

COMMENTED SUMMARIES FROM CURRENT MEDICAL LITERATURE

MODULATING THE PROFIT MOTIVE TO MEET NEEDS OF LESS-DEVELOPED WORLD

Summary: The success, despite the problems of academic/industrial collaborations over the past decade owes much to the profit motive. However, market-driven research and development has little to offer to patients in the less-developed world. Some flexibility has already been demonstrated on drugs for orphan (rare or under-researched) diseases. Many diseases in less-developed countries are not rare. Academic researchers should be encouraging the establishment of funding for basic and clinical research that is directed at patients' needs in the less-developed world and that is independent of commercial ethos.

Comment: In this article, Dr. Schieppati and his colleagues from Bergamo (Italy) bring up a very important public health problem of developed and developing countries. The relation of academic medicine and industry depends largely on the profit motive to meet the therapeutic requirements of patients. In this way, researchers and physicians are encouraged to discover the therapeutic tools necessary for the management of patients with common diseases, which are more favorable and profitable in the drug market. In other words, industry-sponsored clinical research might be conditioned by the need to generate a profit for shareholders. Bodenheimer T¹, Newman TJ², Bellin E³, and many other researchers, in the New England Journal of Medicine highlighted the danger that industry's profit motive could determine which and how studies are designed to analyze, interpret and publish data in favor of these companies; this causes scientific studies to become biased. Bellin et al ask whether academic medicine is for sale or not. Another issue of concern is the limited market for the drugs used in the treatment of genetic diseases. Rare diseases illustrate a conflict between the interest of physicians, healthcare units and industry. Patients with rare diseases have been termed "Health Orphans" and the drugs used in their treatment are called 'Orphan drugs'. Fortunately, for such diseases laws have been passed in the more developed countries, which help both academy and industry. The U.S. Orphan Drug Act, for example, provides incentives for drug industries to develop new drugs for rare diseases. The same efforts can be seen in Japan, Australia and recently in the European Union. In America, more than 900 drugs and biological products have been classified as orphan products, more than 200 of which have received marketing approval from the FDA.

The problem in developing countries is different. For people who live in this part of the world, even prevalent diseases would be considered as orphans. Poverty, famine, war, and fatal diseases shorten their life expectancy. Here, rare diseases are not the main concern, but we have huge numbers of patients suffering from prevalent diseases who are deprived of simple treatments. Therefore, the term *orphan drug* has a different connotation. In these countries, treatment is not available for most prevalent diseases, partly because the drugs are too expensive for these nations and partly because researchers are not interested in studying such diseases. Tuberculosis (TB), for example, which is the most common killer among chronic infectious diseases has not received much attention for many years. Only after the HIV/AIDS epidemic, some research has been done on tuberculosis. Insufficient research has been done to find newer drugs for the treatment of these diseases and the newest antituberculosis drugs were produced 30 years ago. This is because research and development of new drugs is insufficient for the treatment of diseases such as malaria, leishmaniasis and TB that are prevalent only in developing countries. Since these countries are economically poor and cannot afford the drugs, they may be called *orphan countries*. More than 95% of the patients with AIDS live in the less-developed countries and about 2 million people die of it each year. As estimated, a year's treatment cost for HIV patients is approximately US\$15,000, which is many times higher than the average per capita annual GDP per Capita of these orphan countries.

Since without sufficient funding, prevention and treatment of diseases such as TB, malaria and HIV/AIDS in the developing countries can not occur, it is the duty of international healthcare units, such as the WHO and other organizations, to develop ways to help people in the less-developed countries. Companies, which

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have previously thought in terms of their profit and not in terms of developing new drugs for the treatment of rare diseases, should subsidize to develop new drugs for the treatment of diseases prevalent in these countries. As stated in the Orphan Drug Act, pharmaceutical companies should be encouraged to take such action. Academic researchers and scientists should encourage the governments of the more affluent countries and international organizations to establish special and sufficient funds to support orphan countries.

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Source: Schieppati A, Remuzzi G, Garattini S. Modulating the profit motive to meet needs of the less-developed world. *Lancet*. 2001; **358**: 1638-41.

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