ICC COLUMN: THE VOICE OF THE PATIENT

Physician bribes in the US and China

Weidong Zhang¹, Lawrence Grouse²

¹Department of Thoracic Surgery, Tianjin First Central Hospital, Tianjin 300192, China; ²University of Washington School of Medicine, Gig Harbor, WA, USA

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This article discusses the issues related to proprietary organizations such as pharmaceutical companies providing payments to physicians to influence their prescribing of the company's products. Such payments, or bribes, may not be associated with an explicit agreement to prescribe the products or it may be a quid pro quo agreement to do so. The recent finding that employees of the British-based company Glaxo SmithKline (GSK) provided funds to physicians in China to influence their prescribing has made this a topic of concern in China as well as in many other countries.

The dictionary suggests that a bribe is a dishonest attempt to persuade someone to act in one's favor by a payment or other inducement. Studies have shown that physicians' behavior is influenced by company payments, and it is also known that the outcomes of clinical trials are much more favorable for a company's product when the company supervises the trial compared to physicians not receiving any payments from the company (1). When physicians with responsibilities to patients and authority to influence other physicians as opinion leaders receive payments from proprietary companies, they are put in a very real conflict of interest position.

We describe the situation of physician payments and bribes in the US and China. Dr. Grouse, a Co-Deputy Editor of the Journal of Thoracic Disease and a licensed physician in the US, describes the situation of physician bribes in his country while Dr. Zhang, a licensed physician in China, describes the situation in China with particular reference to the recent discovery of bribes being given to physicians in China.

Corresponding to: Prof Weidong Zhang. Department of Thoracic Surgery, Tianjin First Central Hospital, 24, Fukang Road, Nankai District, Tianjin 300192, China. Email: zwd@medmail.com; Prof Lawrence Grouse, MD, PhD. University of Washington School of Medicine, 8316 86th Ave NW, Gig Harbor WA 98332, USA. Email: grouse1@msn.com.

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Situations that physicians experience in many countries

Scenario 1: You are a medical specialist—say a pulmonologist—walking to the ICU to see one of your patients and you pass a roomful of your colleagues in the hospital auditorium crowding around tables piled with food and drink. Outside in the hall you see a sign on a stand that says MEGA Pharma welcomes the attending staff to a Pizza and Pasta Lunch brought to you by GALE FORCE, the new fixed combination medication for asthma and COPD! An attractive young person stands in front of you and asks you to join the luncheon and hands you a flier with the program for the talk that will be given. "FREE CME" it says. The other pulmonologist at the hospital is giving a talk based on a study in which he had been an investigator. The talk is The Use of a New, Improved Fixed Combination Medication as First-Line Therapy for COPD.

Scenario 2: You are attending the annual lung society convention somewhere in a large city in your country, and the conventioneers are walking around with convention bags, pens, programs, inhalers, packages, and even neckties emblazoned with pharmaceutical product names and logos. You notice that these same names and logos are on the placards and signs in rooms and hallways, in the programs, and even on the convention buses.

Prior to the convention you received letters and postcards for the nightly gala dinners and CME symposia sponsored by pharmaceutical companies with the best-known pulmonology experts as speakers. You notice that there are 3 speakers at each symposium; two of the speakers are giving interesting scientific talks and one is giving the talk The Use of a New, Improved Fixed Combination Medication as First-Line Therapy for COPD. You find that many of your clinical colleagues from various countries have been given "grants" or "sponsorships" from pharmaceutical and other commercial medical and device companies (referred to in this essay as Pharma) to attend the meeting as "consultants".

Scenario 3: A Pharma representative buttonholes you as you enter your office and hands you a free copy of the latest single-sponsored practice guideline from the lung society and with it an ad slick for GALE FORCE along with free drug samples, peak flow meters, and pens with the GALE FORCE colors and

logo. She hands you three published, state-of-the-art randomized controlled trials from the lung society journal written by the top experts in the field and funded by the makers of GALE FORCE that explicitly state the point of view that GALE FORCE is a better choice than the three drugs you currently prescribe.

These vignettes portray the environment that almost all physicians in the US and China as well as in most other countries have experienced. Proprietary companies have subtle and not-so-subtle ways of bribing them to use or speak in favor of their services and products. Several authors have written their perspectives about the destructive effects of commercial interference with the physician-patient relationship in violation of medical ethics (2-9).

The financial beneficiaries of these commercial bribery schemes are the commercial organizations and the physicians who receive payments. The losers are the patients who bear the expense and inappropriate medical care. In the US, it is not financial need that drives physicians to accept bribes. Many of the specialists who have expensive procedures or tests that they perform such as cardiologists and cardiac surgeons, radiologists, ophthalmologists, and gastroenterologists have salaries that average almost \$500,000 USD per year and yet many seek payments and consultations from proprietary companies whose products they endorse and use. US physicians in training do often incur large debts to complete their education. Escaping this financial burden may affect their willingness to accept bribes just as it apparently induces medical graduates to become specialists in high-paying fields rather than practicing primary care medicine.

In China, things are different. It takes a compulsory five years for a medical student to complete his/her undergraduate education, compared with only four years for other training programs for professionals in financing, marketing, or managerial posts. Thereafter, they find that the 5-year undergraduate training in medical sciences is not sufficient to provide a promising future for their career given the ever-developing medical technology and improving methodology in the medical community; nor would it even qualify them for an opportunity to get a job in a hospital, given the more than one million medical undergraduates nowadays surging out of university gates each year in China. To improve their chances they need to obtain an MD or PhD degree, spending six more years of their lives for the whole process, probably with their aged parents striving in the faraway countryside to earn the hefty tuition they have to pay.

Still, after these arduous years of examinations, probations and training, as well as the life-long learning in their careers, all their work does not translate into a reasonable income and acceptable social position in contrast with their friends with non-medical occupations. Few physicians in China can earn an income greater than \$40,000 USD per year (10). Even salespersons who sell a popular brand of Chinese Dim Sum or tea-pickled eggs can be

much richer than you (11). One may loudly declare that they think nothing of this disparity, always being proud of themselves as an erudite scholar and physician, but when it comes to the travel expense and registration fee for international or domestic meetings, most physicians can't afford such expenses out of their own pocket and the offer from Pharma who are "honored to sponsor" them is very attractive. What follows? It is an established conception among Chinese people that one has to do "something" for "something" you receive—you know it.

Pharma operates in the realm of business and their actions should be in accord with national laws. They are conducting legal businesses regulated by business ethics while physicians are bound by medical ethics. When physicians violate these principles of medical ethics they lose their professional identity and authority (12). As the above scenarios imply, practicing physicians are constantly bombarded by bribes from commercial organizations trying to win their support.

However, Pharma and other commercial organizations do on occasion break the laws of the US (and other countries), and they are sometimes prosecuted for offenses such as illegal promotion of products, illegal payments to physicians and others who prescribe or distribute their products, and concealing information about side effects or defects of their products. In an extreme case unraveled recently in China, Pharma representatives were found to stay in the physicians' office, sitting unscrupulously beside the physicians as the latter interviewed and examined their patients and served as the latter's "assistant" who "helped" by typing electronic prescriptions (13). Very likely, this role made their sales assignment easier and probably succeeded in obtaining a large bonus from their company for over-fulfillment. For allowing the representative to be their "assistant" the physicians received some benefit. It is noteworthy that in almost every such case a fine will be levied on the company, but no individual responsibility for the activities will be enforced on the representatives of the company or the physicians.

There is a line between taking a bribe with no expressed agreement or contract as to the performance of the physician who has taken it and the taking of a bribe when there is a specific *quid pro quo* agreed upon. In the US, where 95% of physicians accept some gifts or bribes from industry (14), many of less than \$100 value, it is rare that specific written obligations are undertaken by physicians to prescribe drugs or use devices for pay. When this occurs, fines and medical disciplinary action will often result for physicians and fines will be levied on companies.

For physicians, such penalties will often have a negative and life-long effect on their reputation; however, for companies the fine that they receive in general is much less than the profit they have made by providing the bribes and since no personal responsibility or penalty for any individual is assigned, the managers who have been responsible for the bribes are heroes at

the company rather than being censured.

In colonial times the American patriot, scientist, and politician Benjamin Franklin wrote, "Never make your physician your heir!" A contemporary Franklin might write, "Never let Pharma bribe your physician!" A consequence of such a serious conflict of interest that involves bribes from Pharma to physicians would be the destruction of the credibility of the medical profession.

Pharma control of post-graduate education

Another form of bribe that Pharma provides to physicians masquerades as the gift of education. Pharma, through its funding, has assumed extensive control of post-graduate physician medical education (aka CME in the US and China). It would be of interest to see whether or not the education that is provided results in improved and appropriate patient management. Recent data indicate that appropriate treatment for patients in the US is given in only 50% of physician visits. In fact, longer clinical experience, and hence more post-graduate education, is correlated with inferior quality of care (15). By this measure the value of current forms of post-graduate education must be questioned.

In the US more than 30,000 people were employed in the Pharma-funded CME industry (16). Until recently, they were reputedly crafting drug promotion disguised as education that focused on the advantages of the sponsor's product and minimizing discussion of dangerous side effects. The US Senate Committee on Finance wrote to the organization—ACCME that supervises US post-graduate education to express its concern about the conflict of interest when Pharma spends more than 1 billion dollars a year for education about topics that highlight the use of their products. Who pays the piper calls the tune, they imply. ACCME replied that their policies and procedures for developing educational materials are sufficient for ensuring their objectivity. However, the Senate Committee pointed out that although ACCME surveyors review accredited organizations' procedures for ensuring the independence of certified CME, they do not analyze the actual content that is presented (17). Review of hundreds of CME-certified presentations sponsored by Pharma made it clear that in the vast majority of instances a bias was introduced in the communications in favor of the product produced by the sponsor of the CME. In some cases it was not so much that the information presented was false, but that the fair balance and clinical perspective that should have been present was predictably distorted by the proprietary interest. ACCME has recently introduced new procedures designed to eliminate some of the conflict of interest that has occurred in many CME activities. It may improve the education that is provided if it is implemented. However, if there is no mechanism to analyze the resulting content of the medical education activities, the Pharmafunded medical educators who actually conduct the activities have many opportunities to introduce undetected Pharma promotion.

Because of the increasing visibility of these problems with Pharma-funded medical education, the US Institute of Medicine and the Association of American Medical Colleges are conducting inquiries into conflicts of interest in medical education. Because of the increased vigilance of regulatory agencies such as the FDA and the HHS, millions of dollars in fines and penalties have already been imposed on Pharma and many of the most egregious activities have now been stopped. In Europe, laws enacted in France and Italy are similarly limiting Pharma promotion in medical education. Because of these concerns, Pharma-funded CME is decreasing in the US.

Acquiring the KOLs

The close relationship of Pharma with physician leaders in the US and in many other countries is based on an elaborate scheme of bribes. These physician leaders are very important to Pharma, and they are recruited as lecturers on the Pharma speakers' bureaus, investigators for their clinical trials, consultants on their advisory boards, and experts for their medical education symposia. These leaders are referred to by Pharma as KOLskey opinion leaders—and we have used this term as well. It is important for Pharma that the cooperation of KOLs is acquired. Their activities with Pharma provide them with substantial revenue and prestige. These activities provide Pharma with access to the decisions of medical professional organizations in which the leaders have influence. Some of these physician leaders, who are generally academics, are soon making more money from Pharma than from their academic day jobs. The lucrative Pharma advisory groups, lectures, research grants, symposia, business-class flights, and other payoffs for the physician leaders encourage their cooperation. They begin to work for Pharma, perhaps without realizing it. Full disclosures of such payments to KOLs are rare although the so-called "Sunshine Law" in the US Affordable Care Act may affect that in the US. A typical specialist leader has had payments from 5-15 Pharma companies in a given year. In addition, very little is known about the nature of the arrangements that led to the payments or their actual amounts. These are "trade secrets".

In China, Pharma also invite many Chinese KOLs to domestic and international conferences, but unlike many payments in the US and EU, GSK in China not only covered KOLs' travel expenses, but also gave them large speaking fees, although many of them were not program speakers in the conferences. Other physicians were given speaking fees without even attending conferences by using false tax-invoices to claim cash refunds (18). In some domestic conferences, GSK arranged meetings longer than one day, and many KOLs were invited to travel to attractions near the conference location rather than attending medical meetings.

Pharma involves KOLs in leading clinical trials, and they provide premiere showcasing of the KOLs' educational skills before their peers in symposia organized by Pharma. As a result the KOLs become recognized as experts if they were not already so recognized. They become the peer reviewers of important articles in their specialty in the peer-reviewed medical literature where their Pharma-created biases can prevent publication of results or ideas that are opposed to their proprietary interests. Throughout the world, Pharma use their relationships with KOLs to downplay the adverse effects of their drugs in multicenter clinical trials led by these KOLs (19). Equally destructive is the fact the KOLs are chosen to be consultants to governments. They serve on FDA and EMEA advisory panels to give advice on which drugs should be licensed and which rejected. They serve on NIH advisory panels to review grant applications. With this power, the KOLs can influence the entire direction of new research; competing ideas, directions, and the products that will or will not be used. These obvious conflicts of interest are finally beginning to be discovered. Experts are now often required to file disclosures about payments that they receive that could represent conflicts of interest. However, in most instances, these experts' opinions are still accepted in spite of their conflicts of interest. They should not be.

Implications of KOL acquisition for peer review

The pervasive funding system that Pharma has established for the KOLs, and which is now coming into wider view and harsher criticism, has other important implications for the peer review system that is at the heart of the NIH basic and clinical research enterprise as well as the medical literature. The thesis has always been that science is self-correcting; if an unethical researcher fakes data then there would be other, more ethical researchers who would do the experiment correctly and right the wrong. But what if the key researchers in a particular area are on the payroll of the companies that have a vested interest in a certain result? What if the companies designed the studies to get the result they wanted and only the studies funded by the companies and managed by their KOLs would ever be conducted? What if the experts that do the peer review of the studies for the medical journals are KOLs for the companies that funded the studies? Why does it seem to happen so often that all the published studies funded by company A show that the products of company A are better than those of company B while those of company B show the reverse? We believe that the peer review system, before which medical scientists genuflect, often fails.

The interpretation of medical research is by no means straightforward and uncontroversial. Different groups of respected scientists study the same question and get diametrically opposed results all the time. Study exclusion criteria and other technical features of studies can affect their

general applicability. Studies of a therapy that are conducted in clinical research facilities staffed with experienced investigators and staff may not give the same results as those seen in a busy primary care setting. And if the arbiters of these studies, the expert peer reviewers, have conflicts of interest in judging the results, how can we be sure what to believe? The situation can easily develop in which large randomized controlled trials can show significant benefits of drug therapy while the use of the drug in actual clinical practice will introduce large costs but no benefit for patients. Improvement that results from therapy in surrogate clinical variables such as glycemic control may not result in improvements in mortality or other patient outcomes as data concerning rosiglitazone have suggested (20).

Do Pharma bribes negatively affect patients?

Because marketing expenses are usually intermixed with other Pharma expenses such as research and development, it is difficult to identify specific Pharma budget lines to quantify what they pay to influence physicians in the US. Reports have suggested that the actual amount was about 20 billion dollars per year. Nearly 95% of US physicians receive gifts from Pharma sales representatives (16). If these funds went instead to provide more and more appropriate health care, they could substantially benefit patients and public health.

We urge our colleagues consider these issues (21). If we are regarded by patients as being bought and paid for by industry we will not retain our professional status. We can start by remembering the words that many of us in the US spoke from the Oath of Maimonides when we graduated from medical school: "Thy eternal providence has appointed me to watch over the life and health of my fellow human beings. May the love for my art actuate me at all times; may neither avarice nor miserliness, nor thirst for glory, or for great reputation engage my mind; for the enemies of truth and philanthropy could easily deceive me and make me forgetful of my lofty aim of doing good to my patients". Also we hope the health system reform in China could lead to a generous and secure income and social trust for Chinese physicians. How comes the embarrassing income and social reputation for physicians in today's China? That should be discussed in another story, but not in this article which focuses on physician bribes.

The international reporting of the GSK payments to travel agencies in China to pay physicians' expenses has not been clear as to what illegal activities have resulted. The authorities are right in taking action against law breaking; however, for cases in which the funds have been given to physicians to attend truly educational activities that benefit patient outcomes and public health, we wonder if this a concern. In the West, most major Pharma for many years provided funds for physicians to travel to the international meetings of their medical professional

organizations. Each company would fund thousands of physicians' expenses each year, particularly in the EU. These payments resulted for the most part in physician and patient benefits. However, this practice has greatly decreased in the past few years in the West because of concerns about conflicts of interest, but colleagues in China should realize that to the extent that Pharma have provided funding for legitimate medical education, this is not substantially different from what has occurred worldwide for many years and the activities of companies such as GSK working in China should be understood in its global context. It should also be realized that it is difficult for large global companies to monitor all the activities of their representatives in each country. The support of legitimate medical education should be viewed differently from the cases in which illegal bribes were given.

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