New Drug Development and the Health Care Crisis

Five years ago, in an editorial for Hypertension, I expressed concern about the rising cost of new drugs, the decreasing effective patent life of such compounds, and the impact of these issues on the vitality of the pharmaceutical industry in general and, specifically, in the United States.¹

Since then, attention has become increasingly focused on the escalating costs of health care in the United States and legislative means for counteracting this trend. In this environment, I believe that it is important once again to suggest a mechanism whereby health care costs can be reduced. This suggestion is inextricably interwoven in the relationships that exist among industry, academia, and government. As a journal concerned with investigative medicine, Hypertension is an appropriate forum for confronting these problems.

One of the costs of health care delivery that continues to attract public attention is the price of new (ie, nongeneric) compounds. Actually, prescribed pharmaceuticals account for only 7% of all health care costs, although they continue to represent a large item of the public's out-of-pocket costs. Nevertheless, it should be recognized that, as a result of new therapies over the past several decades, outcomes from hypertension and other cardiovascular diseases have dramatically improved. Treatment has markedly reduced morbidity and mortality from hypertension and its complications, including a 70% reduction in deaths from strokes and almost a 50% decrease in deaths from coronary heart disease. Moreover, the benefits of these innovative drugs have been carried over into other cardiovascular problems (eg, arrhythmias, cardiac failure, myocardial infarction, stroke) as well as other diseases (eg, chronic renal disease, diabetes mellitus). As a result, quality of life has improved, hospitalizations for catastrophic diseases and their complications have been reduced, and, consequently, costs related to these illnesses have diminished remarkably. To be sure, the aggregate costs for treatment of each of these clinical problems have increased. This can be attributed not only to the rising costs of medications and hospitalizations but also, and perhaps more subtly, to the fact that during these decades in which efficacy has been demonstrated, our population has increased and our patients are living longer. Thus, costs cannot be attributed exclusively to hospitalizations, procedures, and fees. There are increased numbers of people who have become the beneficiaries of therapies that are now available.

Another aspect of these rising costs relates to pricing new pharmaceutical entities. The drug industry emphases that one very pragmatic aspect is the cost of new drug research and development. This has increased because of a number of factors: increasing costs of modern basic and clinical investigation; added costs necessary to conduct these studies; and the requirements now mandated by regulatory agencies to ensure safety, efficacy, and bureaucratic oversight. Examples of these additional costs include the need for improved animal care and oversight; more costly procedures involved in demonstrating efficacy that require expensive "high-tech" testing; and of course, the important and extremely expensive multicenter controlled trials, including the more recent need to conduct comparative outcome studies.

Each of the foregoing aspects of drug development takes place during the patent life span of 20 years—the time from the filing of the initial patent (while the drug is still in its developmental infancy) to the time that it can be legally marketed by other manufacturers without such close evaluation in demonstrating safety and efficacy. Those companies that provide the cheaper generic equivalents of the parent compounds need only demonstrate bioavailability and bioequivalency, processes that are less expensive and not as well monitored by the regulatory agencies because of the agencies' priorities, increasingly more severe budgetary restrictions, and possibly interest.

There continues to be a healthy respect by all for the need for new drug research, development, and monitoring that provides the substance of argument by the pharmaceutical industry for their drug pricing. The thesis of my argument 5 years ago as well as today is the laissez-faire acceptance of the process by industry, regulatory agencies, and the scientific community as well as the general public. Innovations, legitimate modern time-conserving measures, and genuine commitment by all concerned to change are not apparent. Some relaxation in this rigidity is evident when the process relates to drugs for the treatment of AIDS or cancer or to other lifesaving agents, but even with these considerations, the average time for review of a new drug is still 24 to 30 months.

Most new drug development today is achieved by multinational corporations; frequently, this research is conducted by their independent national companies (under the central corporate control), often in a non-contemporaneous fashion. The process whereby a new drug application and its evaluation is conducted follows the same bureaucratic regulatory process demanded by the different nations involved without any attempt to take full advantage of modern means of data storage, retrieval, and communication. Occasionally, a large company may submit data for new drug approval from

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experiences in other countries; but this is by no means
designed to shorten the approval processes internation-
ally or reduce the drug costs to the consumers, our
patients.

To my way of thinking, what must be considered are
innovative means for abbreviating the regulatory pro-
cesses without jeopardizing the need to demonstrate
safety and efficacy. What I once more urge for consid-
eration is for large multinational companies to submit
for ad hoc approval a system of specific drug evaluation
using protocols designed well in advance for simulta-
neous approval by regulatory agencies of several coun-
tries (eg, the United States, Great Britain, Germany,
France). Certainly, if these nations can sit down with
each other to negotiate treaties to ensure the economic,
political, and social well-being of their citizens, in this
day and age it is no less possible to engage in a much
simpler means of assessing the safety and efficacy of new
pharmacological entities. Data can be stored and re-
trieved at any given time by companies as well as the
various regulatory agencies on a “need-to-know” basis.
Periodic meetings can be conducted to determine the
progress of this drug evaluation process by the compa-
nies and their investigators as well as by companies and
the regulatory agencies in much the same fashion as
other international communication takes place.

The net effect would be threefold: (1) a shortening of
the initial process of drug approval, (2) an effective
commercial lengthening of the patent life of the agent,
and (3) the ability to amortize the investment of drug
development over a longer period of marketing. The
result would be the realized ability to put the newly
developed agents to useful purpose earlier and thereby
improve human well-being. All this is achievable with
the resulting lower price for the patient. No part of the
suggested format for achieving these goals is impractical
or impossible. The academic community stands by to
help in any way as it already does in providing consult-
ative advice, investigative expertise, and other support
to the regulatory agencies and industry. Perhaps under
the new and interested commitments of our legislative
bodies to effect innovative and cost-effective changes it is
now possible to move ahead for the benefit of all
concerned.

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Reference

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