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Author
Rosenbrock, Rolf

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by
Rolf Rosenbrock
Berlin Science Center for Social Research (WZB)
Research Unit: Health Risks and Preventive Policy with:
Institute of Governmental Studies
University of California at Berkeley

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RECENT DEVELOPMENTS AND REFORM PROPOSALS
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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
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
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
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 be condensed to the short formula of: too much, too many, not safe enough,
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
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.  

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
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,
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,
ENDNOTES


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: Enquete 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.


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.
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