ICC COLUMN: The Voice of the Patient

Cost-effective medicine *vs*. the medical-industrial complex

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Submitted Jun 29, 2014. Accepted for publication Jun 29, 2014.
doi: 10.3978/j.issn.2072-1439.2014.09.01
View this article at: http://dx.doi.org/10.3978/j.issn.2072-1439.2014.09.01

Moneyball medicine

In the fascinating non-fiction book Moneyball (and the movie produced therefrom) the story is told of a major league baseball general manager whose team (the Oakland Athletics) did not have the revenue to compete with other major league teams in hiring the expensive superstar players whose celebrity and superior abilities were thought to be necessary for a winning baseball team.

To combat this business model, he analyzed the ability of lesser known (and less expensive) players to get on base and score runs, which is the goal in winning baseball games. He found that a team of carefully selected ordinary players who had the ability to deliver hits and runs (and victories) for the team could be organized for a small fraction of the cost of hiring superstar players. By focusing on selecting the most cost-effective players in achieving victories, his team beat the teams that paid many times more for players. His strategy is working again this year!

Western medicine is increasingly suffering from an analogous malady of an overly expensive health care business model (1) whose goal is maximizing profit by overusing high-priced procedures and diagnostic tests and forcing patients to take expensive, unnecessary medications through-out the rest of their lives. With this strategy the losers are the patients and the health care systems. In most cases physicians can choose a much less expensive medicine that is as effective as the highly promoted brand name medicine that costs much more. I believe that health care would be benefited by changing its business model to cost-effective medicine with the goal of maximizing favorable patient outcomes at the lowest cost. Many US academic groups agree with the value of cost-effective medicine (2).

Wallowing in unnecessary expense, Western medicine embraces new, high-price diagnostic and therapeutic approaches whether or not they benefit the patient and public health. Published articles about new therapies seldom even mention cost, as if it were irrelevant to health care. In reality, high cost, even of a good therapy, greatly limits its availability and greatly increases the damage done to patients who are forced to bankrupt themselves in seeking the expensive care or to go without any care. The problem has become so pervasive that experts have advocated that high cost of medicines be listed as a side effect of their use (3).

As US President Eisenhower warned in 1961, the people of the world face serious danger from the global power of what he called the "military-industrial complex", which is the influence of the powerful multi-national corporations that are driven only by the quest for profit and power. The danger persists today, and it is represented globally in the medical arena by what Dr. Arnold Relman, the former editor of the New England Journal of Medicine, referred to as the "medical-industrial complex" of medical companies. These medical companies focus on profit and power without regard for patient and public health outcomes (4,5). The purpose of this article is to discuss whether or not medicine that focuses on cost-effective management would provide better patient outcomes than the current expensive medical overtreatment that is forced on many national health care systems by the medical-industrial complex.

Pharma business plans

Pharmaceutical companies have been one of the most profitable global industries for many decades. Their business plan depends on marketing new "blockbuster" drugs and maximizing their profits from these drugs to drive their profitability. They sell these proprietary "branded" drugs at huge mark-ups during the period of their patent

protection. For example, for the new anti-coagulants like Xarelto, a daily dose in the US (assuming twice daily dosing) may cost $20 USD, while the generic warfarin 5 mg tablet costs about $0.10.

In many cases Pharma target patients with chronic diseases that are not curable, and their medicines are designed to reduce or delay the severe effects of the diseases or often just to reduce the symptoms of the diseases. In the case of COPD, the medicines often force patients to suffer with an unhealthy life for a longer time. The companies' goal is to have patients take their expensive medicines through-out their lives with diseases such as hypertension, diabetes, elevated lipids, COPD, and asthma. The problem with this business plan is that new drugs that actually benefit clinically-relevant patient outcomes more than established inexpensive therapies are rare. In order to force broad usage of "me too drugs" and other drugs of questionable efficacy, the companies are forced to falsify clinical trial data, conceal serious drug side effects, fail to release patient-level clinical trial data, bribe physicians to prescribe the drugs, pay to have false and misleading information released in medical communications, pay to prevent cheaper generic drugs from being available, market the drugs heavily during their early release to maximize profit before side effects and other problems are discovered following longer use, and provide payoffs to politicians to pass legislation that will increase company profits without benefiting patients (4-7). While some categories of new medications, such as anti-neoplastic drugs, often can provide life-saving results (at a great cost), treatments in most other clinical areas have not been so successful.

In a recent interview of former US Vice President Al Gore by Dr. Eric Topol on Medscape, the Vice President described how the vast majority of US senators and representatives are dependent on money they receive from corporate interests. These politicians spend half of their time meeting with lobbyists, and when they receive their payoffs from the corporations they are committed to vote for laws that benefit their donors and harm their constituents. That is what American democracy looks like today (8).

Cost-effective versus cost-ineffective COPD therapy

Cost-effective care could be implemented in medical treatments for COPD. One example in the US is the availability of generic formoterol inhalers, which provide a therapeutic dose at about $0.37 each, while newly-introduced branded indacaterol inhalers provide a therapeutic dose at about $7.00 each (9). Yet there is no convincing evidence that the branded drug provides improved survival or better exacerbation reduction or quality of life than the generic drug, and the use of the less expensive drug could save COPD patients and the health care system millions of dollars each year. However, because companies heavily promote their new drugs as major advances and physicians are insensitive to their patients' costs, they are used in preference to generic drugs by US physicians.

In the US, the FDA's criterion for approval of a new drug is not improved patient benefit, but non-inferiority to other available medicines. Many other countries' regulatory authorities have more cost-effective approaches to drug approvals by insisting on cost limits and improved patient benefits over existing drugs for approval of a new drug to be given. This is a proper exercise of the use of cost-effectiveness in selecting medical therapy, but because it reduces corporate profits it is seldom done in the US and other countries where the medical-industrial complex controls medical practice and bribes the political system for their own profit and to the detriment of patients.

Another example of cost-effectiveness in COPD management is the use of products such as acetylcysteine and long-acting theophylline oral medications. N-acetylcysteine is difficult to obtain in the US, probably because it is so inexpensive that drug companies do not want to waste their time making and selling it, and they do not want it to compete with their expensive brand-name drugs that are no more effective. As a result, few physicians prescribe N-acetylcysteine for COPD because it is not marketed to them, but studies have established that it reduces COPD exacerbations for a daily dose of $0.12 while other therapies that are said to delay next exacerbations, such as roflumilast, cost about $8.00 for a dose. In Asia, however, N-acetylcysteine is regularly used, and this represents cost-effective COPD management.

Similarly, inexpensive oral long-acting theophylline preparations are seldom used for COPD in the US even though they are effective and much less expensive than other broncho-dilators. Although methylxanthines can have serious side effects at high blood levels, use of long-acting theophylline products in clinically relevant dosages has been shown to be safe and effective (10). However, the profit from an inexpensive, non-branded product such as long-acting theophylline is miniscule compared to the profit from the array of new branded long-acting beta

agonists (LABAs) and long-acting anti-muscarinic agents (LAMAs) whose use has been heavily promoted by Pharma and endorsed by clinical practice guidelines developed by physicians who have received large payments from the many companies who market and sell these agents. Few, if any, of these guideline experts receive payments from generic long-acting theophylline marketers. New perspectives on the benefits of theophylline use in COPD and new clinical trials with long-acting theophylline have been undertaken and may provide even stronger evidence for its cost-effective usage (11).

US government promotes cost-ineffective care

COPD prevention and early diagnosis of COPD offer the best hope of cost-effective management of the development and early treatment of COPD. However, since these approaches are contrary to the high profit business plan of the medical-industrial complex, they are seldom implemented. In the US, tobacco companies pay large fees to state governments to allow them to promote COPD development among their populations by marketing and selling their tobacco products. In providing this deadly permission for tobacco companies, US states promised to use the large fees they received for tobacco use prevention and programs for smoking cessation to protect their citizens; however, almost none of this promised preventive medicine funding has ever occurred. Instead, US politicians direct the money to projects that benefit them and their donors. This is a perfect example of cost-ineffectiveness in managing COPD (12).

In the US, multi-national corporations pay generic drug companies to prevent them from producing inexpensive versions of their drugs that come off patent protection. By maintaining their monopoly on the drugs they can force patients to continue to pay artificially high prices. The US Supreme Court, in considering the legality of this anti-patient policy, ruled that in many circumstances it is legal for corporations to pay to keep their monopolies (13). This ruling is another example of institutionalized cost-ineffectiveness for medical care. There are many examples of collusion by drug companies to increase profits and take actions that injure and lead to patients' deaths, particularly in the US (14).

Steps to oppose the medical-industrial complex

It is apparent that the policies of the global medical-industrial complex are not only cost-ineffective in managing COPD (and other diseases) but they harm patients. Theirs are the economic policies that kill, as Pope Francis explained (15). Those who wish to improve global public health and help COPD patients must look elsewhere to find cost-effective approaches for COPD to implement. We must oppose the policies of the medical-industrial complex worldwide and its corruption of physicians, governments, and health care systems that lead to patients' suffering and death.

Developing countries should steer away from health care systems like the US that harm patients. To help patients they should do as is currently being done in China by acting to foster lower cost generic drugs. For COPD it is hard to think of a circumstance in which the expensive new drugs provide any substantial medical advantage over older, less expensive drugs, but generic drugs save the patient and the health care system an enormous amount. In some developing countries, hospitals and physicians make excessive profits from selling drugs. This is not a proper approach. For physicians, the problem is that their salaries are much less than they should be, and physician charges should increase. For hospitals, they should charge more for the valuable services they provide; they should not encourage the sale of expensive drugs that are a bad buy for patients.

Acknowledgements

Disclosure: The author declares no conflict of interest.

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Cite this article as: Grouse L. Cost-effective medicine *vs.* the medical-industrial complex. J Thorac Dis 2014;6(9):E203-E206. doi: 10.3978/j.issn.2072-1439.2014.09.01