

ETHICS IN DEALING WITH PHARMA INDUSTRIES

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Ethics in general is philosophical issue and is defined as philosophical study of morality. The scientific study of morality is descriptive ethics and it is generally concerned with explanation of moral views and it's causal origin. However, philosophical ethics involves normative ethics acknowledging what is morally right or wrong in relation to human behavior. Thus biomedical ethics can be understood as branch of applied ethics, some identify it as practical ethics. The main goal of biomedical ethics is to resolve the related problems in medical practice. If we believe that medical ethics is applied ethics then it is also prudent to consider that the ethics is also going to be influenced by political, social and economical aspect and policies of our environment.

So in essence medical ethics imply

- Subject that deals with values, and opinions
- Developed by human behavior
- Open to time, place and situation
- Related to benevolence
- Related to patient care
- Related to society at large
- Related to humanity in general

The virtuous physician in general is not irrational & uncritically intuitive about what represents the respectable. Medical practice essentially is rational & involves matter-of-factly wisdom. That is the crucial conclusion of professional act of medical practice. The difficulty & question arise when self interest becomes superior aspect in comparison to well being & care of the patients.

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Guideline 1

Medical practitioner in general is expected to evolve as a professional for ultimate benefit & well being of his patients

GROWING CONCERN

Since the time of Hippocrates, Western Physicians have taken an oath in which they swear to protect their patients from whatever is deleterious and mischievous. Hippocratic oath guides the highest aspiration of the medical professional . It talks about not only duties towards the patient but also duties towards fellow colleagues of medicine. By & large it talks about medical professional's obligation to help & not to harm the patient. [1]. The declaration of Geneva acknowledges medical practice with conscience and dignity in keeping with honor and righteous tradition the profession.

Guideline 2

Psychiatrists as medical professional will always protect their patients from whatever is deleterious and mischievous.

However over the years these aspects in medical practice remain a matter of concern. Physicians in today's world are living in morally relaxed environment, mainly sweeping commerciality. The recent practices in medial profession are more contradictive in terms of self interest versus altruism. Many of their practices are blurred by:

1. Opportunities for profit from patient's illnesses.
2. Narrowing the issue of service to personal benefit
3. Adapting a proprietary attitude with respect to medical knowledge
4. Shifting the loyalty from patients to commercialism

Slowly all over the world it is obvious that physicians are getting engaged in selling services for whatever that market will bear. Getting lured by commercial aspect of medical world is common observation. Many Physicians may get into it without realization or they may rationalize a deontological ethics.

There is growing debate about the ethics of relationships between the pharmaceutical industry and the medical profession. Concerns include bias in research, funded by the pharmaceutical industry and conflicts of interest with regard to prescribing by medical practitioners who accept industry gifts and hospitality. The marketing environment with a rapid increasing medical costs is resulting into endangering the patient centered ethics at the moral core of medicine. So they need to decide about benefit of treatment to the patients are worth the cost to society. Sociologist, economist corporate executives & even, many doctors acknowledge that the doctors also have an obligation to save resources for society.

Guideline 3

- *Psychiatrists need to decide about benefit of treatment to the patients is worth the cost to society.*
- *While doing so they also have a commitment to save resources for the benefit of society.*

It is acknowledged beyond doubt that the interaction of doctors and pharmaceutical companies is consequential for patients, doctors, and the larger society. The marketing by the drug industry mainly aimed at improving industry profits. Consequences are seen in terms of increasing drug costs and the misuse or overuse of medications in ways that may adversely affect patients. Pharma is business and is expected to function as per legal guidelines of nation. They are guided by *business ethics*, whereas medical physicians are guided by *medical ethics*. When physicians breach the principles of medical ethics, they lose their professional uniqueness and power.

Guideline 4

- *Psychiatrist will maintained their professional uniqueness and credibility*
- *Psychiatrist will avoid the misuse or overuse of medications in ways that may adversely affect patients.*

MEDICAL PROFESSIONAL ORGANIZATION (MPO) AND PHARMA

Major alarm is also the running of Medical professional organization(MPO) so dependent on Pharma funding that these funders almost control over MPO policies and thereby damaging the guideline of medical ethics. [2]. The pharma industry pay out aproximayely over \$21 billion yearly in US to maneuver our thinking and action as well as what we teach. Physicians and the pharmaceutical industry share a common interest in providing safe and effective medications to patients, but are divergent in their practices and ethical standards. Interactions between them are inevitable and desirable, but may create conflicts of interest for physicians. [3]. Dr. Marcia Angell, former editor of *The New England Journal of Medicine*, has a simple solution to MPO hypocrisy and conflicts of interest. She believes that MPOs should be self-supporting . [4].

Following leading professional organizations are working towards revamped guidelines regarding physicians' interactions with drug companies

- The American medical association,
- The American college of physicians,
- The accreditation council for continuing medical education
- European Federation of Pharmaceutical Industries an Associations (EFPIA)

Guideline 5

The running of professional bodies in psychiatry will not jeopardize the basic interest of profession and professional commitments to the patients and to the society at large due to support from pharma industry.

PHARMACEUTICAL SALES REPRESENTATIVE

A pharmaceutical sales representative is the key part within the sales of all drugs. In the field of Pharma industry, ethical promotion can be described as communication of ethical values to promote their product to the physician. [5] . The number of sales representatives has increased dramatically. This then increased the competition to seek time with the physician. With increased competition the practice of gift giving increased to reward the physician for time they give to listen to pharma. This was not an effective strategy and can no longer substantiate the marketing strategies. So new modus operandi were brought in for their marketing techniques. They now explore private and personal information about doctors, their likes and interests in various areas Eg; non-vegetarian food or music etc. This also open out further with pharma celebrating birthday and anniversaries of Doctors and their families.

Guideline 6

- *While dealing with pharmaceutical representative, psychiatrist will be committed to the wellbeing of the patient.*
- *Hence psychiatrist will not utilize his time with medical sales representative at the cost of the patient time.*
- *They will always keep the professional and ethical outlook while dealing with medical sales rep*

PRESCRIBING UNDER THE INFLUENCE OF GIFTS????

Today It is not easy to find any practicing doctor who has not been the recipient of small "educational" or academic gifts such as pens and memo pads or lunch for the office staff. Gifts from drug companies to doctors have repercussion on patient interests. Accepting gifts is trendy practice and is taken as normative by many young physicians. Otherwise also Physicians are usually not interested in talking to pharma representatives unless they have something to catch their attention. This lead to all-expensespaid trips to luxury resorts. The doctors participate in seminars for several hours. They enjoy the amenities of the locale. They ultimately remember the product for which they enjoyed all these perks.

Physicians generally say that

We don't get influenced.....

"It doesn't influence me at all.

They are not going to buy my soul with a laser pointer.”

- ✍ The revealing truth is otherwise, the physicians may need to reconsider this. A doctor is not going to prescribe something he or she has never heard of. A recent letter in the Journal of the American Medical Association demonstrated the impression of powerful drug advertising. They found the difference between the physicians who were coached by pharma landed up writing the desired prescriptions and approved the view of Pharma & they did not endorse the scientific view of the molecule [6]. U S Journalists have also exposed abuses among US specialist practitioners who enhance their revenue with costly intervention and pharmco therapies and procedures that do not benefit their patients.[7]. Guidelines regarding gifts are based on various studies indicative of their impact and generally recommend that they should be limited or avoided altogether. Free samples may be of benefit to patients, but must be used with caution to avoid inappropriate drug choice. Resistance from physician. Some physicians have joined an organization NO FREE LUNCH..... which asked physicians to make a pledged to not accept any pharmaceutical companies gifts no matter how large or small. The members base that gifts giving forms relationships, which influences behavior and creates a conflict of interest. **(No Free Lunch)**

Guideline 7

The psychiatrist as a scientific professional will always endorse the scientific views of the pharmaceutical drugs hence will always promote rational and appropriate use of them

Guideline 8

- By and large the psychiatrist should avoid accepting the expensive and personal gifts from Pharms.
- Gifts and inducements must provide value to the practice of medicine or pharmacy.
- They have to be reasonable and promote professional education and efficacy.
- If the gifts are intended to promote education or scientific character of doctor's practice, they need not be objected.

CONFLICT OF INTEREST

The pharmaceutical industry (pharma) pay out over \$15 billion annually promoting its products in the U.S. market [8]. The widespread peer-reviewed literature indicated that reliance on such promotional sources for medical information can prove to be harmful to the health of the patients. Professional way of thinking about the wellbeing of patients may be unsuitably biased by a secondary interest. In such cases, the personal benefits are consequential from alliance with pharmaceutical companies. We should be attentive to the reality of expenditure pharma spend on research and entertaining doctors. The pharmaceutical industry spends approximately \$12 billion annually on gifts and payments to

physicians. To a significant extent, growth in promotional activity has paralleled the rise of the industry's importance as a funder of mainstream research and education. In case of wronged alliance of this kind the loser is the patient. Beginning in January of 2004, pursuant to an agreement between the National Health Service and the pharmaceutical industry, it is essential for doctors in Scotland to report to an official, publicly available registry any links to pharma companies, including shareholdings, lecture fees, payments to attend meetings, and research grants [9]. This is the first government regulatory program related to a fast-growing grassroots movement among of physician in this area. In India many psychiatrists are a part of government sector either in service units or in education system. It is mandatory for them to follow this system as they are the part of system.

Other regulatory boards include

- European Medicines Agency (EMA)
- World Health Organisation (WHO)
- Food and Drug Administration (FDA)
- Pharmaceutical Research and Manufactures of America (PRMA)

Guideline 9

- *The psychiatrist will be transparent in his alliance with the pharma industry & will always focus on ethical & regulatory standard.*
- *The psychiatrist will not indulge in the practice of accepting funds for personal benefit of any kind.*

Bioethics: New York Times - Conflict of Interest Study revealed, a survey of medical experts who write guidelines for treating conditions showed that nearly 9 out of 10 have financial ties to the pharmaceutical industry, and the ties are almost never disclosed. We must note that financial support from drug manufacturers can affect the course of academic research. News and world revealed that 19 out of the 27 task force members for DSM-V, due to be published in 2012, had financial ties to drug companies. Nearly 20 drug companies this year have invested an estimated \$3 million into the APA's convention alone.[10].

Guideline 10

- *While developing therapeutic guideline the psychiatrist will not get influence by pharma industries*

Many clinicians attend dinners to listen to a hired expert talk about a product, take educational trips to resorts, or receive funds (explicitly without strings attached). There are physicians who spend their life time in being "hired" speakers for the marketing of DRUGS with benefit of having global picnics and other perks.

Fortunately, some doctors do not get entrapped in this vicious cycle, but many more do. The result is

costlier medicines being thrust on the patients in general and poor patients in particular. The price of free gifts or free holidays or free excursions, which is quite overpriced, has to be put up by the poverty stricken patient, about whom nobody even thinks. Remember, in reality there is no free lunch. Because somebody is paying for this. Sadly may be very poor, non-affording sick and helpless patient paid for this. Attending pharma guided presentations given by pharmaceutical-representative speakers was also associated with non-rational prescribing, [11].

Many years it was also noted that articles signed by academic physicians or researchers and submitted to peer-reviewed medical journals were actually result of Drug marketing techniques including the sponsorship. Many of these articles are written by ghostwriters who work for pharmaceutical companies or medical education companies hired by pharmaceutical companies.

Guideline 11

- The psychiatrist will not get involved in the ghost writing practices that are commercially involved in increasing drug sale.
- Psychiatrist will not choose to be hired speaker and promote non-rational prescribing associated, in increasing drug sale by pharma
- The psychiatrist will avoid endorsing pharma products at personal level by allowing to use their photographs or focused comments in pharma newsletters or promotional pamphlets.

THE ROLE OF PHYSICIANS AND CONSUMERS

Physicians and consumers need to be part of the solution. Consumers have to be more realistic. They need to have knowledge about the medical and economic dynamics. This force will be able to curb wrong practices. The sale of products from the physician's office might also be reflect on by some to be a form of self-referral, and it is detrimental to the trust necessary or doctor patient relationship.[12]. Physicians are not suppose to sell products out of the office unless the products are exclusively pertinent to the patient's care, propose a clear benefit based on enough clinical evidence and research, and meet an imperative need of the patient.

Guideline 12

- Psychiatrists are not supposed to sell products out of the office unless the products are exclusively pertinent to the patient's care.
- The psychiatrist should never give incentives to the patient to buy particular brand of pharma products.
- In the case of patients getting carried away by pharma advertisements and thereby likely to have adverse health effects, the psychiatrist will guide the consumers in right direction.

ETHICS AND MEDICAL STUDENTS

There are serious ethical issues that should be considered by medical educators. Firstly, the character of medical students are shaped in important and long-lasting ways by their medical education; and secondly, that some character traits are ethically more desirable than others. This suggests that students take on their medical identities in line with prevailing medical mores. Gift-giving invokes the reciprocity rule, which creates a feeling of indebtedness in the recipient together with the desire to repay the favor in some way. [13] However, there is evidence that limiting pharmaceutical industry contacts during postgraduate training produces specialists who perceive drug company information as less useful, and who see industry representatives less frequently than specialists who were exposed during training. [14-15]

Guideline 13

The psychiatrist as teachers and medical educators

- *have a duty of care both to safeguard their students and to protect their students from inappropriate influences of pharma industries*
- *should guide the medical students about the relationship and probable adverse effects of pharma industry on their professional development.*
- *The students should be encouraged to practice scientific and rational prescriptions guideline*
- *The students should be taught to be professional & ethically oriented with while dealing with marketing personnel from pharma industries*

SUMMARY

Medicine is not a trade to be learned, but a profession to be entered [16]. A profession is described by a specialized body of knowledge that its members must teach and expand, by a code of ethics and a duty of service that put patient care above self-interest, and by the privilege of self-regulation granted by society. [17].

Should we accept the benefits so aggressively provided by pharma ?

A critical question to be answered candidly. However we need to be reasonable as we look at social welfare of the patient and society virtuously. We do find multiple drugs with long prescriptions being used by many physicians to entertain as many pharma companies as possible to keep everybody happy and thereby enjoy all sorts of reward from pharma. This trend is obvious when one looks at these prescriptions. The patients and relatives ignorant about this practice land up taking these medicines at the cost of their money and side effects of the drugs

All these pharma industries have a promotional budget, which necessarily should be used for educating the doctor about the newer developments in the field of medicine. At the same time there should be an appropriate thought from the pharmaceutical companies to cut back costs by keeping

away from a pointless gifts and trying to subsidize the medicines as much as possible. There is also a need of giving free medicines for the benefit of some poor patients. There are better ways for the pharma companies to spend their promotional money, keeping in view the research, development, and education of doctors as well as the end user-the patient especially in developing countries. Very often pharma companies have social welfare budgets and physicians can use this avenues to help the patients and improvement of their health care

We need to take into following ethical consideration for being medical practitioner.

- Our Professional integrity
- Human right consideration of patients
- Pharma getting into Social welfare for Better community health and Health oriented healthy guidelines.
- We must be sensitive to consumer concern
- We need to Strengthened guidelines to cut back on bribery in the form of gifts
- Rejecting those pharma which are identified as nuisance due to their unethical business.

Summarizing, one must remember that ethics, like beauty, lies in the eye of the beholder. In the end, it is up to the individual doctor to decide the 'Lakshman Rekha', the boundaries that prevent the damage to the patient, profession and society at large .

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