and over the counter tests. A common consensus and description of these tests is necessary in order for us to move forward with a common purpose.
- b) The principles should expect that test providers put into the public domain their research into the clinical validity and utility of the genetic tests which they are offering to the public. This would create a public form of peer review whereby academics and experts from other laboratories can review the gene- disease association data of these tests.
- c) At the heart of the principles would be the need to provide adequate, accurate and appropriate information and support to members of the public. There is currently a lot of inaccurate information in the public domain regarding genetic tests available to consumers. As already mentioned the principles would create a mechanism whereby, the evidence base for the gene-disease association relating to these genetic tests could be put in the public domain. However, as the

general public will probably not read the scientific research papers which prove this association it is essential there is a trusted information provider which the public can access to gain information in relation to these genetic tests. This body could provide guidance to consumers on the predictive value of specific tests. The bodies to perform this role would be Genewatch or the UKGTN.

- d) The relevant standards that tests should meet, before they can be sold to the public, would be set out in the principles. These standards could be tailored to the nature of the test (e.g. ranging from genealogy testing up to single gene disorders) with the critical factors being the level of impact the test information could have on an individual. Certain standards such as appropriately informed and recorded consent, confidentiality of information and quality assurance would be applied to all tests. Further standards associated with a test, such as involvement of a physician and proof of the clinical validity of tests, would only be a requirement when test information could have a greater impact on the life of an individual.
- e) Companies wishing to supply genetic tests to the public will be given the opportunity to sign up to the framework of principles and in doing so they will be agreeing to work within them. Such action would enable these commercial services to gain the public's trust in relation to the tests they are providing. The "trusted information provider" can be responsible for informing the public which laboratories have signed up to the principles and gained the "seal of approval".
- f) Regulators such as the MHRA and the ASA and the equivalent national bodies in other countries would endorse the framework of principles. Parties wishing to highlight bad practice in this area can do so through these current regulators.

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Part 2:
Gross-border medical
treatment

5. Justice in Health Care and Medical Tourism – Should Private Money Talk?

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5.1. Introduction

In the following, I will address two main questions: 1) according to which general principle(s) should health care be distributed? And 2) given this or these principles, what problems of justice do so-called medical tourism¹ give rise to? I will argue that there is reasonable disagreement over what basic principles of justice are most appropriate regarding the proper distribution of health care. However, when applied to health care, all reasonable principles in this area support some kind of egalitarian policy as regard the distribution of health care, although details may vary. The principles that do not are for various reasons not appropriate as principles of justice within health care, or so I will argue. Given that this is accepted, and egalitarian principles and policies are given a special standing within health care, I argue that three problems of justice arise as a result of medical tourism, especially on a global level and in relation between developed and developing countries.

¹ Although the term “medical tourism” is increasingly considered as a misnomer, for instance since many of those travelling abroad for medical services do not consider themselves as tourists, but as doing something out of medical necessity they rather would have done at home if they could, I will use it in the following rather than the more neutral term “cross-border care”. The simple reason is that “medical tourism” still is a common term and the term I was invited to speak about.

5.2. Principles of justice

What is just? What makes a question a question of justice? The following story says something about these questions:² five girls find a beautiful doll in an old attic. They engage in a fierce controversy over who should have the doll. “I should have it”, says the first girl, “since no one would be as happy as I from getting the doll”. You see, this doll is the only piece missing in her otherwise complete collection, so she claims she would benefit the most by getting the doll. The second girl protests that she should have, since she has no dolls at all, unlike the other girls. Then the third girl claims that she saw it first and called for it, therefore, of course, the doll is hers. The fourth girl then protests that their finding the doll was the result of her efforts to find the key to the attic, so she deserves the doll. The fifth girl then says that she should have the doll, since she is the strongest one among them. And unless she gets the doll, she will start a fight, and she is sure to come out successful.

The story is about who should get what when not everyone can get everything they want, i.e. how important resources should be distributed when resources are scarce (which almost always is the case). That makes the story a story about justice, since justice is about the proper or defensible distribution of goods; in this case a doll. The story also teaches us two things about discussions of justice: 1) that there are different kinds of considerations or *principles of justice*, and 2) that these principles of justice may conflict, i.e. they may give different and incompatible answers as regard to how some resources should be distributed in some situations. Each girl reasons in a way that represents a special view on what is just, and all these views have an intuitive pull and have been invoked in discussions of justice.

In fact, in the discussion about justice, the suggestions as to what makes a distribution just are legion. For instance, it has been suggested that a just distribution is one that maximises the net benefit, since it would be unfair to those who could gain more from a resource to give it someone who does not get as much out of the same resource (Hare 1991; Harsanyi 1977). This is the *utilitarian* principle of justice, invoked by the first girl (who claims that she would get the most out of receiving the doll, making her collection of dolls complete). Another suggestion is that

² This story was originally presented by Tännsjö, 1998, p 165–166.

a just distribution is according to *desert*, as claimed by the fourth girl (Rachels 1991).

Then there are various *egalitarian* suggestions, such as Rawls' famous idea that a just distribution is such that the situation of the worst off cannot be improved further (Rawls 1972). This idea is implied by Rawls' *difference principle*, which states that, "social primary goods...are to be distributed equally unless an unequal distribution...is to the advantage of the least favoured." (Rawls 1972, 303) However, Rawls' theory of justice has some inherent problems that should not be overlooked. One such problem is the difficulty of identifying the worst off group.

The more general moral intuition reflected by Rawls' theory of justice does not have to solve this kind of technicality, however. It is enough to claim that the worse off someone is, the stronger the obligation of others to help her. This general idea is summed up by the *priority principle*: "[b]enefiting people matters more [morally] the worse off these people are" (Parfit 1997, 213). This is what unites egalitarian theories: they all agree that a distribution of resources should be to the advantage of those being worse off, even if this leads to a net loss of goods totally (Juth 2003). Of course, the girl who has no doll is referring to an egalitarian principle. In health care, egalitarian theories are often cast in terms of *need*, as we will see.

Moreover, there are principles of justice, claiming that how the distribution comes about is what determines whether it is just or not, not how the distribution looks like (if it is equal etc), i.e., it is the procedure leading to a distribution and not the pattern of the distribution that matters. The third girl, who "called" for the doll when she first saw it, is referring to such a principle. The most influential *procedural principle* of justice since Nozick is *libertarian principles*, according to which a distribution is just if it is the result of voluntary exchange of justly acquired property. The theory's basic assumption is that we have certain absolute rights, first and foremost to our body and to property acquired justly. Justly acquired property is property acquired without coercion or deceit, e.g., property that are the result of voluntary donation or transaction. By virtue of these absolute rights, no one may prevent the individual from using his body and justly acquired property in the way he himself sees fit, as long as the individual does not violate the same rights of anyone else (I may destroy my justly acquired car if I want to do so, but not by driving it through

your porch). If all property is justly acquired, every voluntary transaction that does not violate any one's rights will result in a just distribution, no matter what the pattern of distribution looks like. "A distribution is just if it arises from another just distribution by legitimate means" (Nozick 1974, 151) is Nozick's concise statement of this idea.

Then there is the fifth girl, who says that she will get the doll anyway, since she is strongest and successfully can fight for it, i.e., she is claiming that *might is right*. This is the view that there really are no valid principles of justice, and that the strongest parties will get what they want anyway.³ Since very few are prepared to defend such a view, especially regarding the distribution of health care, which is primarily targeted to not fully functioning, and in this sense weak, individuals to start with, I will disregard it in the following. I only mention it to draw attention to a way of thinking about justice that is hard not to end up in, if one denies that questions of justice cannot be rationally discussed at all.

In order to complicate things further, there are *communitarian theories of justice*, which typically claim that different principles should be applied to different goods. The most elaborated communitarian theory of justice is Walzer's theory of complex equality, according to which distribution of goods should be made according to the *social meaning* of the good (Walzer 1983). Walzer's point of departure is that a society has shared values. Different societies regard different things as goods, depending on these values (Walzer 1983, 8–9). The term social meaning, then, refers to the common evaluation and understanding of a certain kind of thing in a certain society. This common evaluation is partially determined by the function that the good in question fulfils in people's relations. Money is an example: it is considered of value and therefore a good in our society because it functions as a means of exchanging commodities and services. Some things are valued in several different cultures, but often to different degrees and for different reasons. For instance, cattle are considered valuable due to their property as food in one culture, while another culture values cattle for their religious significance.

These examples illustrate the fact that different goods have different social meanings. According to Walzer's theory of justice, the principle of distribution that should be applied to a certain good is determined by or a

³ The most (in)famous proponent of this idea in the history of philosophy most likely is Thrasymachus, the character in Plato's dialogue *The Republic*, book 1.

part of the social meaning of this good (Walzer 1983, 20). For western societies, Walzer discerns three basic principles of distribution (Walzer 1983, 21 ff.): the principle of desert, the principle of need (resembling the principles of equality discussed above) and free exchange (resembling the libertarian principle discussed above). For instance, it is part of the social meaning of punishment in western societies that it should be distributed according to guilt (negative desert). Favoured positions, such as jobs, should be allotted to the person with the best merits (positive desert) and health care should be distributed according to need. Non-vital material commodities, however, are to be distributed on the basis of free exchange. The trivial ring of all this is due to the fact that we have a common understanding of the social meanings of these goods, which also tell us how they should be distributed.

Following this, a just society is a society of complex equality, as opposed to simple equality (where everyone has the same amount of every good). Complex equality means absence of dominance (p 16), which means that we should not be allowed to use one type of good to acquire goods that have another social meaning. In our society, the commonly agreed injustice of being able to use money in order to avoid punishment is an obvious example. Walzer expresses this thought by saying that different goods demarcate different spheres, and that justice prevails when spheres do not impose on one another.

5.3. Justice in health care

So, how should health care be distributed? Considering this multitude of principles, can there be any hope of saying anything definite about what is just? In most cases it is difficult. However, as regards health care, there is almost universal agreement that *some* kind of egalitarian principle is appropriate. It is actually not easy to find anyone in the academic debate of just health care who outright denies this, but it is not hard to find explicit proponents of equity within health care. To take one example, consider the following quote from Guido Pennings:

Access to high quality health care is a fundamental right. As a consequence, it is one of the basic tasks of the government to guarantee this right. Social security systems are based on solidarity, collective responsibility and equal contri-

butions in order to ensure accessibility of high quality health care for all. Universal access also implies that health care should be provided on the basis of need rather than on the ability to pay. (Pennings 2007, 505–506)

To cast egalitarian principles of just distribution in terms of need when it comes to health care is common indeed. So does Norman Daniels, who has developed an egalitarian theory of distribution within health care, which he bases on the Rawlsian principle of “fair equality of opportunity” (Daniels 2009). Daniels argues that health care institutions should be arranged so that each person reaches the normal range of opportunities present in her society, at least as far as possible. Disease and disability are restrictions to persons’ opportunities to reach their basic goals, goals that often require a normal or “species-typical” level of functioning. So, the goal of health care, or at least public health care, is to maintain or restore normal functioning as far as possible, but not beyond. Daniels sometimes cast his ideas in terms of needs: medical, or health care, needs are such we have, then, if disease, injuries and disabilities limits our species-typical level of functioning. We then have a right to, as far as possible, be helped to reach that level.

Daniels view has some important implications. One is that the needier should be prioritized to the less needier – if someone is farther away from normal functioning than someone else, he has a greater entitlement to get his health problems addressed, if both cannot. This is in line with the official guidelines in Sweden regarding prioritization within health care, as formulated for instance in the Swedish government’s official report on the allocation of health care resources (SOU 1995:5). Another implication is that there are no basic rights to get medical measures beyond what is needed, i.e., there is no duty for society to provide so called medical enhancement. Medical enhancement is medical measures to get “better than healthy”, e.g. cosmetic surgery for those not injured or genetically malformed or Modafinil in order to improve working memory. The fact that there is almost consensus that medical enhancement lies beyond the scope of public health care, and that more pressing medical needs should be addressed first, demonstrates the extent to which egalitarian thinking has a grip on how we think about just distribution of health care.

Although there are other principles of justice than egalitarian ones, some of them have been used to argue in favour of the same kind of conclusions as regards how health care should be distributed in practice.

Walzer argues that health care is a typical example of a good that should be distributed according to need (Walzer 1983, 86 ff.); in virtue of the very fact that this is what most of us consider to be the proper distribution of health care. Accordingly, the principle of need is a part of the social meaning of health care. The principles of the market should therefore not interfere with the distribution of at least basic health care. So, communitarians seem to agree with egalitarian conclusions regarding health care.

Also utilitarian premises have been employed to argue in favour of adopting egalitarian policies within health care. Although such arguments are complicated, they rest on two premises: 1) to determine directly which measure will generate the most benefit is difficult. Instead we have to rely on simple and reliable rules of thumb (as the utilitarian Hare argued, see Hare 1991), and 2) the principle of diminishing marginal utility, according to which, in general, resources generates more utility the worse off someone is. According to this, the principle of need in health care can be a good rule of thumb, prioritizing those worse off and, thus, in general, generating the best benefit of resources.

Now, I am not claiming that anyone of these particular principles is the correct one. In fact, they each do have some inherent problems. For instance, Daniels' theory has a hard time defend a clear and morally relevant line between treatment and enhancement, due to the problems with the underlying concept of species typical functioning (Juengst 1997). And the communitarian theory of justice makes it hard to see how one can question the values and goals of a practice, since it is the values and goals of the practice that determines what is right and wrong within the practice to start with (Dworkin 1985). However, despite these problems, they are all at least reasonable ideas of justice within health care, and they all appear to arrive at the same general conclusions, i.e. that the more medically needy in general ought to be prioritized within health care.

There are then two principles left that outright reject egalitarian policies of distribution within health care: the principle of desert and libertarian principles. I will briefly suggest why these principles are implausible, at least within health care.

One problem with the principle of desert is that it has to rest on some idea what makes us deserve something, i.e. a property of desert, and that this property is within our control. This is part and parcel of the idea of desert: that which you yourself cannot control cannot make you deserve

something. A classic suggestion of a property of desert is contribution to production: the more good you produce, the more good you are entitled to. However, it is obvious that the extent to which we contribute to production is not something that we entirely control ourselves. It is, at least partly, due to various genetic and social factors over which the individual has no or little control at all. Principles of desert thus have to sort out which part of the contribution is genuinely due to the free choices of the individual himself. We have yet to see how this should be done. Until that problem is solved, principles of desert are practically useless in order to determine who should get what.

The major problem with libertarianism is that it has normatively unacceptable consequences. According to libertarianism, taxation is a violation of the right to property, even if tax money saves lives or extensive suffering (Kymlicka 1990, 96–97). People in dire straits instead have to rely on the voluntary beneficence of others. If someone suffering from a serious disease is without any benefactor and lacks means of his own, he may be left totally without means to provide for the most basic material necessities for survival. Then the state, or anyone else, has no obligation to provide these material necessities. This consequence should be enough to make most people reject libertarianism.

Moreover, it is unclear how Nozick reaches his libertarian conclusion on the basis of his liberal premises. Nozick defends his libertarian ideas with reference to the ideal – vital to all forms of liberal ideals – that each individual's right to live his life according to his own ideas of what is valuable should be respected (Nozick 1974, 50). If the ability to lead the life the individual himself finds valuable is the basic tenet underlying Nozick's theory, why is there according to him no obligation to support those who cannot do this without the help of others (Holtug 1999, 289)?

The at least tentative conclusion of all I have said so far is, of course, that principles of need are appropriate within health care. This probably does not shake the value foundation of most readers. However, I think it is sometimes a good idea to reflect on the reasons why one should accept something, even if it is in accordance with the received wisdom, rather than just dogmatically affirm it. Moreover, if this, granted, very rough characterisation of justice within health care

is accepted, it has some important implications for the topic at hand, namely medical tourism.

5.4. Three problems of justice with medical tourism

More specifically, given that egalitarian policies of distribution are particularly important within health care, medical tourism presents us with three problems of justice. First, medical tourism can undermine the quality and equity of health care for those worse off in developing countries (so I am focusing here on the kind of medical tourism going from developed to developing countries). Now, it is not established precisely to what extent this happens or will happen.

The extent to which local health care is undermined is determined by the extent to which medical tourism leads to crowding out (Bookman and Bookman 2007, 175–177). “Crowding out” means that health care resources, such as doctors, equipment, medicine, and hospitals, are diverted from the local less affluent population. Crowding out may occur when there is a dual structure, in which one segment is of higher quality, accessible to wealthy foreigners and local high-income patients, while a lower quality segment is accessible to the poor.

There are different kinds of crowding out. One kind is the crowding out of health care personnel, where profitable private services attracts the best physicians, nurses, etc, “reducing staff levels, lowering staff quality, and/or raising salary costs for the public sector.” (Woodward et al. 2002, 7) Another kind is crowding out of attention, so that less glamorous large-scale health care programs, such as the de-worming of people in Indian villages, gets less coverage and support than more exciting and thrilling high-tech operations. A third kind is crowding out of resources, where tourism industry requires foreign imports of high-tech medical equipment which deplete scarce foreign currency reserves that could have been used, for instance to import anti-malaria medicines.

Of course, it could be argued that medical tourism brings economic resources to developing countries, and that these resources can be used to investments that benefit also the health care of the local non-affluent population. However, this most likely presupposes active public measures of redistribution (Pennings 2007, 508–510).

A related problem is presented by another kind of medical migration, not of patients but of health care personnel: developing countries can be drained of health care personnel that they themselves have trained (Hooper, 2008). This can be seen as a double injustice: not only are the developed countries benefited by getting well-trained and often cheap medical staff, the developing countries also lose out on an investment they have made. That is, not only do the well off benefit and the worse off lose, the well off benefit at the expense of the worse off.

A third kind of problem is that some medical tourists get medical services abroad which are outlawed in their own country, e.g. assisted reproduction and abortion. Of course, this gives rise to the moral question of the extent to which we are entitled to follow the laws of our own country. However, it also gives rise to a problem of justice: the laws of the country, in effect, only apply to those who cannot afford to go abroad, i.e. the economically worse off. This group then, not only has less means to realize their life plans within their countries. Moreover, they lack the opportunities to sidestep regulation, intended to cover all the citizens of the country. Should the law only apply to those who cannot afford to sidestep it? I take it that this seems unjust to most of us. And it is a reminder of George Orwell's famous saying in *Animal Farm*: "All animals are equal, but some animals are more equal than others."

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6. Medical Tourism – A Contradiction in Terms

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6.1. Introduction

The focus of this paper is on “Medical Tourism” which refers to patients travelling abroad to seek treatment for various diseases. Under no circumstances does this have anything to do with tourism. These treatments are mainly surgical interventions, which idle patients across borders, as opposed to medical treatment. Absolutely no one is eager to leave his or her own home country in search of treatment unless it is absolutely necessary in order to survive a life threatening disease – or at least obtain life prolonging treatment. A more appropriate title would be “Traveling for Treatment” or “Cross-border Treatment”, since these patients are doing so in despair and hope of proving the doctors in their home country wrong. Often they have received a “death sentence” and have been given up on by their doctors, who have said, there is no hope or means of treatment.

Patients refusing to accept given facts are often considered difficult and demanding which seen from the patients’ or relatives’ point of view is far from the truth. They are individuals who share the responsibility of their own health and well being in order to prolong own and family life.

Is it really so bad to have a desire to live? What if it was you? Would you seek the best possible treatment or hope in another country, no matter what the cost may be? Patients are – in despair – forced to sell their homes or spend their savings, and other families are left in huge debt

mainly because of authorities' unwillingness to pay for cross-border treatment.

6.2. Patient mobility within the EU

Even though Articles of the EU Treaty states that all inhabitants within the EU member states share the same right to cross-border treatment and reimbursement of expenses for treatment as stipulated in several judgments ruled at the European Court of Justice, many countries, especially Denmark, are very reluctant to reimburse expenses, as they ought to according to existing regulations. Why, seems to be the obvious question? Is it because the authorities do not understand patients' willingness to seek treatment across borders? I choose not to think so, but believe that it is mainly a matter of money, as the home state is obliged to pay for the treatment – or at least the part of the expense the treatment would cost in the patient's home country.

To prevent patients from claiming their lawful right to reimbursement of expenses, the Danish authorities maintain a demand of prior authorization in order to be entitled to seek treatment in another membership country, which is far from the truth according to already mentioned rulings by the European Court of Law. Strong forces within the EU are working intensively to implement prior authorization from the home country in order to be entitled to reimbursement when being treated in another EU-country. They would also like to see so-called experimental treatments ruled out of the reimbursement regulations, when they have not been approved by their national board of health.

6.3. Common Market – Common Approval of Treatment

In order to avoid national differences in treatment methods and medical care it would be desirable to have a common EU board of health, which, based on medical and practical evidence, could approve various treatments within all member states. It seems rather peculiar that treatments considered "good enough" for 80 million Germans is not good enough for a little more than 5 million Danes. When Danes are seeking treatment in

Germany, they are very often met with the argument: “the treatment given is experimental and not approved in Denmark and therefore not refundable”. We have several statements and evidence of patients with severe cancer, who have been given up on by Danish doctors and who have made a controversial decision and left the safe environment of their home to travel to Frankfurt for treatment. Today many of them are completely free of cancer. Despite the proven fact that the cancer is gone, Danish doctors still refuse to face the facts, and the authorities will not reimburse the expenses.

6.4. Inadequate doctors

Doctors tend to be unwilling to recommend other kinds of treatments than practiced and approved in their own country, which seems to be due to reluctance of showing their inadequateness. Not even approved treatments in other member states are being considered adequate and efficient for patients despite successful track of records. It can be called a harsh accusation, but to the best of my belief doctors rate their own personal reputation and professional pride higher than consideration to the individual patient, who clings to even the slightest hope of cure – and life!

I wouldn't hesitate one second to seek even “just” life prolonging treatment abroad, if that is the last option for buying more time with my loved ones – no matter the costs. Costs are exactly the main issue, as doctors tend to take this into consideration when potential treatment is evaluated. This tendency is brought upon them by their employers – the politicians.

6.5. Politics and money leaves no room for the patient

Despite regulations within the EU, politicians and councils in Denmark refuse to reimburse expenses for treatment leaving a patient and family with debt and empty pockets when having faced and dealt with severe illness. It is simply unworthy to put money before individual consideration when possible treatment is available in another country than your

own. In a modern society there should be sufficient room for cross-border treatment, especially when this is stipulated by regulations within the EU.

Narrow-mindedness and economic considerations rule out patient and basic human rights. It would be suitable for the authorities to look upon patients as individuals in need of care instead of as an economic burden. Speaking about money, it is even more expensive to prolong illness by not offering proper treatment in due time or in worst case to leave the patient to die. This equals huge sums paid in sickness benefit, medical bills and personal care. Not only do relatives have to deal with the possible loss of a loved one, but also with financial problems due to huge sums paid for treatment abroad – unnecessary expenses if doctors worked together and referred to expertise achieved in other countries.

6.6. Who, why and when?

Often the right to seek cross-border treatment is met with skepticism from doctors, politicians and authorities who predict increasing interest from all patient groups – regardless of disease – seeking treatment abroad. This is not realistic and an inaccurate picture of patients' needs and wishes. It blows relevant matters out of proportion when claiming that patient after patient will leave the country looking for treatment combining this with holiday or tourism – which indeed is a contradiction in terms. No patient is in any way eager to leave the safe environment of their home with relatives nearby, when it comes to minor procedures such as the need for a hip or shoulder operation. It is such a huge decision to go to another country and leave behind the comfort and safety of home, relatives and friends in exchange for uncertainty and possible language problems when looking for alternative treatment, that absolutely no one will choose this option unless all possibilities in your own country have been exploited. Of course the “modern” and young mother of two small children looks for hope and treatment, where offered, if this means her being able to see her children grow up – regardless of the cost. The situation is different when an elderly patient has to face the above mentioned language problems and all other aspects of travelling for treatment with no guarantee of efficiency.

In this contribution to the debate I have chosen not to include fertilization treatment, as I (well knowing this attitude may cause protests) consider this as a luxury “problem” compared to people with life threatening diseases. Nor am I dealing with abortion forbidden by law or religious reasons in some member states within the EU. Ongoing stem cell research is another big topic that has been discussed. This is a rather debatable issue with believers and opponents in each their separate camps campaigning for and against the necessity and ethical use of stem cells in treatment and research. I am in no way qualified to evaluate on when and where to stop this research, nevertheless I see a great possibility in the fight against cancer and various other related diseases, as well as fertility treatment.

6.7. The new breed of patients

Way gone are the days when patients blindly trusted the doctors and accepted the faith given by diagnosis or word. Daily reports in the media and on the Internet brings to mind that we all live in a small world, where national differences in medical or surgical treatment offered are being made public and hope provided to those in need. Therefore, a new breed of patients has arisen. The patient who asks critical questions, demands an answer and last but not least adequate treatment with proven results. This kind of patient is often referred to as being difficult, too demanding and a huge cost to society and national economy, which is far from the truth. This patient is in fact a person, who shares the responsibility of their own health, wellbeing and treatment. In all other aspects of life, we are encouraged to act when faced with problems or challenges, but especially doctors tend to be offended by critical questions and remarks, which bring their authority into dispute. The big and open question is why shouldn't you actively take part in your own disease, treatment and wellbeing?

6.8. The Internet a potential hazard to health

Increasingly patients with various diseases have begun to diagnose themselves through the Internet. This is not all good, as they often pick and add

symptoms to their own diagnosis or ailment. Therefore, the doctors may face difficulties and problems in explaining any given plan of treatment.

Even though there may be similarities in diagnoses and symptoms, it is essential to emphasize that all patients and their situations are individual, when it comes to providing the right treatment in due time. A pointed finger against blindly trusting information randomly sought on the Internet, is appropriate, as this kind of information often is insufficient and statements taken out of context.

Recently a big debate has raged in the Danish media as to the effect of Chinese treatment of cancer at a substantial cost to the patient – in some cases with no medical evidence and proven results. We have learned about patients selling their belongings or putting themselves and relatives in huge debt in order to pay for treatment as a last hope in their struggle for survival. Chinese doctors and hospitals use marketing, similar to the holiday industry, spending huge sums of money to tempt weak and sick people to travel to China and get “cured” for cancer. This is not only an exploitation of people in distress, but also very unethical – in other words Medical Tourism seen from the hospitals point of view and false hopes for the patient.

The problem is furthermore that opponents of patient mobility within the EU very often mix the terms and use China as an example to “scare” patients away from seeking alternative treatment in other member states, where the treatment might be approved and practiced.

6.9. Specialized hospitals

During the recent campaign for election to the European Parliament, a Danish politician suggested that 10 specialized hospitals be set-up within the EU, which would provide treatment in a specific disease. This would mean highly trained doctors within their specialty with huge benefits for the individual patient regardless of diagnosis and nationality when approved to seek cross border treatment. Seen from a Danish perspective, diabetes treatment could be a prospective for an international contribution to health care. A report from Health Consumer Powerhouse (2009) stated that “If you have diabetes go to Denmark”. Hip hip hurray, but when dealing with severe cancer the trend seems to be: leave the country.

It is simply unworthy not to offer sick people the best medical and surgical care possible – regardless of geographic location. If you don't like the weather in your own country, unlimited information of alternative holiday options are available at hand.

6.10. Information desperately needed

There is a lack of information being provided to patients in order for them to make their own decision as to where, when or what kind of treatment to consider. They have, therefore, not been supplied with the proper information for their final decision, which leaves them worried and confused. This very often results in rash conclusions – with financial problems as the sole result. The doctors act as if they are members of a secret brotherhood, which consists of judges, who decide who lives and who dies. Some trust the message given, some are uncertain, and yet again some refuse to accept the fact. Lately we have received evidence of treatment, not offered in Denmark, proven to be not only partly effective but also curing.

When having a law within the EU stating that citizens of any member state are entitled to free movement of goods, labour and services, it is unfortunate that there are no clear rules and information to anyone regardless of home country. Disagreements have until now been settled in the European Court of Justice, and all rulings have been in favor of the plaintiff. Having the legal right to reimbursement is encouraging to know, but imagine how many patients who don't have the strength nor the financial capacity to go through a long lawsuit.

Another aspect missing is information to relatives. When a person is diagnosed with a life threatening disease, he or she might be offered some advice, counseling or help in some matter to deal with the situation, but immediate help is rarely offered to the family, which is grave, since when a family member gets sick it strikes the whole family.

It is a lot easier to get information, when you need your car fixed than to obtain relevant information or treatment for various diseases, as well as where to go. Everyone knows that the certified Mercedes garage can fix your transmission and clutch when your Mercedes breaks down, but you don't have to go to a certified garage in order to retain your warranty.

National advertising campaigns bring the information you need about getting your car fixed, but when it comes to cancer, heart failure and other severe diseases, you have to look up any information you want by yourself. An open and relevant question to authorities and doctors would be: Why not provide relevant information about any given disease, possibilities of treatment and where to go? To quote Bob Dylan: “The answer, my friend is blowin’ in the wind”.

6.11. The system vs. the patient

When coming to final decisions of which treatment to offer and at which cost, the patient very often is the big loser, as member states national politics and consideration for local interests within their national health care come before individual needs – i.e. the system is rated higher than the patient. Public health care is financed through taxpayers’ payment in expectation of repay when needed. It, therefore, seems an improper mismatch between “system” and “patient”, when it comes to payment for appropriate treatment. Only the strong and very persistent person is likely to obtain his or her right to reimbursement, and in most cases it includes lawyers and spending more money in order to beat the mighty system – even though being the underdog.

In the beginning you have, as a patient, to deal with reluctant doctors, who will not inform you of alternatives, and afterwards it all comes down to money. A well known expression is that “money talks”, and when patients use that option in order to receive treatment, the “silence of money” appears, when trying to get reimbursed as entitled to according to existing regulations. In the public debate it is often claimed that national economy cannot afford to pay the huge expenses for medical or surgical services provided abroad, but the big question is rather: can we afford not to?

6.12. Patients are participants in a game of Monopoly

Doctors, politicians and civil servants are so eager to maintain all kinds of health care, as a national matter, that patients’ well being are left behind in a game of Monopoly. When appropriate treatment is available in other

EU-countries this is often not offered in one's own country because of national and economic considerations. Patients feel they are a tiny piece in a huge puzzle, where you only fit in if you have the right amount of money or if you know someone who might have heard of someone – hence the comparison to Monopoly, as the member of the game with the most personal belongings stands a fair chance of winning.

Authorities tend to turn the debate into an economic issue, which is hard to understand, when you are a patient with a mortal disease. Strong political sections within Denmark and the EU are struggling to prevent patients in their right to seek cross-border treatment. Their arguments are many:

- We need to control who is being treated when and where, this must and shall be based on a medical and professional judgment
- This is self-evident, but often patients are not even informed about alternatives and options provided by doctors.
- If patients are entitled to seek treatment in other countries, this will cause huge expenses and undermine national health care economy.
- As previously dealt with in this article the majority of patients will prefer treatment in their home country in a safe environment having their family and loved ones around. To the best of my knowledge, only a tiny fraction of patients will take advantage of this option, therefore payments to other countries will be of an absolute minimum.
- The Danish hospitals will be flooded by e.g. patients from Bulgaria, who will look for better care than provided for them in their home country.

Regulations within the EU stipulates that a patient, seeking treatment, in this case, in Denmark, is entitled to reimbursement of an amount which equals to the amount, a similar treatment would cost in his or her own country. In Denmark medical care and surgical operations are at considerable costs, which will refrain the Bulgarian patient from going to Denmark. Let's say an operation is at the cost of 30.000 Euro in Denmark, but is offered in Bulgaria at only 15.000 Euro, the patient must pay out of his own pocket the other half – a substantial amount of money and in most cases not affordable to the individual, and therefore not applicable to citizens of less fortunate countries.

There will be national differences in medical and surgical treatments provided in some cases with unproven records of result.

Establish a common approval of all treatment provided within the EU. Today the national approval system differs from country to country. If a method of treatment is good enough for Germans, it ought to be so for Danes.

When something goes wrong in the treatment, it will be difficult for patients to make a complaint due to national differences in dealing with complaints.

An EU “Ombudsman” of complaints would solve this problem in association with the European Court of Law and assure patients the same basic rights and access to making a complaint. I will not hesitate to point out that the complaint system in Denmark is inadequate and not an example to copy.

These were just a few of the arguments put forward by politicians in their struggle against patient mobility and rights. There are several more or less conflicting arguments from both opponents and supporters of free right of movement across borders seeking treatment, but the main sticking point is money!

6.13. When money talks

Payment of medical or surgical treatment within and across national borders is often set above individual consideration and health – in some cases with fatal consequences. Is this worthy of a modern society in which everything else is adapted to international standards, when it comes to holidays, business, labour and investments? Local and national interests prevent the ultimate objective of the Common Market – making it common to all. Patients are ruled out of this objective and looked upon as a financial burden, whereas healthy members of the work force are an asset who contributes to the overall economy.

It is true that patients are a considerable cost to national economies. Therefore the obvious action to take would be to see them as an investment in health and possible cure, which will turn them into contributors instead of costs. But this costs money up front and demands both medical and political willingness to solve. Cross-border cooperation between all

parties involved will result in the best possible medical care regardless of diagnosis and money. This is where intentions meet contradiction in terms. When coming to epoch-making decisions conservative thinking in national politics and reluctance to give away power trips up any action.

6.14. Urgent changes needed

In order to turn the situation around urgent changes have to be made within national and international politics, as well as a need of international cooperation within medical health care. Is this at all possible to achieve? As a representative of an independent national patient organization, I believe it is, but it takes an extensive and open-minded health care reform without stubborn national interests.

It should be obvious to anyone that no doctor in any country can specialize in all aspects of treatment, therefore joint research, exchange of experience and expertise would be of great benefit to all patients regardless of nationality. So called “highly specialized hospitals” in various locations in the EU, as suggested by a Danish candidate for EU-parliament, could unite specialists in their effort to provide the best possible care available.

Politically it is possible to come to an agreement on financing and building bridges bringing countries closer together – e.g. between Denmark and Sweden and the upcoming bridge from Denmark to Germany. Why not build bridges between patients and hospitals, across borders? Free movement of goods, services and labour within the EU is a right given by law. When retired you are entitled to settle in any member state and receive your national pension in the country of your choice. As long as a product, service or a person comes with money he or she is more than welcome. This is a fundamental and unworthy discrimination of patients who very often comes with little or nothing at all – apart from a disease and hope for cure!

6.15. United we stand

Despite national differences we stood united when the Common Market became a reality in order to compete with other international markets, and since then we have grown to the current size of the EU – regardless of ongoing national differences of opinion between member states. The European Union has turned into an institution many people love to hate, but also accept as a necessity to compete on an international scale. I therefore urge politicians, patients and doctors to unite in the effort to live up to the original intentions of the Common Market – to make it common to all and secure equal rights to all patients in need of medical care! Politicians ought to fulfill their promises to electors during election campaigns, when trying to secure votes by promising more welfare, social improvements and better personal economy – this all requires efficient health care.

Doctors ought to fulfill their medical promise and ensure free and equal right to proper and appropriate treatment when needed regardless of social status, political orientation, religious belief or race. Patients should unite in a cross-border organization in their struggle to achieve basic human rights. All countries have numerous patient groups and organizations fighting for their individual causes, which makes them easier to “control” by politicians and authorities in general. When united internationally in a public demand for cross-border treatment they would be more likely to be heard and achieve results to the benefit of all. Is it so hard to understand, that patients refuse to give up hope, if it is out there regardless of geography? You might be next in line!

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7. The State and the Infertile Patient Looking for Treatment Abroad: a Difficult Relationship

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7.1. Introduction

Cross-border reproductive care (more commonly called “reproductive tourism”) refers to the phenomenon of people travelling from one country where treatment is unavailable for them to a country where they can obtain infertility treatment. Such cross-border movements for medical services have existed for decades as the history of abortion shows. The phenomenon attracted a lot of attention because the media focussed on rather extreme, extraordinary or strange cases of medically assisted reproduction. To name just a few: a 59-year-old British woman going to Italy to get pregnant, a 62-year-old French woman crossing the Atlantic ocean to carry donor eggs fertilised by her brother’s sperm, a British couple going to Spain for social sex selection etc. This image, however, is strongly distorted. Recent studies indicate that the overwhelming majority of instances of reproductive travelling is done by “normal” people for “standard” in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI).

7.2. Reasons for travelling abroad

The reasons why people seek infertility treatment abroad can be put in three categories: treatment cost, treatment quality and treatment availability. First, as with all types of medical tourism, the treatment cost is an important motivator. Many countries reimburse only a limited number of IVF cycles (or none at all), and if these are unsuccessful or if patients want more children, additional cycles amount to a serious financial burden. This burden might be considerably lighter if they seek treatment abroad. A second possible motivator is treatment quality. This incentive may refer to numerous aspects: success rate, length of the waiting lists, general attitude of the doctors, patient-friendliness of the treatment and privacy considerations. A third factor – which is of particular interest for our discussion – is the availability of treatment. Again several aspects can be discerned: treatment might not be available because of lack of expertise or equipment (like preimplantation genetic diagnosis), certain groups of patients are excluded from treatment on the basis of certain characteristics (age, sexual orientation, unmarried...) and certain interventions are forbidden by law because they are considered ethically unacceptable (like oocyte donation and social sexing) (Pennings 2004).

Oftentimes, several of these factors are intertwined. A recent European study showed that the main reason for going abroad for fertility treatment was to avoid legal restrictions at home (Shenfield & Pennings 2009). In an analysis of the data collected in a study on the patients coming to Belgium for infertility treatment, we found several instances of a correlation between regulation in the country of residence of the patient and the extent of the patient flow towards another country (Pennings et al. 2009). Between 2004 and 2005, the number of Dutch patients attending Belgian fertility clinics for donor sperm doubled. In 2004, a law came into force in The Netherlands which abolished donor anonymity. The consequence of this law was a reduction of the number of sperm donors with more than 70% and a reduction of sperm banks by 50% (Janssens et al. 2006). Dutch patients travelling to Belgium for donor sperm could thus be motivated both by law evasion (provided they preferred to use “anonymous sperm”) and the practical unavailability of donor sperm in their own country with the connected long waiting lists.

A similar trend could be observed for Italian patients. In 2004, the Italian parliament adopted a law that forbade the use of donor gametes, restricted the number of embryos that could be created with IVF to three and obliged patients to have all three embryos replaced (Setti et al. 2008). We know from a limited study that since then, the number of Italians seeking reproductive care abroad has increased tremendously (Fornasiero 2005). In the meantime, decisions by the Italian Constitutional Court have turned back some of these measures but it may take some time before the Italian patients prefer infertility treatment in their own country again (Rinzi 2009). The Italian law is special in the sense that it not only prohibits specific treatment types and bans services for single women, homosexual couples and in general unmarried couples, but that it also affects the effectiveness of the available services. As a consequence, even married couples who need in vitro fertilization or intracytoplasmic sperm injection (which are standard treatments for female and male infertility) opt to go abroad. In the Belgian study mentioned earlier, the Italian patients mainly came for these two types of treatment (Pennings et al. 2009). They decided to go abroad because they believed that they would obtain better quality treatment with a higher chance of success. One should be aware, however, that patients do not necessarily have the same perception of “better quality” and “higher success rate” since there is some evidence that they also want to avoid the restrictions on the number of embryos to be transferred. While the transfer of multiple embryos increases the patients’ chances of having a baby, it also increases their chances of a multiple pregnancy with all the related complications and concerns for the health of the offspring. The treatment quality can therefore not be measured by the take-home baby rate. In the same study, the number of Italian patients entering Belgium went from 37 patients in 2003 to 295 in 2007 (an 8-fold increase). When one takes into account the fact that the primary destinations for Italians are Switzerland and Spain, one realizes that a real exodus took place in Italy.

7.3. Legal problems

In most leaflets by patient organizations and other societies involved in the management of patients, patients are warned about possible legal

conflicts. This kind of problem was nicely illustrated by a recent case that concerned foreign surrogacy between the United Kingdom and Ukraine (Theis et al. 2009). A British couple went to Ukraine to find a surrogate. The eggs of an anonymous Ukrainian donor were fertilized with the husband's sperm and placed in the womb of a surrogate. She delivered twins. The British couple paid the surrogate 27.000 euro. After the birth, they found out that they had stepped into a legal minefield: according to Ukrainian law, the commissioning couple are the legal parents (that was presumably the reason why the couple went there in the first place). However, according to UK law, the surrogate and her husband are the legal parents. Due to this incompatibility of the legislations, the children were parentless and, as a consequence, stateless. They could neither stay in Ukraine, nor leave Ukraine. The case also shows another very tricky aspect of cross-border reproductive care, namely the possible violation of the law of the home country. The British law only allows reimbursement of reasonable expenses. However, both the commissioning couple and the surrogate never made a secret of the fact that the money was payment for the service rendered, not to cover expenses. In principle, the payment made the parental order (which acts like an adoption order) difficult since benefits had been given without authorization from the court. Could it be argued that this violation of the rules was sufficient to annihilate the surrogacy arrangement as far as the UK is concerned? Several other conflicts and problems can come up due to the specificity of the rules in certain countries. In the case mentioned above, an additional problem was the obligation to apply for a parental order within 6 months after birth.

The other problems mainly regard legal parenthood. Does the donor or the recipient of the gametes have legal responsibility for the offspring? Margaret Brazier, in her evidence to the House of Commons, mentions that there have been cases where couples went outside the United Kingdom for treatment with donor sperm, after which the intended social fathers changed their minds about the enterprise and denied being the legal father (House of Commons Science and Technology Committee 2005). The normal provisions for determining parental responsibility only apply in licensed clinics in Britain. Another case regards the rules of legal paternity when a woman uses the sperm of her deceased husband. Will the man be recognized as the legal parent with all the inheritance rights involved? Diana Blood, who received permission to export the sperm of her

deceased husband to Belgium, illustrates the complexity of these questions (Blood 2004).

7.4. Attitude of the government

Most states have some type of regulation regarding medically assisted reproduction. As discussed earlier, some people travel to avoid restrictive regulation. Obviously, this option only exists when other countries do not impose the same conditions. The more restrictive the legislation in a country, the more people are excluded from treatment and the more people have an interest in going abroad. Regulation takes different forms, including guidelines from professional societies and generally accepted implicit norms. Regulation expressed in laws can be broad (a prohibition on the use of donor gametes like in Italy) or small (a prohibition on the anonymity of gamete donors). If the demand for services such as surrogacy or donor gametes remains sufficiently high, alternative systems will develop like internal black markets and illegal or uncontrolled import. Externally, it will lead to “jurisdiction shopping” both by patients and practitioners and by clinics. One could argue that there will be a “race to the bottom”; people and companies will move to the least restrictive jurisdiction (Carbone & Gottheim 2006).

A government’s attitude towards citizens travelling abroad to obtain fertility treatment will depend to a large extent on their motives. The state has few good reasons to prevent patients from seeking cheaper, better or faster treatment options abroad. If anything, these patients’ journeys should act as a wake-up call to governments of countries where fundamental structural problems cause long waiting lists or suboptimal treatment. The trips signal the need to adapt the health care system to better accommodate their citizens’ needs. The situation is different when law evasion is the main motive to travel abroad. In principle, one would expect that when a certain matter is important enough to regulate it, efforts will also be made to uphold the legislation and to prevent people from evading it.

There are different degrees to which a state can counter law evasion in the context of assisted reproductive technology. We will look in more detail at some of these: (a) it can try to prevent patients from leaving by force; (b) it can prosecute patients who return after committing a crime;

(c) it can forbid all collaboration with patients leaving the country; (d) it can put pressure on other nations to change their law.

a) Preventing travelling

Some people may find it strange that the government does not intervene when it knows that its citizens travel to circumvent the law. If the state knows about it, why does it not undertake steps to prevent it? An element that is particularly important for the present question is the toleration of wrong. Although tolerance towards other opinions – especially when they are of an ideological nature – is an important moral value in pluralistic countries, it holds an inherent paradox: if one considers a procedure, decision or act as morally wrong, than how can it be morally right to allow it? There is the idea that people who turn a blind eye share part of the responsibility for the wrongs that they choose to tolerate (Kissell 1999). The simple solution would be that the state, by means of the courts, would bar people from crossing the border. A crucial problem for this solution concerns the practical impossibility to find out beforehand why people go abroad. Moreover, it would be extremely difficult to certify beyond reasonable doubt that a person is going to commit a crime. Finally, criminal law applies to people who committed a crime, not to those who intend to commit a crime. Still, in some cases, planning and preparing for a crime (like a terrorist attack) suffices to be prosecuted and condemned.

In the law of some countries, compulsory child protection measures can be taken when a child is at risk of female genital mutilation (Leye et al. 2007). These measures include suspension of parental authority, removal from the home and withdrawal of travel permission. However, the best illustration of the problem is the Irish abortion case. In 1992, a 14-year-old rape victim was restrained from leaving the country for nine months. This injunction was later overturned by the Supreme Court (Lawson 1994). Rules to prevent people from obtaining services lawfully available in another country would directly violate articles 59 and 60 of the European Community treaty which guarantee free movement of services. The Supreme Court finally decided that the right to travel of a woman was superior to the foetus's right to life. If one really considers the foetus as a person with interests, and if one is certain that the woman goes abroad to abort, this is a surprising decision.

In addition to the practical problems, a country would also be confronted with a consistency problem. If a country forbids such trips for its own citizens, it should also refuse to treat foreign patients entering the country for reasons of law evasion. As far as we know, no country does that. However, some countries do restrict access to their own citizens. In the Human Fertilisation and Embryology Act 2008 in the UK, it is stated that for an application for a parental order “either or both of the applicants must be domiciled in the United Kingdom or in the Channel islands or the isle of Man” (art. 54, 4b). This implies that foreign patients who would use a British surrogate cannot take the child out of the country. Normally, however, when a country for instance accepts to treat lesbians, it seems obvious that they also accept foreign lesbian couples. Still, one could refuse them on the grounds that the child would not be recognized as their legal child or would be harassed when the family returns home. If a country allows foreign patients to obtain treatment in their country, but forbids its own citizens to go abroad, there seems to be only one good explanation; they consider their own law as the only good law.

b) Prosecute after the fact

The legal problems with punishing someone for planning a crime would be bypassed by waiting for their return. Early 1990s, Germany for instance has forced gynaecological exams on German women returning from The Netherlands, checking for post-abortion symptoms. Prosecutors also brought charges against women who obtained abortions in other countries (Kreimer 1992). Again, such cases may be extremely difficult to prove firstly because there is always the possibility that things happen naturally and secondly because clinics have a duty to maintain confidentiality.

The central question that needs to be answered is whether a country has a moral right or duty to uphold its laws on ideological matters abroad, or if relativism and tolerance demand that they limit themselves to practices taking place on their own territory. From a moral point of view, the place of crime is irrelevant, although the consequences and the interpretation of the act may differ from one culture or country to the next. Thus, it is natural that a country will disapprove of people seeking locally forbidden reproductive care abroad. Whether such disapproval warrants prosecution of these people is another matter. Two principles have to be bal-

anced: the duty to obey the law of one's country and the principle of (reproductive) autonomy. A number of questions regarding cross-border reproductive services correspond with the problems encountered in the domain of stem cell research. An intense debate has been conducted regarding the permission of German researchers to perform stem cell research abroad that is not permitted in Germany (Mertes & Pennings 2009). In accordance with the principles adopted there, it could be argued that as long as the treatment that the patient obtains is legally permitted in the country where it is performed, the patient should be free to travel without fear of being prosecuted or discriminated (Hinxton Group 2006). However, one could also defend the position that the treatment should be permitted in both legislations in order to be acceptable, based on the rule that the regulations of both countries apply to individual patients without regard of where treatment will be performed (International Society for Stem Cell research 2006).

Jurisdiction can be claimed on the basis of a number of legal principles: the territoriality principle, the nationality principle, the passive personality principle, the protective principle and the universality principle (Brownlie 1998). We will only consider the principles that are relevant for the topic of cross-border movement of patients. The territoriality principle grants a state the authority to punish crimes committed on its territory. When people travel, they become subject to the rules of the country to which they travel. The nationality principle states that a country has the power to control its citizens' actions wherever the conduct occurs. This principle is reserved for serious crimes such as sexual abuse of children. Usually, such crimes are also covered by the universality principle. The latter allows countries to prosecute crimes that are not linked to them but that are internationally prohibited such as genocide or paedophilia. This argument cannot be used when some states allow the act (like abortion or oocyte donation) since that act cannot qualify as a universal threat (Ries 1992). According to Ries, who was looking into the question of extraterritorial abortion laws, only the nationality principle could be used to allow the state to proscribe certain behaviour by its own citizens beyond the territorial boundaries. This principle would be based on the duty of allegiance the citizens owe to the state. Ries' final conclusion was that a state would exceed the limits of its sovereignty if it attempted to punish citizens who obtained abortions in another state. Interestingly, part of the

argument to defend this position lies in the fact that these countries cannot refer to the idea that abortion constitutes murder of an unborn human person since most countries allow abortion in cases of incest, serious genetic defects and when the life of the mother is in danger. If they really believed that abortion is murder, these exceptions cannot be justified. As a consequence, they can only have gradual arguments (based on specifications and restrictions of the general permission to abort) and these are insufficiently serious to justify extraterritorial legislation.

It would be very hard for a government to justify a strict prohibition simply because they themselves adopt an intermediate position. A number of patients, for instance, leave the country because they want to use an anonymous donor. The idea of a third party that would be identifiable in the future is unacceptable for them. Some countries, like Sweden, United Kingdom and The Netherlands, enforce identifiable gamete and embryo donation. However, none of these countries force parents to tell their children of their donor origin. As a consequence, children who are not informed by their parents do not know about the donor and are not able to look for him or her. In other words, the right of the child to know its genetic origins, as expressed in the abolishment of donor anonymity, is not considered so important that there is a legal guarantee that this information is provided to the child. Parents who go abroad to obtain an anonymous donor are certainly evading the law but it does not come down to the serious violation of a right. The same position can be argued regarding commercialization and payment of gamete donors. Some countries, like the UK, allow egg sharing which constitutes a form of payment in kind. Other countries, like Spain, offer a more generous reimbursement of expenses that, at least for some, should be seen as payment. When the different reasons of patients to look for fertility treatment elsewhere are scrutinised, it is clear that almost all of them are of a gradual nature. Most criteria (age limit, number of cycles, costs, etc.) are matters of degree and thus to a certain extent arbitrary. It seems far-fetched to argue that people who choose jurisdictions in order to be eligible for treatment are committing a serious moral offence or a capital crime. The same view is defended by the British government: "We believe that any attempts to curtail reproductive tourism would not be justified by the seriousness of the offence" (Secretary of State for Health 2005).

c) Discouragement and forbidding aiding and abetting

Countries that stop short of prosecuting people who seek treatment abroad to evade their local legislation can still attempt to discourage such travelling. Respect for reproductive autonomy can lead to the tolerance of patients travelling abroad, but most will consider reimbursing these patients as a bridge too far. A country of which the majority of the citizens oppose certain types of treatment, should not fund the obtainment of this type of treatment when citizens go abroad.

Besides ruling out monetary assistance, clinical assistance from within the restrictive country can be prevented. The Human Genetics Commission in the UK recommended that British physicians or centres should not help those who are planning to go abroad for treatments not licensed in the UK. Clinics should not prepare nor collude with the patients who go abroad. This attitude could be justified by the wish of the clinic, and indirectly the country, to avoid direct complicity. It is well known that many physicians help their patients. Two questions can be raised regarding this issue: 1) what exactly does “treatment not licensed in the UK” mean? Egg donation is allowed in the UK but due to the shortage of donors, many patients travel to Spain to avoid the long waiting lists. Part of the explanation for the number of donors in Spain lies in the reimbursement of approximately 900 euro. This amount is much higher than the 250 pounds that is allowed in the UK but it is not self-evident that it should be seen as payment. Would a court decide that this difference was sufficient to forbid any collaboration by British doctors? 2) Which acts should be considered as “preparing and colluding”? Does that include counselling the patients about what they should ask when going abroad? Is referring a form of help? These issues become complex when one takes into consideration the reality of international consortia of clinics with branches in different countries with different legislation. Physicians may also have strong financial incentives to channel patients to clinics abroad (Heng 2006). There are indeed indications that fee splitting (the receiving doctor pays a fee to the referring doctor for each patient sent to him or her) is a common practice in private clinics. Heng’s strongest argument, however, refers to the special position of the doctor: “because fertility doctors received a licence to practice medicine in a particular country, it would therefore be their contractual as well as fiduciary obligation to uphold rather than undermine the “spirit and essence” of any legislation pertain-

ing to clinical practice in their country” (Heng 2006). The question is important because some organizations defend the position that the doctor in the home country still carries a responsibility and should take the best interests of the patient at heart. Leaving the patients to fend for themselves might have bad consequences when the patient attends a clinic that offers poor quality services. Thus, while the best interest of the patient pleads against accepting “referral fees”, it does not plead against referral in itself. Besides referral, also counselling in the patient’s home country may be advisable especially since not all clinics provide counselling and even fewer provide counselling in the patient’s native language (ESHRE Task Force on Ethics and Law 2008). By forbidding these supporting actions, the country shows that it attaches more value to obedience to law and regulation than to the welfare of the patient. The British government, while defending that it would be inappropriate to encourage people to go overseas, still focuses on better information for patients about specific safety and legal concerns associated with treatment abroad (Secretary of State for Health 2005).

d) International pressure

Finally, a country can make efforts to uphold its laws abroad by persuading less restrictive countries to review their policies. The call for harmonization should frequently be seen in this light. Every country hopes that harmonization will lead to others adopting their laws, not to them adopting another country’s laws. Moreover, most countries highly value their national sovereignty and thus may consider it an insult when another country openly tries to impose its views. In the context of human embryonic stem cell research, it has been argued that consistency requires that a country that objects to certain practices should be committed to stopping this unethical practice outside its own country, regardless whether its own citizens are involved (Savulescu 2000). Even if this would be right, there would still be many ways in which a country could do that, the most realistic of which is probably to plead their case on a European or international level. Human Genetics Alert recommended that the British government “should make the utmost efforts towards promotion of the international harmonization of legislation and the discouragement of reproductive tourism” (House of Commons Science and Technology Committee 2005).

7.5. State and pluralism

A restrictive country has a number of ways in which it can try to discourage or prevent its citizens from seeking cross-border reproductive care or to punish them if they do so anyway. But should they? While it is in principle praiseworthy that a government tries to entice moral behaviour in its citizens, it is quite another thing to coerce citizens into moral behaviour, especially when reasonable people disagree on what is or is not immoral behaviour. In many western societies, there is a trend to move away from sanctioning acts that many perceive as immoral, but that do not pose a direct threat to others. Examples include adultery, sodomy, voluntary prostitution, suicide, use of soft drugs, gay marriage et cetera. This trend indicates a receding influence of religion or other ideologies on public policy and an increased importance of the protection of fundamental rights and liberties such as freedom of expression and freedom of religion. In this atmosphere of increasing moral pluralism, extraterritorial jurisdiction is unwarranted. We have previously argued in the context of embryonic stem cell research that in the face of a reasonable moral disagreement that exists both within and between different nations, the best way to maintain state neutrality (while being forced to regulate a certain field) is to allow citizens with diverging views to travel to jurisdictions that are more in accordance with their own beliefs.

With regard to limitations that are not of an ideological kind, but founded on safety concerns (such as the number of embryos transferred or an age limit), one might argue against a relativist approach as in this case possible victims are involved, being the children that might result from forbidden procedures. The reason why these laws are issued are indeed to protect future offspring, a concern that legitimately limits the right to reproductive freedom. That being said – as we already indicated – the differences in legislation between countries are of a gradual kind (for example the number of embryos implanted or age of the mother), and the chosen cut-off points are arbitrary. While the health concerns for a 45 year old woman may indeed be higher than for a 42 year old woman, it seems oddly disproportionate to fund a 42 year old woman's IVF-treatment, but to prosecute her if she seeks the same treatment abroad 3 years later. Skene (2007) proposed that nations develop national ethico-legal barometers that link the acceptability of a relativist approach (and

thus of accepting their citizens to travel abroad for reasons of law evasion) to the existing legislation regarding specific morally charged issues. If a country allows (or even funds) certain procedures, it is unrealistic that similar procedures which present a gradual difference with what is allowed, rather than a fundamental divide – would suddenly fall into the barometer's red zone (in which a relativist approach is unacceptable as it includes grave activities that are condemned on an international scale). In these cases, not imposing one's own views on morality on citizens abroad is not a sign of turning a blind eye or betraying one's beliefs. It is rather an effort to reach a compromise between countries that can be justified reciprocally (Gutmann & Thompson 1997).

7.6. Valid analogies?

In bioethical discussions, it is always useful to take a look at similar or related issues. Reasoning by analogy is a very valuable approach for two goals: (1) to reach a better conceptualization of new situations and (2) to obtain guidance about the right way to deal with new developments (Hofmann et al. 2006). The formal principle of justice stipulates that similar cases should be treated similarly. If similar cases are treated differently, one must be able to point out the relevant differences that warrant a different approach. Based on the structure of analogies in ethical reasoning as specified by Gillam (1997), analogies with patients travelling abroad to obtain reproductive care not permitted in their home country should have the following format:

- Extraterritorial jurisdiction is morally (un)acceptable in situation A.
- Seeking cross-border reproductive care is the same as situation A in all (or most) morally relevant respects.
- Applying extraterritorial jurisdiction when people seek cross-border reproductive care is morally (un)acceptable.

The UK Human Genetics Commission (2006) made an analogy between couples travelling abroad for reproductive care and parents travelling abroad for female circumcision (although it judged that the analogy was invalid). Could one argue that consistency requires that we adopt the

same attitude – either a relativist approach or the application of extraterritorial jurisdiction – in the case of cross-border reproductive care as in the case of female circumcision? Take a couple who had their daughter circumcised abroad because they believe it is in her best interests. How does this situation differ from a couple that goes abroad for an anonymous donor because it thinks it is better for them and the child that he/she can never contact the donor? Is the difference the seriousness of the violation? Or is it the fact that harm is done to a child that already exists? It is an interesting analogy because if it proves to be valid and strong, we can transfer the rules applied in that context to some applications of cross-border reproductive care. We would, for instance, never accept that a doctor in a country that condemns female genital cutting would refer the parents to a clinic abroad or would help them in any other way. The analogy would be fairly strong if the action of the parents to seek reproductive care abroad is considered as an instance of child abuse. Some authors consider withholding the possibility of finding out its genetic origins from the child as a violation of a basic human right (Blyth and Farrand 2004). This not only applies to couples who intentionally leave the country to find an anonymous donor but also to couples who visit a country (like Spain or Denmark) where donor anonymity is compulsory. Some people will assess female genital cutting as much more serious than genealogical bewilderment but one could argue that this is only a matter of degree, as for some donor offspring persons, the quest for one's genetic parents has an enormous negative impact on their life.

However, besides the obvious semantic dissimilarities between cutting out a child's genitalia and *in vitro* fertilization, there are also two major structural inconsistencies undermining this analogy that were crucial in our defence of cross-border reproductive care. The first one concerns the extent of disapproval. Painful, non-therapeutic surgical interventions on children unable to give their informed consent, resulting in increased child and maternal mortality rates is a clear human rights violation. Even countries with a high prevalence of female circumcision have now outlawed the practice following the ratification of the 2003 Maputo Protocol of the African Union (CAB/LEG/66.6), making it a crime that is fiercely denounced on an international scale. This is obviously not the case for donor insemination or inseminating a woman in her 40s. The second inconsistency is that the difference between legislations on female circum-

cision is not of a gradual kind. It is not the age of the girl to be circumcised that is the matter of debate, but the practice is outlawed in its entirety. Due to these two differences, the case for relativism is much weaker when female genital mutilation is concerned than when cross-border reproductive care is under consideration. What this analogy does illustrate though, is that even in this case, where we would expect less relativism, extraterritorial jurisdiction based on the nationality principle is not applied lightly. In Denmark and Austria, double incrimination is added for the extraterritoriality principle to apply. This implies that the act is only illegal if performed in a country that also prohibits genital cutting. In Italy, Denmark and the UK, the victim must have the nationality or residence of the country that applies the principle. In Austria and Belgium, the perpetrator must be found on the territory (Leye et al. 2007).

The second analogy was already discussed above, namely abortion. The strength of this analogy depends to a large extent on whether or not one attributes a person status to the foetus. Countries that do, will consider abortion as homicide and might want to apply the extraterritoriality principle. Those who do not, will consider violation of the law (for instance by going beyond the gestation limit) is insufficiently grave to invoke extraterritoriality.

The final analogy is the regulation of sex offenders. In the United Kingdom and a number of other countries, extraterritorial legislation can be used to prosecute UK nationals who commit such offences against children abroad (House of Commons Science and Technology Committee, 2005). There are two remarkable differences with cross-border fertility care: 1) child sexual abuse is illegal in almost all countries, and 2) these are offences against existing persons. The latter point opens a box of tricky philosophical problems.

Conclusion

Many infertile people seek reproductive care abroad. Some are motivated by the treatment cost or treatment quality, but for many the main reason is that they are unable or not eligible to receive the treatment they require in their own country. Opinions about which procedures are or are not ethically acceptable vary widely and this translates into a myriad of different

legislations. Besides a number of legal questions that surface when people undergo treatments that are not lawful in their country of origin, countries are also faced with a philosophical question, namely whether or not to accept so-called reproductive tourism. If they decide not to accept it, they can either take measures to prevent infertility patients from travelling, to prosecute them after the fact, to discourage them (financially or by prohibiting aid by their physicians) or to influence the policies of more permissive countries. We have argued that restrictive countries have good reasons *not* to intervene when patients seek treatment abroad. Not only because of the practical difficulties this would entail, but also out of respect for people's autonomy. Reproductive freedom is not an absolute right, but the case for relativism on this issue is bolstered by the fact that the supposed "crime" is not only legal but often even publicly funded in neighbouring societies and by the fact that the divergences between national policies are often of a gradual – not categorical – kind. Invoking extraterritorial jurisdiction when there is no double incrimination and no grave offence would therefore be a disproportionate measure. The most a country could do is to forbid the assistance of medical doctors but this measure is likely to cause more harm than good.

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8. Consumer Medicine Challenges

National Governance of Patient Rights

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8.1. Introduction

Consumer medicine has many dimensions. Services, patients, professionals and products cross borders. Even though concrete volumes are still unknown, it is an increasing phenomenon with both positive and negative implications. The positive is that people have a choice. The negative, related to treatments abroad, is that they escape national oversight and governance of health services which are built to serve the health system and its financing on the one hand, and to protect patients' rights on the other hand. The same applies for medical products ordered over the internet. European Union member states regulate pharmaceuticals and medical devices, but direct-to-consumer marketed genetic tests lack control.

Medical research, education and benefits of novel medical innovations progress differently in different countries. Countries have different amounts of resources. The nation states can prohibit certain services in their territories, if they think it violates their public moral. Provision of sensitive treatments, such as infertility treatments, abortion and euthanasia are thus regulated on the basis of national moral choices, but such laws are applicable only inside their territory. National moral does not, however, necessarily appeal to those citizens who have a concrete personal problem to solve. Furthermore, certain operations, such as plastic and eye surgery, may be significantly cheaper in a neighbouring country.

There is more information than ever about treatment options and services abroad and goods are easy to order over internet. People do not have to be satisfied with what their home country can offer, but they can actively look to other options. However, there is doubt whether patients in general are truly empowered consumers making rational choices, but are in fact subject to many deficits of information and rationality.¹

Whilst respecting patient autonomy, Nordic welfare states are built to protect the patient, to regulate distribution of limited resources, and to provide means for compensation if something goes wrong. The notion of “managed care” is applied when authorities try to influence costs, volume, quality and safety of health services. Complications due to a care that is not managed by the home country burden the local health care. This novel freedom of people to make their own choices has thus the capacity also to challenge the national health systems, governance and financing.

In this chapter I focus on two contemporary issues from a legal point of view: do-it-yourself genetic tests and patients crossing borders. I view these issues in light of the traditional patient rights regime and the challenges they pose to national systems. At the end I will briefly address the EU patient mobility initiatives.

8.2. Direct-to-consumer genetic tests

Genetic tests targeted for consumers through the internet have become more common. They offer determination of an individual risk for many genetic conditions. A person can discover whether he or she has an alcohol flush reaction, or male pattern baldness. A child can be tested to find out if he has especially beneficial genes for sports. A risk for more serious conditions can also be tested. However, these tests are rarely diagnostic, i.e., confirm a certain genetic condition. Instead, they indicate risk based on predispositions for common complex diseases, the possible onset of which are influenced substantially by lifestyle and environmental factors.

The main problem from the patient rights of view is the lack of appropriate information and counselling, accuracy of the results and their use-

¹ Buchner, Benedict. The Pharmaceutical package of the European Commission: Empowerment for Patients? Editorial in *European Journal of Health Law* 2009;16:201–206.

fulness. There may not be even any real treatment options. People also tend to have problems in dealing with figures describing probability.² The interpretation of test results and their implication for an individual belongs to genetic counsellors in the normal health care setting. Counselling is required both before and after the test. Particularly detecting causes for infertility is a complex exercise, and ambiguous results are prone to decrease reproductive confidence instead of bringing any assuring knowledge. Ambivalent risk figures are likely to worry people but actually the current public health knowledge can provide the same information. In brief, the results of these tests may have severe implications to individuals' life and behaviour and, for instance, to their reproductive choices. Therefore, they need special attention.

From a regulatory point of view, these tests have two elementary problems: at the moment, the majority of these tests are marketed from outside the European Union, and national laws usually apply only to health services performed within the health care system. They also combine a product and service, since only the test kit is sent to a consumer, but the medical service, analysis and consultation, occurs in a third country, usually outside the EU. It is thus a distance sales contract that combines both goods and services. Do individual countries or the European Union have means to interfere and regulate these new consumer markets?

So far legislation pertaining directly to genetic self-testing is lacking at the European level. The *In vitro* diagnostic –directive (98/79/EC) is applied to genetic tests also, but because they are classified as a low-risk device, no prior market authorisation is needed in the European Union. A research team that explored policy issues around genetic tests for common, complex diseases published its briefing for competent authorities in 2007.³ They highlighted some major problems in the *In vitro* diagnostics directive, and suggested certain policies for the Commission, such as, revisiting the risk classification and independent premarket evaluation, introducing a provision of analytic and clinical validity and clarification of some key concepts.

² Welkenhuysen M, Evers-Kiebooms G, d'Ydewalle G: The language of uncertainty in genetic risk communication: framing and verbal versus numerical information. *Patient Educ Counsel* 2001;43:179–187.

³ Hogarth, Stuart and Melzer, David. The IVD Directive and Genetic Testing – Problems and proposals. A briefing presented to the 20th meeting of Competent authorities. Cambridge 2007. Accessible via www.eshg.org.

One solution to govern the genetic tests would be to require similar premarket authorisation or bring them under the same scrutiny as other medicinal products.

Indeed, compared with medicinal products, the oversight is non-existent. Finnish customs recently reported a constantly increasing number of hazardous counterfeit medicines that are ordered through the internet, in particular erection pills. In Finland, for instance, it is a crime to import prescription-only medicines, and customs can confiscate unauthorised medicinal products ordered by postal delivery from abroad. A crime is committed when the goods arrive at the customs even though the client never receives them.⁴

Consumer rights legislation is applicable as regards to basic consumer protection provisions, such as the requirement of accurate information and fair contract terms. The EU Commission recently proposed a revision of the consumer legislation in Europe. The objective of the revision is to enhance consumer confidence in the internal market by decreasing the fragmentation, tightening up the regulatory framework and providing consumers with a high common level of consumer protection and adequate information about their rights.⁵ The Consumer directive is applicable as long as self-test kits and distance communication do not fall under other authorisations of law.

The Council of Europe Convention on Human Rights and Biomedicine (ETS No. 164, 1997, later referred to as the Convention) has relevant provisions on genetic testing. The Convention is an international legal instrument. However, it becomes a binding national law in the countries that ratify it. At the moment 22 countries have ratified it. Sweden is the only Nordic country that has not ratified the convention.

Article 12 of the Convention limits the use of predictive genetic tests to “tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling”. According to article 23 of the Convention, countries bound by the Convention shall

⁴ Finnish supreme court decision KKO 2007:49.

⁵ Proposal of the European Parliament and of the Council on consumer rights. Brussels 8.10.2008 COM(2008) 614 final.

provide appropriate judicial protection for infringements of the rights and principles of the convention.

The Council of Europe gave an additional protocol to the Biomedicine convention on genetic testing for health purposes (CETS No. 203, later referred to as the Protocol) in 2008. The general objective is to protect against improper use of genetic tests. Member states to the Council of Europe who have ratified the Biomedicine Convention can ratify this protocol to enforce it in their own jurisdiction.

Under article 2, the Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify genetic characteristics of a person, which are inherited or acquired during early prenatal development. Tests fulfilling this definition are called genetic tests in the protocol. Central to the definition is that tests are performed for health purposes. Thus, tests to determine sports genes or other non-medical conditions are not covered.

Article 5 requires that parties to the Protocol take the necessary measures to ensure that genetic services are of appropriate quality, they are scientifically and clinically valid, there are quality assurance programmes, and persons providing these services have appropriate qualification. Article 6 sets clinical utility as an essential criterion for deciding to offer the test in the first place. As regards the direct-to-consumer genetic tests, the article 7 is central: it sets forth that a genetic test for health purposes may only be performed under individualised medical supervision. This is the basic rule, and exemptions include tests that would not have important implications for the health of the person concerned or members of their family or with important implications concerning procreation choices.

The Protocol also establishes an obligation to parties to facilitate access to objective general information on genetic tests, including their nature and the potential implications of their results. The Protocol thus offers an excellent framework to develop criteria and conditions for legislation regarding genetic tests in general, and direct-to-consumer tests in particular. The scope of the protocol is not limited to the official health care setting. So far only five member states have signed the Protocol, with Finland representing the only Nordic country. This is a pity, because the Protocol is thoroughly drafted and reflects a multidisciplinary expert working group. Specifically concerning the direct-to-consumer genetic

tests I argue that parties to the Protocol are obliged to implement its provisions effectively.

Considering EU and international trade rules, restrictions to free movement of products and services need to be justifiable in the notion of public health interests.

Paternity tests also require testing for the child. This can be seen to interfere with the child's integrity and needs thus special consideration on the whole procedure

8.3. Cross-border travel for medical services

Patients have many reasons for seeking health services abroad: infertility treatments due to lack of appropriate services in home country ⁶, cheaper plastic surgery for non-medical conditions (eye surgery, bust operation), faster access to heart or hip operations, last source for medical innovation to cure serious illness, such as organ transplantation or stem cell treatment. Causes vary, but we should not value the acceptability of these choices under each individual. Instead, we should care about the quality and safety of these services, the information that is available and aftercare in view of patient rights.

Medical travel for organ transplantation is particularly susceptible to violation of human rights somewhere far beyond western eyes. One of the most appalling examples comes from China, where the state was involved in executing camp prisoners for organ transplant patients from abroad. The victims of this human rights violation were Falun Gong -practitioners whose activities China wanted to eliminate by imprisoning thousands of these practitioners.⁷ In brief, for every organ transplanted, one person of Falun Gong was killed. Travelling to the Philippines for kidney transplantations has also been criticized. There nobody dies, but the other kidney is removed from the poor people for money.

The European Society for Human Reproduction and Embryology (ESHRE) has been collecting information on fertility treatments per-

⁶ See Pennings and Mertes in this volume.

⁷ Matas, David and Kilgour, David. *Bloody harvest. The killing of Falun Kong for their organs*. Seraphine Eds. Canada 2009. The preceding reports can be downloaded also at <http://www.organharvestinvestigation.net/>.

formed in European clinics.⁸ In a recent study, ESHRE produced concrete evidence of fertility travelling in Europe. During a one-month period, the ESHRE Task Force analysed data from six clinics in Belgium, the Czech Republic, Denmark, Slovenia, Spain and Switzerland. The main reason for going abroad for fertility was to avoid legal restrictions at home, followed by the problems to get treatment.⁹

Nordic countries have also great variety in the available palette of reproductive treatments, restrictions and their implications to those involved.¹⁰ Sweden was one of the first countries in the world that abolished anonymity of the sperm donors in 1985. It was followed by Norway in 2004 and Finland in 2007. Abolishment of donor anonymity has resulted in movement of patients to Denmark for anonymous sperm donation. Until recently, ovocyte donation was not allowed in Sweden and surrogacy is still not possible. Couples or women went to Finland for surrogacy and ovocyte treatments. Thus, only within Nordic countries people travel due to different legislation and available services.

Seeking abortion from abroad is clearly one medical action most clearly influenced by national restrictions. An abortion may be almost totally prohibited except for some serious conditions. Therefore, thousands of Irish women travel to the United Kingdom for abortion every year. The European Court of Human Rights (ECHR) has examined a number of cases related to abortion. At the time of writing this text, the application of three Irish women is subject to hearing in the Grand Chamber of ECHR. They claim that their human rights are being violated under several articles of European Human Rights Convention, because they cannot have abortions according to the Irish Law.¹¹ International activities related to abortion have also emerged, such as a Dutch ship which claimed to have the intention of providing information for women in need of an abortion, and in general promote freedom of abortion. Upon approaching Portuguese waters, the Portuguese authorities prohibited access of the ship to its waters and harbours, among others, because they

⁸ The 9th such report, see: V. Goossens, G. Harten, C. Moutou et al. ESHRE PGD Consortium data collection IX: cycles from January to December 2006 with pregnancy follow-up to October 2007. *Human Reproduction* 2009;24:1786–1810.

⁹ ESHRE Press Release June 2009, at www.eshre.com. Study not published yet (?).

¹⁰ Burrell, Riitta. Assisted reproduction in the Nordic countries. A comparative study of policies and regulation. TemaNord 2006:505. The Nordic Council of Ministers, Copenhagen 2006.

¹¹ A, B, and C v. Ireland. Application No 25579/05. ECHR Press release 9.12.2009. A decision of admissibility and a potential judgement will be made later.

alleged that once on board, Portuguese women would be treated with abortion bills, which are illegal in Portugal. The Dutch and Portuguese associations involved brought the case into the ECHR complaining that Portugal violated several human rights provisions. The ECHR ruled that Portugal had violated freedom of expression under Article.¹²

The timeframe to perform abortions also varies in national laws. In Sweden, abortion is allowed up until 18 weeks of pregnancy on request; i.e., without specific reasoning. Swedish clinics had reported an increase in foreign couples who came to Sweden for abortions due to the undesired sex of the baby. In May 12, 2009 Sweden was in the headlines all over the world, when Socialstyrelsen had declared that medical personnel cannot deny abortion even if it is performed for sex-selection.¹³ Norway is explicitly prepared for such requests in its abortion legislation, as under Norwegian law (*lov om humanmedisinsk bruk av bioteknologi 2003:100*) the sex of the future baby shall not be revealed before 12 weeks pregnancy (save for some serious sex-specific diseases), and on the other hand, abortion after 12 weeks requires specific grounds (*lov om svangerskapsavbrudd 1975:50*).

Medical injury compensation regimes also vary internationally. Nordic countries are among the few who have adopted a non-fault system, and hospitals have patient ombudsmen to assist a patient in case of an injury to show how to make a claim. Litigation is not necessary, but possible later, if the decision of the Patient Insurance Board is not satisfactory. In many other countries the patient has to prove negligence in the course of medical treatment through litigation procedure.¹⁴

International clinics advertise for controversial medical treatments that are considered at most experimental by European standards. Still they attract some people. Medical innovations aiming at curing the patient and research trying to achieve scientific results should be distinguished.¹⁵ Who is responsible, if the medically dubious operation or, for instance, a stem cell treatment results in serious complications once back in home country? Even though there may be a contract between foreign clinics and

¹² See *Affaire Women on Waves et autres c. Portugal*. Requête no 31276/05. (Only in French).

¹³ *Dagens medicin* 12.5.2009. www.dagensmedicin.se.

¹⁴ Douglas, Thomas: Medical Injury Compensation: Beyond "No-Fault". *Medical Law Review* 2009;17:30–51.

¹⁵ Lindwall, Ole and Hyun, Insoo: Medical Innovation Versus Stem Cell Tourism. *Science* 2009;324:1664–1665.

the patient, an ill patient is hardly in a position to pursue his contractual rights on the other side of the world. On the other hand, patients are not entitled to compensation of a bodily injury from the national patient compensation scheme because the treatment was not provided in the geographical area of jurisdiction. For instance, the Finnish Patient Injuries Act (Law 585/1986) applies to bodily injuries sustained by patients in connection with medical treatment and health care given in Finland. All health and medical care providers must be covered by insurance against liability arising as provided under this Act. So, if a Finnish patient goes elsewhere for treatment, any injuries arising out of such treatment are not covered under the Finnish patient injury scheme. The question arises as to who pays if the patient is so severely injured that he can no longer work or needs a long sick leave.

The national health care system has to deal with the consequences, because it has to provide for at least necessary emergency treatment for a patient. Further, will the social security systems be affected, if the injured person can no longer work or will require long intensive therapy to recover?

The more complex the treatment, the more prone it is to complications. Complications can of course occur from treatments belonging to normal medical practise in the home country. However, treatments abroad may not meet the international medical standards and quality requirements pursued in the Nordic countries. National health policies aim to influence the level and quality of services. Allocation of resources demands assessment of the safety, impact and efficiency of the treatments. For instance, secondary health care usually requires certain conditions set by this assessment.

The ultimate question is then who should bear the risk? As stated above, the establishment of national requirements and oversight mechanism entail an element of risk calculation. Are taxpayers obliged to pay for treatments that have been performed outside the national regulatory system?

8.4. The European Union and patient rights

European Union member states have in principle competence to plan their health systems and services and means to finance them. European Union's competence is complementary and supportive according Article 168 (ex 152 in EC Treaty) of the Treaty for European Union (so called Lisbon Treaty). However, the Commission has gained slightly more competence to contribute to the achievement of the objectives set out in Article 168, for instance, by co-decision procedures. Harmonisation of national laws in the health field is excluded.¹⁶

As stated above, the member states are thus entitled to rule and organise their health system as they like. This competence has been affected substantially by the provision of freedom of services under Article 56 the Treaty for European Union (Ex Article 49 in EC Treaty). Under the established practise of the ECJ, health services are included in the provisions of freedom to provide services within Article 56. Albeit the member states have a certain margin of appreciation, they are not allowed to apply measures that restrict the free movement of services. Countries have tried to defend their restrictions by appealing that they are necessary in order to maintain the balanced social security system, or to protect public health or morals. It has remained to the ECJ to determine the acceptability of the derogations in each case. ECJ has also since long ruled under which conditions a patient may obtain health care in another EU member state and to have the costs reimbursed by his home country. Such conditions include that the treatment is normal in professional circles and that it is necessary for the person in question. Given the plurality and complexity of national health systems as regards to health insurance schemes, reimbursement issues and services packages, patient rights protection, and so forth, the legal environment is still far from clear.

To clarify the legal situation, the European Union started drafting the directive on patient rights after health services became excluded from the Services Directive in 2008. The proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care was presented in July 2, 2008. The aim of the

¹⁶ For a good analysis of EU competence in the health field, see Hervey, Tamara K & McHale, Jean: *Health Law and the European Union*, pg. 69–106. Cambridge University Press 2004.

directive is to establish a general legal framework for provision of safe, high quality and efficient legal framework in the European Union and to ensure free movement of the health services. The directive would not change the rights of the member states to define the benefits and services packages they provide. Equally, patients will not get any new entitlements to have certain treatments abroad.

Instead, the draft directive strives for developing clarity so that patients get clear information which enables them to make informed choices about their health care and to use their rights. It will also establish clear rules which member state is responsible in each case. De facto, the directive means that member states may have to upgrade their quality and safety standards according to international medical science and generally recognised good medical practices. They shall also ensure that healthcare providers are monitored and corrective actions are taken when necessary so that patients have means of making complaints and are guaranteed remedies and compensation when they suffer harm from the healthcare they receive. Patients from the other member states shall be treated equally.

The issue has been politically sensitive after the services directive. Gradually, however, a consensus has been achieved and the large majority of the delegations and the Commission have been reported to be ready to accept the last version of the draft directive. Still, in their meeting on November 25, 2009, the Council of the European Union was invited to examine the draft once again because certain issues had remained unsolved and the entry into force of the Treaty of Lisbon will require some technical amendments in the draft.¹⁷

Conclusion

Contemporary legal provisions rightly emphasise the autonomy of patients. However, at the same time they have established safety mechanisms to enable autonomous decision-making; such as the right to appropriate information, system of patient rights and complaints, oversight of legal professionals, marketing licences for drugs, etc. Despite the free markets, or

¹⁷ Note from the Permanent Representatives to the Council November 26, 2009. 16005/09. At <http://register.consilium.europa.eu/pdf/en/09/st16/st16005.en09.pdf>.

maybe just because of them, societies must pay attention to these new phenomena to protect their citizens even if this entails some elements of paternalism. On the free markets, consumers have been traditionally regarded to require a certain level of protection, as there usually is some imbalance between the service provider and the consumer. This notion is still valid as the consumer legislation is currently under revision to tighten up regulation to protect the consumers, as mentioned above. To be able to act as an enlightened and alert consumer on the markets of medical services and medicinal products, one should be a master of many curricula. We should therefore be careful if we take a rational consumer as a starting point when we think of regulation on these issues, and not throw the baby – i.e., achievement of patient protection regimes – with the bathwater.

9. Mobilities of Medical Care – A note on the Political Economy of Health

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Today, more and more people from wealthy industrialized countries travel abroad to get better or cheaper medical treatment – or any treatment to their rare or difficult disease. In addition, cross-border and off-shore medical services, or even “miracle” cures allegedly based on cutting edge medical science, are increasingly available through the Internet or other global media. It is undeniable that these phenomena represent an important trend in current medicine that has potential to affect the ways and ethos by which we are engaged with medicine and health care services, in the Nordic countries as well as in the rest of the Westernized world. In this paper, I approach this change in medicine from a perspective of political economy by situating it in two context: first, as regards to historical metamorphoses of public health care, especially the recent neo-liberal turn; and, second, as a part of increasing global mobility of knowledge, personnel, technology, medicines and even body parts and tissues within the field of medical care.

It is obvious that travelling for medical care is not an invention of our time. In the 19th century, it was commonplace among wealthy and educated classes in Europe to travel long distances to receive treatment for tuberculosis in specialized countryside sanatoria, or to enjoy water treatments in numerous spas around central Europe (e.g. Heikkinen 1991; Häggman 1995; Seeliger 1988.) It is worth remembering that the quest of medical help abroad by an individual person was also involved in the onset of abortion wars in the U.S., while Sherri Finkbine, a mother of four

children and pregnant with a Thalidomide affected fetus, travelled to Sweden to have her pregnancy legally terminated in the early 1960s (Luker 1984, 62–65).

However, the tendency that people increasingly seek medical services abroad and travel long distances to receive the treatment they want should be seen in a slightly different light than the mentioned historical examples. In the past quarter of a century, global circulation has become a major characteristic of all aspects of medicine: research, clinical practices and commerce. Never before have knowledge and research data, technologies, medicines and other means of cure, organs, tissues, personnel and money, in the forms of payments, revenues and investment capital, moved across national borders so rapidly and swiftly as they do today. Also, medical institutions from research biobanks to private companies providing health care services are becoming multinational. It is quite clear that these developments have been greatly facilitated by the strengthening of trends which transform medicine into a transnational business at the turn of the millennium. This is the context in which the increased medical travelling and the extended supply and demand of cross-border and off-shore medical services should be situated today.

Before I move on to discuss cross-border travelling for medical care as a form of global medical mobility I will present an outline of motivations for such travelling. People travel abroad in hope for appropriate medical treatment for a number of reasons. First, the treatment they want might not be available in their home countries. This might be due to legal restrictions. The paradigmatic case of medical travelling motivated by legal or policy restrictions is the patients crossing national borders while seeking services in reproductive medicine, both historically (abortion) and today (assisted reproduction). In addition, more and more people with rare or life-threatening disease seek cures from experimental or maverick treatments disallowed for clinical use in their home countries. Various treatments for cancer, and “miraculous” gene and stem cell therapies for many difficult conditions are increasingly available around the world. The unavailability of some treatments may also derive from the fact that national health services cannot afford certain sophisticated treatments; in these cases, patients may opt to seek such treatment abroad, if they can afford it.

Further, people may travel abroad if they face difficulties in accessing medical service they need or want. The global market of illegal organ transplantation is an infamous example of this (see Scheper-Hughes 2005). An example from Finland is less dramatic where many people who have waited for quite a long time to get a minor heart or hip operation through the public health service have travelled to Estonia and had the surgical operation done faster and cheaper there. This brings us to the third motivation of medical travelling. For some people, the reason to seek medical service abroad may be to get better treatment at affordable price. In these cases, medical travelling is based purely on a consumer choice.

What I will say about the expanding mobility of medicine and the parallel development of increasing commercialization of health care will highlight the latter aspects of medical travelling. I will leave aside the mode of medically motivated travelling that can be seen as a means to circumvent restrictive legislation or policy (see Pennings and Mertes in this volume). In most cases, people with this kind of motivation to travel abroad seek abortion, some form of assisted reproduction or some experimental treatment that is prohibited or strictly restricted in their home countries. Instead, medically motivated travelling in which personal wealth and aspirations to seek medical care – sometimes desperate, sometimes more wellness oriented – play a crucial role will be the focus of my discussion. Undoubtedly, the latter sort of “medical tourism” is a growing trend in our society. Thus, I ask how do the current cross-national, even global medical business and neoliberal changes in health policy of the western welfare states encourage people and open new opportunities for them to seek medical services wherever top quality treatments at affordable price are available, even abroad and at long distances.

9.1. Medical care as a social service: nation and community-based health care

Before discussing the sources and consequences of the increase and expansion of mobility in medical care, I will present a sketch of medical care as a social service within the welfare state. What I am going to say is based particularly on characteristics of public health services in the Nor-

dic countries and the National Health Service in Britain between the end of the Second World War and the turn of the millennium.

The way medicine as a social service was conceived and organized basically discouraged and hindered mobility of medical care, especially the mobility of persons, both personnel and the patients. This was obviously due to the fact that public health care provision was embedded in the national system and community-based institutions and services with regionally defined populations. According to a core principle of organizing medical care within the national health services, people should have gotten basic medical care or have access to specialized services where they lived, worked or studied. (E.g. Armstrong 1983; Porter 1999, 196–218) Moreover, the national health care system held the great majority of the professional positions available for the physicians. Thus the state was capable of gently constraining the traditionally liberal profession through professional and economic ties. The state also attached the authority of the medical profession to public power. Within the welfare state, the professional identity of the physicians was firmly connected with their status as expert civil servants. (E.g. Allsop 1995; Erichsen 1995; Jauho 2004)

However, a feature of medicine as a set of activities and institutions which extend beyond the national boundaries was established during the heyday of the western welfare state. This internationalization of medicine took primarily place through international organizations that connected national actors, not by mobilization of multitude of actors to travel and connect across the borders. Consequently, it was thought that if knowledge, things and people relevant to medical care moved across the borders and around the world in a large scale, this mobility and circulation ought to be engendered and governed by international organizations or systems. An example of this development is a significant role of the World Health Organization in health policy in the latter half of the 20th century. Another example is provided by blood banking. Blood banks based on voluntary donations – a system hailed by sociologist Richard Titmuss (1970) as an embodiment of the altruistic ethos of the welfare state – have been national organizations with permanent international cooperation and coordination through organizations like the International Red Cross. With advances in blood processing technology in the late 1960s and the 1970s, international exchange and circulation of blood products became more intense – and troublesome because the “altruistic”

European blood banking system was mixed up with the U.S. system based on commercial blood banks. (Waldby & Mitchell 2006, 41–49.)

9.2. Medicine starts to travel

As is well known, public health care systems created its own cracks and dilemmas and ended up in an organizational and financing crisis by the end of the century. There were numerous inherent sources for these problems, and here I want to point out only two of them. First, public health care systems have extended the scope of medical care and encouraged the demand for services. This development, referred to as “medicalisation” by many scholars (for an overview, see Conrad 2007), has ploughed the soil for health consumerism to grow in. Second, the pace of introducing technical novelties in medical care has been rapid in the past decades. Advances in diagnostic and care technologies have made the scope of treatments wider. Rapid technical renewal has also made many treatments more expensive and thus considerably increased the costs of maintenance of the whole medical machinery. These tendencies have facilitated the increase of the unmet needs and dissatisfaction towards the public health care.

The development has brought public health care institutions to a situation familiar also from other welfare services: they have become incapable and indecisive when limited resources can simply not meet the unlimited needs (see Rahkonen 1995; Salter 2004, 5–7). Certainly, this has led people who can afford to seek medical services from private market, even abroad, and thus created a niche for consumer-oriented medical traveling. However, I claim that problems with public health care provision are not enough to give rise to a growing potential for travelling abroad in hope of medical treatment and to actualize that potential. This can only happen in a social environment in which overall mobility of knowledge, techniques and people has become a dominant feature of medical care.

I would like to point out three factors that have greatly facilitated the emergence of such an environment. First, pharmaceutical companies have grown into multinational enterprises marketing and selling their products, carrying out research activities and lobbying physicians and medical authorities all over the world. The expansion started in the 1960s, and since the 1980s the revenues of pharmaceutical companies have increased in an

incredible manner, making it one of the most profitable global industries. (E.g. Angell 2004; Avorn 2005.) This development has had a major influence in the making of global business as the framework of today's medicine; at the moment, global business networks and transnational corporations are spreading rapidly into the areas of medical research and provision of medical services.

The second development that has put medical technologies, things and people really on the move around the world is the rapid technological development of medicine since the 1980s, genomics being the prime example and spearhead field of high-tech medicine. Although the Human Genome Project was an U.S.-based endeavor, it connected laboratories and research groups across national borders. The HGP and the technical inventions in genomics which made it possible were greatly based on the work of private laboratories and small innovation companies which sought commercial applications of the knowledge and techniques they produced (see Rabinow 1997; Davies 2001). At the turn of the millennium, genomic medicine became impregnated by commercial interests, practices, institutions, competition and expectations in a manner well exemplified by the rise and fall of Decode Genetics in Iceland (Pálsson & Rabinow 1999; Pálsson 2002; Rose 2003). Another example of commercial saturation of a medical specialty is reproductive medicine, in particular assisted reproduction technology. All in all, medicine and health care form the main global playground for the biocapital, and it is the mobility and circulation of biocapital that form a major condition of all medical care today (see Sunder Rajan 2006; Rose 2007, 31–39.)

9.3. Health care turns into commodities

The third factor enhancing the mobility of medicine and the related tendencies of commercialization of medical care is the recent neoliberal season's change of the health policy in Northern Europe where universal health insurance and public health care system create the basic condition of the provision of medical care. Surely, consolidation and expansion of the global medical business have not engendered the turn of health policy towards market and business rationales, yet the line of change that could be called privatization of health care has a great affinity with the global

commercialization of medicine. In Northern European countries and also in the EU in general, the economic rationale has become more intensive in policy-making on all levels of health care during the past quarter of a century. As a consequence, the aspiration to subsume every aspect of health – even “quality” of both life and services – under cost/benefit calculations and auditing is becoming the ethos of public health policy. (E.g. Salter 2004; Hänninen 2009; Ollila & Koivusalo 2009.)

Privatization of health care is a cornerstone of this “new public health”. The current situation of welfare services and policy, health care included, in Northern European welfare regimes, especially in the Nordic countries is all too familiar from numerous studies and policy documents. Politically, the leading idea is to define limits to the welfare state, and in practice the state is withdrawing from responsibilities and rule concerning the provision of services and even from guaranteeing social security. Economically, costs of services are rising and expected to climb rapidly. (For an overview see Julkunen 2001; 2008.) Privatization refers to an array of responses, or lines of action, in this situation.

There are three prime elements in privatization. First, the role of private medical companies, including pharmaceutical corporations, have become bigger in public health care due to three developments: increase of markets of new pharmaceuticals and therapies, outsourcing of public medical services, and the expansion of “public-private partnership” arrangements as a mundane way to develop or re-organize service provision (E.g. Salter 2004, 157–187; Vuorenkoski & Hemminki 2004; Ollila & Koivusalo 2009). Second, the New Public Management rationale has introduced a lot of new styles of organizing health care and also other welfare services like opening of public services to “competition”, creating virtual markets inside public administration, organizing public health care institutions as if private companies, and introducing corporate management models and ethos, or rather pathos, into public services (Mills et al. 2001; Salter 2004, 68–82; Ollila & Koivusalo 2009). Finally, health and medical care have become more and more individualized, even if they are considered as subjects of public policy. At the turn of the century, three trends have reinforced the notion of health as a primarily personal matter. People are increasingly encouraged to take responsibility of their own health and health care by many medical experts and authorities, politicians and advocates of wellness culture (e.g. Greco 1993; 2004; Rose

2001; Palola 2009). Lay awareness and expertise of medical treatments and health issues have become more sophisticated with the expansion of patient activism and health consumerism (e.g. Greco 2004; Novas 2006). Expectations of so-called personalized medicine, embedded in the promises of high-tech medicine like genomics and stem cell technology, have intensified among the medical profession, business and the public (Hedgecoe 2004; Helén 2004). The latter development in particular has encouraged people to seek experimental or maverick treatments, either as a last hope or enhancement, wherever they are available.

Privatization has reinforced the notion of health care – or even health – as a profitable business in our public health rationale and institutions and in the environment that public health care operates in. This requires from practitioners, authorities, policy-makers and the public to think every aspect of health and every activity of health care and medicine as a commodity that can be priced and then bought and sold. And it also requires that the environment – from legislation to marketing – should be molded into marketplaces where medical goods can be exchanged. Telling examples of this change is provided by the EU legislation and policy that increasingly subsumes public health viewpoints to the objectives of commercial and industrial policy to remove “obstacles” from free competition and the movement of goods and services within the Common Market area (e.g. Koivusalo 2009). The current EU policy and also national policy in many European countries emphasize increasingly consumer or client centered medical services as the new core rationale of public health services. This idea is very congruent with the tendency of commodification of medicine and health, and it has emerged in different contexts: in New Public Management discourse, professional discussion in nursing, among health authorities and in demands of patient activist groups. All this have created a rationale by which the patients are replaced by clients and customers who have needs and demands of medical goods and services and to whom health care system, both public and private, should provide these goods and services (E.g. Tritter et al. 2009). In a sense, such a view of medical treatment as a service to match consumers’ needs and aspirations and as a good to attract consumers has made the treatment of illness and curing people secondary tasks of medicine.

9.4. Ethics within a political economy

It is not hard to see how a growing trend of cross-border or off-shore medical services is congruent and related to the developments discussed above. With an increased mobility of medical knowledge, techniques, goods and people, with the increasing commodification of medicine and health, and with neoliberal trends in health policy supporting cross-national health care markets, new opportunities have been created for medically motivated travelling and people are increasingly encouraged to travel abroad to get treatment they want. Simultaneously, the general trends of globalization and commercialization of medicine have affected medically motivated travelling so that seeking medical services abroad is more and more motivated by consumer aspirations and supplied by commercial institutions. This tendency towards consumer orientation is well exemplified by the change of the focus of “reproductive tourism”: between the 1950s and the 1990s, the patients of cross-border reproductive medicine were mostly women seeking abortion prohibited in their home countries (Sethna & Doull 2009); today, they are increasingly clients of full service infertility clinics with transnational networks (Blyth & Farand 2005).

In the final section of my paper, I discuss how medical business and health politics that encourage global mobility of medicine potentially increase also the patients' mobility. I also explicate how ethical problems of medical travelling are entwined with the ones of policy-making in the context of commercially oriented and cross-national public health care.

Besides the foundational principle of medical ethics that the physician should not deliberately cause harm to the patient, there is also a basic ideal that the patient should be provided with the best possible treatment by the practitioners of medicine. Ethical principles are actualized and given a concrete content in a context of society and institutions of medical science and care. In general, medical machinery today is characterized by rapid technological advances and intense global connections through which knowledge, devices and people move. These basic features facilitate the widening of what can be considered as the “best possible” medical treatment. The commercial activities and institutions in medicine reinforce this extension by making the “best possible” – and more expensive – treatments more desirable and attractive among the public. All in all,

the key condition of the actualization of medical ethics today is the extension of the notions of what medicine is capable of doing.

Obviously, health politics and the rationale by which public health services are organised and provided form a context for actualisation of medical ethics. In the framework of the post-Second World War welfare states and national health policies in Northern Europe the principle of providing the patients the best possible treatments were given interpretations which can be summarised by the following welfare principle: *every citizen is entitled to appropriate medical care*. In the rationale of welfarist health policy, it is not assumed that individual citizens or citizen groups would actively demand medical services they are entitled to; rather, the principle of equal entitlement of citizens was seen as an idea guiding policy-making and planning of health services. Moreover, the definition of what is considered appropriate care is the matter of policy-making and planning, carried out by health authorities, politicians and medical experts.

A tendency to put limitations on medical treatments provided by public health services is inherent in the welfarist rationale based on the principle of equal entitlement. In other words, every citizen has equal access to limited range of medical treatments, and the scope of public medical care is defined by political and administrative decisions. The mentioned trends of current medicine – advances of technology, increased mobility, and expansion of health care business – put pressure on public medical services and, consequently, the limitations of publicly provided treatments and medical care become highlighted. In practice, the limitations set by public medical services are actualized in two ways. Either access to certain medical treatments are restricted by means of testing of the patients or suspended by, for example, putting people in need of a surgical operation onto waiting lists. The second way to actualize limitations of medical services is prioritization. Evaluation and making decisions which medical technologies or groups of patients have priority over others in public health care are routine activities in all levels of medicine – from clinical settings to national and EU health authorities. Assessment of new medicines and other medical treatments by the National Institute of Clinical Excellence (NICE) in Britain is an example of prioritization of technologies, and the evaluation of patients case by case for allowing or denying the reimbursement of psychotherapy by the special board of the So-

cial Insurance Institution (KELA) in Finland is an example of prioritization of the patients.

Once the public comes to understand that public health institutions limit the scope of medical services they provide, pursuits to overcome the limitations are intensified and demand of treatments beyond the scope of public service provision is also created. Private medical services provide one means to overcome the limitations of public services, and when people increasingly seek services from private clinics and physicians, health care markets expand and business opportunities are increased. In many countries with a traditionally strong welfare state, for example Finland, public health policy has given strong support to this “market solution” (Ollila & Koivusalo 2009). Patient activism and activities of mutual self-help by the people somehow afflicted by a certain disease form another type of “solution” to the limitations of public medical services, which has also become a reinforcing tendency affecting medicine and health policy both nationally and globally. In many cases, responses of patient activist groups or networks are political, aiming at expanding the scope of treatments provided or reimbursed by the national health care institutions. However, it should be noted that patient activism has interfaces with the expanding health care market. On the one hand, many patient groups work in alliance with pharmaceutical and health care companies. On the other hand, they advance health consumerism by promoting personal rights and choices as the primary mode of engagement with medicine and health care. (Novas 2006; 2007; Tritter et al. 2009; Toiviainen 2009.)

Furthermore, external limitations to what medical institutions can provide to people, both economic and administrative, have increased during the past decades. In the market oriented health care system in the U.S., the managed care system has greatly restricted the scope of treatments and medicines that are reimbursed to the patients by health insurance companies (Cutler 2004, 88–99). Neoliberal policy in the Nordic and other countries with a developed welfarist health care system has resulted in a similar narrowing of the public provision of medical services. Promotion of New Public Management and market rationale in national health services are not direct responses to shortcomings of those institutions. However, the basic ideas of the new rationale are congruent with the expansion of the market of medical services and of patient activism. On the one hand, neoliberal policy programmes seek to increase efficiency

(and profitability) of public services through the mechanisms of commercial markets and by methods of corporate management. On the other hand, they emphasize that the reforms of “rigid” welfare institutions increase opportunities for clients and patients to make choices over services. (Ollila & Koivusalo 2009; Palola 2009)

The expansion of the private health care market, intensification of patient activism and neoliberal health policy facilitate consolidation of another ethical rationale of the provision of public medical care, side by side or even overshadowing the welfarist idea of citizens’ equal entitlement to services. This novel idea can be called consumer principle and formulated in a following way: *the client has a right to choose the best possible medical treatment*. This idea is based on an assumption that people are active individual clients or consumers who seek medical services and other means of health care. It implicitly requires that people should personally demand and be on guard of accessibility and quality of public services.

If health policy and rationale of public provision of medical services are based on the consumer principle, then they should be against any limitations, prioritization or suspension of treatments by medical institutions or public authorities and encourage the expansion of the scope of services from which clients and patients can choose. Obviously, this sort of policy would also encourage regional and cross-national mobility of services and people, both patients and experts. Examples of such a tendency are numerous: in Finland, proposals to allow people to seek public medical services everywhere in Finland regardless of regional location have been made in public and they have gained support from experts of health administration and economics. Similar suggestions of arrangements by which national health insurance would reimburse patients for the treatments carried out in another country have been frequently made in the EU health politics as a part to include medical services into the opening of services to free competition in the Common Market area.

9.5. Pitfalls of the mobile medicine

Tendencies of medical care to become cross-national, saturated by commercial interests and driven by expectations of consumers in wealthy

industrialised countries in the West have problematic political and ethical implications. The new orientation of the provision of medical care may increase the patients' power of their treatments and bring some democratic tones into medical expertise, but it also has a great potential to create grave inequalities both globally and on a national scale. Strengthening the role of medical business in medical care and health policy supporting market orientation with client-centred ethos in public health care allows money to rule more and more in health care. As a consequence, wealthier people will have better access to medical services, and more opportunities for choice of treatments are opened to them. Better-off people benefit from increased mobility of commercial medicine, cross-border medical services and medical travelling included. Should national or regional public health services fight inequalities created by this tendency? This is a crucial question for health policy in the near future.

One response would be an arrangement by which public health insurance reimburses the patient for medical treatment abroad or imported services. An example of this comes from Israel where organ transplantations abroad are reimbursed by public health insurance. In many cases, a global illegal business that exploits poor people and violates ethical and professional codes of medicine is financed by the money of Israeli government. (Scheper-Hughes 2005, 158–159.) More generally, reimbursement of cross border or off-shore treatments would increase public health expenditure in an uncontrollable manner, thus depriving resources from national or regional health care and impoverish it. This development may lead to a situation in which people with rare or difficult diseases are increasingly compelled to travel abroad to get treatment.

Another option for national or regional health services is to participate actively in cross-border competition over the patients and their money. The policy suggestions aiming at “self-supporting” welfare services in many European countries encourage this sort of response. One consequence of this orientation is the detachment of medical care from the local needs. This, in turn, facilitate the formation of two-tier health care in which people and money coming from long distance skim the best services from the health care institutions while poorer local patients are provided worse treatments. This development may also increasingly compel people to seek medical care abroad. In addition, if local hospitals or clinics are involved in transnational business of medical research, provision

of public health care may become very dependent of medicines or other medical technology research agencies give them for testing. As a consequence, their clinical practices may be compromised to the point in which the patients are put in danger. Former socialist countries in Eastern Europe provide many examples of this (Petryna 2009).

Commercialized, client-oriented medicine has also provided space for growing patient activism and allowed patient groups' demands for their *right* to specific treatments, services or social benefits to become influential in health politics, both nationally and transnationally. Undoubtedly, this development has made medicine more democratic and, in a way, turned medical expertise into a negotiable issue. However, the growing impact of patient activism gives rise to political and ethical problems which can be summarised in the following question: Should prioritization of technologies or patients in regional or national health policy be made according to the demands of the patient activists? It is not easy to justify a negative answer, if the patient groups are considered to give people in need of medical care a voice and articulate their needs and expectations. However, if the scope of public health services will be defined primarily on the basis of the activists' voice and demands there is a danger that the making of health policy turns into an endless lobbying competition and into a sort prioritization from below. In this game, the most skilful and resourceful patient lobbies would probably be most powerful.

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