**FROM OTHER JOURNALS**

**Why drugs cost so much...**

Controversy surrounds the price of prescription drugs in the US. In 1999, when drug industry profit margins were higher than most other sectors of the US economy, drugs accounted for 44% of the total increase in health care costs.

As the post-development costs of drug manufacture are only 20-30% of the sale price, the industry justifies the rest on the basis of two factors. The first is that modern pharmaceuticals, apart from providing therapies for conditions which were previously untreatable, have reduced spending for hospital stays, surgery and other costly treatments. The second factor is that the industry needs to recoup the enormous overall cost of drug development where for one successful drug, the industry screens 5,000 compounds in the lab and 10 are subjected to expensive clinical trials.

While there is some truth in the first argument, in that drugs have reduced cardiovascular mortality and lowered elective surgeries for diseases like peptic ulcer disease and prostate hyperplasia, the cost of long-term drug therapy spread out over many years is very high and therefore may not save much. Cost-effectiveness analyses are being used in Australia, over the strenuous objection of the industry, as a constraint on drug costs.

Are the large costs associated with drug development justified? Computer-assisted drug development is expensive and has produced only a tiny number of drugs. Use of genomics in drug development may be even more costly because the genetic component of most diseases involves multiple rather than single genes which interact with environmental factors to cause disease. Therefore genomics will need to tailor drugs to the hundreds and thousands of multi-gene variants in individual patients resulting in enormously expensive drugs applicable to a very small market.

Instead of government price controls on drugs, or regulation by a non-profit institute set up by private insurers and government, the industry could voluntarily lower prices. The prime beneficiaries would be patients. Health care systems would be able to spend the saved dollars on other badly needed basic medical services. Primary payers such as government and employers would benefit from these reduced costs. The pharmaceutical industry also would benefit. Its less-than-public spirited image would improve and in addition it would reduce the threat of government regulation which is a major concern to the industry.

*Davidoff Frank. The heartbreak of drug pricing Ann Int Medicine 2001; 134 (11): 1071.*

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**And the other point of view...**

This article was commissioned by the Pharmaceutical Research and Manufacturers of America as a counterpoint to the above article.

Pharmaceutical price controls are being proposed to curtail increases in health care costs. However the increase is caused more by an increased use of drugs and switching to newer, more effective drugs than by an increase in price of existing drugs. The industry's position is summarised below.

1. Pharmaceutical research is motivated primarily by the possibility of large profits from the rare success in research. Financial calculations suggest that after accounting for risks and the role of research and development as an investment, pharmaceutical industry profits have not persistently exceeded competitive levels.

2. Drug price controls cannot rest on objective, predictable standards including the benefits or costs of individual drugs, as medical and economic benefits cannot be determined until well after marketing (depending on the size of treatable population, changes in medical practice etc.). Research costs are shared among numerous drugs and, sometimes, firms. Advertising costs, though considered wasteful by some, make markets more competitive and are socially beneficial as advertising overcomes information deficits of patients and doctors.

3. In the absence of objective standards for price control, price regulators would reduce drug prices below levels sufficient to reward innovative research. Decisions would be dominated by political forces and advocacy groups who would each try to pass on the cost to other groups. Drugs already on the market would continue to be available as long as prices remain above cost but a drug in development would suffer as there would be no group advocating to price it above its cost which would be unknown at that time.

4. Research firms would anticipate the effects of price controls and curtail research because potential payoffs would be reduced. Firms undertaking the small probability, high payoff research that is essential to pharmaceutical advances would have reasons to doubt that they could obtain the financial returns necessary to recoup their costs and sources of funding would dry up. The deleterious effect of price control is evident in the slow progress on drugs for such massive problems as malaria as the nations where malaria is a major problem are likely to exert price control through disregarding patent rights to a breakthrough drug.

5. Finally, once established, price controls would tend towards complexity and entrenchment of vested interests and could become permanent regardless of the harms that they cause. In summary, pharmaceutical price controls offer short-term gains for a small proportion of patients at the cost of curtailing research that promises to bring far better therapies in the future.

*Calfee John E. Pharmaceutical Price Controls and Patient Welfare Ann Int Med 2001; 134(11): 1060-1064*

**Participating in direct to consumer advertising**

Direct-to-consumer advertising (DCA) may be conducted through print media, television, audiotapes and videotapes. DCA serves two purposes: it informs patients about a product and it attempts to persuade them that one company's product is superior to that of its competitors. Although DCA may be regarded as educational, it is also a marketing tool. Pharmaceutical or medical device companies may solicit neurologists to participate in DCA. This Practice Advisory is based on the following tenets: 1) Patient education material produced by pharmaceutical or medical device companies will provide education as well as advertising and should therefore be regarded as DCA; 2) Mass marketing through DCA may promote a drug or device that is unsuitable to an individual; 3) Participation in DCA may harm a neurologist's professional reputation and trusted relationship with patients; 4) The relationship between neurologists and industry merits further analysis and improvement; 5) Public information about advances in therapy should be conveyed from impartial sources. Neurologists may participate in DCA by writing or editing material that is used as an insert in an article from the sponsoring company, by authorising excerpts of their oral or written presentations for video/audio tapes or pamphlets. Neurologists who participate may be motivated by the belief that they are providing useful information to a wide group of patients. However, the neurologist's contribution may be distorted or her/his participation may be wrongly interpreted.

Distortion could occur if the neurologist's qualifying or cautionary statements are omitted from the final product. Opinion could get presented as fact. A neurologist's preference may make it harder for another neurologist to recommend an alternative medication. Conflict of interest may occur if a neurologist has accepted compensation for DCA. She/he may not be completely objective when assessing the relative merits of competing products. Full disclosure to the public is the most common means of mitigating a conflict of interest. Recommendations - A neurologist who participates in DCA should insist on the following conditions:

1. She/he should have the opportunity to review the finished product for accuracy and fairness and to withdraw it if it cannot be modified to her/his satisfaction.
2. The neurologist's participation should be contingent upon the inclusion of a disclosure statement similar to those used for scientific meetings and publications. It should indicate the payment or other compensation received and should clearly state conflict of interest, if any.

*The Ethics, Law and Humanities Committee of the American Academy of Neurology. Practice Advisory: Participation of neurologists in direct-to-consumer advertising. Neurology 2001; 56: 995-996.*

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**Reflections of a medical professional and editor**

George D. Lundberg, a distinguished pathologist and editor-in-chief of the Journal of the American Medical Association for 17 years, knew that his sacking in 1999, as editor, was inevitable. He had upset too many people for too long a time. His editorial strategy, he has said, was 'to deliberately give (readers) something to complain about'. This had eroded the patience of his corporate supervisors at the AMA. In the end his editorship collapsed not on a point of principle or integrity but over his decision to publish a study of students' attitudes about oral sex during the public travails of President Bill Clinton. Lundberg is rueful about the outcome: "The Monica Lewinsky affair resulted in the loss of my job," he writes, "but not Bill Clinton's."

Lundberg begins with a series of stinging indictments of the AMA. The present organization has 'lost its credibility' and 'lacks leadership'. It has 'bloated senior staff', along with 'a group of pampered voluntary officers' and executives enjoy 'inflated per diems and multiple junkets'. According to Lundberg, the fact that over two-thirds of physicians in the United States refuse to join its ranks proves that the AMA is reviled by its constituency. He watched as the AMA adopted staunchly pro-Republican policies, campaigned for the interest of the doctors rather than patients, failed to protect the fragile mantle of professionalism surrounding physicians and preferred to fight within its own committees rather than openly on behalf of the public.

He is equally scathing about his clinical colleagues. There has been a 'disastrous severance of trust', the origins of which lie in the ways in which doctors, their egos inflated by the prospect of unbridled affluence, have sought new ways to make money from the sick. As a result, professional standards have plummeted. Medicine has been seduced by business. Lundberg wants doctors to take back their profession and he believes they can do so only if they provide a package of basic health care to all citizens. To achieve such an ambitious goal, rationing must be embraced, not resisted. As unpleasant an idea as this might seem, the benefits in tackling health inequalities and quality assurance, would be overwhelming. On the whole, his account of a life and its times has the ring of honesty. He also recognises that his expulsion from the AMA was to the journal's eventual advantage. Stronger systems to safeguard editorial independence are now in place for which his successor owes him a huge debt.

*Horton, Richard. Book review NEJM 2001; 344 (26): 2032 Severed Trust: Why American Medicine Hasn't Been Fixed George D. Lundberg, with James Stacey 371 pp, New York, Basic Books, 2001.*

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