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DILEMMAS IN REGULATION OF THE MARKET FOR PHARMACEUTICALS

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In most pharmaceutical markets, there are well-established systems of clinical trials of drugs to determine the effectiveness of different therapies. Yet, according to an analysis funded by The Commonwealth Fund, there is an emerging consensus that pharmaceutical regulation is incomplete if it does not take into account the costs of competing drugs. Moreover, the article suggests, drug utilization should be controlled by better education, incentives, and enforcement.

"Dilemmas in Regulation of the Market for Pharmaceuticals," by Alan Maynard and Karen Bloor, health economists at the University of York, appears in the May/June issue of *Health Affairs*. In the article, Maynard and Bloor review regulatory interventions from European countries and offer lessons for policymakers in the United States and abroad.

Influencing Patients and Providers

The researchers find that policy innovations to influence pharmaceutical markets have rarely been evaluated scientifically. For example, there is consistent evidence across countries that patients reduce use of drugs when they have to pay part of the costs of prescription drugs. However, little is known about the effects of user charges for drugs on utilization, access, and health outcomes.

Prescribing Guidelines to Physicians

Evidence suggests that it may be possible to influence providers by creating prescribing guidelines that take into account not only the effectiveness of a drug, but also an assessment of its relative cost-effectiveness. But information alone will not influence prescribing—incentives and enforcement are also needed to monitor implementation of guidelines.

Regulating Industry

With the exception of the United Kingdom, all European Union countries regulate the prices of drugs by comparing prices among neighboring markets. Reference pricing—in which payers only reimburse for the average price within a therapeutic class—is common. Yet, the researchers find, price controls must be supplemented with volume controls to have real impact.

Regulators in Australia, Britain, and Canada have begun to require drug companies to submit evidence of costs and effects of new products in relation to existing therapies. This focus on relative cost-effectiveness, the authors say, should be incorporated into the drug approval process, along with the three existing tests of safety, efficacy, and production quality.

Facts and Figures

- Spending on drugs in the U.S. in 1987 was 9.3% of all health expenditures; by 1998 it had grown to 10.3%—1.3% of the gross domestic product. Drug spending in France was 18.5% of health expenditures, and 17.0% in Japan.
- In 1998, spending per capita was $428 in the U.S., $391 in France, $312 in Germany, $295 in Japan, $239 in Australia, $236 in the U.K., and $196 in New Zealand.