

Physician-Pharmaceutical Industry Interaction: Changing Dimensions and Ethics

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The last century, has witnessed a phenomenal growth in science and technology including medicine. The noble traditions of medical profession have been virtually washed away by the strong financial and economic reasons. Number of medical practitioners and medical institutions has increased at an alarming rate leading to higher competition between groups and individuals. Many of the present day ethical problems have originated because of the cut throat competition and degeneration of the moral and ethical values in the society.

Pharmacy and physician are among the integral components of health care delivery system. Drugs are the basic tools available to a physician in treatment of an illness. Thus, the knowledge about old and newer drugs is a must for a physician. Virtually, daily a pharmaceutical weapon is added to the physician's therapeutic armamentarium. The information about a new drug is mostly provided by the pharmaceutical industry, through its sales representatives, brochures, banners *etc.*

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The average cost of developing a new drug is estimated to be \$300 million to \$600 million(1). The drug companies spend huge amount of money on developing new drugs, as well as they also spend lavishly in sales promotion to earn profits. This highly competitive pharmaceutical industry is also the most profitable in United States with a 13% return on the sales in 1989. It is estimated that at least \$5 billion were spent on marketing in USA a decade ago(2). As per the informal discussions with marketing executives of different pharmaceutical companies, it was found that about 21-25% of different companies spend the turnover on the sales promotion. According to the latest annual report of Glaxo-SmithKline Pharmaceutical Ltd., the company spent 20 crore rupees on sales promotion for the year ending 31st Dec. 2001(3).

Social scientists describe and the pharmaceutical industry follows the, "norm of reciprocity" *i.e.*, the obligation to help those who have helped you, as one of the fundamental guiding principle of human interactions. It is not surprising, therefore, that pharmaceutical companies rely on this principle of human nature by giving gifts to physicians in hope that they will prescribe their firm's product in return.

Physician and Pharmaceutical Industry Interaction

Interaction of the medical professional with the pharmaceutical industry starts as early as in medical school. The physician and sales representative meet about 4 times a month(4). These interactions are controversial in many ways(5-7). According to one school of

thought, the interaction is necessary for education, information and biomedical research(8). In contrast, others see in such arrangement “the essence of good bribery”, and have concern that all such contracts between doctors and industry involve compromise and should therefore be avoided as far as possible(5).

According to a US Senate Staff report, the drug companies spend around \$10 billion yearly for promoting their products(9). The one to one interaction between a physician and pharmaceutical representative is too difficult to regulate. The pharmaceutical company and physician interactions vary from merely providing information about their products to lavish incentives for prescribing the specific drug. Major portion of the mammoth sales promotion budget of pharmaceutical companies is devoted in modifying the drug prescribing behaviour of the physicians. The policies adopted by the pharmaceutical firms may include extravagant marketing practices like: (a) Offering vacation/travel expenses; (b) Gifts of substantial value; (c) Lavish meals and entertainment; (d) Offering cash/commission for prescribing a particular brand/drug; (e) Offering money for drug trial; (f) Samples and promotional material; and (g) CME funding and honoraria(10).

(a) *Vacation Expenses*

As per the physician’s and pharmaceutical company executive’s testimony to Senate Labour of Human Resources Committee in US, more than half a million dollars are spent by drug companies in sponsoring physicians and their spouses on trips to different places for “educational” symposia(2). The physicians for such favor are not selected randomly. But, they are selected on the basis of their clientage and speciality. While, only the 3% residents were paid the travel expenses, this percentage

was 42 for consultants(11-12). The expenses for travel, stay and even local sight seeing are paid directly to the tour operator by the pharmaceutical company or travel ticket and hotel accommodation are booked by the company in the name of the physician. The expenses of not only the physician but also of their spouse and family are borne by the pharmaceutical companies(13). This new dimension of family sponsorship is threatening to reduce academic exercises to social outings(14). Evidence supports that drug company sponsorship of travel expenses change the prescribing behavior of physicians. These doctors who avail the travel expense are 4.5-10 times more likely to prescribe the company’s product after such sponsorship than before(15).

(b) *Gifts of Substantial Value*

In Canada, on an average 6 gifts are received per year by physicians with average value of \$60(11). In India, as per discussions with colleagues, every doctor working in clinical specialty receives a minimum of 5-7 gifts per year. The quality and quantity of gift in different categories of physicians vary from interns to senior consultants. The physicians receive gifts and even incentives in cash directly proportional to their prescribing abilities. More the prescription, more the gift/commission. Special gifts are also given on the occasion of festivals like Diwali, New Year etc. The value of gifts may be somewhere between Rupees 50-5,000 or even more and they may be in the form of utility items not necessarily related to the medical practice.

A reminder item may also be anything from a notepad to a personal computer that displays the pharmaceutical company’s name or logo. Few physicians even demand specific gifts item of substantial value in lieu of the prescription of particular brand of drug

manufactured by the company. One of the senior executive belonging to a fairly well known drug company during informal chat disclosed to this author that one doctor even demanded honeymoon package in Switzerland for his son in lieu of prescribing a newly introduced drug by his company.

(c) *Lavish meals and entertainment*

Eighty per cent of residents eat pharmaceutical industry paid meals about 14 times in a year in Canada(11). The drug companies in India are no exception. They also sponsor lavish meals during conferences, symposia's, seminars, CME, launching of new drugs *etc.* A large number of such activities are organised even in five star and other big hotels with huge expenditure to the pharmaceutical industry.

(d) *Cash/Commission for prescription of a particular brand*

This is relatively a new trend that has emerged in the physician-pharmaceutical industry interaction. Some of the physicians have become commission agents for writing the prescription of a particular drug/brand having an unholy understanding with the drug company. The pharmaceutical company pays a fixed percentage of the selling price of the drug to the prescribing physician. This practice is commonly employed by little known/ upcoming companies and by the sales representatives of even some of the established companies in order to achieve their sales targets.

(e) *Money for drug trial*

Newer drugs are added in the pharmaceutical market at a very fast pace. Before license to manufacture a drug is issued, it is mandatory to have clinical studies about its advantage and other related issues. Most clinical studies that help in bringing out new

drugs from bench to bedside are financed by pharmaceutical industry(16).

The ties between clinical researchers and industry include not only grant support, but also a host of other financial arrangements. Researchers serve as consultants to these companies whose products they are studying. They also join advisory boards and speakers bureaus, enter into patent and royalty arrangements, agree to be listed authors of articles ghost written by interested companies, promote drugs and devices at company sponsored symposiums, and allow themselves to be plied with expensive gifts. They may also have equity interest in the companies(17).

India, being a developing country with large patient load, that is usually illiterate and economically jeopardized, has enormous potential for being exploited by multinational drug companies with mammoth financial strength. All this makes our population an easy target of even some of the very risky drug trials. More so, when lucrative incentives are offered to the physicians. Some of the pharmaceutical companies offer money based on the number of patients/volunteer recruited for drug trials by the physicians.

(f) *Samples and promotional material*

Almost all pharmaceutical companies offer drug samples and promotional material meant specifically for physicians. Nearly more than 90% of residents receive patient education items(18). Frequency of receiving drug samples varies from 5.4% daily to 48% monthly among physicians(19). There appears nothing wrong in accepting drugs samples and related promotional literature that helps in improving the knowledge and skill on new drugs and devices. However, offering a physician \$100 to simply read a company's literature that encourages prescribing of a

highly toxic drug for use that was not even approved can not be justified?

(g) *CME funding and honoraria*

More than half of the income of the organizers of CME/symposia is generated from pharmaceutical industry(13). Spending by the pharmaceutical industry in US has increased from \$34 million (inflation adjusted) in 1975 to \$165 million in 1988, on account of symposia, gifts and reminder items. The lion's share of this increase is attributed to increased funding of symposia from \$6 million to \$86 million (a 14 fold increase)(2). Average frequency of physician receiving honoraria is found 1.2 per year in one study(20). These physicians are usually senior consultant that receive such favor from drug firms. It has been stated that sponsorship of CME/conference at personal and organiza-tional level influences these activities in a big way(14).

Ethics of interaction

The interaction between physicians and pharmaceutical industry shares some common interests like: (a) use of drugs in treatment and care; (b) monitoring of the drug use; and (c) innovation of new drugs. However, both parties have different emphasis and focus on different stakeholders. Physicians are primarily interested in patient care and scientific advances, while industry is more interested in commercial outcome(21). Business houses or corporate bodies run pharmaceutical firms. They spend huge amount of money in interacting with the physicians. This is not done as an act of generosity, but it is a well planned marketing strategy employed by the pharmaceutical industry to bolster their bottom lines. During the period 1981-1988, 25 largest US drug manufacturers introduced 348 drugs. Out of these only 3% drugs had important potential contribution to existing therapies whereas

84% had little or no potential contribution(2).

Despite this, all these drugs were sold in the market with the help of prescribing physicians. The increasing cost of marketing a drug is simply passed on to consumers *i.e.*, patients. The drugs prices escalated 88% between 1981-88 in US, when the general price inflation was 28%. According to the annual report of Glaxo Smithkline Pharma, the selling price of drugs is double the cost of materials used for manufacturing them(3). Market sources reveals that some small-scale drug units keep the selling price of a drug 4-5 times the manufacturing cost. The prices of some of the drugs are so high that average citizens of our country cannot simply afford them. It is fact that the costs of the industry sponsored trips, meals, gifts, conferences, symposiums and honorariums, consulting fees and research grants are simply added to the prices of drugs and devices(17). Patients in effect pay twice: once when they visit the physician, and then indirectly once more when they make their drug purchases.

The act of receiving gifts and other benefits from the pharmaceutical firm by physicians establish relationship with the giver and assumes certain social duties such as: grateful conduct, grateful use, and recipro-cation. It is bound to compromise the physician's decision making. Further, it is also unrealistic to expect the pharmaceutical industry that contribute large sums of money in different manner to physicians, will not influence their attitude and behavior towards them. Since no profit minded company would distribute gifts and other freebies out of disinterested generosity. In the context of medicine, however, many feel that the act of accepting a gift has far reaching ethical consequences that put the "gift" at too great a price(22). Considering the above ethical issues, on December 3, 1990 the Council on Ethical and Judicial Affairs of the

American Medical Association (AMA) issued its guide-lines on this aspect of physician-pharma-ceutical industry interaction. These guidelines has also been incorporated in the AMA's code of ethics for medical profession and are listed below(23):

- I. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and any gifts are appropriate if they serve a genuine educational action. Cash payments should not be accepted.
- II. Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (*e.g.*, pens and notepads).
- III. Subsidies to underwrite the costs of continuing medical education, conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship that could influence the use of the company's products. Any subsidy should be accepted by the conference organizer who, in turn, can use the money to reduce the conference registration fee. Payments to defray the costs of conference should not be accepted directly from the company to the physicians who are attending the conference.
- IV. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of the physicians who are attending the conferences or meetings, nor should subsidies be accepted to compensate for the physician's time. Subsidies for hospitality should not be accepted outside of modest meals or social events that are held as part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.
- V. Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution.
- VI. No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

It is not only US, but other countries have also framed/ urged to frame similar guidelines for interaction between physicians and pharmaceutical industry(21,24,25). The recent regulation of Medical Council of India (MCI) also suggest that doctors should prescribe drugs by generic names and not by trade names in order to marginalize association

Key Messages

- The interaction between physicians and pharmaceutical industry has transformed into a marketing strategy.
- The freebies offered by the pharmaceutical industry to physicians are not an act of disinterested generosity and ultimately costs the patient.
- Formulation and strengthening of ethical norms and MCI code to regulate the physician-pharmaceutical industry interaction is the need of the hour.

between the drug firms and doctors. The Section 6.1 of chapter 6 in MCI notification also states, “a physician shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect to any drug, medicine, nostrum remedy, surgical or therapeutic article, apparatus or appliance or any commercial product or article with respect to any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature or photograph in any form or manner of advertising through any mode or shall he boost of cases, operations, cures or remedies or permit the publication of any report through any article”. The Section 6.4.1 of the same notification states that, “a physician shall not give, solicit or receive nor shall he offer to give, solicit or receive any gift, gratuity, commission or bonus in consideration of a return for referring, recommending or procuring of any patient for medical, surgical or other treatment”(26).

However, the notification is silent on soliciting or receiving any gift, gratuity, commission or bonus from pharmaceutical industry. Hence, the above steps of MCI are not enough in curtailing the tendency among physicians to accept the freebies offered by pharmaceutical industry. A beginning to

discourage such interactions between physicians and pharmaceutical industry can be made by incorporating specific code of ethics on this issue by MCI/Academies/Associations of different specialities in our countries. MCI should incorporate in the code of ethics, “that soliciting or accepting any gift of substantial value (amount can be fixed say more than 500 rupees), gratuity, commission or bonus, travel grant by a medical practitioner from any pharmaceutical industry would amount to unethical practice and would be taken as infamous conduct.” At individual and society/association level a general awareness campaign against the freebies can be launched. The societies/associations can also amend their membership clause by adding one more section, specifying that, “if any member found indulging in soliciting/ accepting gifts of substantial value, cash in any form (except for purposes of the society), commission, gratuity, bonus, travel grant *etc.* from any pharmaceutical industry, his/her membership can be terminated.”

However, if any pharmaceutical firm wishes to donate any amount in cash or kind it should be in favor of professional society/association and not for personal expenses of any individual practitioner directly. The society if wishes can reimburse the expenses incurred by any physician that it deem fit in order to foster the scientific/academic activity.

But, the importance of strengthening the basic morals and principles of medical profession on this issue cannot be over emphasized. As rightly said by Dr. Margolis, Pediatrician, “Physicians ought to ask themselves whether or not they would tell their patients, I am going off to Aspen for a week, and by the way, you are paying for it. If they are not willing to say it, that to me is a good sign their conscience is concerned about the activity”(22).

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