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EDITORIAL

Financial Interests Constrain Drug Development

One of the reasons for the existing discrepancy between patients' needs and the availability of new drugs is that our society has delegated drug development almost entirely to the pharmaceutical industry. Industry, which by definition is motivated by economic reasons, is very keen on producing new drugs with a large market, even if they are not the first such drugs. As a result, little research is focused on developing drugs to treat rare diseases, even though the 5000 or so such diseases are estimated to account for almost 10% of overall pathology. In addition, millions of people with tropical diseases will lack effective treatments until their developing countries accumulate enough resources to sustain a market that is large enough to make investment in research by pharmaceutical companies profitable.

The disparity between patients' needs and the interests of industry can be further illustrated by the problem of resistance. No drug can cure or improve the health of all patients; for every treatment, a varying but certain proportion of people will not respond. No systematic studies have been done to determine whether a patient who is resistant to one drug may respond to another that is in the same therapeutic class. Research is needed to develop drugs for these resistant patients, yet it is constrained by those drugs' potentially limited market.

Other areas that may be of great interest to the public are equally difficult to support financially. Good comparative studies on the similarities and differences of drugs belonging to the same therapeutic class could establish different toxicity profiles which, in turn, could determine those drugs' specific uses in subsets of individuals. These sorts of studies do not interest pharmaceutical companies and indeed are seldom represented in the scientific literature, perhaps partly because such data could show that "equivalent" drugs are in fact not equivalent. However, these data ought to be available to state-supported health care providers because equivalent drugs may have widely differing prices.

Finally, some effective treatments, such as hypocholesteremic, antihypertensive, and platelet-antiaggregating agents, must be administered for many years and sometimes throughout life. These drugs have a relatively high cost and must be given to many patients in order to obtain benefits in only a small proportion. Thus, many patients are treated with no advantage, meaning that the cost per life saved is relatively high. For instance, 1000 patients with a previous myocardial infarction must be treated for 2 years with aspirin to avoid 40 major adverse events (death or another myocardial infarction).^{*} Similarly, 1000 patients must be treated for about 6 years with simvastatin, a hypocholesteremic agent, to avoid 33 deaths.[†] If studies could be designed to predict which patients are most likely to benefit from a certain treatment, fewer patients could be exposed to the drugs, thus avoiding undue adverse effects and reducing the financial burden. Again, this type of research is unlikely to be done. Industry is interested in treating the largest possible number of patients with a particular drug, although the national health services would like to reimburse the drug costs only of patients who benefit from treatment.

The above examples clearly show that we need to change our approach to developing and evaluating drugs, in order to reduce the discrepancy of interest between industry and the ill. Special collaborative programs linking industry, governments, and academic or scientific institutions are needed. These programs could be implemented on a national, European, or worldwide scale. Governments should indicate the needs while industry and scientific institutions make their know-how available. Incentives to investigate specific areas could take the form of grants and contracts or of various types of tax relief. Such programs could complement industrial drug development and direct more resources to meeting patients' needs.

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^{*}*Br. Med. J.* **308**, 81 (1994). [†]*Lancet* **344**, 1383 (1994).