

Theses for Creating a Sustainable Healthcare System – “Vision Paper”

By a Task Force of the
following research-based pharmaceutical companies in
Germany



Synopsis

Key points for a future healthcare system

We advocate a healthcare system that focuses on the insured and patients, in which the quality of care is a priority and patients benefit from medical advances through innovative products.

The compulsory healthcare (GKV) system will therefore introduce more competition on all levels, because competition always results in an efficient utilization of resources. In return, our citizens need to assume greater responsibility for themselves with respect to health insurance and healthcare and with respect to the decision about possible alternatives.

Health insurances gain leeway for increased competition both from contributions and differentiated services. Compulsory health insurances guarantee healthcare for all within the scope of a healthcare service catalog supported by the societal consensus. Health insurances can use the leeway for extending the services beyond the basic service catalog. However, access to innovative drugs and treatment methods must remain a viable option for every insured person.

Individual contracts are a prerequisite for competition between health insurance companies and service providers. This also includes contracts between drug manufacturers and other partners in the system. For this purpose, it is essential that the rules of the applicable competition and antitrust laws are unreservedly enshrined in the social law. The current rules governing discount agreements represent an inadequate basis for individual contracts.

With respect to the drug market, central or regional regulations should be replaced by incentive systems which promote the competition for high quality and innovative healthcare. Price regulations such as compulsory discounts and fixed amounts as well as reference rates and profitability analyses conducted by physicians are getting in the way of individual contracts between health insurances and drug manufacturers.

Health insurances dispose of effective instruments to control the drug-related expenses. Against this backdrop, physicians can once again assume the responsibility for the quality; the economic responsibility should exclusively rest with the health insurances.

Access to information and incentive systems for patients should be improved on all levels. Those insured and patients should have the possibility to obtain information about drugs and vaccines directly from manufacturers. The legal provisions should be changed in such a way that the open exchange of information between manufacturers and patients is possible.

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Preamble

Despite the numerous reforms in the past years, it has not been possible to ensure the long-term financing and efficiency of the Statutory Health Insurance System (SHI).

Complaints about the shortcomings of the SHI from all those involved have reached an unprecedented level: More and more patients and insured persons feel that services are being rationed. Cost constraints limit doctors in their decisions concerning therapy. The pharmaceutical industry lacks planning reliability, especially with regard to the introduction of new and innovative drugs.

Experts note that an unmanageable number of regulations present obstacles to competition and innovation. The healthcare system is laden with national, sectoral and regional authorities who lack integration. In the drug sector, for instance, side by side there are central benefits/cost-benefits analyses, national guidelines for regional drug budgets and regional agreements concerning prescription ceilings, quotas for generics, lists of recommended drugs and examinations of cost-effective prescribing. The repercussions of such contradictory regulations are felt in the use of innovative treatments for patients. In comparable industrial nations such as Great Britain or France, the market share of newly approved drugs in the last five years is 14.6% and 14.9% respectively, while in Germany that share is only 6.3%.¹

Even with the Act to Strengthen Competition in the Statutory Health Insurance System (*GKV-Wettbewerbsstärkungsgesetz* or *GKV-WSG*), long-term financing of the SHI cannot be achieved. Standing in the way of the stated goal of improving competition and quality are newly created regulations. The existing competition among sick funds carriers with regard to contributions will end with the planned central health fund (“Gesundheitsfonds”). One prerequisite of competition is that insured persons have options in terms of both contributions and the scope of services extending beyond a catalog of basic healthcare benefits that is to be defined.

The following theses outline a system that, instead of national and central decisions, is based on a competitively organized healthcare market that is open to innovation and targets the increasing healthcare needs of an aging society.

¹ Perspektive 2011, VFA Press Conference, 10/10/2007,

Five Theses

1. Healthcare must be centered on the needs and self-determination of insured persons and patients.

Need for reform:

There are very few incentives or opportunities for insured persons and patients to take responsibility for the scope and type of health insurance they have and to be able to choose between various benefits options. The fact that all insurance carriers are legally required to have nearly identical healthcare benefits catalogs, which is paramount to a full-value insurance, renders making individual decisions about the scope of one's own health insurance on one's own responsibility a moot point, and for the most part also makes it impossible to deal responsibly with the benefits.

Self-responsibility brings more efficiency to the system. The patient is at the center of the healthcare system. All services are geared toward him. The well-informed patient decides on his own responsibility what services he will use from what service providers. The service providers provide transparency with regard to the costs of treatment. Self-responsibility is therefore more than just a co-payment.

Freedom of information is a prerequisite for self-responsibility. In today's healthcare system, patients are confronted by an equal measure of a paucity and complexity of information ("where, by whom and how can I be helped the most"). In order for patients to be able to make their own decisions, they need high-quality information about the results that they can expect to achieve with the relevant services.

Self-responsibility requires freedom of choice. Patients have a right to basic healthcare, but they are also free to choose any level of healthcare beyond that, and to use quality as a criterion in making their decisions. To allow patients to exercise freedom of choice, the "regulation jungle" has to be thinned out.

Solidarity in basic healthcare means consistency for our society. Basic healthcare ensures a right to medical services at a standard below which healthcare may not fall. The criteria and processes for specifying the medical standard must be disclosed and democratically legitimized. They are to be defined parliamentarily and implemented by experts with the help of guidelines. The basic healthcare benefits catalog should be arranged in such a way as to be open to innovation and should be dynamically adapted.

Benefits beyond the level of basic healthcare are chosen, covered and paid for on an individual basis. Additional healthcare benefits accommodate the relevant preferences of the insured persons. Their coverage is subject to competition among sick funds.

2. Competition is the central mechanism by which quality and efficiency in the healthcare system can be achieved.

Need for reform:

The catalog of basic healthcare benefits in the Statutory Health Insurance, which is extensive in comparison to other countries, only allows competition of quality and benefits in non-core areas. Neither competition in contributions alone, to which the health insurance companies are forced to largely limit themselves today, nor the pure competition of costs that will be triggered by the health fund can mobilize the advantages for the efficiency and quality of the system.

Efficiency is the primary competition parameter in basic healthcare. Today's catalog of benefits is too extensive, especially in an international comparison, and requires a comprehensive-coverage mentality. In basic healthcare, it can no longer be the scope of benefits, but the quality and efficiency of care for clearly defined services that must be the criterion of competition. The benefits included in the basic catalog must be made patient-friendly and ensure quality.

Competition in the individual advantages of additional healthcare. The competition in additional care involves competition in the individual advantages. Those services that provide the highest individual advantages to patients will prevail.

A competitively organized healthcare system should be based on individual contracts. Insurance companies execute contracts with service providers, from which the insured person can cover the services he requires—both for basic healthcare and for additional services. A market for healthcare contracts in which service providers can freely negotiate their services with the insurance companies must be created.

Competition must take place under fair conditions. The competition law and anti-trust law apply without restriction to all contracting parties, including service providers, service recipients and cost-bearers in the healthcare system.

Transparency is a prerequisite for competition. Today's healthcare system and the regulations behind it are exceedingly non-transparent. For competition to function, transparency regarding the quality and costs of services must prevail. Service providers and sick funds should be held to disclose information about the price and benefits of their services in a form that allows the general public to make rational comparisons and decisions.

3. Innovations can only prove their worth if there is competition in terms of their advantages for patients and the overall costs of treatment.

Need for reform:

The healthcare system is one with the most intensive research and most innovative sectors in the economy. However, Germany is in danger of falling increasingly further behind in innovation competition internationally. In the medium term this will also have a negative effect on the quality of healthcare and general access to innovations in the German healthcare system.

Today innovations are assessed by (semi-)governmental institutions, often solely based on isolated price parameters far removed from the reality of treatment, and their integration in the German healthcare system is selective or delayed. This slows down the dynamics of innovation and leaves physicians with fewer treatment options, thus putting the quality of patient care at risk.

Innovations are desired and necessary. The quality of medical care has reached the level it is today thanks to numerous innovations. Innovations allow advances and improvements in the quality of medicine and increase efficiency in medical care. The shortcomings and unsolved medical problems are still so great that striving for continued progress is an absolute necessity.

Competition promotes the choosing of innovations that contribute to effectiveness and efficiency. It is not the government, but competition that separates the wheat from the chaff. Competition among providers (technology push) and competition in demand (demand pull) provide for this in equal measure. The innovations resulting from this free competition of powers are evaluated on the healthcare and healthcare insurance markets, and those that provide the greatest benefits to the patient prevail. This results in the most cost effective treatment of diseases and residual effects.

Free access to innovations must be ensured. Once they have been approved, innovations should be available to every citizen. Here, too, the criteria for basic and additional healthcare as defined in the democratically legitimized process must apply. The goal must be to acknowledge the evolutionary advances in medicine and make innovative therapies available to those patients for whom they were developed and who need them.

4. The supply of pharmaceutical products is a central part of competition-based patient care.

Need for reform:

Over 40 different legal interventions concerning quantity and price control have an impact on the pharmaceutical market. Physicians are subject to increasing economic pressure, as a result of which their prescribing behavior is determined more and more by outside forces. For patients this system is hardly transparent. They are unsure whether they are being prescribed the drug that is truly the best for them or simply the least expensive drug. This lack of transparency makes physicians and patients unsure in equal measure and potentially jeopardizes the quality of care.

The pharmaceuticals market should be organized according to the same principles as the entire healthcare system. Competition, transparency and freedom of information are the bases by which efficiency and quality in the supply of pharmaceutical products can be achieved. Drug therapy is one of the most efficient methods of medical care. This potential benefits both individual patients and insured persons as a whole, when the physicians have the right to prescribe drugs after weighing their benefits and risks and quality and price. A cost-benefit ratio for the individual drug emerges from this competition.

Basic and additional benefits are reflected in the supply of pharmaceutical products. The pharmaceuticals catalog in basic healthcare is defined in a democratically legitimized process according to the same criteria that are also applied to other medical benefits. The scientific bases for this are established by an independent committee that is not corporately organized, but bound only to the standard of medical knowledge.

Pharmaceutical committees of individual sick funds assess the benefits and cost-benefit ratio of drugs. Each sick fund is obligated to provide unlimited coverage for the drugs included in basic healthcare. As long as sufficient alternatives of care are offered, the individual health insurance has the right to exclude from the basic healthcare coverage those products for which generics are available on the basis of a cost-benefit ratio. The pharmaceutical committee of the individual sick fund can allocate active ingredients that are not part of basic healthcare to the additional benefits package. The individual sick fund must disclose to the insured person the standards of the benefits and cost-benefit analysis on the basis of which the drug coverage is allocated to the additional benefits package or the drug is excluded from coverage.

In contracts between pharmaceuticals manufacturers and sick funds, the contracting parties can continually optimize the price-performance ratio in the supply of pharmaceuticals. Insurance carriers and pharmaceutical manufacturers can execute supply agreements that, in addition to drugs, can also include medical, diagnostic or preventive care as well as other services. Such supply agreements can pertain to both basic care as well as additional care. In this way, insurance carriers can accommodate their economic goals more flexibly than if they are forced into sectoral budgets. The competition experienced among sick funds provides them with a strong incentive to search for customized healthcare concepts tailored toward their own clientele.

Quality and efficiency of care are a safeguard against unfair rationing. Quality is based on intersectoral treatment guidelines that are provided to physicians and sick funds by medical boards and form the basis of treatment contracts. Compliance with these guidelines is an integral part of quality assurance and control, instead of using prescription ceilings that, as monetary methods of examination, usually assess quantity rather than quality. Due to the ensuing cost pressure, the border to rationing is being crossed today—a consequence that is desired by neither politicians nor physicians, and that is not made transparent to patients.

Freedom in prescribing and treating ensures a trusting relationship between physician and patient. Patients expect optimal medical care from their physician. Freeing the physician from forces regulating the drug market allows him to prescribe drugs according to medical standards and based on the patient's needs. Prescribing drugs on a medical basis significantly contributes to quality and efficiency in the healthcare system. The physician should not have to fear any economic disadvantages when prescribing drugs based on the state of medical knowledge. The threat and assertion of recourse claims impede a quality-oriented supply of pharmaceutical products.

Patients have the possibility to obtain comprehensive information about drugs. More and more individual responsibility and personal contribution is expected of insured persons and patients. As a result, they bear more and more responsibility for their own health. The prerequisite for this, however, is the possibility to obtain comprehensive information about medical prevention and treatment options. This also includes the possibility to obtain information about drugs and vaccines directly from the manufacturer. The quality of this information is subject to strong controls.

5. Pharmaceutical manufacturers involved in research assume responsibility and are partners in an effective healthcare system.

Need for reform:

Research-conducting pharmaceutical companies invest an average of 12 years in the research and development of a new drug. Constantly changing regulations in the drug market present an obstacle to a goal-oriented research process that focuses on the benefits for the patient. Ever-changing opportunities in marketing cause more and more uncertainty in the funding of research. Reliable basic conditions in the market are needed in order to be able to obtain future research investments. In this regard, adequate protection of intellectual property and competition in the market are the strongest incentives for targeting research and development toward the needs of patients and the sick funds.

Research-based pharmaceutical manufacturers develop innovative drugs at high financial risks. They do so largely without government subsidies and bear responsibility for proving the efficacy and safety of their products. Only one of 5,000 to 10,000 substances makes the leap to become a drug on the market.² The development of drugs is therefore a high-risk business. Thus, the capital market demands risk premiums from the manufacturers. Rapidly changing basic conditions or interventions in the market increase these risk premiums unnecessarily and hinder important investments in innovative drugs.

Research-based pharmaceutical manufacturers invest substantial amounts in healthcare research. In this process, larger numbers of patients are examined under the conditions of daily practice so that the benefits for the patients are documented better than is possible at the time of their approval.

Research-based pharmaceutical manufacturers face competition. In a legally based competitive healthcare system, even the supply of pharmaceutical products is not left out in the cold. Drugs that are no longer protected by patents are subject to price competition; patented drugs are subject to quality and innovation competition and find their prices through market mechanisms. The prerequisite for effective competition is the use of the generally applicable regulations of the competition and anti-trust law.

Research-based pharmaceutical manufacturers welcome the early dialog with all those involved. Research-based pharmaceutical manufacturers are aware of their social responsibility and invite policy makers, the self-administration in the healthcare system and patients to an open dialog about new pharmaceutical agents that are still in the development phase. An early dialog promotes trust, facilitates the efficient allocation of resources and allows quicker access to innovations.

² http://vfa.de/download/SAVE/de/presse/publikationen/fundekonkret1/fundekonkret1_neu.pdf

Private and public research must be more closely interlinked. Through research co-operations, the diffusion of expertise and the exchange of scientists both sides profit equally: boosting basic research, third-party funding, development up to marketability. Bureaucratic hurdles, especially in clinical research, must be taken down and applied research must gain significance again.

The path to a sustainable supply of pharmaceutical products

All of the healthcare system regulations under collective rights—especially in the pharmaceuticals market—should be put to the test. It should be examined whether these regulations are obsolete or hinder competition or innovation, and whether it would be better to place them in the relationship between the insured person, health insurance company and service provider. The principle of decentralizing solutions and offers is paramount because it can be better targeted to the individual desires and needs of all those involved.

The increase of decentralized contracts that pharmaceutical manufacturers can execute with sick funds or service providers must be accelerated. The prerequisite for this is that forced discounts and reference prices used as nation-wide price regulations and cost-effectiveness controls and prescription ceilings used as regional market interventions must be abolished. These regulations stand in the way of the politically desired development of decentralized contracts and block the chances of such contracts being included in the measures for improving the quality and efficiency in healthcare. They can be used more precisely through contractually agreed measures and also promote the targeted and beneficial use of innovations. The goal of the contracts should be to have sick funds assume responsibility for cost-effectiveness and physicians assume responsibility for therapeutic quality.

It must be examined whether the supply with medical services is consistent with the political goals. For this, healthcare research from public funds must be intensified. Identifiable gaps in healthcare must be politically evaluated and closed if necessary, if they are not socio-political in origin.

Insurance companies must be given more room for competition and be able to offer insured persons differentiated benefits packages. Once innovations have been approved under the drug law, sick funds should decide for themselves whether they will include innovative methods of treatment or drugs as part of services granted in their statutes or charge additional rates for them. This is true regardless of the examination or evaluation of these services for inclusion in the catalog of basic benefits. In order to intensify competition in innovative offers and trigger the positive effects of competition for the entire system, health insurance companies and service providers should communicate these services simply and understandably.

The funding of sick funds must be more flexible. Sufficient room for offering differentiated benefits should be achieved this way, too. A rigid corset such as a standard national contribution rate with marginal flexibility for additional contributions does not provide this room. With the introduction of the central health fund (“Gesundheitsfonds”), beginning in 2009 there will be such a standard contribution rate, and the sick funds will only be allowed a flexible surcharge of a maximum of 1% of income subject to contributions. This limitation will in no way spur more competition in the benefits sector.

The *Heilmittelwerbegesetz* [German law on the advertising of medicinal products] should be amended so that the pharmaceutical manufacturers have the right to provide patients with information about drugs. The insurance carriers' and patients' increased need for information should be taken into account in a system with flexible benefits packages. This does not involve advertising. Rather, it involves providing proper information based on the latest state of knowledge, and it is the manufacturer that is most likely to have the most comprehensive knowledge at its disposal.

A stronger framework for competition must be created, instead of creating detailed regulations plagued with problems. For all those involved in the healthcare sector, lawmakers should set a clear and standard framework for competition law and anti-trust law, within which competition for better quality, services and prices can develop.

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AmCham Health Care Committee

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