Medical Costs and the Drug Industry

By Harry Schwartz

Recent developments in this country suggest that medicine and money are becoming more intertwined than ever before. The most spectacular example is the radical change of course by the American Cancer Society with regard to the frequency of cancer detection examinations and the ages at which they should be taken. The ACS is now recommending fewer such tests to be taken at wider intervals because it judges that the benefits its former policy achieved in terms of lives saved, especially the lives of younger adults, did not justify the costs of all those millions of frequent cancer tests.

About the same time it became widely known that the Massachusetts General Hospital has decided against going into the heart transplant business. The reason: a heart transplant requires about eight times the financial and other resources needed for conventional open heart surgery, but the probability of patients benefiting from coronary bypass operations and other such now routine open heart procedures is far greater than the probability of a patient benefiting from a heart transplant.

Non-monetary considerations still seem to play a large role in medicine, of course. When Allard Lowenstein's bullet-riddled body reached a Manhattan hospital emergency room after his shooting some weeks ago, a large surgical team automatically began a heroic but finally unavailing effort to save his life. Apparently there was no economist there to calculate whether the likely benefits of keeping him alive indefinitely—benefits figured perhaps in terms of the future income taxes he might pay—were worth the hours of determined surgical effort in this case, efforts whose probable hopelessness must have been evident from the beginning.

Medicoeconomic Decisions

But it was clear even before the American Cancer Society policy shift that great pressure exists to use economic criteria in determining medical actions. For years now Americans have been exhorted to realize there is no infinite store of resources to give everybody all the medical care he or she might want. We shall have to decide who may live and who must die in making medicoeconomic decisions, we have been told, and even some Congressmen have been heard criticizing the federal program that pays for kidney dialysis and transplants because it benefits all comers regardless of age, occupation, social usefulness or what have you.

In this atmosphere of growing and forced medical cost consciousness, one might expect that the most cost effective form of medical therapy now available would receive special favoritism. That form, of course, is treatment with pharmaceuticals.

Just the other day, for example, a surgeon reported publicly about the recent sharp decline in stomach and related gastrointestinal surgery. The reason, it turns out, is that a new drug, Tagamet (cimetidine), is so effective against ulcers that many patients who would have been operated on to remove those ulcers in the past are now adequately taken care of by Tagamet prescriptions. The saving, of course, can be reckoned in terms of pain and apprehension avoided as well as of dollars saved in hospital and surgical bills.

A generation ago frequent polio epidemics killed thousands and paralyzed other thousands, many of whom could never be economically independent and some of whom could survive only by living in iron lungs which permitted them to breathe even though their respiratory systems had been paralyzed. Today the great majority of American-trained doctors under 40 have never seen a polio case and iron lungs have been relegated to museums of medical technology. We enjoy the fruits of the fantastic effectiveness of the Salk and Sabin polio vaccines, but simply take them for granted.

So similarly do we now take for granted the human and monetary savings of effective antibiotics which have routed most infectious diseases, of the phenothiazines which have revolutionized the treatment of psychotics and permitted many of them to return to the world of work or of L-dopa which has created a new era in the treatment and lives of many victims of Parkinson's disease.

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Yet one need not do much research to discover how adversarial government relations these days are with the pharmaceutical industry, and how little connection exists between the enormous cost effectiveness of many drugs and the treatment the leaders in pharmaceutical research and development receive from Washington.

The adversary relationships have many facets. Perhaps the most important is the fact that to introduce a new drug in the United States and meet all the Food and Drug Administration requirements now takes on the average about ten years and costs anywhere from $50 million to $60 million. Conditions for developing and testing new drugs here are so unpropitious that an increasing amount of pharmaceutical research is being transferred abroad.

Much of the problem arises from the changes in the food and drug laws adopted in the early 1960s in the wake of the thalidomide tragedy. That disaster focused attention properly on problems of drug safety, but the legal changes that resulted focused on tightening the requirements for drug efficacy.

At another level the adversary relationships arise from the anxiety of government to decrease the cost of drugs while excluding consideration of the losses caused elsewhere by this "cheap is better" policy. There can be no doubt of government's burning zeal to promote generic drugs at the cost of brand name drugs, and to introduce price ceilings for generic drugs used in government medical programs.

But apparently few, if any, people involved in this zealous effort ever bother to ask themselves what the long run implications are for pharmaceutical innovation. Why should drug companies invest huge sums in drug research if government policy is so determined to minimize the profits from the successful ventures while ignoring the losses from the many unsuccessful ventures which are inevitable in such probing of the research frontiers?

Finally, of course, there is the whole issue of product liability. Concretely, the problem arises from the damages that may be and are assessed against drug firms when, as is inevitable even under the best of circumstances, some people are injured by drug side effects. Moreover, not all of these side effects can be predicted even after the intensive and substantial testing that takes place before a drug can be marketed. Additionally some American courts are showing a tendency to award damages even when there is considerable doubt that a particular drug or a particular drug company is responsible for the damage at issue.

Thus a Florida jury last March 21 awarded $20,000 to a couple who claimed that their son's birth defects were caused by the morning-sickness drug Bendectin. Bendectin was thus convicted even though it has been taken by 30 million pregnant women, including five million in this country, without any previous serious evidence that it is harmful.

The SmithKline Corporation recently reported that there have been 24 deaths and 363 cases of liver damage among the hundreds of thousands of Americans who have taken Selacryn, an anti-high blood pressure drug that has been taken off the market. There is apparently no confirmed proof yet that Selacryn caused either the deaths or the liver damage, but SmithKline has already felt it prudent to announce that lawsuits may be filed against it, and that the punitive damages asked for in those suits may not be covered by the corporation's insurance. Yet Selacryn has been used widely in other countries without any evidence of the organic damage now said to be occurring here.

DES Lawsuits

The case of diethylstilbesterol (DES) produces the most fear among pharmaceutical manufacturers. It now appears that about one in a thousand daughters of mothers who took DES 20 to 30 years ago may have developed vaginal cancer. Not surprisingly damage suits are being filed, and in some cases awards are being handed down. In one case, a pharmaceutical company was ordered to pay a plaintiff even though there was no evidence that company had produced the DES taken by the plaintiff's mother. It was enough for the court that the company had produced DES.

But if drug manufacturers can be sued successfully for the results following ingestion of their drugs 20 or 30 years ago, shouldn't all drugs be tested for 20 to 30 years or longer to make sure they are safe in the long run as well as in the short run?

By such reasoning it would be easy to make a bureaucratic case for simply refusing to let any new drugs be marketed in this country until well into the 21st Century. Yet there is no doubt that drugs are, and will continue to be, the most cost effective therapy we have available, while many sick people need better treatments and better drugs for their ailments.

Is it beyond the wit of the American people to produce a better set of arrangements for encouraging the development and marketing of needed drugs—particularly against the most serious illnesses such as cancer—while reaching an agreed balance between risk and benefit? And shouldn't a government so concerned about the high costs of medical care take another look at its prejudices and preconceptions about the pharmaceutical industry whose products every day make possible vast savings on medical care?

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Micawber as a Hardware Store Manager

By Edmund Fuller

Anne Tyler's eighth novel, "Morgan's Passing," opens with the emergency delivery of a girl child in the back seat of an automobile. We see this hectic incident in a comic rather than melodramatic vision and encounter some highly surprising, engaging characters. The parents of the child

Arising in the morning, "He snapped on the closet light and stood deciding who to be today. Next to Bonny's wrinkled shorts and blouses the tumult of his clothes hung, tightly packed together—sailor outfits, soldier outfits, riverboat-gambler outfits. They appeared to have been salvaged from some traveling operetta. Above them were

which perhaps she means me to do—to that extent succeeding. Yet Morgan, with the immense problems before him, now at 54, and in this case quintessentially Micawberish, is humming buoyantly at the book's last line: "Everything he looked at seemed luminous and beautiful, and rich with pos-