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Medical Professionalism and Contemporary Challenges

*J.S. Bajaj**

Chief Guest Dr. M.S. Swaminathan; President, Officers, Fellows and Members of the National Academy of Medical Sciences, Distinguished Guests, Ladies & Gentlemen:

I deem it a great honour to be invited to this conference and asked to address such a distinguished gathering. It is with immense pleasure that I wish to congratulate the recipients of Orations, Awards and Fellowship and Membership of the Academy. I see many distinguished persons of achievement amongst the recipients. They represent the best of biomedical research, clinical professional excellence, community health research and medical education in this country. It is a most well-deserved recognition and my heartiest felicitations.

In the first Convocation Address delivered on the 8th December, 1963 in Vigyan Bhawan, New Delhi, Rashtrapati Dr. S. Radhakrishnan, stated, "A Fellowship of the Academy must be a matter of Honour and not a matter of maneuvering or intrigue but a matter of straight-forward work which is acknowledged as first class in nature. That should be the quality which we should encourage." That has been, and continues to be, the directive principle of the Academy during the last 45 years. On behalf of the Members of the Credential Committee and NAMS Council, may I extend most sincere greetings to all newly elected Fellows who now join this enlightened fraternity.

Our Academy has a twin purpose; the *cultivation and recognition of scientific research, and its application to human health and welfare*. A perusal of scientific programme at this Conference reflects a blend and balance

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overarching this mission. Some of the Orations being delivered relate to the cutting edge of basic sciences such as cellular and molecular biology of ageing, and neurobiology of brain transmitters. The focus of other Orations is on critical clinical areas such as Non-alcoholic Fatty Liver Disease, Oral hydration, Intraocular tuberculosis, Parasitic diseases, and Reproductive health. The Scientific Symposium on "Health Impact of Climate Change", and the CME Programme on "Fetomaternal Medicine" deal with ***three*** of the ***eight*** UN millennium development goals such as environmental sustainability, improving maternal health, and reducing infant mortality. Of course, NAMS has also responded most effectively, and with complete success, to a fourth millennium development goal namely, promotion of gender parity and empowerment of women as is reflected in the gender profile of present officers of the Academy. They deserve our appreciation.

While dealing with intellectual pursuits the Academy must also take cognizance of profound professional concerns. I wish to share with you a matter of profound contemporary relevance. The pharmaceutical industry involved in drug development, production and marketing, the manufacturers of medical devices such as stents, and the manufacturers of laboratory and diagnostic equipments etc., have been interacting with clinicians and other health professionals for a long time. Their interactions in the past were by and large within ethical parameters. However, their involvement in recent years has become all pervasive. The pharmaceutical industry sponsors medical conferences, CME programmes, and clinical drug trials. Air travel of not only conference speakers but also intended participants as well as accompanying persons, sometimes of several members of the family, is generously financed by the industry. Board and lodging in 5-Star hotels has become a common phenomenon. Dr. Frank Davidoff, a former Editor of Annals of Internal Medicine in a publication titled, "Navigating the Unchartered Territory of Industry-Sponsored Research" mentions several aspects of conflict of interest, now euphemistically called "Dual Commitment". Citing an important paper submitted for publication in the Annals where the author had gone well beyond

the data in emphasising the efficacy and safety of the drug under trial, it was subsequently found that the sponsoring drug company had reserved the right to "Review the manuscript before it was submitted" and that the language in the paper mostly came from that source.

Likewise CME programmes, usually planned, organized and conducted by faculty from academic medical centres, lay emphasis on the most recent advances in clinical disease management, including current drug therapy. In addition to the perquisites provided to the Faculty, there is a variety of gifts for the attendees. Many years back, it used to be a simple note book with a relatively inexpensive ball point pen. Nowadays, there are CDs and pen drives, and even DVDs along with other expensive items including silk neck ties, sometimes with a blatant display of the Company's logo. The sponsors of the CME programmes may at times choose not only the speakers but also may advise them about what is to be presented, and with what emphasis.

What about the link between industry and individual researcher? Clinical researchers often establish relationships with industry that may vary both in timing and intensity. An extreme, but real example, is holding a sizable amount of stock in a company, whose product is being tested in the research study in question. Common areas of conflict include research grants from the industry, payment of honoraria to academics as consultants, speakers, members of the drug advisory panels, and even as 'ghost writers' (1).

Until recently, independent clinical investigators with sound academic credentials played a key role in the design of clinical trials, development of protocols, patient recruitment, and collation, analysis as well as interpretation of data. With the escalating costs of clinical trials in the developed world, the pharmaceutical industry recognized the need to reduce costs with the result that private nonacademic research groups i.e. Contract Research Organizations (CROs) came into existence. Over the last few years, major share of clinical trial revenues, as much as 60% of research grants from pharmaceutical industry in the USA in the year 2000, were allocated to the CROs, as against only 40% for academic clinical investigators (2). Let alone the bias in the distribution of financial

grants, corporate sponsors have been able to direct (even dictate) the terms of participation in the trial. These terms, to say the least, are draconian for independent, righteous, self-respecting investigators. Nevertheless, these terms are easily accepted by some of the CROs.

International Committee of Medical Journal Editors (Vancouver group) developed a consensus statement, published sometimes back in twelve leading medical journals worldwide (3). It was explicitly stated: "we will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data, or the right to withhold publication." Be as it may, can any single remedy including disclosure of interest be a perfect solution to a problem as complex and pervasive as a conflict of interest? Relationships between academia and industry are rapidly changing, alas, at the cost of a steep decline in professional ethics.

Another practice which is perhaps unique to India is the foray of pharmaceutical industry into Hospital industry. All of you know some of the big pharmas who have built 5-star superspeciality hospitals. Over time such hospitals and the consultant staff may conduct clinical trials of drugs developed by the same company.

Similar tactics are employed by the food and beverage industry. Only recently there was a report about an international meet of the cardiologists where a very thin audience listened to a most interesting plenary lecture, while a large crowd had lined up outside a stall serving red wine so as to provide a personal experience of beneficial effects of antioxidants to the cardiologists! And presumably, to disseminate this information amongst their patients. Recently, a research study in rats showed that sucralose, an artificial sweetener may suppress beneficial bacteria in the gut, and thus may lead to weight gain. The manuscript was reviewed by three independent experts, who recommended its publication with minor revisions. Only later it was found that the study was sponsored by sugar industry and the dose administered to rats was several orders of magnitude higher than that for human consumption. Isn't it high time to draw the *Lakshman rekha* between independent academic research and for-profit industry sponsored projects?

I am of the firm belief that NAMS must take a lead, first by taking a

committed initiative, and later building a consensus amongst opinion leaders in different professional associations. Time is of essence. In the post modern era of globalization and outsourcing, drug companies are shifting mandatory clinical drug trials to developing countries such as India. Clinical Research in India is becoming a big business. By 2010, i.e. in another year or so, India will host nearly a fifth of all global clinical trials with a tremendous potential for financial and possibly some scientific gain. The Academic Council has taken a decision to conduct a Symposium on "Ethics in Clinical Research" and develop national guidelines regarding planning, conduct, functioning, and publication of clinical research with emphasis on protecting human rights.

My concern is that in the name of research, but with the ulterior motive of financial gain, unscrupulous elements may take undue advantage of the laxity of present situation as the requisite regulatory reforms and essential ethical practices have not yet been put in place. On the contrary, abolishing the service tax on clinical trials of new drugs in India has provided an attractive incentive. To my mind what was essential as the first step was to safeguard interests of patients rather than that of industry.

Drug pricing is an essential prerequisite for safeguarding patient interests. The oft-repeated argument from drug manufacturers is that high price of drugs is necessary to internalize costs of research and development (R&D). A critical scrutiny generally reveals that expenditure of advertising and drug promotion contribute substantially to drug costs. A recent article analyses the pharmaceutical marketing expenditure in the US in 2004 and provides the following information as tabulated (4).

From these estimates, it is obvious that pharmaceutical industry spends almost twice as much on promotion as is done on R&D. If this is the state of affairs in the US with several regulatory mechanisms, it is not difficult to surmise the prevailing situation in India where perhaps the use of RTI (Right to Information) may provide a clear picture.

Finally, there is a failure of the multinational pharmaceutical industries to respond with sensitivity to the needs of developing world, both in terms of product development as well as drug pricing. The success of a concerted

Type of Promotion	IMS ◆	CAM ◆◆	New Estimate	% of Total of New Estimate
	(US $ Billions)			
Samples	15.9	6.3	15.9 (IMS)	27.7
Detailing	7.3	20.4	20.4 (CAM)	35.5
DTCA (Data provided by CMR)	4	4	4 (CMR)	7
Meetings	nd	2	2 (CAM)	3.5
E-promotion, mailing, clinical trials	nd	0.3	0.3 (CAM)	0.5
Journal advertising	0.5	0.5	0.5 (CAM/IMS)	0.9
Unmonitored promotion (estimate*)	nd	14.4	14.4 (CAM)	25
Total	**27.7**	**47.9**	**57.5**	**100**

* *includes incomplete disclosure and omissions by surveyed physicians, promotion to unaudited physician categories, promotion in unmonitored journals, and could possibly include unethical forms of promotion funded out of the firms' marketing budget.*

DTCA, direct-to-consumer advertising

◆ http://www.imshealth.com

◆◆ http://cds.camgroup.com

public effort to counter high pricing is reflected in the failure of a group of multinational companies to block the South Africa government's attempt to provide low-cost generic drug for people with AIDS (5).

In order to overcome the looming danger, we have to generate a momentum of intellectual power. We know that the power of pill makers shall make every endeavor, financial, political, and at times personal to oppose this most vehemently. Nevertheless, the integrity, advocacy, and competence of biomedical scientists and professional organizations such as National Academy of Medical Sciences must succeed in generating

awareness among public, health administrators, policy planners, and national decision makers.

I thank you for your most patient and gracious hearing and for your invitation to be with you this evening.

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