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Recent developments and reform proposals in the policies of pharmaceutical supply in the Federal Republic of Germany

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RECENT DEVELOPMENTS AND REFORM PROPOSALS
IN THE POLICIES OF PHARMACEUTICAL SUPPLY
IN THE FEDERAL REPUBLIC OF GERMANY

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In the following discussion, I would like to present a brief overview of west german political reactions to some of the problems that have emerged in regulating and financing the medical drug supply. To understand these activities and to judge their appropriateness, it is necessary to provide a short outline of the regulation framework employed by the german social health insurance system (Section I). In Section II, I will briefly examine the conditions of behavior of the pharmaceutical industry, given the structure of the industry and its market as defined by this framework, and how the industry deals with these conditions.¹ This leads me, in Section III, to a short enumeration of four basic structure- and regulation-related problems of pharmaceutical politics.² Finally, in Section IV, I shall show how the two large ideological blocks and political factions - the conservatives and the social democrats - try to deal with these problems in what, in a few weeks, will be a unified Germany.³

In West Germany, as in nearly all countries with a developed, western-style medical care system, the approach of drug-, or drug-related therapy plays the major role; at least in outpatient medicine. Taking or prescribing a drug is often perceived by patients and physicians alike, as being nearly identical to treating a disease.

For 100 years of social- and health politics in Germany, it has been a cornerstone of social stability to provide free and equal access to health care, irrespective of personal income and wealth. This goal is roughly reached by the system of sickness funds, which cover 92% of the total population, including all the poor. Premiums are proportional to income level and include full insurance for all family members. The sickness funds are federally legislated under joint administration of unions and employers.

The application of this basic rule of free access leads, in an industrialized market economy concerned with pharmaceutical supply, to the following configuration of actors and their interests:

The industry can bring into the market any drug which has been licensed, after checks of safety and efficacy (with far more priority given to the former than the latter), by the Federal Health Administration (Bundesgesundheitsamt), which has procedures comparable to the FDA,

with sufficient, though sometimes less effective performance. For market admission, there is no proof required of pharmaceutical innovation, therapeutic progress, or medical need. The effect is high-intensity product competition with few true innovations. From an average 1,000 new drugs licensed yearly, less than 50, according to independent expert panels, contain relevant therapeutical progress or innovation. There are a total 140,000 different drugs in Germany, licensed for use by humans, including different doses, galenics and package sizes. Besides creating difficulties for safety management and problem monitoring, this constitutes a highly nontransparent market.⁴

Doctors are entitled to prescribe any drug they deem appropriate, to any patient. Being paid by fee for service, the prescription of drugs is the most turnover- and income-effective form of patient treatment, beyond the application of their own medical technology. There is no strong economic incentive for individual physicians to lower the expenditures for drugs. Without a sufficient education in pharmacology, and not being trained in cooperation with pharmacists, they find themselves confronted with the overwhelming spectrum of market supply and marketing efforts by the industry, which spends more than 25% of its costs on marketing and information, including more than 10,000 full-time representatives, whose

job is to visit physicians. The physicians' reaction to this confusing market situation is reflected in studies, which show the poor and often overutilized performance of pharmaceutical therapy.

Patients receive their drugs for a current nominal fee of 3 DM (about \$2.00) per prescription, regardless of the drug's price, at all pharmacies, which are, in turn, reimbursed by the sickness funds. This fee is controversial, as it has an influence on only the very poor, for whom even a \$2.00 payment may pose an obstacle to obtaining a needed prescription, and who did not manage to obtain a waiver according to current administrative rules of exception. The direct drug payments of the bulk of the non-poor population are seen as a mere augmentation of the overall amount for health services, which should be covered by the sickness funds. Over-the-counter drugs, which are not paid for by the sickness funds, account for 30% of drug turnover, in terms of packages, and for 18% in terms of money.

Until recently, the sickness funds had only to pay for drugs which were licensed by the Federal Drug Administration, brought to market by the industry, prescribed by doctors and taken from the pharmacy by the insured. There were no opportunities for control or influence on this level, with regard to quality, quantity, or pricing.

So, in effect, we find a somewhat asymmetrical constellation of supply and demand. On the supply side is a powerful, highly-organized, profit- and growth-oriented industry. The demand side is split: the doctor prescribes, the patient takes and the sickness fund pays; none of them having any direct interest in lowering the overall costs.

II. It is clear that such an environment is highly conducive to profits for the pharmaceutical industry. In fact, its position is better in Germany than in any other country in the European Community, where price regulations, high co-payments, or different patent policies restrict, somewhat, the industry's liberty of action. These differences contribute to still unresolved problems for the unification of the European Market in 1992, but the West German industry has no chance, in this process, to further improve its conditions. The German pharmaceutical industry is in a position to make effective use of these possibilities: From 1970 until 1988, the yearly expenditure for drugs by the sickness funds increased from 4.2 Billion D-Marks to 20.5 Billion D-Marks. The present growth-rate is about 6 to 8 percent per year. The sickness funds pay for more than 700 million drug packages a year (in Germany, drugs are only sold in complete packages), for a population of approximately 60 million in the FRG, which places them in about the middle, for drug consumption in Europe. The

given structure of incentives supports marketing strategies of diversification. This leads to a supply structure, in which more than 50% of the drugs are questionable combination-products. Due at least partly to an absence of any criterion for therapeutical improvement in the licensing procedure, more than 25% of total drug expenditures are for drugs which, from the point of view of rational therapy, are highly questionable. The absence of strong price interest on the parts of physicians and patients leads not only to strong competition in advertising and diversification, but also, of course, to a low level of price-competition. So, the Federal Republic of Germany scores in the highest third in drug-price levels in Europe. This is quite natural, since, given the confusion of a glutted market supply, combined with the lack of rational selection criteria at doctors' and patients' disposal, there even evolves an inverse price-incentive: What is more expensive is supposed to be more effective, what is new on the market (and, thus, usually more expensive), is believed to be state-of-the-art treatment.

In this constellation, it is only due to increasing public pressure and some, more symbolic, attempts at persuasive regulation, that the increase rates per year, dropped from more than 15% in the 1970's, to 6 to 8% in recent years, when the number of prescriptions dropped in absolute

number. The latter shows that doctors and patients have become effectively more aware of the problems of drug over-use, both in terms of quantity and quality, as well as cost. Meanwhile, the industry continues to follow the path of expansion.

Earlier attempts to change some of the rules in this game were impeded by the power and organization of the pharmaceutical industry. It is part of the chemical industry, the most powerful branch of west german industry, and includes the multinational IG-Farben-successors: Bayer, Hoechst and BASF. The west german pharmaceutical industry is highly concentrated and highly connected, inter-nationally, exporting nearly 40% of its production, including the sale of ethically questionable drugs in developing countries. The industry has a highly organized lobby and PR apparatus, and maintains costly, but effective coalitions with the further actors in health politics, especially, physicians and pharmacists, and their organizations.

III. As the outcome of the regulations of overall structure, incentives and restraints of the drug supply and its actors, we have, for decades, faced four basic structure-related policy problems. They can be condensed to the short formula of: too much, too many, not safe enough,

and too expensive.

Too much, means that there are apparently material, professional and cultural incentives that are too strong in favor of drug therapy. At the same time, they discourage the development of new-, as well as the application of already-existing alternatives for intervention, in the field of public health and individual prevention and treatment, such as diet, physiotherapy, exercise, psychotherapy and social support. This is only part of the larger problem of how to reorient medical therapy towards those health problems and problem areas, where it is really the best and, often, only form of intervention.

Too many, refers to two different points of criticism. First, there is the sheer quantity of more than 140,000 different drugs, creating irresolvable problems of market-confusion, for physicians as decision-makers, and of safety, for the responsible authorities. Of course, "too many" also refers to the number of prescriptions per patient. In this way, it is a consequence of "too much". It is too much, if the number of psychoactive drug packages prescribed annually, nearly equals the total population of the Federal Republic of Germany. Older people, especially, are often the subject of, or perhaps better, the victims of scientifically not-well-founded, polypragmatic medication programs of

sometimes ten or more drugs at one time.

Not safe enough, refers at first to the fact that, in spite of remarkable progress since the Contergan (Thalidomide) disaster in Germany at the beginning of the 1960's, several scandals have occurred with licensed, but not sufficiently tested drugs, which resulted in numerous disabled victims and fatalities. Although drug-related medical risks are low compared to other areas of health risks, improvements in this field are necessary and achievable. An effective nationwide drug monitoring system, for example, as exists in other countries, would help in the early detection of unintended drug effects. "Not safe enough," also refers to the severe problems of drug addiction. While alcohol is the most addictive drug with, at present, at least 1.5 million victims in the west-german population, the number of people with medical-drug addiction problems is estimated to be somewhere between 500,000 and 800,000. Just for comparison, hard drugs, such as heroin and cocaine, are taken by about 150,000 people, according to the same estimations. No liability is assigned to the producers for addictive- or other health risks of drug intake, as long as those risks are correctly identified in the accompanying obligatory package information.

Too expensive, refers at first, to the profits made with

pharmaceuticals. The gross profits of the German pharmaceutical industry are, in any given year, about 50% higher than the average profits of industry in general. This is explained by the extraordinarily liberal market conditions, combined with the split nature of the demand-side structure, and is illustrated by international price comparisons, which show Germany to be in a high price-score position.

Every policy in the field of pharmaceutical drug supply needs to address these four problems (too much, too many, not safe enough, too expensive), if it is to be considered effective. But - and this is not only true for Germany - the approach of government towards health policy is usually characterized by typical policy reductions⁵: 1.) Health policy is reduced to the problem of patient care; 2.) problems in patient care are reduced to cost considerations.

IV. This is also true for the approach chosen by the presiding liberal-conservative federal government and its majority in the federal parliament. In late 1988, the so-called Health Reform Law (Gesundheitsreformgesetz) was passed, coming into force at the beginning of 1989. For the drug supply, it contains practically no means for reducing the problems of "too much, too many and not safe enough." However, in the

area of pricing, it goes far beyond the various cost-containment laws of previous years, whose regulations were either too detail-oriented, or only persuasive. In order to lower the de-facto monopolistic prices and to stimulate competitive pricing, the concept of fixed amounts (Festbeträge) was introduced. This regulation was passed after a long and somewhat heated public debate, which saw the pharmaceutical industry come under strong public pressure, with disagreement arising amongst its own members. Meanwhile, the interest-groups of physicians and pharmacists were neutralized by attractive coalition offers from the government.⁶

As a first step, a body of representatives from the sickness funds and from physicians' organizations identifies, on the federal level, drugs with identical active substances, putting the trademark drugs together with their generic counterparts in these thus composed groups of equivalents (between 1981 and 1989, the market share of generic products in Germany increased from 7.2% to 20.4% of packages-sold, and from 7.2% to 15% of pharmacy turnover.).

In a second step, the sickness fund representatives define a price-ceiling for which all sickness funds will refund a particular prescription. This price is supposed to be high enough to ensure high-quality treatment as well as to provide for continued private

research. Any amount above the limit of the fixed amount must be paid entirely by the patient.

The first applications of this procedure were highly successful: the leading producers, who also often demand the highest prices for their trademark products, decreased their prices, at times, up to 60%, with an average decrease of 30%. Doctors and patients were extremely reluctant to choose drugs with prices above the refund-limit. The amount saved by the sickness funds in 1989 was accounted at 500 million DM.

Since the insured do not even have to pay the 3DM per drug fee, for drugs with prices at or below the limit, this regulation seems to have only socially beneficial effects. But, of course, there are some cloven hooves here, as well. Fixed amounts have been provided until now, for drugs in Stage 1, which are easy to compare and group according to their identical active substances. This sector comprises less than 40% of the market, and fixed amounts will not be available for it before the end of 1991, the schedule depending highly upon the effectiveness of the regulating bodies, composed of representatives from the sickness funds and physicians. The procedures for comparing and grouping "drugs with pharmaco-logically and therapeutically *comparable active substances*"(Stage 2), or drugs with "pharmacologically and therapeutically *comparable effects*"(Stage 3), are

not yet clear and are already heavily debated. It is clear, that the implementation of these concepts requires a certain degree of non-obstruction on the part of the pharmaceutical industry, in the form of lawsuits, public disinformation campaigns, etc. It is not clear at all, whether these conditions can be maintained. That will depend, at least partly, on the industry's expectations with regard to the regulation of the common european market in 1992, as well as the duration and intensity of public pressure. The long-term reactions of the single firms are also hard to foresee. While, in 1989, the fixed amounts yielded a 500 million DM savings for the sickness funds, the industry, at the same time, increased their prices for drugs not yet subject to fixed-amount regulation, thus recouping more than 250 million DM (over half of the money). Many business groups in the field have trade marks, as well as generic plants. That may lead to different strategies of split marketing. Also, physicians' and patients' orientations to the system may change in the future. If physicians were to advise patients to pay some additional money, in order to get truly "the best," many would do so, irrespective of how reliable this advice might be. Such a tendency would strengthen the orientation of medical treatment according to pricing, including the effects of inverse price incentives. This kind of development is deemed counterproductive,

both in terms of rational medical therapy and in steering physicians' and patients' behavior. Starting in 1992, additional direct payments by the patient may well become an important part of medical drug financing: all drugs which by that time have not yet been assigned a price-ceiling, will require a 15%, or maximum 15 DM (about \$9.00 US) direct payment by the patient. Such regulation would clearly go against the philosophy of the German sickness-fund system, which is to free the patient from economic considerations in acquiring adequate health care. That means conceding to the patient, in economic terms too, the sickness role as defined, for example, by Talcott Parsons.

Meanwhile, as this law, with its interesting but still somewhat unclear outcomes, was passed, the Federal Parliament Commission on the Structural Reform of the Health Insurance System developed alternative options for reforming the medical drug supply.⁷ In the final part of my discussion, I shall outline the option supported by 8 of the 17 members of that body, including all its Social-Democrat and Green-Party parliament members. The standard of this option is the creation of an industry-independent National Drug Institute (Arzneimittelinstitut).⁸ This would be administered by the sickness funds and advised by physicians' representatives and independent scientists. The primary task

of this institute for the improvement of the drug supply, is the creation of positive/negative lists. A drug is placed on the positive list, if it represents a good medical approach towards a defined medical problem, under a mixed criterion of safety, efficacy, existing alternatives and pricing. Those drugs would be fully paid by the sickness fund, thereby free of any charge to the patient. Drugs with questionable effects; with many and/or severe side-effects, unnecessary drugs, or, simply, drugs for which much cheaper equivalents exist, are placed on the negative list. These drugs would not be refunded by the sickness fund. A comparable system has worked well, for decades, in Switzerland. Further tasks for such a National Drug Institute would be a clarification and simplification of the presently obscure drug market; the organization of physician- and sickness-fund-managed quality assurance in drug prescription, including quality-enforcement bodies; the education of pharmacists as drug advisors to physicians and clients; the enlightenment and education of the public in medical drug use; the organization and maintenance of a national drug-monitoring system for early detection of unintended drug effects. Finally, such an institute could also become a place of coordination, clearing, and state funding of privately managed drug research.

Perhaps such an institute could, in fact, diminish some of what are,

here, only roughly sketched problems related to medical drug supply in Germany. However, given the balance of power and its dynamics in present-day Germany, there is not much hope for immediate realization of this goal. But then, social scientists are - and they are forced to be - used to thinking for the future.

ENDNOTES

1. See: V. Friedrich, A. Hehn, R. Rosenbrock: *Neunmal teurer als Gold. Die Arznei-mittelversorgung in der Bundesrepublik*, Reinbek: Rowohlt 1977.
2. See: R. Rosenbrock: *Die Rolle der pharmazeutischen Industrie im Gesundheitswesen*, in: H.U. Deppe (ed.), *Vernachlässigte Gesundheit*, Köln: Kiepenheuer und Witsch, 1980. (pp. 222-256)
3. Until recently, I have been an active witness to this struggle, as one of the eight scientific members of the Federal Parliament Commission on the Structural Reform of the Health Insurance System. This commission concluded the active portion of its work this spring, by publishing an extensive final report: Deutscher Bundestag: Enquête Kommission *Strukturreform der Gesetzlichen Krankenversicherung - Endbericht*, BT-DS 11/6380, Bonn, 1990. In the following discussion, I shall refer to this report, as well as to my own research in this field.
4. The underlying problems are serious, though about 90% of the market is composed of only about 2,000 different drugs.
5. See: R. Rosenbrock: *Gesundheitssicherung durch Krankenkassenpolitik?*, in B. Riedmueller, M. Rodenstein (eds.): *Wie sicher ist die soziale Sicherung?*, Frankfurt am Main: Suhrkamp, 1989. (pp.135-168)
6. See: Ph. Manow-Borgwardt: *Neokorporatistische Gesundheitspolitik? Die Fest-betragsregelung des Gesundheitsreformgesetzes*, Freie Universität Berlin, Berlin: Wissenschaftszentrum Berlin (WZB), 1990.
7. The relationship between the legislative process and the work of this commission is described in: R. Rosenbrock, *A Tightrope Walk Between Two Spheres of Logic. Observations and Self-Observations of A Social Scientist in Parliamentary Politics*, Working Paper 90-28, Institute of Governmental Studies, University of California, Berkeley: Berkeley, 1990.
8. These proposals coincide to a large degree with thoughts and concepts of the author, which were published already a decade ago; see notes 1 and 2.