DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 3(3), 219-225 (1977)

The Social Impact of Pharmaceutical Innovation

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INTRODUCTION

As we approach the turn of the century, Americans are recognizing that good health care should be a universal human right. This notion has raised man's expectations for enhancement of the quality of life and for the cure of disease. Progress toward these social objectives should be a result of the clinical, physical and behavioral sciences. The advancements resulting from medical and pharmaceutical research have been enormous since the end of World War II. These medical advances, especially those associated with pharmaceutical innovations, have resulted in an increase in life expectancy, primarily by lowering the death rate due to infections and other acute diseases. However, as with any progressive movement, there are potentially negative consequences. For example, the tremendous success of the antibiotics in alleviating infections has created the myth among health service providers that nearly all infectious processes may be remedied with antibiotics. This belief has, in part, contributed to indiscriminate and

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irrational usage; resistant bacterial strains; and epidemic proportions of adverse drug reactions.

While serving as one of numerous examples, this scenario leads us to the purpose of this paper, our sole intention being to dramatically increas the awareness of medical researchers, legislative leaders, pharmaceutical manufacturers and health practitioners as to the enormous social impact of drug innovations in both a positive and negative direction.

Historical Perspective

The Food and Drug Administration is the primary drug regulatory agency in the United States and since 1906 has done much to protect the public. Before 1906, American medicine and the public were sometimes plagued by exaggerated therapeutic claims, adulterated goods and false advertising. As a result, Congress passed the Pure Food and Drug Act of 1906, the first major American drug legislation. This Act was concerned with the prevention of misbranding and adulteration of products. In 1938, an amendment was made to 1906 Act. It provided power within the FDA to assure the safety of medicines. As mentioned earlier, the next 35 years were characterized by an explosion in modern medicinal therapy along with the rapid development and expansion of the pharmaceutical industry. In 1961, Senator Kefauver inaugurated the Congressional hearings that dramatically affected the manufacturing of pharmaceuticals. Out of the hearings came several amendments to the earlier Act, imposing far greater responsibilities on the FDA. It requires that to license new medicines for marketing, they must not only be safe but efficacious. Furthermore, the Amendment called for retrospective evaluation of all medicines introduced from 1938 onwards. Academic experts were summoned to aid the National Academy of Sciences/ National Research Council in rating these products as either "effective,

probably effective, possibly effective or ineffective". Finally, the amendment provided the power for the FDA to regulate the advertising of pharmaceuticals to insure that the promotional literature was accurate and truthful.

The authors suggest that this historical perspective is nothing more than another example of an "evolutionary process". Through the last several decades, we have guaranteed the public that pharmaceutical products marketed in the United States are of the highest quality with respect to safety and efficacy. Furthermore, we propose that the next step in the evolutionary cycle is to more closely examine the societal impact of drug innovations, so to better determine if the unexpected costs and externalities, both human and financial, are commensurate with the investment. In other words, we must strive to assess the social impact of new pharmaceutical innovations during the stages of research and development before widespread marketing of the product.

As suggested by the Office of Technology Assessment of the U.S. Congress, the assessment of potential social impacts of medical innovations serves two important purposes: (1)

(1) to obtain information to better formulate policies to insure that research-and-development funds are invested wisely. Once the benefits and drawbacks of a new innovation are considered explicitly, its development might be expedited or constrained; and

(2) to obtain information that could improve the process of planning for the eventual introduction of new medical technologies into the medical service system.

The Office of Technology Assessment (OTA) has raised several questions. Are current R and D efforts being directed at developing the most desirable technologies? Is there adequate planning before introduction of new technologies into the medical care delivery system? Are new medical technologies

having indirect or unanticipated social implications? They strongly feel that technical and social problems cannot be easily separated; in fact, they are inextricably linked. Wertheimer has recently suggested that Hospital Pharmacy and Therapeutic Committees begin to examine these questions. (2) The OTA professes that the medical world must begin to assess the social impact of medical innovations. This is not unlike other industrial organizations. Most all of the large corporations, such as the steel, oil, and electric industries are required to develop environmental impact statements with respect to introducing new technologies. Should medicine, pharmaceutical industry and the remaining health care system be exempt from this proviso?

There are many drug and non-drug innovations that have had a devastating social impact. For example, modern technology has challenged society's traditional view of death and dying. New life-extending technologies such as pacemakers, artificial hearts and renal dialysis can serve as appropriate examples. As mentioned earlier, the introduction of antibiotics, while lowering the death rate, has contributed to the overall increase in reported drug reactions which linked to increased and extended hospitalization. Some believe widespread use of antibiotics and tranquilizers has contributed to the myth that there is a drug-cure for any physical or mental disorder. The introduction of birth control pills has helped limit the population expansion, but in return has directly or indirectly precipitated the rather liberal sexual behavior which is prevalent today. Some profess that widespread use of oral contraceptives has contributed to the breakdown of our moral and family structure within the U.S.

In a more general sense, the Office of Technology Assessment views modern technology and innovation as potentially dehumanizing the individual, altering the way people view themselves and others, and finally providing awesome powers to a third party, the physician. (1)

These examples are those of the past. Vigorous efforts should be made to evaluate current biomedical and drug research that most certainly will pose unforeseen social consequences. However, a warning from OTA should be heeded. It is important that we do not become preoccupied with issues raised by the introduction of new medical innovations to the point that we will not recognize the social problems posed by those diseases in which no therapy is yet available.

In summary, we are strongly urging that the medical care system begin to ask and attempt to answer several questions before a new innovation (i.e. drug) is introduced to the market. In addition to assuring the public that a product is of the highest quality, we should attempt to identify the social consequences before introduction of that product. What are the social implications with respect to the patient, family, society and the medical care system? Some have suggested that an agency be created within HEW to assess the impact of new drug innovations. In addition, it has been suggested that requirements for certification and licensing of new drugs could be expanded to include some form of social-impact assessment before the product is marketed. In fact, the legislation could be modeled similarly to the environmental impact statements which are now required by the government for other projects. In essence, the drug developer might be required to assess its product, or HEW could conduct the assessments.

The authors would be the first to admit that there are many obstacles and limitations in coordinating and developing a rational assessment program, but feel that our proposal is certainly harmonious with the evolutionary cycle of drug-related legislation. Furthermore, the progressive cycle is so evident that the cycle predicts the emergence of social impact statements.

Without going into repetitious detail, the potential value of such a review might be better seen if one considered the impact of insulin, the antiepileptic agents, antipsychotic drugs, blood fractions, hormones, anti-

coagulents, and cardiac glycosides. Some of these drugs keep persons alive who might otherwise have died. Others require the patient to be constantly institutionalized or supervised. Some permit continued employment and reproduction. What will be the effects of such use of drugs in two generations?

This is not such a radical call. The concept of cost to benefit ratios for a society from new drugs was proposed by Weikel in 1971. He suggested that

> ". . .the industry will find it critically important in the future to conduct socio-economic studies for all their drug products in order to approximate what contribution they are making to medical care. It will be important to know the cost to benefit ratios for all products. Socio-economic studies should be conducted at the same time as clinical studies." (3)

Manasse, et al. (4) in 1976 proposed a certificate of need/social impact statement for drug introductions. That latter group even listed a number of points to be considered prior to the release for marketing of a new drug product. Among these are: probable impact on the environment, alternatives to use of the product, irreversible changes, etc.

While some students of this domain have posited specific steps for consideration, we would prefer to, at this point in time, air the issue publicly before concerned constituencies and then permit the various deliberations to develop a workable system for the consideration of the social impact of the use of a new chemical agent. This might well be in a limited-time post marketing study, concurrent with the I.N.D. or N.D.A. submission or at any other reasonable phase. The important matter is the examination of the possible questions involved.

Surely, additional study is merited, and the authors believe that such study can come about only after enough people have been sensitized

to the issue and it is in this light that this issue is being brought to the fore.

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