or indirectly by the animal's diurnal rhythms (*12*). Both close similarities and sharp differences exist in the analogous photoreceptor membrane synthesis and shedding in vertebrate rods and cones (*13*). Hence, the effective elucidation of basic mechanisms through comparative study is pragmatically important. A substantial technique like SEM to augment our growing quantitative knowledge of these systems is most welcome.

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Pharmaceuticals: Their Role in Developing Societies

Walsh McDermott

Thirty-one years ago, President Truman in his inaugural address announced a program in which the highly valued technology of the United States would be made available for the development of the badly impoverished nations of the world. Biomedical technology, especially that related to pharmaceuticals, was just starting to flower at that time. Within a short period, medicine had greatly increased its capacity to intervene decisively in the course of a wide range of microbial diseases, including the major ones forming the disease pattern of an industrialized society. Prontosil, the first sulfonamide, was announced in 1935 (*1*) and more potent sulfonamides were rapidly developed soon afterward. Because of the rapid development of antimicrobial drugs between 1941 and 1951, I have referred to this period as the "golden decade" (*2*). In 1941, as antimicrobial drugs we had only quinine, Atabrine, the arsenicals, and the sulfonamides; but by 1951 we had available the penicillins, the streptomycins, the tetracyclines, chloramphenicol, and isoniazid. The antifungal drug, amphotericin B, was developed later; but except for that, it has been more than 25 years since a drug has been developed for a major microbial disease that was previously untreatable.

Examination of the possible usefulness of pharmaceutical technology in the management of the health problems of the developing countries is the purpose of the present article. The overall influence of these drugs has been far greater than is generally appreciated. For example, they not only transformed the disease pattern of the United States and ultimately that of the rest of the industrialized world, but they also made possible today's lung and heart surgery. They led to the development of more efficient techniques for handling viruses and cell cultures in the test tube, and thereby facilitated the production of antiviral vaccines. They also produced extensive changes in the workings of the health care delivery system. For example, fever hospitals and tuberculosis sanitoriums have disappeared, and not the least of the consequences has been the creation in the United States of an essentially new and greatly enlarged system for the nourishment of biomedical science and technology.

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Dependence of Health Care on the Delivery System

The research support system that developed after World War II in the United States involved the federal government, the pharmaceutical laboratories, and the academic laboratories, and had mixed public and private support. Theoretically, the technologies derived from this system could be applied through either (i) the public health system, in which an intervention is made that affects a number of people at once, for example, a program to reduce the incidence of goiter by putting iodine in table salt; or (ii) the personal service system, in which the intervention is applied to an individual by a

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physician or someone delegated by the physician.

Chemicals, as distinct from pharmaceuticals, can be effectively delivered through the public health system. But pharmaceuticals almost by definition require some form of personal service system for delivery. Thus, when the effectiveness of that system to improve a peoples' health comes under challenge, it is also a challenge to the U.S. pharmaceutical industry. For, if its output is not having too much effect on the U.S. people, it might not hold forth much promise for those in developing countries. This issue of the health impact of the personal service system must be resolved (*3*).

The Need for Indicators to Measure the System

Rapidly ascending costs have produced a collection of strange bedfellows, including economists who, in pressing for various "alternative health strategies," suggest that the personal service system is having little demonstrable effect on our peoples' health (*4*). What is not generally understood is that we have devised no indicators to measure the effectiveness of what the doctor *does* on the health status of a society. The outside critic especially, may fail to realize when some indicator is being used to measure something it could not possibly indicate. There is a general failure to recognize, therefore, that what are known as the "usual indices of health status" are indicators that have been developed through the years to measure the public health system, not the personal service physician system. These indicators are based on births and deaths. Deaths get counted as physician failures, but we have no way of measuring the successes of the personal service physician system. Everything that does show up, in effect shows up as a failure. If the personal physician system had a fantastically successful year—a major epidemic of success, so to speak—it might be picked up in the public health system indicators, even though these indicators at best can reflect only a portion of the personal physician system's influence. In such a situation we would have to have within a single year, or a very few consecutive years, a new technology; that is, a new drug that could prevent the deaths of large enough numbers of people to constitute a significant reduction of our annual total of 2 million or so deaths. To do this, the new drug would have to do either of two things: be effective against many different potentially fatal diseases; or be effective against one very widespread, potentially fatal, and carefully reported disease.

These two situations have actually occurred twice in the past 30 years or so, and on both occasions there was a clear-cut decrease in either the overall or the disease-specific death rate. In 1936, Franklin Roosevelt, Jr., the son of the then President, was admitted to Massachusetts General Hospital with a streptococcal sore throat and treated with the new drug, prontosil. Roughly 10 years previously, the son of Calvin Coolidge had died of "blood poisoning" (*5*)—a term then applied to systemic bacterial infections such as those produced by staphylococci or streptococci. Hence, the whole country followed young Franklin's course daily. His prompt recovery represented the most effective of announcements to both the medical profession and the public-at-large that a new drug—the first sulfonamide—had been discovered (*6*). In 1937, sulfonamides were available to personal encounter physicians all over America and no advertisement of their value was needed. The effects were immediately visible: the U.S. age-adjusted death rate, which had been decreasing gradually since 1900, showed a sudden, sharp fall. There was no new vaccine program, no major change in life-style (*7*). A new drug was introduced that was effective against several diseases of large numbers of people, young and old, and was applied only through the personal physician system.

The other type of situation, the introduction of therapy effective against a single frequently occurring disease, may be seen in the case of tuberculosis. Antituberculous drug therapy was widely used for the first time in 1947. Starting that year, there was a precipitous fall in the death rate in all of the industrialized societies (*8*). As with the sulfonamides it is the abrupt onset of the large decrease in death rate coinciding with the first widespread use of the drug that is so impressive.

Disease Patterns in the United States and the Developing World

The disease pattern of the urban rich is very much the same the world over. In some developing countries there is an emerging middle class not yet of large size, but of whom much the same can be said. It is the other people in the developing countries who form the great majority and are our concern. Their disease pattern can be separated into an outer layer and a central core. The core consists of the diseases found virtually everywhere in the developing countries. These core diseases can be separated into those of adults, including surgical conditions, and those of childhood, such as the pneumonia-diarrhea complex of infants. This complex, which is the most important disease condition in the world in terms of number of deaths (*9*), occurs in conditions of poverty and can affect the same baby on repeated occasions.

The outer layer differs from one locality to another and thus provides distinctive local coloration to the disease pattern of a particular region. The group forming this outer layer consists principally of the helminthic or protozoan diseases, such as malaria, Chagas' disease, hookworm, and schistosomiasis, but also includes cholera and yellow fever. It is not always realized that at one time malaria, cholera, yellow fever, and smallpox were important diseases in northeastern United States—hookworm was well known in parts of the rural South. But these diseases are no longer problems in this country.

How did we manage to get rid of the diseases that form such an important part of the disease pattern of the developing world? One way to seek an answer to this question is to find "experiments of nature," this is, situations that occur by chance but are so well recorded as to permit analysis. Such experiments on diseases that are major problems in developing countries are not too common. This is because two contradictory conditions must occur together. One condition is that the locality must be underdevel-

Summary. The appropriate technology for control of diseases of economically underdeveloped countries happens to be mainly that applicable to groups as a whole; whereas that effective for most diseases of industrialized societies must be individually delivered. The latter area is where the pharmaceutical industry has scored its greatest triumphs, yet most of this technology does not fit the major disease problems as they now exist in the developing countries. The argument is presented that in order for the U.S. industry to do more in the developing countries, the most needed invention is not a new drug, but a new system for drug development—a new R & D system tailored specially to both the financial and the biologic needs of the problem.

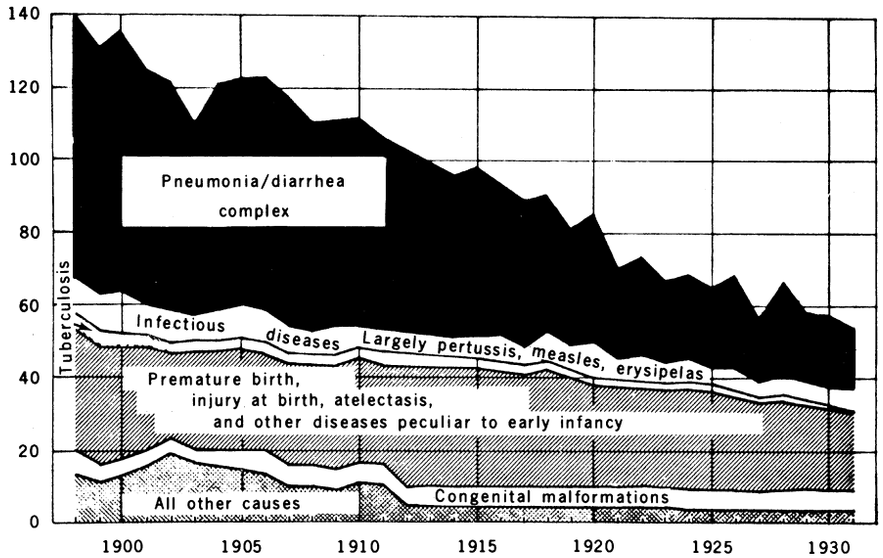

Fig. 1. Infant mortality by prominent causes in New York City (rates per 1000 births). [From McDermott (*18*), courtesy of the *Journal of Medical Education*]

oped enough so that the disease is present, and present in sufficient numbers so that a change in it would be significant. The other condition is that the locality must be developed enough so that its vital statistics are believable. New York City early in this century met these two conditions.

At the turn of the century the infant mortality in New York City was 140 instead of today's 14 per 1000 live births. In Fig. 1, deaths from the pneumonia-diarrhea complex are compared with the number of infant deaths from all the other microbial diseases and from all fatal conditions taken together. The impressive decrease in deaths from the pneumonia-diarrhea complex during the three decades shown occurred before specific therapies or preventives for any of the diseases present had been developed. However, the period was one of a considerable increase in the standard of living.

Another "experiment of nature" shows how a disease pattern at a similar stage, but one including adults as well, was affected after the development of many of our contemporary drugs and vaccines. In the mid-1950's, my associates and I had an opportunity to apply the most up-to-date technology in conditions resembling those of a developing country. This project (*10*) was conducted on the Navajo Reservation in Arizona where people lived far from each other in dirt-floored, windowless, waterless, log huts and maintained a very high birthrate—47 per 1000 compared with the general U.S. rate of around 15.7 per 1000 today. We established in this 800-square-mile project area a health delivery system that included a well-equipped center for ambulatory care, a rudimentary satellite facility, physicians, public health nurses, bilingual allied health professionals, and even radio telephones in the automobiles. The community was wholly cooperative.

The conventional wisdom was that the population was disease-ridden, with about 70 percent of the disease being microbial in origin. Of these microbial conditions, four were especially prominent. Two of them that did not require changes in household practices for their control—otitis media and the transfer of tubercle bacilli—were significantly influenced by the technology. By contrast, the two that did require changes in the home—trachoma and the pneumonia-diarrhea complex—were not affected.

The partial technologic failure was exacerbated by the high birthrate, which ensured that infants and young children would comprise a large portion of the people that were sick at any one time. Our medical technology has relatively little to offer infants in a sanitarily unprotected home environment. We fail to recognize the full significance of these sanitary barriers because most of us have always had them: windows that open so that airborne agents of respiratory diseases can be blown away; tables instead of earthen floors on which to eat; water in abundance readily at hand; soap; household ammonia; and other such devices. Under these conditions an individual is challenged with microbes one variety at a time throughout childhood and adolescence. By contrast, in the impoverished homes of the developing societies, the same viruses and bacteria tend to attack the person in close sequence during the first year of life.

The Role of R & D

I have shown thus far that (i) the pharmaceuticals introduced into U.S. society have had demonstrable effects on its level of health; (ii) a disease pattern of great importance in developing societies—the pneumonia-diarrhea complex of infants—largely disappeared from our society without the use of today's technology, but in a setting of widespread economic uplift; and (iii) attempts to substitute the drugs effective in U.S. society for a complete lack of sanitary barriers in the home may have quite limited value in developing countries.

By the same token, impressive strides have been made by national and international groups in attacking this infant and early childhood disease pattern through work on protein-calorie malnutrition and the development of practical oral hydration. Achievements for both adults and children have also been made by WHO, PAHO, UNICEF, INCAP (*11*), and other groups with the smallpox campaign, malaria control, the tuberculosis and leprosy programs, the development of several vaccines—notably that against measles—and the programs for the provision of a protected water supply. But most of the technologic achievements were those applied through the public health system rather than through the personal service, one-on-one system usually necessary for use of the therapeutic drugs of the pharmaceutical industry.

The question now is whether the system of R & D that has produced such effective drugs for our society can be productively employed in the creation of drugs for the developing societies. Thus, it is appropriate to review how the system developed and what energizes it.

Before Erlich's announcement in 1910 (*12*) of arsphenamine for the treatment of syphilis there was some fine biomedical research, but almost without exception it led only to a greater comprehension of disease. A few vaccines had been developed, notably those against smallpox and diphtheria, but until the introduction of arsphenamine there had been no treatment that had emerged from a systematic program of research and development.

Thus, Erlich's announcement constituted two big events: there now was a highly effective treatment for syphilis; and this treatment had been developed on purpose. Other examples occurred with the use of insulin for diabetes in 1921 and liver extract for pernicious anemia in 1926; then in 1935 came the announcement of prontosil (*1*).

Arsphenamine, Atabrine, and sulfona-

mide came from Germany, and penicillin from the United Kingdom. The United States entered the penicillin field only after World War II had started. People in this country participated in the invention of highly imaginative manufacturing methods, notably deep-tank production of penicillin, and the creation of a system of university-based clinical penicillin investigators financed by government contracts. This was done through the National Research Council of the National Academy of Sciences, which formed this government-supported system largely run by nongovernmental scientists.

Streptomycin, an American contribution, was next discovered, but this drug was still under wartime control and was brought through essentially the same system as penicillin until 1947. At about this time there were two important events: the instrument for the channeling of federal support was changed from the wartime Academy of Sciences to the National Institutes of Health (NIH) of the Public Health Service (*13*); and the tetracycline series was developed in the pharmaceutical industry (*14*).

The development of the tetracyclines is relevant to the evolution of our drug-producing system because it represented the first major antimicrobial series developed in U.S. industry that was not under wartime regulation. Thus it was the first to profit by that part of the 1938 Food, Drug, and Cosmetic Act that had to do with protecting the exclusiveness of the products of one's own research and development. This served as a powerful example of the benefits that might accrue from a well-organized program of R & D on antimicrobial drugs in a company that had a complete system, that is, sales and full marketing capability in addition to the R & D. This development is sometimes regarded as the model on which the present-day structure is organized (*15*). It represented a turning point in the arrangement of roles among the three institutions all necessary for the development of new drugs and preventive technologies. Until this point, sometime in 1948, there had been a considerable blurring of the lines separating the scientific investigators and administrators located in the government, in industry, and in the universities.

Special Nature of the Initial R & D System

What was special about the situation that melded the three sets of participants so closely together at the outset of this highly successful effort? One answer is that the United States entered World War II as the decade began. In my judgment, however, there was more to it than that. There was also a coincidence of motivations only partly attributable to the war; people from industry, from the university laboratories, and from the government all shared a common goal. We were not then so much looking for new drugs, as for additional diseases to conquer. This has not always been true since; but for the brief period of some 4 or 5 years, it was the case. Each success in bringing one more disease under control registered high on the scale of values of everyone concerned. Whether in industry, the university, or government, we believed that we were saving lives.

The last diseases to be brought under control (except for certain fungal diseases) were typhoid fever and the rickettsial diseases. This was done by chloramphenicol and by the tetracyclines (except for typhoid). From this point on, the bonds between university and industrial investigators gradually loosened. By the time of the Truman inauguration in 1949, the irregular but functionally almost unified system had given way to the more formally structured, functionally separate, but intellectually linked system of today. Although I have been telling the story only in terms of antimicrobial drugs, I believe it was much the same for the others.

Present R & D System

In effect, we have two parallel systems. One consists of the R & D effort in industry, which is paid for by earnings and therefore is largely motivated by the prospect of profits. The other is supported as a recognized responsibility of the federal government, through revenues obtained by taxation. It is administered chiefly through NIH and is conducted there and in a countrywide network of other laboratories in universities and research institutes. (In state-operated, university-based medical centers the state governments also contribute by providing laboratories and faculty salaries.) Broadly speaking, the research in the university-NIH system leads to our greater understanding of various diseases—usually diseases to be found in the United States. The most vulnerable links in the pathogenic chain may get identified. The research workers in industry carefully follow this research and indeed have made valuable contributions to it. Their primary concern, however, is to develop the interventionist technologies, most of which have come from industry. They, too, have tended to focus on the diseases of our society.

With this system, the actual inventions or discoveries of the R & D in the pharmaceutical industry have almost exclusively been therapies (or contraceptives) that fit the U.S. disease pattern and require some form of personal service system for their administration. By contrast, the actual inventions or discoveries used in the public health system have largely come either from the university-NIH system in the case of vaccines, or from the chemical industry in the case of water disinfectants and vector controls. (Hilleman's work in industry on respiratory vaccines is a notable exception.) Once the effectiveness of a vaccine has been demonstrated by government or university investigators, the pharmaceutical industry has made it suitable for mass administration.

Use of the U.S. R & D System for Developing Countries

What are the prospects that this U.S. system, that has proved so effective in meeting our own disease problems, can be expanded as it stands to serve also in a productive attack on major problems in the developing countries? To simply expand it as it stands would not look like the road to success. In part the judgment reflects the constraints both economic and biologic that characterize the situation. In large measure, however, it is based on another example from our history.

Almost 20 years ago, an effort was started in the President's Science Advisory Committee to develop an institution to link the worlds of science and technology in industry and in the universities to the foreign aid effort. A system was set up along the NIH-university pattern with the Agency for International Development; there was a first-class and hard-working advisory committee from outside the government, and a grants and contracts program that included health, but was not limited to it. After almost a decade of trial, the effort was judged a failure.

That experience taught us that in attempting to aim the weapon of R & D at a problem it is essential that the institutional framework devised to organize, support, and monitor or manage the research effort be carefully tailored to fit the key characteristics of the problem. A system of research support effective for the Department of Defense may be quite ineffective for the Department of Agriculture. The success we have had in mo-

bilizing our biomedical research and development effort by inventing the twin NIH-university and industry system has tended to blind us to how well the components of that system fit the key elements of the problem.

But the problem to be addressed now is different. The question is no longer, "Can a treatment for x disease be developed?" It is, "Can one be developed that can be purchased and delivered for one U.S. dollar per capita, per year, when the total budget for all health services is only two dollars per person, per year?" Neither arm of our present system has such capability, so that the plea that they do more becomes meaningless. The most needed invention is not a new drug, but a new system for their development—a new R & D system especially tailored to both the financial and biologic needs of the problem.

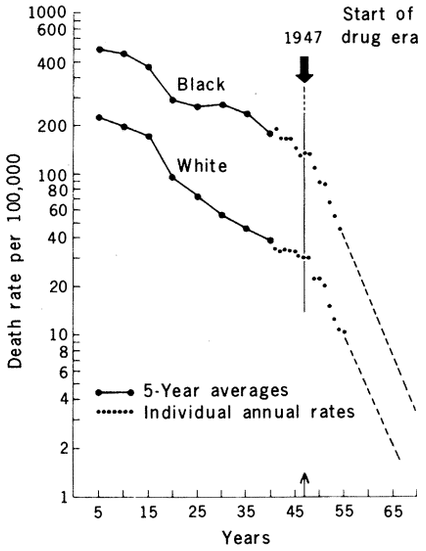

Fig. 2. Tuberculosis mortality for blacks and whites, New York City, 1905 to 1955 (*17*). [From McDermott (*3*), courtesy of the University of Chicago]

Incentives and Trade-Offs

Scientists in nonprofit organizations are not much inclined to spend time in searching for therapies for diseases for which effective therapies already exist, even though the latter may be cumbersome and expensive. They tend to disregard such questions with at least a tacit assumption that they are the responsibility of others, specifically workers in the pharmaceutical industry. At the same time, scientists in the pharmaceutical industry find little support for the conduct of searches for therapies which, if found, would not have much of a market. Consequently, if the industry is to be able to make a significant contribution to the problems in the Third World, it will be necessary to find proper incentives for the scientists from both sides to work on a particular problem. Obviously, this would involve financial subsidies, some complicated waivers of legal restrictions, and some way of inducing the scientists from the nonprofit institutions to devote some time to the effort. A team proposition like those of World War II is needed. Perhaps some of the incentive could be found if such a team effort were devoted to working out the practicalities of a control technology for a particular disease on a large scale in a particular country.

It seems most likely that the problem areas suitable for attack through the pharmaceutical industry will represent a far smaller portion of the total problem than is the case in U.S. society. However, there is a considerable variety in the specific mechanisms by which microbial diseases cause illness in one person or spread to others. Hence, they present different, and sometimes multiple, points of potential vulnerability to attack. These vulnerable sites can be either in the transmission of the disease or in the metabolic activities of the microbe itself. For example, some might be controlled by putting a chemical, such as chlorine, in a central water system used by millions of persons; for some other disease it might be necessary to have someone available to inject a chemical intravenously into each sick person every day. Thus, trade-offs are involved, the most important being whether to attack the link in the pathogenic chain at its "weakest" or at its "cheapest." Frequently the trade-off concerns significant drug toxicity versus the degree of expertise needed to staff the personal service system. For some drugs little expertise is needed; for others the presence of a physician must be visible at least on some days, even if in the background. Another trade-off is between whether the desired effects can be produced by the drug alone or whether some significant change in household habits is also necessary.

In the Navajo study (*10*), two of the problem diseases were tuberculosis and trachoma, both of which are clearly susceptible to antimicrobial drugs. The chain of spread of tubercle bacilli involves the contamination of the air within a dwelling space. This can be stopped easily by the infected person taking a daily pill. But trachoma can be spread by the momentarily contaminated fingers of small children, and how to decontaminate them was quite another matter. Thus there were two different diseases, both with effective drugs, but in the conditions of a developing society, one drug worked and the other did not (*16*).

Conclusions

According to conventional wisdom, if a disease is characteristically bred, or greatly facilitated in the conditions of poverty, it is foolish to try to attack it with a technology—one must do something about the conditions in which it is bred. I maintain that this is not always so. For example, let us consider the chemotherapy of tuberculosis. Figure 2 shows the tuberculosis death rates among blacks and whites in New York City in the period before and after the drug treatment for tuberculosis was introduced in 1947. At the start of the drug era, the rate for whites was slightly less than 35 per 100,000 persons, while the rate for blacks was 150, roughly four times as high (*17*). Once the drugs were introduced, however, the fall in death rate was at least as rapid, if not more so, among the black population as among the white. There is no convincing evidence that blacks have an unusual inherent susceptibility to tuberculosis. In any case, whatever it was that was responsible for that difference between 35 and about 150 tuberculosis deaths per 100,000 people each year, obviously was no constraint on the effectiveness of the technology. And, it seems reasonable to believe that the marked differential in death rates in the pretechnology era reflected the living conditions of the black poor in New York City in the 1940's.

In his inaugural address President Truman said that the material resources that could be used for the assistance of other peoples are limited. "But our imponderable resources in technical knowledge are constantly growing and are inexhaustible." The central truths in that statement for the industrialized societies have been affirmed. To what extent it is also possible to find ways so that they have meaning for the developing world is the challenge before us. And if success comes, there will be many more days than there are now on which one can say with some satisfaction, "Sometimes the poor get lucky."

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