been made. Actually, most publishers have already employed several technological advances to cut costs in both the composition and printing of short-run editions. The gains have been substantial, but far from enough to offset the increases in other elements of operating costs, much less the sharp increase in production cost caused by progressively shorter press runs. Moreover, the problem of production cost alone is not as important as one might reasonably expect it to be. This is because the production cost of the average monograph is usually no more than 25 percent of the list price. (A typical formula for pricing a presumably *profitable* monograph covers other costs—discounts, royalty, advertising and sales, order fulfillment, and general overhead—that typically amount to about 67 percent of the list price. This leaves the publisher some 8 percent for operating profit before taxes at the 54 percent corporate rate—but, of course, neither the typical formula nor the tax charge can be applied to the monograph that does not sell well enough to cover the cost of its first printing.) Thus it is obvious that even a drastic cut in manufacturing cost produced by a technological miracle would not serve to reduce the list price by a noticeably large amount.

No, the publishers of scientific monographs need much more than a breakthrough in cost-cutting production technology. They need either many more customers for their present product or else a revolutionary system for recording and disseminating specialized works of more than article length. Since a fulfillment of the first need is out of the question, and since the second is not likely to be met economically for several years to come, we can, I believe, expect an ad interim crisis that will be shocking to everyone concerned.

Reference

1. D. Lester, *Science* **181**, 220 (1973).

NEWS AND COMMENT

Prescription Drugs: HEW Will Only Pay Lowest Price

The federal government intends to stop buying high-priced prescription drugs for Medicare and Medicaid patients whenever equivalent medications are available at a lower price. This decision to economize, made recently by Health, Education, and Welfare Secretary Caspar Weinberger, could mean that the 10-year war between the government and the drug industry is finally nearing an end, with the government coming out ahead. It is also possible that the ultimate effect of Weinberger's decision, which is in the process of being translated into federal regulations, will be a reduction in the cost of prescription drugs for all of us.

In spite of the fact that we are used to the idea of virtually identical products selling for widely varying prices, depending on the label or brand name, the idea that this practice applies to drugs, just as it does to washing machines, repels a fair number of people. They want to know, for example, why 1000 tablets of a common tranquilizer cost $4.95 if their physician writes a prescription for meprobamate and $68.21 if he calls them Equanil. Similarly, people have asked why 100 tablets of penicillin cost $1.45 if they are called penicillin and $10.04 if those same tablets are called by the brand name, Pentids.

For years, members of Congress have been asking questions like these. So have former Secretaries of HEW. Interest in buying prescription drugs by their so-called generic, or chemical, name rather than by brand name became particularly strong after the passage of the Medicare and Medicaid legislation in 1965. Several bills have been introduced that would have required the government to pay for drugs under their generic names to avoid paying the premium price that often goes with brand name products. But none of the bills ever passed, and HEW Secretaries who considered doing what Weinberger has done were persuaded not to.

The issues, pro and con, are complex. They were 10 years ago and they still are. The only thing that has changed, as far as is evident, is the Secretary. Weinberger is committed to saving money, at all costs, and this decision on drug purchasing will do that. He estimates that, had the "buy low" regulation gone into effect last July, the government could have saved $28 million in fiscal 1974 for Medicaid patients alone. In an interview with *Science*, he said that the decision to save money on prescription drugs for Medicare and Medicaid patients should be seen in the context of the Administration's effort to save money on medical bills across the board. "It is part of a whole package of economy," he said, "and it will be especially important if we're going to pay for drugs under national health insurance." Although he anticipates strong opposition to the new regulations from the drug industry, particularly the Pharmaceutical Manufacturers Association (PMA), which represents about 95 percent of the nation's drugmakers, Weinberger fully expects them to go into effect after passing through normal channels. That means they will be published in the *Federal Register* and interested parties will be invited to comment. You can be sure PMA will comment. Officials of HEW figure that it will be July at the earliest before the regulations actually take effect.

The assumption underlying Weinberger's decision to buy medications at the lowest available price—an assumption the PMA has always contested—is that all drugs are created equal. Therefore, one assumes that, if 20 companies manufacture the same drug, each of those 20 products contains exactly the same amount of active ingredient and that each is made under equally rigorous and sanitary manufacturing processes. One also assumes that each is the same as far as bioavailability or therapeutic equivalence is concerned. Do various versions of the same drug dissolve with equal speed? Are blood concentrations equally high and are they maintained for equal periods of time? Although officials of the current Administration have said that the bioavailability issue has been exaggerated beyond its importance, PMA, as well as many independent pharmacologists, has long insisted that it is the issue on which everything turns.

Weinberger believes that the Food and Drug Administration is in a position to assure equivalency. PMA President Joseph Stetler disagrees, saying flatly that one cannot assume equivalency. During recent Senate hearings on this subject, Senator Edward Kennedy (D–Mass.) asked Stetler why the Secretary would come before the Senate and testify that equivalency can be assured if it is not so. "Why does the Secretary of HEW do a thing like that?" Stetler replied, "I cannot account for him, but I think it is a shocking piece of testimony."

Stetler's position, as one would expect, is that brand name drugs, made by companies that are members of PMA, are of higher quality than others and that to purchase drugs on the basis of price rather than manufacturer can be dangerous. (Many generic drugs are also made by PMA companies. For example, at least 15 of them make the antibiotic tetracycline and sell it for widely varying prices.) He also insists that FDA is by no means able to assure the public that all drugs on the market are as good as they should be, and he has a lot of agreement on that point. A report from the military is revealing.

The military buys a lot of drugs and for a long time has made a practice of evaluating the quality of what it is buying. At a symposium in Washinging, D.C., last November, Max Feinberg, of the Directorate of Medical Materiel of the Defense Personnel Support Center (DPSC) in Philadelphia, told a story others from the same outfit have told before. A company wishes to submit a bid to the military. Someone from the support center goes out to inspect its plant. All too often—as much as 45 percent of the time—companies are disqualified for failing to meet good manufacturing standards. As an example, Feinberg reported that DPSC had occasion to inspect the facilities of 11 of the 27 firms in the United States that make meprobamate. Six of those 11 were disqualified in 1973. Four others had previously been rejected. Among the reasons for rejection were these: In one plant, there were drug containers with two labels, one saying "ascorbic acid," the other, "starch." In one, production equipment was not cleaned before and after use. In another case, there was a live spider in a drying oven.

Problems do not end once a plant is qualified, however. The company sends DPSC a sample of the drug it wishes to sell, and the military checks it out for chemical purity, bioavailability, and so on. The record on that score is not all one would hope either. Drugs the military rejects are nevertheless available to the public. (Previous investigations have shown that, although the bulk of companies whose facilities or products fail to meet military standards are not PMA members, many, of course, are.)

Feinberg supported his case against drug quality with a report from the comptroller general of the United States, pointing out that not all negative findings come from DPSC. He quoted a report to Congress dated March 1973:

> FDA inspections have shown a large number of producers to be deviating from good manufacturing practices. Although such deviations can lead to adulterated drugs, FDA has not enforced compliance with good manufacturing practices by many of the drug producers it has inspected.
>
> In reviewing inspection records of 73 drug producers, GAO [Government Accounting Office] found that 48 percent of the producers critically deviated from good manufacturing practices on successive inspections.

Feinberg also cites an FDA statement from the 5 January 1973 *Federal Register* as evidence that the matter of equivalency and quality is not closed. "It is not possible to specify at the present time the frequency with which lack of equivalence in bioavailability of chemically equivalent formulations may occur."

All in all, it is not exactly reassuring, whether you are buying high-priced drugs or low.—BARBARA J. CULLITON

Briefing

Place in Sun for Marston, Downtown for Sherman

Robert Q. Marston is one of the first persons to obey Florida's "sunshine law," a fact that is not unrelated to his appointment to the presidency of the University of Florida at Gainesville. The law, written to open certain areas of state government to public scrutiny, requires, among other things, that candidates for major state jobs submit to a public interview. The presidency of the state university falls within the scope of the law, so Marston was interviewed in the open. Among those present for the event, one of the first under the new law, were students, reporters, and members of the board of regents. The questions were wide-ranging. Marston was asked about his financial status. He was queried about his views of civil rights. Someone even asked him how long he has been married to his wife. It would seem that his answers were satisfactory.

Marston has spent the last year as a scholar in residence at the University of Virginia and a distinguished fellow of the Institute of Medicine of the National Academy of Sciences. He was director of the National Institutes of Health from 1968 until December 1972, when President Nixon fired him.

John Sherman, who was deputy director of NIH under Marston, and under James Shannon before him, is also getting a new job. He has submitted his resignation to NIH director Robert S. Stone and will become vice president of the American Association of Medical Colleges. He expects to take up his duties with the AAMC sometime in March. —B.J.C.

Stetten Science Deputy at NIH

DeWitt Stetten, director of the National Institute of General Medical Sciences (NIGMS), has been named to succeed Robert W. Berliner as deputy director for science at the National Institutes of Health (NIH). Individuals who were hoping that the new science deputy would be, like Berliner, a man with an intimate knowledge of fundamental research should be pleased. His research has been on diseases of intermediary metabolism, including diabetes and gout.

Stetten was at NIH from 1954 to 1962 in the National Institute of Arthritis and Metabolic Diseases and then left for several years to be founding dean of Rutgers Medical School in New Jersey. In 1970, he returned to NIH to head general medical sciences, the institute most associated with support of basic biomedical science.

As deputy director for science, he will be responsible for the intramural science program at NIH and render opinions to director Robert S. Stone on the substance of various NIH programs. He wryly likens it to being scientific adviser to the President.—B.J.C.