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THE RIGHT TO HEALTH AS A STIMULUS FOR INNOVATION: THE JURISDICTION OF THE FEDERAL CONSTITUTIONAL COURT IN LIGHT OF THE INCENTIVES FOR INNOVATION WITHIN THE GERMAN HEALTHCARE SYSTEM[1]

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ABSTRACT: Professor Wallrabenstein examines the right to extraordinary health care treatment in the German public and private health care system. The article shows that the right to health, in the jurisdiction of the German Constitutional Court, can be understood as counterbalance to the efficiency oriented innovation incentives in the given structures as it allows reimbursement for new treatment methods regardless of their efficiency at least in the field of death threatening diseases.

KEYWORDS: Innovation. Health care. Severe diseases. Constitutional rights. Germany.

Introduction

More than a decade ago, in 2005, an immediate constitutional right to healthcare treatment became established in German constitutional case law. A publicly insured patient suffering from a very rare disease (Duchenne muscular dystrophy) who had exhausted all of the other treatment options was convinced that magnetic resonance therapy would help her. Orthodox medical knowledge regards this treatment as esoteric and without significant benefit. But because all other potential treatments offered under the public health insurance system had been exhausted, the Federal Constitutional Court ruled in the patient's favor. The Court ruled that in cases of life-threatening and regularly terminal illnesses for which no (further) therapy is available within the public health insurance system, insured patients have a right to treatments

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that may not satisfy the general standards of evidence but offer a not too remote chance of a cure or alleviation of suffering.

In constitutional comparison, such immediate constitutional rights to treatment are regarded as typical of the welfare state. The 2005 decision is a leading case in this respect. Even more important was a subsequent decision in 2010 in which the Federal Constitutional Court upheld an immediate constitutional guarantee of a subsistence minimum that is in line with human dignity. Viewed from the perspective of very liberal states, constitutional social rights are regarded as being "socialist." The German constitutional system with its welfare state principle is exposed to similar criticism, although this is not how it understands itself.

In the following contribution I will develop a thesis that to a certain extent cuts across these fronts, namely, that the immediate constitutional right to health is an important and necessary catalyst for innovation in the German healthcare system.[3] Therefore, it is a good illustration of the fact that basic social human rights should not be regarded as being diametrically opposed to liberal positions and goals.

I will develop my position in the following steps. First, I will offer a brief and rough outline of the aspects of innovation of relevance for my topic, namely innovation in healthcare provision. The second step will be to present the German framework conditions for innovation within the healthcare system. As a result it will become apparent that, although the structures of healthcare provision that have developed over the past twenty years are indeed also intended to promote innovation, they focus on one particular form of innovation while neglecting other aspects. This will become particularly clear when, in the third step, they are compared with examples of other framework conditions. Finally, I want to show how in the German setting the immediate constitutional right to health functions as a catalyst for certain innovation potentials that are not sufficiently taken into account in the system. In doing so, I will also point out the specific advantages and disadvantages of the structure of an individual claim to innovative therapy.

[3] For international comparisons of general impacts of a right to health, see Hiroaki Matsuura, "Does the Constitutional Right to Health Matter? A Review of Current Evidence," CESifo DICE Report 12 (2), 2014, 35 (available at: https://www.cesifo-group.de/de/ifoHome/publications/journals/CESifo-DICE-Report/Archiv/CESifo-DICE-Report-2014.html; last accessed on 29.5.2018).

1. Innovation in Healthcare Provision

1.1. Promoting New Treatments versus Efficiency as Goals of Innovation

A variety of definitions of innovation and distinctions between different types or dimensions of innovation are offered in economic theory. They all agree that innovation involves more than a mere invention; rather, the invention in question must possess some additional value or utility. In the field of medicine and healthcare, one can distinguish between two fundamentally different objectives of innovation. On the one hand, innovation can be aimed at making something possible that was previously impossible, such as flying, generating electricity, or the like. On the other hand, innovation can be aimed at making something that is already possible more efficient—in the examples cited, developing more feul-efficient aircraft or generating electricity using fewer resources.

In healthcare provision, there is a fundamental need for both types of innovation. Firstly, it is good and desirable when new treatment methods, new medicines, or other new possibilities for treating illnesses are "invented." Secondly, it is good and desirable that these treatments are delivered as efficiently as possible and use up as few resources as possible, while at the same time being made available to as many people as possible. The development and availability of HIV vaccinations is a good example of both aspects of innovation. The seriousness of the AIDS epidemic in the highly developed countries played an important role in the development of the vaccine; presumably fewer efforts would have been made if the disease had occurred only in the so called third world. But today there is no doubt that the fight against HIV requires the availability of the vaccine worldwide, and hence the costs of vaccination programs must be tailored to the incomes and resources of developing countries.

Often both objectives cannot be achieved simultaneously. The framework conditions for innovation leading to something genuinely new are—at least often—such that resources must be available in abundance and little or no attention need to be paid to their efficient use. One aspect that plays a crucial role here, at any rate under market conditions, is the expectation of profit bound up with such innovation. Someone who may have invested a great deal of resources in developing innovation expects that these investments will subsequently generate a return on the market. To this end, he would like to market the innovation exclusively for as long as possible and therefore is concerned that others should not

copy his innovation. Trademark and patent law have been developed to protect such interests,[4] as can be seen in the pharmaceutical sector. But also when a surgical team masters a special surgical procedure, for example, or a hospital develops a special therapeutic method, the marketing opportunity presented by the innovation depends on how quickly or easily other providers can copy this procedure or method and whether the greater supply leads to a reduction in price.

1.2. Innovation, the Healthcare Market and the Right to Health

Once a medical innovation becomes available, those who can benefit from it—that is, those who are suffering from a particular illness—will naturally want to have access to the treatment. If, in a hypothetical, completely unregulated marketplace, the price of the innovative treatment were determined by the offer of the monopolistic innovator and the demand from the patient side, the price would be very high and, correspondingly, the sales opportunities very limited. Therefore, a healthcare system (also) has the task of making an innovation accessible to all those affected. This benefits not only the patients, but the innovator as well, because it facilitates full access to all patients. The innovator may be able to achieve, if not the maximum, nevertheless a good price, if the healthcare system undertakes to cover the costs also for patients who do not have sufficient personal means to afford an expensive treatment.

From the patients' perspective, the healthcare system thus realizes the right to health by granting them a claim to innovative treatments. It can be more or less successful in this, of course, depending on the level of coverage guaranteed. What is important for the following reflections, however, is that the organization of the healthcare system should also perform this function of promoting innovation. It is precisely in this sense that we should understand Article 12 of the International Covenant on Economic, Social and Cultural Rights when, in para. 2 lit d), it obliges the contracting states to ensure "the creation of *conditions which would assure* to all medical service and medical attention in the event of sickness" (emphasis added).

[4] See Joseph Schumpeter, *Theory of Economic Development*, trans. Redvers Opie. London and New York: Routledge, 1983 [1934].

2. The German Healthcare System: Incentives for Innovation

Under this heading, I would now like to offer a (very simplified) outline of the German healthcare system which is specifically intended to show where and how it enables access to medical innovation.

2.1. Framework Conditions

2.1.1. Statutory Health Insurance

Just under 90% of the German population are covered by and receive services within the public health insurance system (or, to be more precise, statutory health insurance[5]). In return for coverage, the members pay earnings-related contributions that flow into a central (federal) health fund.[6] From there, risk-adjusted lump sums are distributed for each insured person to the approximately 100 health insurance providers.[7] The latter handle the payments for the services delivered to the insured. Through contracts with the service providers, the insurance providers exert a certain degree of influence over the provision of healthcare.

The service providers treat the insured patients and bill the insurance providers directly. There are two different billing regimes, one for outpatient and the other for inpatient care. The scope of the billable services in outpatient care is decided centrally, with the most important body for this purpose being the Federal Joint Committee. Together with other committees it defines a detailed catalog of outpatient services, which assigns a certain number of points for each service. The total number of points received by a particular provider for all services delivered corresponds to that provider's share in the total volume of reimbursements. The result is that a given physician receives a certain fraction of the total reimbursements dispensed in her reimbursement region (for example, Hesse or Bavaria) during a particular billing period. This fraction is somewhat larger when a physician delivers more services and somewhat smaller when she delivers less services.[8]

In the case of inpatient care, the services provided and the reimbursement are negotiated directly by each individual hospital with the health insurance providers operating in

[5] In German: "Gesetzliche Krankenversicherung".
[6] In German: "Gesundheitsfonds".
[7] In German: "Krankenkasse".
[8] Further regulation hinders physicians from increasing their share disproportionately.

its region. The underlying model is a fee-per-case system that pays a lump sum reimbursement based on a catalog of types of illnesses. For example, a hospital can agree with the health insurance providers on a charge of x euro for an appendectomy or of y euro for the treatment of a heart attack. Hospitals are free to choose the concrete details of the treatment administered in each case, within defined quality standards.

This difference between inpatient and outpatient care is important with regard to innovation.[9] The remuneration scheme outlined above presupposes that a particular form of treatment is already established. Otherwise it cannot be assigned a point value in outpatient care, and in inpatient care the contractual partners also take the established forms of treatment as a basis for calculating the lump sum that can be charged for each case. Before new examination or treatment methods can be introduced into outpatient care, they first have to be approved by the Joint Federal Committee. In order to win approval, not only the medical benefit, but also the medical necessity and the cost effectiveness of the new method compared to those already approved, must be demonstrated.[10] As a result, outpatient care—insofar as the public health insurers shoulder the costs—remains within the boundaries of the tried and tested and innovation occurs only when it "pays off."

Things are different in the case of inpatient care. A hospital is indeed free to try out new treatment methods. However, it is more likely to do so if the new method is cheaper, since the hospital receives a single lump sum for each case. Alternatively, the hospital may apply a new method if this is reimbursed separately. This is possible in special cases that are not covered by the diagnosis-related flat fee system, such as particularly rare diseases or conditions involving special complications.[11] Under certain circumstances, this additional, treatment-based compensation has to be agreed upon separately with the insurers in advance. But if no other adequate treatment is available, the health insurers are obliged to cover the costs. In such cases, Federal Joint Committee only has a limited right of veto in that it can expressly exclude methods that have been proven to be problematic.[12] Thus far, however, it has only rarely made use of this right.

[9] On the legal details, see three recent dissertations: Nils Ullrich, *Finanzierungslücken bei medizinischen Innovationen?* (2013); Sina Gottwald, *Die rechtliche Regulierung medizinischer Innovationen in der Gesetzlichen Krankenversicherung* (2016); and Isabelle C. Hägele-Rebmann, *NUB-Methoden im Krankenhaus im System der GKV unter besonderer Betrachtung des NUB-Verfahrens: §§ 137 c, 137 e SGB V, § 6 Abs. 2 KHEntgG* (2017).
[10] § 135 SGB V (Fifth Book of the Social Code – German Health Insurance Code).
[11] § 6 para. 2 KHEntgG (Hospital Remuneration Act).
[12] § 137e SGB V. For a general account of the new examination and treatment (NUB) methods in hospitals, see Isabelle C. Hägele-Rebmann, *NUB-Methoden im Krankenhaus im System der GKV unter besonderer Betrachtung des NUB-Verfahrens* (Frankfurt am Main: Peter Lang, 2017).

2.1.2. Private Health Insurance

This complex regulatory model does not exist in the private health insurance system, which provides coverage to around 10% of the German population. Privately insured patients do not receive services under the public health insurance system. Rather, they receive treatment directly from the health care providers and are reimbursed for their out-of-pocket costs by their private insurer. The service providers (who are the same as for the statutory system, so their private patients provide them with a second "revenue stream") are free to choose the treatment method. Medical costs are regulated by a statutory fee schedule[13] which have not been revised for some time. However, opening clauses allow for innovation by analogy to items included in the existing fee schedule. For a number of years, representatives of physicians and of the private insurers have been engaged in negotiations on the details of a new fee schedule that will ultimately be issued by the Federal Ministry of Health. As a result, many of the elements will be redesigned along the lines of the benefits catalog in the public health insurance system; however, the private system will not include a separate regime for innovation.

2.2. Promoting Innovation and Openness to Innovation

2.2.1. Private Health Insurance Function as a Motor for Innovation?

The coexistence of statutory health insurance and private health insurance in Germany is regarded—at least by the private health insurance system—as an important motor for the openness to innovation of the healthcare system. The budgetary and service restrictions in the statutory system justifiable in terms of its solidarity-based financing could be offset by the fact that service providers can always use innovative procedures, methods and drugs for a smaller circle of private patients and charge for them by using the opening clauses in the fee schedule. This decades-long practice has exerted a certain pressure on the statutory system to adopt the innovative treatments that have proved to be successful in the private system, if possible at a lower price.

From a political perspective, this parallel system has been criticized as a two-tier system. From the perspective of innovation, however, it must be admitted that the interplay

[13] Besides the fee schedule for physicians (*Gebührenordnung für Ärzte*), there is a separate one for dentists (*Gebührenordnung für Zahnärzte*).

between the two systems has promoted innovation. In particular, the two-tier structure makes it possible to secure higher prices for an innovative treatment among a smaller circle of patients, but later to provide the treatment at lower prices for the entire population.

However, since the financial crisis of 2008 the private health insurers have come under unrelenting financial pressure and in my opinion this will lead to major problems for the sector. The source of the problems is the underlying financing concept of the private insurers, which is based on long-term favorable interest rate developments and now, after ten years of low interest rates, is gradually breaking down. Private health insurance contracts are being adjusted accordingly, so that they increasingly take their orientation from the range of services covered in the statutory system. The expected convergence between the statutory fee schedule for private patients and the treatment regulation of the public health insurance mentioned above are another feature of this development. When it comes to contributions, private insurance may still represent an attractive alternative to the statutory system for individual patients. But the potential for innovation of a better paying and less regulated system is slowly being lost.

2.2.2. Leeway for Innovation in the Public Health Insurance System

What potential for innovation exists within the public health insurance system? As already mentioned, the first path that the law foresees for the adoption of new treatments is approval by the central body of the Federal Joint Committee. It can be called upon to evaluate and recommend a new examination and treatment method.[14]

But also of particular interest for the innovatory potential of the public system are the additional opportunities it affords. I mentioned above that about one hundred public health insurance funds—providing coverage for 90% of the population—are responsible for managing the payments to the service providers, and thus also for organizing the concrete relationships with them. Many funds operate only in specific regions, but some also operate nationally. Most importantly, the funds are entitled to conclude selective contracts with individual care providers, which means that they can enter into agreements with specific providers on separate remuneration for innovative treatments. At the same time, the health funds have to convince their members to enroll in the treatment programs established by the selective contracts.

In practice, a wide variety of selective contracts have come into existence covering different ranges of services. The question is how strongly they are oriented to innovation.

[14] § 135a SGB V

Generalizing somewhat, one can say that a large number of these selective programs offer interesting services to the insured, but do so without posing a significant cost risk for the insurance funds. This is hardly surprising given that the selective contracts must be financially self-supporting and at the same time are supposed to serve the insurance funds as a competitive instrument for recruiting members. As a result, the potential for innovation presented by these contracts is limited. The selective contract programs can encourage the implementation of new treatments provided that the innovations in question lead to an increase in efficiency and reduce costs. The savings achieved can be used in turn to finance popular add-on services, such as homeopathic and alternative medical treatments, which may increase the attractiveness of the insurer for customers.

2.2.3. Openness to Innovation in Inpatient Care

What remains to be examined is the potential for innovation in inpatient care, which is not bound to a defined catalog of services. The distinction between outpatient and inpatient care also serves the specific purpose of concentrating and enabling innovation in inpatient care, where there are sufficient resources to deal with complications and complex problems.

In all areas in which the remuneration of the hospitals is calculated on a fee-per-case basis, however, the interest in innovation is limited to increasing efficiency. The incentive for efficiency-enhancing innovation is high insofar as the profits generated by any increase in efficiency in the delivery of services remain with the hospital. However, the hospital has hardly any incentive to adopt novel treatments that ultimately risk generating higher costs that would not be covered by the lump sum paid per case. Therefore, the potential for innovation in hospitals in delivering novel treatments is limited to areas that are not covered by lump sums per case. Thus, the more inclusive the flat rate catalog, the narrower is the scope for innovation not oriented to efficiency.

2.2.4. Interim Conclusion

I have tried to show that, in recent years and decades, the incentives for innovation that previously existed in the German healthcare system have clearly developed in an efficiency-orientated direction. In a nutshell, medical innovation occurs when costs can be reduced as a result, and this may also be associated with better treatment. However, where an improvement in treatment leads to higher costs or the development of new methods entails

corresponding risks, the system offers little or no incentive for innovation.

3. The Right to Health as a Motor of Innovation

Within a field dominated by efficiency-oriented incentives for innovation, the constitutional right to health introduced by the decision of the German Federal Constitutional Court that I introduced at the beginning can be interpreted as a counterbalance.

3.1. The Federal Constitutional Court: Basic Right to Health Provision.

In principle, the Federal Constitutional Court in 2005 accepted the restrictions on benefits and the associated focus on efficiency in the public health insurance system. This makes it clear to the healthcare providers that the public health insurance market leaves hardly any room for treatments that do not meet the standards of efficiency required by the Federal Joint Committee. Therefore, care providers must offer their services to privately insured patients; and the more restrictive the private insurance system becomes, the more they will have to focus their offers on patients who ultimately bear the costs themselves.

Yet for a very small group of patients, the Federal Constitutional Court made an exception. In the case of life-threatening and regularly fatal illnesses, the Court has ruled that publicly insured patients should also have access to extraordinary treatments, even if their effectiveness has not been demonstrated, provided that the approved treatments have been of no avail. From the perspective of innovation, this exception provides a stimulus for innovation that pursues two objectives. Firstly, innovation should be possible and should be financed by the public health insurance system precisely where no sufficiently effective treatment has existed until now. Secondly, the innovation activity funded by the statutory health insurance system is not supposed to apply to every type of illness, but only to those in which there is a chance of saving lives or of alleviating suffering in the face of imminent or approaching death.

3.2. The Legislature: Statutory Extension

In 2011, the federal legislature enshrined this constitutional case law in statute[15]

[15] As it is put in the explanatory memorandum to the law BR-Drs. 456/11, p. 83.

and extended it. In the German Health Insurance Code (the Fifth Book of the Social Code), an entitlement to healthcare services that are not included in the regular benefits catalog has now been adopted for life-threatening, regularly terminal illnesses, but also for illnesses "of at least comparable severity." In other words, the legislature established a broader right to health than required by the Federal Constitutional Court based on the German constitution.[16] Whether the legislature is "only" complying with its obligations under international law, or is offering more than is required by Art. 12 of the International Covenant on Economic, Social and Cultural Rights, is open to debate, but this is not even a topic of discussion in Germany. The extension of the right to healthcare to include extraordinary treatments is interesting for the perspective of innovation under discussion here, because it provides a stimulus for innovation in the case of other severe illnesses that are at present untreatable or for which no better treatment exists.

3.3. Legal Practice

Many cases can be found in the jurisdiction of the social courts in which insured persons have claimed a right to an extraordinary treatment by appealing to this statute or directly to the constitution. Although an exhaustive evaluation of the legal implications of the Federal Constitutional Court decision has not been made to date,[17] the many court rulings show that such a claim to benefits outside the benefits catalog also has important effects in the real world.

The demarcation criteria developed in the case law are informative: the decisive factor in determining whether a right to extraordinary treatment exists is less the method of treatment than the type of illness. Generalizing somewhat,[18] suffering from aggressive and difficult-to-treat tumors is most likely to ground a claim to extraordinary treatment. Although this seems plausible in the light of the jurisdiction of the Federal Constitutional Court, it represents a rather restrictive interpretation in view of the statutory extension to illnesses of comparable severity.

In fact, social courts regard the statute as a concretization rather than as an extension of the Federal Constitutional Court decision.[19] In addition, it is considered to be congruent with previous decisions of the Federal Social Court, which has also recognized an extraordinary right

[16] See later jurisdiction of the German Federal Constitutional Court: decision of 10.11.2015, BVerfGE 140, 229; on this, see Wallrabenstein, KrV 2015, 240; for established case law, see BVerfG, 11.04.2017, NJW 2017, 2096 with further references.
[17] But see: http://www.nikolaus-beschluss.de/pages/statistik (last accessed 8.1.2019).
[18] See, for example, the list provided by Plagemann, in Schlegel and Völzke (eds.), *juris-Praxis-Kommentar SGB V*, § 2 Rn. 58-59.
[19] See Noftz in Hauck and Noftz (eds.), SGB, 05/17, § 2 SGB V, Rn. 76a.

to treatment in the case of so-called rare diseases.[20] Due to their rarity, it is practically impossible that reliable studies will be available to prove the benefit and efficiency of a new method of treatment for these diseases. If the approval regime of the Joint Federal Committee described at the beginning were nevertheless applied to such rare diseases, it would mean that new treatment methods would never be accepted and patients would never receive regular treatment. This is why, according to the Federal Social Court, in such cases treatments may be administered that are approved for other illnesses (off-label use) or that are completely outside the scope of the benefits catalog, and the health insurance funds must bear the costs. At the core of this reasoning, therefore, is the claim that the regime foreseen for the adoption of new methods of examination and treatment cannot function in certain constellations.

3.4. Evaluation

However, the view that both lines of argumentation lead to the same results is not tenable. Even for an individual patient, it is not irrelevant whether her claim to treatment is justified in accordance with the reasoning of the Federal Social Court as a case of a rare disease for which there is no adequate treatment or, following the argument of the Federal Constitutional Court, on the grounds that it constitutes an extreme situation of life-threatening illness. For rare diseases do not necessarily lead directly to death, just as acute life-threatening illnesses may be relatively common, or at least not rare.

But here I am interested in the aspect of innovation. Without the jurisdiction of the Federal Constitutional Court based on the right to health, the incentives for innovation that we have identified within the German healthcare system would be oriented exclusively to increased efficiency. Since the chances of deriving a profit from innovations that target only a small number of people are slim, developing innovative treatments for rare diseases is unlikely to arouse the interest of research companies. The jurisdiction of the Federal Social Court that establishes the claim to "off-label" treatments of rare diseases does not even attempt to encourage innovation that runs counter to this economic rationale. Instead, its aim is to justify treatment that is more or less suitable but does not call for costly innovation. This jurisdiction aimed at efficiency rather than innovation is not a reason to criticize the Federal Social Court. On the contrary, the Court thereby demonstrates a correct understanding of the intention of the Health Insurance Code. But this merely underlines the importance of the countervailing

[20] On this, see (with references to case law) Noftz in Hauck and Noftz (eds.), SGB, 05/17, § 2 SGB V, Rn. 76b.

stimulus provided by the jurisdiction of the Federal Constitutional Court.

The individual right to treatment in cases of life-threatening and terminal illnesses and the associated claim of healthcare providers to compensation represents an important incentive for research on new treatment methods regardless of their efficiency.

Following the 2005 ruling, a malicious rumor did the rounds that the Federal Constitutional Court upheld the right of the plaintiff only because one of the judges was a strong supporter of Magnetic Resonance Therapy. However, even if orthodox medicine proves to be right concerning the ineffectiveness of this specific therapy, other efforts at innovation can build on this ruling. There is a famous saying among German judges that sometimes the law is wiser than the legislator. As a scholar, I am tempted to conclude that sometimes a judgement is wiser than the judge.

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