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The Academia - Industry Symposium 2005-2006

Where is Medicine Heading? Pointers and Directions from Recent Law Suits Against Industry:

Medicine As A Corporate Enterprise, Patient Welfare Centered Profession, Or Patient Welfare Centered Professional Enterprise?

> Ajai R. Singh, M.D. Shakuntala A. Singh, Ph. D.



Mens Sana Research Foundation Mumbai, India 2005-2006

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Mens Sana Monographs

A Monograph Series Devoted To The Understanding Of Medicine, Mental Health, Man, And Their Matrix

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The Academia - Industry Symposium 2005-2006

Where is Medicine Heading? Pointers and Directions from Recent Law Suits Against Industry:

Medicine As A Corporate Enterprise, Patient Welfare Centered Profession, Or Patient Welfare Centered Professional Enterprise?

Ajai R. Singh, M.D. Shakuntala A. Singh Ph.D





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Medicine As A Corporate Enterprise, Patient Welfare Centered Profession, Or Patient Welfare Centered Professional Enterprise?

Medicine today is at the crossroads. There is as great an influence of new knowledge as of sponsors. On the one hand the latter ensure the faster output of new knowledge, on the other they try to skew its growth in their favour. Moreover, industry influence has come under the scanner of patients, activists and regulatory authorities. This has resulted in a spate of lawsuits against industry. This phenomenon is hardly likely to abate. In fact if present portents are any indication, it will increase, taking in its grasp clinicians and researchers too. Medicine and its ancillaries will have to do some serious soul searching to keep themselves firmly on course and prevent hijacking of their patient welfare agenda. A number of short term and long term measures will have to be put into place to ensure this. Short-term measures are related to preventing malpractice at various levels because of ulterior motives, both of clinicians and sponsors. Long-term measures are related to how we wish to chart the course of medicine in the future. For the latter, it is time a serious dialogue ensues on whether i) medicine should become a corporate enterprise; ii) remain a patient welfare oriented profession; or iii) become a patient welfare oriented professional enterprise.

This monograph is an effort to promote this dialogue.

It is most lovingly dedicated to one of the doyens of Indian Psychiatry, Prof. N.N. Wig.

About the authors

Ajai R. Singh, M.D., Editor, *Mens Sana Monographs*, is a Psychiatrist who has earlier worked with the WHO Collaborating Center In Psychopharmacology In India.

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They are Founders of the Mens Sana Research Foundation, India.

Call for Papers on the topic: What Medicine Means To Me

To be published in the *Mens Sana Monographs*, Vol. IV, No. 1, July 2006. Papers should be 2000-3000 words, complete with an Abstract (300 words max.), Concluding Remarks (200 words max.), References and suitable subheadings, including an Introduction. Topics that can be dealt with by prospective authors are:

- 1. Where is medicine heading?
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- 9. Medicine as a corporate enterprise: a welcome step?
- 10. Medicalisation of life
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- 13. Role of money in medicine
- 14. Balancing patient welfare with professional advancement
- 15. How much pharma/industry influence is tolerable in medicine?
- 16. Medicine as treatment of diseases, or for promotion of health?
- 17. What patients expect, and what doctors do?
- 18. The philosophical basis of medical practice (Indian and Western)
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Authors must convey their topics selected from the above by 1st January 2006. They maybe more than one topic for one paper, but not more than three. Full paper for potential publication should reach the Editor in Microsoft Word format by 1st March 2006. All papers will be submitted for peer review and a decision of acceptance or otherwise will be conveyed to the authors by 15th April 2006.

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Dr. Ajai R. Singh Editor.

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Dedicated to Prof N. N. Wig

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Brief Biodata

Dr. N. N. Wig

Dr. Narendra Wig is amongst the foremost psychiatrists of India. He had his medical education at Medical College, Lucknow, where he obtained his degrees of MBBS and MD (Medicine). He also holds a double diploma in Psychological Medicine – one from England and another from Scotland. He is a fellow of India's prestigious National Academy of Medical Science. In 1991, the Royal College of Psychiatrists, London, honoured him with the highest award of the Honorary Fellowship of the College. Prof. Wig is the only psychiatrist from India to be thus honoured. In 1997, Dr. Wig was designated as Professor Emeritus, Postgraduate Institute of Medical Education and Research, Chandigarh.

Dr. Wig started the Department of Psychiatry at the Postgraduate Institute of Medical Education and Research, Chandigarh in 1963 and was its Professor and Head from 1968. In a few years, this became one of the leading centers of psychiatry in India. In 1976, the department got international recognition as WHO Collaborating Centre for training and research in mental health. Among his various research studies, Prof. Wig will be particularly remembered for his work in Community Mental Health in the villages of Raipur Rani Block in Haryana, which became a model of Primary Mental health Care Programme in India and in many other countries.

In 1980, Prof. Wig moved to the All India Institute of Medical Sciences, New Delhi, as Professor and Head of the Department. In 1984, he joined World Health Organisation as the Regional Advisor Mental Health and remained at Alexandria, Egypt, till 1990. In this capacity, he was responsible for developing mental health programmes in 22 countries, from Pakistan to Morocco in the Middle East and North Africa.

Dr. Wig is a leading figure in International Psychiatry. He has published over 300 scientific papers in different journals and books. He is currently a member of the WHO Advisory panel on Mental Health. For the last ten years, he is on the Steering Committee of

the World Psychiatric Association's International Programme to reduce stigma and discrimination due to mental illness.

Dr. Wig has won many national and international awards. In October 2000, on his 70th birthday, a book *Mental Health in India* 1950 – 2000 was published in his honour in which many leading national and international mental health experts contributed. In April 2003, Bombay Psychiatric Society honoured him with a Life Time Achievement Award. In September 2004, Fountain House, Psychiatric Centre at Lahore, Pakistan, named a newly constructed building as *Prof. N.N. Wig Unit*, in recognition of his services to the development of mental health in the countries of South Asia.

Dr. Wig has travelled widely to many parts of the world. After his retirement he has settled in Panchkula. He is happily married and has two sons. He continues to be active in clinical service, teaching and voluntary social service activities. He is closely associated with the work of Servants of the People Society, Lajpat Rai Bhawan, Chandigarh, where he conducts free mental health clinic twice a week and also organizes regular lectures and discussion groups on mental health for the general public.

Prof. N.N. Wig: Pioneer, Conscientious Researcher, and a Multi-faceted Personality



Dr. Anirudh Kala

I met Prof. Wig for the first time on 1st January 1970. That was the day I joined the Department of Psychiatry at the Post Graduate Institute of Medical Education and Research, Chandigarh, as a junior resident. That was also the day I received a piece of very unusual advice. When, like any keen to please new junior resident, I asked him as to which books should I read as a new comer in Psychiatry, he said, "You have a long residency;" (it used to be four years in PGI at that time), "during the first year, read other things." When I asked, "What other things?" he said, "Anything but Psychiatry."

It was only later that I could gauge the depth of that advice about the extreme importance of "other things" in the practice of psychiatry, and that I was being told to absorb those "other things" when I had a fresh mind before I plunged into the main stream of psychiatry.

It has been a matter of joy and pride to have known Prof. Wig for these thirty-five years. One feels special because of this association.

Early seventies were heady days for Indian Psychiatry and for the general hospital psychiatry movement, which I am convinced has been the only true revolution in Indian Psychiatry to have happened so far. (Others were just matters of quantitative growth. Community

Psychiatry could have been another but it has not happened on a scale to have made a difference). Prof Wig was one of the few pioneers of the general hospital psychiatry movement in the country at that time.

A series of seminal research projects on motivation and psychological sequelae of family planning measures were also ongoing in the departments those years. Prof Wig used to share the progress in an enthusiastic manner with even the junior-most resident. Some years later, when Sanjay Gandhi's aggressive family planning campaigns during Emergency came into force, he would lament in the coffee room that years of hard work and data had become less relevant.

Thorough and Conscientious

Prof. Wig has been a very thorough and conscientious research worker from the very beginning. He was very particular about details and honesty of data collection. On the other hand, at times, he alone could see the direction a set of data was pointing and would make suitable interim changes. The latter quality I could experience first hand many years later when he was the leader of a task force of ICMR in the early eighties, which formulated and monitored a whole slew of important research projects all over the country. I used to participate as an investigator from Goa in the then famous multi-centred Acute Psychosis study. His contribution as a national research leader in those years was immense and it permeated to the whole country, although it is not often talked about in that deserved a manner.

This expertise as a research leader came to fore many times over the years, particularly during the famous community psychiatry experiment of Raipur Rani.

Prof Wig was trained in UK. He belongs to a clinical tradition, which in those days was very different from the American tradition in many ways (including diagnosing more Affective disorders than Schizophrenias, generally paying more attention to Organic factors and putting emphasis on Phenomenology rather than Psychoanalytic factors). All of these incidentally have borne the test of time and the difference in American and British Psychiatry has now narrowed.

In departmental discussions, whether about a contentious diagnosis or a theoretical standpoint, the atmosphere was highly democratic (we took it for granted then but realized later that it was not so everywhere), and heated discussions were very common. I remember the case of a young woman who had been admitted for a

month and used to have multiple hysterical fits in the wards. The case was taken to the departmental clinical meeting where the discussion revolved around the early childhood and psychodynamic and psychoanalytic aspects of the symptoms and formulation of analytic psychotherapy as plan of treatment. Everybody, including the residents, senior residents, and two of the three consultants, agreed about almost everything when Prof Wig surprised everyone by saying that the woman was primarily a case of hypomania and hysterical fits were only secondary. None of us agreed till her second admission, a year later, when she was admitted with a frank excitement, and with no fits.

Prof Wig was adept at looking out for and focusing on the hidden positive aspects of even a thoroughly hopeless situation, or a person. During discussions, when we would get restless about a particular resident's long winded discussion which was even factually wrong, Prof. Wig, at the end of it, would pick up a sentence (which was spoken as an aside, or not spoken at all!) and expand it into something very nice, coherent and positive. His teaching method was through encouragement and by promoting redeeming features of a student, or for that matter of any body else he came across.

Fair and Encouraging

He was very fair and encouraging as an internal examiner, without taking sides. Towards the end of my residency I was posted in consultation–liaison and saw a particularly interesting case which I requested him to see and give his opinion on, since my own diagnosis of the case seemed far fetched even to me. I thought the patient was suffering from Acute Intermittent Porphyria. Dr Wig saw the patient, agreed with the diagnosis (it was subsequently confirmed by biochemical investigations) and patted my back for having thought of such a rare condition. Six months later during my MD examination, the external examiner (Prof K. C. Dube) asked me some questions about episodic psychosis. I gave the standard answers but he wanted more and rarer causes and even gave me a hint about the King of England who was called mad. It did not occur to me till Prof Wig said, "It is the same rare diagnosis that you yourself made on a real patient six months back". And the penny dropped!

He would sometimes get angry with us, but it was very subtle and would have a long lasting effect. I remember once, Salman Akhtar (brother of lyricist Javed Akhtar, and now a famous psychoanalyst in America) who was one year senior to me, came to the wards wearing a flowery shirt of mauve and purple colour. Prof. Wig looked up and down at him and said, "Salman, sometimes I think, it would be a good idea for us to wear white coats." Salman never wore that shirt again in the hospital.

Encyclopaedic Knowledge

Apart from Psychiatry, Prof. Wig has an encyclopaedic knowledge of almost everything – be it films, literature, classical music, historical maps (one of his hobbies), rare species of birds (bird watching is another hobby), genealogies, wines (he hardly drinks), or Urdu poetry. One of the Indian Psychiatry Society, North Zone's, Conferences was once held in Solan and a visit was arranged to the famous brewery there. I overheard Prof. Wig talking to the brewery master about the intricacies of making beer. He was so awestruck at the end of those twenty minutes that he came down all those steps with folded hands to see him off. Every winter, Jalandhar (about 150 kms from Chandigarh) hosts the famous Harvallabh festival of classical music. Till a few years back, Prof. Wig would attend it often, in spite of the biting cold.

Prof. Wig's wife, Dr.Veena Wig is a remarkable person in her own right and would need a separate write up to do her justice. She has a doctorate in the history of art, she is very elegant, very graceful and has a distinct presence of her own, not an easy task under the circumstances. As to who is the scholar in the house, the question is still open. She is his constant companion at most of the academic events. Students in the department were frequently invited to their home and she has been looked upon by generations of residents as a mother figure.

Prof. Wig's students are spread out throughout the world today but they keep in touch with him out of deep affection and gratitude, and probably also to continue this process of nurturing by him for as long as possible. May God grant him a long life.

Dr. Anirudh Kala, the Founder President of Indian Association of Private Psychiatry has been a distinguished researcher and clinician practising in Ludhiana, Punjab, India. He has recently joined the Honorary International Advisory Board of Mens Sana Monographs. We most heartily welcome him on the Board and thank him for his engaging write-up on his teacher.

Prof. N.N. Wig : A Larger than Life Persona who Makes People Feel Immediately at Ease



Dr. Ravinder Kala

Prof N.N. Wig is a handsome man with a warm smile. He makes people feel immediately at ease. My first meeting with Prof. Wig was in his office at Psychiatry Department, Post Graduate Institute (PGI), Chandigarh, in May 1973. My friend Anuradha and I were posted at Psychiatry Department, PGI for four months of internship from Delhi School of Social Work, Delhi University. We presented our papers at the tiny administrative office attached to the professor's office and were pleasantly surprised when we were called in within fifteen minutes. His warm smile immediately made us feel calm and confident and we could discuss the details of our training programme with an immense feeling of comfort.

I have had the honour of knowing Prof. Wig as a doctor, a teacher, a researcher and personally as a guide and mentor. During my training period, I found he was a doctor with immense compassion, concern and positive regard towards his patients. His body language, interviewing style, choice of accurate words and his humane approach towards patients were great learning experiences for the trainees. We would often hear the patients and their family members saying that half the illness just went away after meeting Dr. Wig and talking to

him. He had extremely busy outpatient days. But each patient went back satisfied with the faith that he would definitely recover because the great doctor had seen him.

Powerful Personality

He has a powerful personality and no one can remain untouched by his aura. During my training, Prof. Wig asked me to take up the very challenging case of a severely depressed girl who was admitted in the psychiatry ward. She didn't recover in spite of being in the ward for two weeks. I remember his expression of deep concern for the patient as he asked me to start the counselling process. I still remember his words when, while referring the patient, he told me that as a young girl, I may use empathy and try to enter her sad inner world to help her find a spark that could help her develop a wish to live. His words filled me with an inner urge to help the patient and to come to the wards in the evenings to assess her psychological state at different times. We all as a team were finally able to treat this patient and all of us seemed to be working through the compassion and concern experienced by our team leader, and enthused into us.

I came for my training under Prof. Wig fired with an ambition to be a successful counsellor and psychotherapist. At the Psychiatry Department of PGI, I found a very rich environment for learning. We all were in great awe of Prof. Wig, and he provided us with a number of suggestions, reading material and lectures, which made difficult concepts seem very easy. We also developed an obsession for researching each and every aspect of a topic before making any presentation. He encouraged us to develop a positive and helping attitude towards each other. So, if one person was working on a topic, everybody gave him/her further references whenever they found anything related to that topic. He encouraged group discussions and valued opinions expressed by each of us, which helped us mature into confident professionals.

I once remember coming to work 15 minutes late. Dr. Wig just looked at his watch and then looked at me. Even today, I remember that incident and it makes me punctual and organized in all my work schedules. He also has an extremely good sense of humour. Once a resident was late for the rounds and Prof. Wig greeted him by saying, "Good Afternoon!"

When I completed my training on 31st August 1973, I was offered my first job by Prof. Wig. I started my career as a Research Assistant on a project with the Indian Council of Medical Research. Prof. Wig is an innovative researcher and has been actively involved in the research projects of ICMR and WHO. He is an honest researcher and whenever our research results differed from the reviewed literature, he helped us find the underlying reasons for these differences and this helped us develop an ability to look for newer insights into complex problems. In 1976, the Psychiatry Department, PGI, got international recognition as WHO Collaborating Centre for training and research in mental health due to the excellent research work done by Prof. Wig and his team. He started the Community Mental Health work in the villages of Raipur Rani Block in Haryana. I was fortunate enough to be associated with the Raipur Rani Project, which helped me developed the skills of working with the community. Raipur Rani became a model of Primary Mental Health Care Programme in India and in many other countries due to Prof. Wig's efforts.

In 1980, Prof. Wig became the Professor and Head of Psychiatry Department at All Indian Institute of Medical Sciences (AIIMS), New Delhi, and this gave him the distinction of heading two premier institutions of India. After that, he took long strides towards rare achievements in his career. He joined the World Health Organization in 1984 as a Regional Advisor, Mental Health and was in Alexandria, Egypt till 1990. During this period, he touched the lives of millions of people in 22 countries from Pakistan to Morocco in the Middle East, and North Africa. As a researcher, he has enriched Psychiatry with innovative work and has published over 300 scientific papers in different journals and books. He is on the Steering Committee of the World Psychiatric Association's International Programme to reduce stigma and discrimination due to mental illness. His contributions to the field of mental health have earned him a number of awards and we feel proud of our Professor's image in both the National and International arena.

Dr. (Ms.) Veena Wig

Prof. Wig and his beautiful, charming and artistic wife, Dr. (Ms.) Veena Wig have been an inspiration for all the people who have had the pleasure of interacting with them. Dr. (Ms.) Veena Wig is a Ph.D in Fine Arts and has continued to study and enhance herself after her marriage due to a supportive and caring husband. She is an

exceptionally compassionate and intelligent woman. She is a multifaceted personality with interest in arts and literature, and is today an eminent social worker of North India. She has been a role model and an inspiration for me. She has made a great contribution in shaping me as an individual.

Parties at home and Colourful T shirts too

There were departmental parties to welcome new people and to wish farewell to those leaving the department. This charming couple hosted these parties at home in order to give a personal touch to the professional relationships. These beautiful gestures of Prof. Wig created life-long bonds with him in us all. And then we had those departmental picnics where Prof. Wig used to wear colourful T shirts and participated with us in all group games. The memory of these picnics even today makes me feel immensely happy.

Prof. Wig's impressive personality also helped in attracting a lot of intelligent doctors towards Psychiatry and has helped in making Psychiatry popular and fashionable. Being a student of Prof. Wig has been a fortunate experience for me. It was the experience of being shaped completely as a professional with a sense of responsibility, discipline, work ethics and developing the personality of a therapist. All the students of Prof. Wig have been so similarly shaped by him, by his ethics and his values besides the clinical training.

I met my husband, Dr. Anirudh Kala in the Psychiatry Department of PGI. We got married and worked together at the Psychiatry Department of Goa Medical College, CMC, Ludhiana, and are still working as a team at our private Psychiatry Nursing Home.

We are grateful to Prof. Wig for shaping us as professionals and we still work with the professional approach, ethics and values given to us by him.

Today, as I look at Prof. Wig's persona, he seems larger than life. I wish him and his graceful wife, Dr. (Ms.) Veena, a happy, fulfilling and a long life. I will always be grateful to them for being such an inspiration in my life.

Dr. Ravinder Kala, Ph. D. is a Clinical Psychologist practising in Ludhiana, Punjab, India, and the better half of Dr. Anirudh Kala. We most heartily thank her for this endearing write-up on her teacher.

MSM

The Tenth Mens Sana Monograph

The Academia - Industry Symposium 2005-2006

Where is Medicine Heading? Pointers and Directions from Recent Law Suits Against Industry:

Medicine As A Corporate Enterprise, Patient Welfare Centered Profession, Or Patient Welfare Centered Professional Enterprise?

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Musings

Junkets and Trinkets

During the brief interregnum of a recent medical conference, we sat by the side of a pool. It was dusk. And just before the entertainments for the evening were to begin with cocktails and dinner, we were chatting about conferences and sponsorship.

The arrangements were, to say the least, lavish. And docs from all over were visibly wallowing in five star luxuries. Strolling the lawns, sipping drinks, moving in and out of chauffeur driven cars, being treated like some feudal lords of yester years. *Gratis*. The joy of meeting friends, and networking with colleagues for positions and honours, was palpable. And that all this was complementary added to the fun. Although it was taken for granted. And accepted as part of conference commitment of sponsors, who made their bucks due to docs' prescriptions anyway.

I had lately been studying the working of pharma sponsors. Talking to some of them too. Well, I found they had their priorities perfect. No option but to pamper docs, they said. But see to it that prescriptions poured in. The greater the pampering, the greater the doc's commitment expected. If it did not work out that way, discreet reminders. Later, more insistent ones. Finally, stoppage of sponsorship. Never talk about the idiosyncrasies and demands of one doc to another, howsoever idiotic they may be. (I meant the demands, but applying it to the docs may not really be invalid.) And never forgot that all activities were with only one motive in mind: translating into profits for the company.

What did we talk at the poolside? I expressed my concern to my fellow docs. Where did all this money come from? The sponsors put in millions for delegates. Plus ads. Plus now litigation costs as patients and activists had become belligerent. And the litigation costs were sky rocketing, as drugs reported serious side effects. Plus the brakes on price escalation of drug by legislators and activists. Was it not time to rein in the expenses? For docs to expect less pampering, and for pharma to place a voluntary cut on junkets

and trinkets? Would not both pharma and docs have to bear the brunt as litigation keep increasing?

Well, the docs heard, bemused. They appeared convinced. But in no mood to do anything about it. I suggested a voluntary moratorium on spending by pharma, and on unrealistic expectations by fellow docs. Well, it went in a bit.

By then it was time for the jamboree to follow. And the pharma sponsors came in their ties and their smiles to welcome the docs for the waiting festivities.

All consciousness evaporated with the spirits flowing in.

And the high decibel DJ saw to it that no other sounds registered. Including that of the conscience.

Well, one lives and learns.

This monograph is the result of that arousal of the spirit.

And that sound.

And I would like to believe that this sound is of the conscience being in the right place.

Ajai Singh

EDITORIAL.

Emphasising Prevention, Developing Therapies, Complementing Approaches

Innovation in medicine is keeping in step with aggressive marketing of health services. The patient-consumer has at his disposal a vast array of therapeutic facilities, all attractively packaged, and convincingly portrayed. The physician too has to keep abreast of a sea of fresh information bombarding him from numerous quarters, some genuine, some not so genuine. And he often finds himself at a loss to discriminate between the two.

Health awareness has increased. So has the average life expectancy. Medical science boasts of a vast array of treatment modalities for an equally vast array of diseases. Distress has been ameliorated, disability curtailed, death postponed.

And yet, if the booming medical practice and pharma industry are any indication, the patient population has not reduced. In fact, it has multiplied. Not all of this is because of increased health awareness. While individual distress may have been reduced, individual disability curtailed and individual death postponed due to better treatment facilities, the *number* of distressed have not reduced. Neither have the number of disabled, nor that of the dead.

What does this signify?

It signifies, if nothing else, that while individual disease treatment is progressing, so also is human pathology. Newer and more ingenious ways of falling ill are seeing the light of day, and the body is finding newer ways of getting out of order.

Sicknesses are not reducing in number. They are changing in type. If infectious diseases and malnutrition took their toll in the earlier centuries (and in certain sections of the world even today), life style diseases, chronic conditions and neoplastic disorders are taking their toll in the present. It is almost like changing fashions in the world of disease.

Wireless Technology, Permissive Morality and Greater Commercialization

If we ever do feel we are successful in reducing morbidity and mortality of these conditions, along will come new diseases introduced by use of modern gadgetry. This century will surely witness an upsurge in sicknesses from use of wireless technology, permissive morality and greater commercialization. It will be compounded with deaths not because of infectious epidemics, but mass destruction due to external calamities like earthquakes, floods, *tsunamis* and hurricanes. As also man-made ones like terrorist attacks using modern technology on inimical civilizations. As though aiming to convert modern technology itself into an inimical civilization.

Wireless technology in the form of the Internet, the cell phone, the computer and the television has invaded most homes. The long-term effects of these radiations have still not been studied on a large enough scale for us to draw definite conclusions. But they have the distinct potential of becoming an important source of new disease proliferation.

Similarly, newer, more efficient transport will result in greater vehicular and other accidents, and greater environmental pollution, which will further add to human disability and mortality. Death and disability will find alternative methods to manifest.

We know how permissive morality has already resulted in an epidemic of AIDS. But this may just be a precursor of many such conditions that will pervade and influence many disease processes, either as distinct entities, or as important co-morbid manifestations. The subtle influences of such socioethical factors are hardly studied and poorly understood for obvious reasons: it is inconvenient, and science has poorly validated methods to study them.

Greater commercialization will increase social competitiveness and strife. The effect this will have on newer disease manifestations as stress levels rise all around, will be to keep the man with the stethoscope busy, and the eyes under the microscope strained.

It is as though the kaleidoscope of disease changes its form with every new twist of the passage of time and human condition.

The bottom line is: it is naïve to believe that medicine will capture disease. It will, hopefully, ameliorate symptoms and make life live able. Diseases as an entity will always exist, indeed prosper, assuming new forms and playing new roles, almost like stars in films. Only we are talking of tragedy roles here, if not villainous ones. Similarly, the man of medicine who sells his wares will keep prospering. But essentially, it will be a criminal-policeman, or catchathief game. Diseases will find newer ways to manifest, doctors will find newer ways to treat. The process to stem the *origin* of disease itself is not one

that is attractive to mainstream medicine, for it may undermine its very existence. And the considerable clout it wields, as also the burgeoning establishment it helps support. Trust the fact that very little work will ever be done in this direction.

One thought that comes to mind here is: is it possible to get out of the frame of this kaleidoscope? To think in terms of living disease free? Could, individuals, families, even societies decide to live that way? The ways of the Abkhasians for example, who reportedly live relatively disease free and long lives? Could more studies of longevity and health predominate in our research agenda? Could we change focus from treatment to prevention? Not the lip service that it is often given today, but the concerted, focused effort of really bright dedicated minds. Minds that are preoccupied at present with treatment rather than prevention? That is the point at issue.

The challenge before modern medicine is of course to utilize technology to ameliorate disease. But the greater challenge is to curtail the processes that germinate and bolster disease. In doing the former, we make life live able. But in doing the latter, we make it glorious.

Preventive Medicine, Complementary Medicine and Religious Spirituality and Practices

In bringing about the latter, there is a great role for Preventive and Social Medicine. It is the only branch that concentrates energies on prevention of diseases, and looks at those biosocial processes that generate it. Its importance in today's world can be hardly overemphasized, although that does not mean it will be given the position it deserves. Moreover, it must become an attractive branch where the brighter minds go; not, as one is sorry to note, just a refuge for the also-rans, as it often is in medicine today.

The importance of preventive and social aspects of all medical conditions will have to be researched on a war footing. This must combine with Alternative and Complementary Medicine. We, in mainstream medicine, look with bemused tolerance at their antics. Especially at their fantastic claims to treat everything with their relatively small therapeutic arsenal. They make fantastic claims probably more to justify their existence rather than their scientific sustainability. But we may neglect their approach, or pooh-pooh their achievements, at our own peril. These branches are indeed handling a number of chronic conditions, in which mainstream medicine is offering poor help, if at all. And if their burgeoning clientele is any guide, they seem to offer solace.

The effect of life style changes and attitudes that religion in general and spirituality in particular emphasize, maybe another close ally in disease prevention and amelioration. The eternal tenets of all religions are human growth and nurture oriented. The importance of prayer, compassion, peace of mind, brotherhood and philanthropy must be studied as means of stress level reduction, and whether they can help in overall disease amelioration. The man with inner calm is more likely to be disease free. Can scientific evidence be generated for this hypothesis, either way?

The Other Trinity

Hence, we envisage a two-pronged strategy. At the disease *treatment* level, newer treatment approaches must be sought for, and we must continue to do our bit. But at the disease *prevention* level, which we must consider of equal if not greater import (more so as it has been neglected hitherto by mainstream medicine), we must take a close look at the Trinity of *Preventive Medicine, Complementary Medicine* and *Religious Spirituality and Practices*. And see if it works.

If these approaches can understand their significance, and learn to work in tandem rather than at loggerheads, somewhere down the line, disease as an entity may significantly reduce. That is the challenge before modern medicine, as much as before the modern man.

But if disease reduces, how would death occur? For it has to, as man cannot survive indefinitely. Neither can the globe support an ever-escalating population. Man will then voluntarily reduce progeny production, which is already happening in some sections of society. And man will have a greater chance to decide when and how he wants to give up living, after he has lived a full and complete one. This is possible only for a fortunate few at present. It will be so for a larger section of the populace. Deaths due to life style and other such problems will reduce, and death as it should occur – as the culmination of a life led fully and well – will have a greater chance to manifest.

That also is the challenge before modern medicine, as much as the goal to achieve for modern man.

Editors, Mens Sana Monographs

The Academia-Industry Symposium 2005-2006

Where is Medicine Heading? Pointers and Directions from Recent Law Suits Against Industry:

Medicine As A Corporate Enterprise, Patient Welfare Centered Profession, Or Patient Welfare Centered Professional Enterprise?

Ajai Singh Shakuntala Singh

ABSTRACT

There is an alarming trend in the field of medicine, whose portents are ominous but do not seem to shake the complacency and merry making doing the rounds.

The wants of the medical man have multiplied beyond imagination. The cost of organizing conferences is no longer possible on delegate fees. The bottom-line is: Crores for a Conference, Millions for a Mid-Term. However, the problem is that sponsors keep a discreet but careful tab on docs. All in all, costs of medicines escalate, and quality medical care becomes a luxury. The whole brunt of this movement is borne by the patient.

Companies like GlaxoSmithKline, Bayer, Pfizer, Bristol-Myers Squibb, AstraZeneca, Schering-Plough, Abbott Labs, TAP Pharmaceuticals, Wyeth and Merck have paid millions of dollars each as compensation in the last few years. The financial condition of many pharmaceutical majors is not buoyant either. Price deflation, increased Rand D spending, and litigation costs are the main

reasons. In the future, the messy lawsuits situation would no longer be restricted to industry. It would involve academia and practising doctors as well. Indian pharma industry captains, who were busy raking in the profits at present, would also come under the scanner. If nothing else, it means industry and docs will have to sit down and do some soul searching.

Both short and long-term measures will have to be put into place. Short-term measures involve reduction in i) pharma spending over junkets and trinkets; ii) hype over 'me too' drugs; iii) manipulation of drug trials; iv) getting pliant researchers into drug trials; iv) manipulation of Journal Editors to publish positive findings about their drug trials and launches; v) and for Indian Pharma, to conduct their own unbiased clinical trial of the latest drug projected as a blockbuster in the West, before pumping in their millions.

The long-term measures are related to the way biomedical advance is to be charted. We have to decide whether medicine is to become a corporate enterprise or remain a patient welfare centered profession. A third approach involves an eclectic resolution of the two. Such amount of patient welfare as also ensures profit, and such amount of profit as also ensures patient welfare is to be forwarded. For, profit, without patient welfare, is blind. And patient welfare, without profit, is lame. According to this approach, medicine becomes a patient welfare centered professional enterprise.

The various ramifications of each of these approaches are discussed in this monograph.

KEY WORDS: Law Suits Against Industry, Price Deflation, Increased R and D Spending, Litigation Costs, 'Me Too' Drugs, Medicine As A Corporate Enterprise, Medicine as a Patient Welfare Centered Profession, Medicine As A Patient Welfare Centered Professional Enterprise, Professional or Business Ethics in Medicine

Introduction

There is an alarming trend in the field of medicine, whose portents are ominous but do not seem to shake the complacency and merry making doing the rounds. The party and dance seem to be endless, and everyone involved seems to be having a gala time. The atmosphere is electric, and the mood buoyant. Money seems to flow as smoothly as does the spirit; and the conversation is as sparkling as the wine in tall goblets. Pygmies stand tall in three suits, and wax eloquent in august company. And then shed their formals to shake an informal leg at banquets and cocktails. And the clang of brimming glasses matches the cheer of the spirits that soar in the gastronomy of excited medics.

One is reminded of the state of the Yadavas during Krishna's times. Busy with revelry and debauchery. Before disaster befell. And not even the Lord's protestations and caution sounding had any impact. Or, the fall of the Romans at the height of their glory. Who thought nothing, just nothing, could ever go wrong. And were busy indulging themselves in the wildest of orgies before the Roman Empire sank without a trace.

Well, you might ask: why are we ringing these alarm bells?

It's because the wants (not needs) of the medical man have multiplied beyond imagination. Each one of them wants to be pampered by the pharmaceuticals. Conferences have to be in Five Star hotels, and delegates must be housed in Five Stars too; they must travel by air, and must be shown around the place. Complementary. The odd gift will no longer do. Expensive holidays, foreign trips, personal accessories must be lavishly thrown in to pamper the man of medicine. And he is like a man-eater. Having once tasted the blood of pampering, he will not settle for anything less.

The cost of organizing conferences is no longer ever possible on delegate fees. The sponsors have ensured that they can never be done away with. The plastic smiles and courtesies in looking after delegates, who expect all on the house, hide snide but happy inner faces of sponsors. Snide at the way medicine is gravitating. Happy at the way medicine is playing itself completely into the hands of commerce.

Crores for a Conference, millions for a Mid-Term. That's the bottom-line.

The medical man, of course, never had it so good. He is anointed a God in his clinic, and worshipped with the choicest *prasads** by the sponsors.

Except for a slight problem.

The Problem

The problem is that the sponsor keeps a discreet but careful tab on him.

The cost of organizing conferences is no longer ever possible on delegate fees. The sponsors have ensured that they can never be done away with.

Crores for a Conference, millions for a Mid-Term. That's the bottom-line.

^{*} Prasad means offerings to a God. Ed.

On an average, one new drug comes from the laboratory to the pharmacy shelf after 12 to 13 years. It is after 5000 to 10000 promising ones have had to be shelved due to extensive testing in the R and D phase that a drug is approved as a quality, safe and efficient marketable product (EFPIA, 2005).

The sponsorship must translate into prescriptions. Else first gentle and then more insistent reminders make their way into conversation. Well, if the healing man feels irked, it's absolutely on purpose. It pays to be loyal, to write the latest molecule hyped, to speak well of the new drug launch at sponsored CMEs, workshops, conferences etc. Never mind the doc concerned is really not convinced. Who is?

The patients get taken in by the new drug bait too. They go along, and the $\ensuremath{\mathsf{T}}$

placebo effect of novelty and hype ensure the drug appears to work for a while. Then, a descendo effect stares in the face. Not to bother. By this time a new drug launch is on its way.

All this is irksome, wrings the conscience, true. But is conveniently shrugged off.

And the merry go round whirls fast, as all the participants hold on to the bar and shriek in glee.

Spanner in the Works

Unfortunately, a few spanners in the works have been placed lately. Patients expect drugs to work beyond placebo effect. Patients expect docs to be clean. Patients expect docs not to get involved in a nexus with pharmaceuticals.

Look at it from the pharmaceutical's angle. On an average, one new drug comes from the laboratory to the pharmacy shelf after 12 to 13 years. It is after 5000 to 10000 promising ones have had to be shelved due to extensive testing in the R and D phase that a drug is approved as a quality, safe and efficient marketable product (EFPIA, 2005). Also several studies put the cost of researching and developing a new chemical entity (NCE) at Euro 895 million (EFPIA, 2005). The R and D costs are staggering. Research driven pharmaceutical companies invest about 20% of their sales in R and D, which represents a higher percentage than any other industrial sector (including high-tech industries such as electronics, aerospace or automobiles) (EFPIA, 2005).

Moreover, do not forget. The price of a new medicine carries within it a contribution towards the cost of discovering the next (EFPIA, 2005). Hence that too is an add-on to the MRP.

The marketing departments have smart alecks who want handsome pay packets too. The man-eater must have his lion's share as well. And, of course, handsome profits must be made in this booming industry.

So they have every reason to add on costs to every new molecule. And try and devise ingenious add-on molecules too, which equally ingenious researchers manufacture, and the marketing departments latch on to. A small twist in a molecule, and a new 'me too' drug is ready for celebrity launch, and potential celebrity status.

All in all, costs of medicines must escalate, which means quality medical care must become a luxury. This anyone getting any fancy investigation or treatment will vouch for. The docs also have become market and media savvy, and masters at projecting themselves. All at a price, which their treatments offered must incorporate.

The whole brunt of this movement is borne by guess who - that hapless consumer, the patient waiting patiently outside the clinic door.

Probably, he had rightly been called a patient. Patient.

He has been patient enough.

Ominous portents: law suits against industry

Already ominous portents that he will no longer keep quiet are visible. As the medical man is busy waltzing with the medicine producer, the patient has decided to stop the DJ's enchanting music.

How? By filing law suits against industry.

The connect between docs and industry was under wraps till a decade

So they have every reason to add on costs to every new molecule. And try and devise ingenious add-on molecules too, which equally ingenious researchers manufacture, and the marketing departments latch on to. A small twist in a molecule, and a new 'me too' drug is ready for celebrity launch, and potential celebrity status.

GlaxoSmithKline, Bayer, Pfizer, Bristol-Myers Squibb, AstraZeneca, Schering-Plough, Abbott Labs, TAP Pharmaceuticals, Wyeth, Merck. None of them small names.

And all of them have paid millions of dollars as compensation in the last few years.

ago. Concerns gathered momentum only in the last five years, with the dawn of the new century. That itself was not a small matter of concern. However, the matter of real big concern, which should make the blissfully unaware dancers sit up and take notice, are the recent events detailed below.

GlaxoSmithKline, Bayer, Pfizer, Bristol-Myers Squibb, AstraZeneca, Schering-Plough, Abbott Labs, TAP Pharmaceuticals, Wyeth, Merck. None of them small names.

And all of them have paid millions of dollars as compensation in the last few years.

GlaxoSmithKline agreed to pay US \$ 2.5 million for charges that it suppressed findings that showed its antidepressant, Paxil, was harmful in children. It paid \$75 million for allegedly overcharging patients and insurers for its anti-inflammatory drug, Relafen. Again agreed to pay US \$ 92 million to end law suits over Augmentin, its antibiotic. Bayer settled over 2000 cases brought up against its drug Baycol, at a cost of US \$ 800 million. Pfizer paid US \$ 430 million to settle claims against off-label use of its drug, Neurontin. It is being sued at present by consumer groups claiming that the company misleadingly marketed its blockbuster cholesterol-lowering drug, Lipitor (Datamonitor Newswire, 30 Sept 2005). Bristol-Myers Squibb promised to pay US \$ 300 million to fend off a lawsuit by its own shareholders. In 2003, AstraZeneca settled criminal fraud charges of US\$ 355 million in a case dealing with its drug Zoladex (Peterson, 2003). On July 14, 2004, Schering-Plough pleaded guilty of and was fined US \$ 350 million in part for providing 'educational grants' to physicians, which were more appropriately called 'kickbacks' by the prosecutors (Harris, 16 July, 2004b). It faces an ongoing investigation whether it used sham consulting arrangements and clinical trials to remunerate doctors for writing its hepatitis drug, Intron A (Harris, 27 June, 2004a). TAP pharmaceuticals, a joint venture of Takeda Chemical Industries and Abbott Laboratories, entered into a settlement and paid US \$ 290 million in criminal fines, plus US \$ 585 million in civil penalties, out of which US \$ 100 million went to whistle blowers (United States v. TAP

Pharmaceuticals, Dec. 14, 2001). It continues to face further lawsuits by insurers and patients for unnecessary and costly services. All related to the way it used urologists to promote its Lupron, a potent gonadotropin-releasing hormone used in treating prostrate cancer. Wyeth has had a US \$ 1 billion verdict against it for its Pondimin, an anti-obesity drug. The most recent Vioxx catastrophe is likely to result in a US \$ 10-15 billion litigation bill (Horton, 2004b) for the company involved, Merck, and probably cripple both its financial status as well as its reputation beyond repair.*

The pharmaceutical industry no longer commands the respect that once made it a beacon of innovation and achievement (Horton, 2004a). In fact, a former Editor of the *New England Journal of Medicine* details the ways in which pharmaceuticals are busy hijacking medicine and its research agenda (Angell, 2004).

Financial Condition of Pharma Majors on the Decline

The financial condition of many pharmaceutical majors is not buoyant either. Their sales seem to show a stagnant trend and their stock prices a downward one. A reflection of the reduced confidence investors seem to have in the continued profitability of the pharma industry:

Global sales for AstraZeneca fell by 0.6% in 2003. GlaxoSmithKline grew by only 3.9%; Bristol-Myers Squibb by only 4.0%. The fastest growing company was little-known Schwarz, which benefited from the patent expiry of AstraZeneca's version of omeprazole. Worse, the rate of US market growth—half of global pharma sales occur in the USA—slowed, thanks largely to fewer blockbuster drug launches. 2004 has been no better. Merck has forecast a fall in share earnings. Stock prices for AstraZeneca and GlaxoSmithKline have been extraordinarily volatile. As big pharma feels the squeeze, it seems its chief executives

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The CEO and MD, Mr. Brian Tempest, is reported to have said that they had a budget of US \$ 30 million as litigation cost for the year, adding that the budget was going to remain more or less the same next year. So, pharmaceuticals had indeed started budgeting for this eventuality in right earnest

will risk litigation and court settlements to extract the maximum revenue from increasingly unforgiving markets (Horton, 2004a).

The Recent Ranbaxy Showing

On 22nd Oct 2005, a leading newspaper reported an interesting, if rather disquieting, story (TNN and Agencies, 2005). Ranbaxy, a pharma multinational from India, reported a Rs. 10.77 crore loss in Q3 (the third quarter

of 2005, ended Sept 30), as against a net profit of Rs. 141.3 crore for the same period last year. The reasons: continuing price deflation in the US market, increased R and D spending, and litigation bills.

The main reason cited was increased R and D spending, which rose by 79% as against the same period last year. But also mark the last item. Litigation bills. The CEO and MD, Mr. Brian Tempest, is reported to have said that they had a budget of US \$ 30 million as litigation cost for the year, adding that the budget was going to remain more or less the same next year. So, pharmaceuticals had indeed started budgeting for this eventuality in right earnest.* Also worth noting was the fact that for Ranbaxy and its subsidiaries, its PAT (profit after tax) was down by 90.8% in Q3, from Rs. 200.1 crore to a measly Rs. 18.4 crore. Moreover, price deflation in the world's biggest pharma market, the US, was on in right earnest, and the situation was hardly likely to improve in the rest of the year. Result: a tighter squeeze on profit margins. And if a drug really bombed, the litigation bills could inflate to ominous proportions, wiping out profits. The company expected to make up by new drug launches lined up for next year, and two of them in early 2006. So hopes were kept alive. But worth noting was the fact that the tide had turned towards the red.

And the reasons were not hard to find. Price deflation, increased R and D spending, and litigation costs.

Ranbaxy litigation budget is mainly for legal costs in fights with another pharmaceutical. But the day is not far when it, and others, will mainly budget for suits brought up by patients / activists/ governments. Ed.

And what was happening with Ranbaxy was not an isolated phenomenon. The impact of these three factors were being felt all over the industry and were worth a close look before matters reach an irreparable stage. We say so even if the pharma industry seems to be riding a crest at present. For, the crest may quickly transform into a trough if urgent measures were not carried out now.

Why price deflation, increased R and D spending and litigation costs?

Let us briefly look at the three factors: price deflation, increased R and D spending and litigation costs.

Why price deflation?

Because activists and regulating authorities are firmly resisting any further cost escalation. They have had enough. They can see through the 'pharma-doc' merry-go-round game, and are busy decelerating the wheel. And charging fees for the deceleration too!

Why increased R and D spending?

Because R and D has become more an eyewash, and drugs with real potential to swing profits the company way on merit are hardly

coming through. Most industry is busy producing also-rans and second quality make-believe champions for drug launches (the so called 'me too' drugs). Which is because industry is busy recruiting and manipulating pliant researchers to skew results. Ultimately, this must result in inflated R and D bills, with no big profit-making real blockbuster drugs coming out of the assembly line. For, the drug's innate quality, its rigorous clinical trial and market potential - all were being blissfully tampered with at every stage.

Fudged figures, inflated positive results, and suppressed adverse effects might get a drug approved and launched all right. But ultimately it will

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Why litigation costs?

Because, side effect profile is either not studied, or conveniently suppressed. However, as side effects make their presence felt, (and this will increase in the days to come), industry runs for cover. And the activist-advocate guns are out shooting wildly.

falter at the litmus test of patient welfare. Improvement is bound to be poor, and, more important, side effect profile is likely to be great. In an already compromised patient population exposed to numerous health hazards from all around, side effects are likely to be experienced all the more so. And this state of affairs is not likely to abate in the foreseeable future.

However, this is hardly a serious consideration for industry, wallowing as it is in profits made hitherto. But not for very long, as profit margins are

getting squeezed. And the squeeze was being felt all over the industry, which might get converted into a stranglehold if suitable action is delayed further.

Why litigation costs?

Apart for the usual infighting with fellow pharmaceuticals and others over patents and other rights, because side effect profile was either not studied, or conveniently suppressed. However, as side effects make their presence felt, (and this will increase in the days to come), industry runs for cover. And the activist-advocate guns are out shooting wildly. Lawsuits are slapped. Patients and lawyers make a killing. And big pharma, for all its clout, becomes a lame duck in the bargain.

Well, you could say, and justifiably so, that they asked for it. But the flip side is that all cost escalation would ultimately be passed on to the consumer. Bad for him, but equally bad for the producer. For it could result in an inevitable backlash from the consumer, resulting in price deflation. And could also result in decreased sponsorship for docs and researchers. Maybe not a flip side, if you looked at it a little calmly. For we all know what use most from the medical fraternity are busy making of this juicy sponsorship carrot dangling in front of their eyes.

Set Rethinking Process into Motion

Hopefully, it may set a much-needed rethinking process into motion, both from the sponsors and the recipients. For, nothing works

better to reorient thinking than a big *jhatka*.* A real jolt that shakes the very foundations of present thinking so that one goes hunting for a better one. The present spate of litigations would have served their purpose very well if this happened.

What did all this mean? If nothing else, it meant industry would have to sit down and do some soul searching. Enough of cost escalation to pamper docs and their appendages. They would have to bring it down to manageable proportions. Enough of spending over questionable researches from high spending R and D departments. Or over pliant researchers in academia who produce stillborns. Enough of fudging with figures. Enough of portraying also-rans as champions. Enough of suppressing adverse effects. Enough of games playing. For the game was almost up.

Well, what should they do?

They should try and go for the real champions. And work their R and D smart alecks to clean up their act. And the marketing departments would have to work over and project the real winners. And patients would have to really get well. And side effects come down to a minimum. And mainstream medicine would have to once again assume its rightful place as a beneficiary of patients. Which

position it appeared in danger of relinquishing to alternative and socalled complementary medicine at present.

Would the guys who matter remove the blind-fold? Or, are they ready to get handcuffed? And tried in the court of the present, and condemned in the court of posterity?

The choice is better made now.

Is The Spate of Lawsuits Going to Increase?

The recent spate of lawsuits, no doubt, has had a significant impact on

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^{*}Jhatka means a big jolt. Eds.

It is necessary to chastise industry, true, but disastrous to uproot major pharma players from business itself, as some lawsuits have the potential of doing.

This is where temperance is called for, which activists may lack for obvious reasons, but government and academia must exercise, and judiciary ensure.

the reduced profitability of pharma majors. And if the present is any indicator of the future, this is only going to increase. Surely, a disturbing enough development to take a short break in the merry making, and conduct a small appraisal of events before further spokes in the wheel ground it altogether.

There is a silver lining to this whole phenomenon. The number of recent lawsuits successfully brought up against industry reflects attempts by patient welfare bodies and others to remedy the tilt in academia-industry

relationship, which was decisively swinging towards the latter. It will result in a newfound confidence in academia that augurs well for academia-industry relationship in the long run. For academia had, in a way, given up the fight, deciding to play second fiddle to industry. And join the merry bandwagon of industry orchestrated biomedical advance. Although one must be careful not to overbalance the other way too. For it is naïve to believe that all academia-governmental-activist victory is necessarily beneficial for patient welfare. Amongst other things, the cost of litigation is bound to be passed on to patients (Singh and Singh, 2005), someway or the other. And it is necessary to chastise industry, true, but disastrous to uproot major pharma players from business itself, as some lawsuits have the potential of doing.

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What Do These Lawsuits Indicate?

What do these successfully fought lawsuits against industry portend?

They mean patients, and their activists, are no longer ready to buy the patient welfare bait. They have seen through the game, and want their rights protected. They will increase their surveillance in the days to come. And the legal profession will have its hands, and pockets, full. A pretty messy future, if ever there was one.

As more suits are successfully brought up against industry, it would affect company bottom lines. And the merry funding of academia and professionals would come under pressure. The messy lawsuits situation would no longer be restricted to industry. It would involve academia and practising doctors as well. The press and media were having a great time anyway, portraying in gleeful detail the malpractices of erring docs. To this would be added the details of financial sponsorships of doctors and researchers. And how that influenced publication of research findings in prestigious journals, and translated into prescriptions and profits for sponsors. Already books by concerned academics that exposed the messy goings on were on their way to making it to bestsellers' lists. Public awareness would increase, and so would lawsuits against the man in white coat as much as the man who made the white pill. Of course reputations would take a real beating all around. The docs would rant and run to protect themselves. Consumer courts would be as active as professional bodies of docs: one exposing, the other protecting them. And the activist would cozy with the man in black coat to go hunting for the one in white.

Already professional indemnity insurance premium was high in developed countries. They would soar, and those in India and other developing countries would sprint to catch up. The medical professional's reputation was already undergoing a downgrading. It

would slide to match that of other professionals. (Good, according to them, probably. They were waiting for the doc to be pulled down from his high pedestal, anyway)

This is what these lawsuits indicate.

Indian Pharma Industry

Indian pharma industry captains, who were busy raking in the profits (for the pharma industry never had it so good), would also come under the scanner. One might expect Indian

As more suits were successfully brought up against industry, it would affect company bottom lines. And the merry funding of academia and professionals would come under pressure. The messy lawsuits situation would no longer be restricted to industry. It would involve academia and practising doctors as well.

Now. because of the opening up of world economies and liberalization. drug launches abroad find very quick echoes in Indian markets. Which was good to rake in the profits, but would be disastrous when drugs like Voixx and Lipitor bombed. Because so would their Indian counterparts.

trends to follow western trends, as it does in everything else. Lawsuits against Indian pharmaceuticals were also bound to go up, as they blindly imported western technology and drugs, often without even the fig leaf of a multi-centered clinical drug trial. Drugs that come under the legal scanner abroad are hardly likely to escape a similar fate here, especially because western technologies, and latest drugs, were making a swift entry into Indian markets. Gone were the days when obsolete technology, or obsolete drugs, entered India. Now, because of the

opening up of world economies and liberalization, drug launches abroad find very quick echoes in Indian markets. Which was good to rake in the profits, but would be disastrous when drugs like Voixx and Lipitor bombed. Because so would their Indian counterparts. And Indian pharmaceuticals would soon start running up huge compensation bills, which would seriously start eroding company bottom-lines. So there was every reason for them to sit up and take notice of the impending storm too.

One hates to be a doomsday prophesier. Or a spoilsport. But the writing is clear on the wall if the blinkers could be removed for a while.

Remedy, Short term and Long

But all this can change. And it better change. How?

The steps will have to be short-term and long-term. But both will have to be taken now, if reputations have to be protected, and medicine has not to become unduly protectionist or combative, both of which would go against its essential thrust and purpose - the principle of beneficence.

A. Short Term Measures

Let us look at some of the short-term measures that have to be put into place with some alacrity before the situation becomes irreparable:

1. Reduce Pharma spending on junkets and trinkets.

- 2. Increase search for real trend setters in drug research rather than hype over the 'me too's'.
- 3. Avoid manipulation of drug trials so the real champion could be separated from the 'also rans', and then go for the publicity blitz, if at all.
- 4. Avoid getting pliant researchers into drug trials, for they were a deadly component of the production of 'me too's', and the movement towards manipulation of drug trials.
- 5. Avoid manipulating Journal Editors to publish positive findings of their drug trials and launches. For the final arbiter was the patient, and if he did not get well, or if he suffered side effects, both the pharma concerned and the pliant researcher and journal would have the muck hurled in their faces. And suffer reduced credibility, which would only hurt their fortune in the long run.
- 6. For Indian Pharma, to conduct their own clinical drug trial of the latest blockbuster so projected in the West, and find out whether it was really worth the hype. For they may be betting their millions on a lame horse. Secondly, they must use the services of researchers whose credentials are above board. Apart from ethical reasons, it was also simply because they would then know the truth. And could then decide whether they could pump in their millions to hype it up. And rake in the profits that would inevitably ensue.

B. Long Term Measures

The long-term measures are related to the way biomedical advance is to be charted. It is intimately related to the way we look at ourselves today, and wanted to be considered by posterity tomorrow. Which may not be as charitable as we may wish it to be, if we did not make some fundamental and foundational moves today. For that we must take a close look at the prevalent scene.

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If medicine has to continue its forward movement as it is, it has to become corporate a enterprise. In other words, it must be run as an industry. Profit should be its watchword. Patients should be clients who are offered services as different packages. And research advanced according to what earned more profits, not necessarily guided by what served patient interests on a large scale.

There are two parallel developments in medicine today. Both seem to be at loggerheads, and both vie for our attention. The first, which is manifestedly more recent, (but which, we suspect, has been present in the field for a long time), would want us to think of medicine as a corporate enterprise. The other, which is hallowed by tradition, passed on from generation to generation, and considered the essence of good medical practice (but which, we suspect, more mouthed than practiced), considers it a patient welfare centered profession.

Let us here consider the essential thrust of their respective positions.

1. Medicine as a Corporate Enterprise

This approach would insist that if medicine has to continue its forward movement as it is, it has to become a corporate enterprise. In other words, it must be run as an industry. Profit should be its watchword. Patients should be clients who are offered services as different packages. And research advanced according to what earned more profits, not necessarily guided by what served patient interests on a large scale. In other words, medicine turns into business. And, as all socially conscious business enterprises do, it could apportion part of its funds from profits accrued for socially relevant causes. This could include welfare of socially and economically disadvantaged sections, and those disease entities which were rampant but whose treatment does not rake in the dollars. Like it was done in all socially conscious businesses, which apportioned a percentage of their profits for socially relevant causes. But none of this at the cost of their primary motive, which was business to make handsome profits.

In this model, ethical practices are to be followed, but those of a business, not of a profession. The basic difference between the two being that for the former it is profits *with* patient welfare, and for the latter it is patient welfare *with* profits. For some the difference may be

difficult to spot. But it will be immediately clear when we say that for a doctor, medical practice means getting the patient well *with* charging a fee, not charging a fee *with* getting the patient well. In other words, it is a matter of what gets precedence, and what will not be forsaken in case of conflict. A sound corporately run medical practice would ensure there was minimal conflict between profits and patient welfare. In other words, it would indulge in only such profit as resulted from, and in, patient welfare, and carefully eschew all others. But, it would run it as an efficient corporate enterprise.

There are many advantages in this approach. Infrastructure, paramedical staff and treating doctors' qualifications and practices would be spruced up and become more evidence based. Patients would get the most recent medical care delivered efficiently and competently. The patronizing and condescending attitude of physicians, their fossilized and archaic knowledge and practices, will be eased out. Hospitals would become cheerful looking, sparkling places, like well-run business premises are. Not the dim dingy looking spaces, with patronizing, ill mannered but golden-hearted docs that still are the norm at most places all over the globe.

There are four main hitches here. One is the massive cost escalation, which is inevitable. The cost escalation could be managed by competition, and increased earning capacity of the consumer. Plus the attitudinal change that better facilities came at a price. And medical

facilities also were like any such facility you paid for. You could not get five star facilities at one star prices. And profit was not a dirty word in medicine. In fact it was desirable, but according to certain sound business practices which maintained ethical parameters of a good business. And whoever said business could not be run on ethical principles? And whoever agreed that profits must involve fleecing someone, or duping a hapless customer? Those days were past, mainly because the consumer was well aware of his rights, and vigilant and emphatic about

For a doctor, medical practice means getting the patient well with charging a fee, not charging a fee with getting the patient well. In other words, it is a matter of what gets precedence, and what will not be forsaken in case of conflict. A sound corporately run medical practice will ensure there is minimal conflict between profits and patient welfare.

Overhead costs, infrastructure up-gradation, competition/unhealthy practices from fellow corporates in the field, cost over runs, over investigation and lengthier indoor stay, costlier treatments and investigations – all these add on to medical costs.

The way out is again the same forces of the marketplace, which will help keep medical costs under check because of competitive pricing, enlightened consumer activism, and necessary judicial support to tackle the erring.

exercising them. And legislation and activism were his comrades in arms.

Second hitch is neglect of disease conditions that afflicted the socially disadvantaged, whose treatment could not rake in the dollars. In such spheres, government and philanthropic organizations, with partial subsidy from medical business with social responsibility, could manage to do justice. Or medical business would pay a 'Social Welfare Tax,' which could go to finance such needy activities.

Third hitch is how to curb the questionable business practices of the less scrupulous, which would have a field day when the fig leaf of being a profession was removed. Here market forces would play their role. As would practice guidelines by professional bodies and guilds. As well as peer

review and pressure. As also legislation. And of course vigilant patient welfare bodies and activists, and the ever-hanging Damocles' sword of litigation. All in all, numerous checks and balances would be in place to see to it that profit maximization was not at the expense of patient welfare. In fact it was based on, and maximized, it.

Fourth hitch is how to tackle forces of the marketplace, which compel questionable activities on to a business concern. Medicine would be no less immune to it. Overhead costs, infrastructure upgradation, competition/unhealthy practices from fellow corporates in the field, cost over runs, over investigation and lengthier indoor stay, costlier treatments and investigations – all these add on to medical costs. And while some of these factors are inevitable, making medicine a corporate enterprise may legitimize so many others. The way out is again the same forces of the marketplace, which will help keep medical costs under check because of competitive pricing, enlightened consumer activism, and necessary judicial support to tackle the erring.

There will be some black sheep in this enterprise. But appropriate procedures would take care their influence is at a minimum. In any case there are black sheep in the medical profession even today. And there is no evidence to prove that calling medicine a profession rather than a business has reduced its prevalence. In fact it may have given it a license to continue under wraps.

Greater accountability, more transparency, and heightened efficiency are what the sick consumer could then ask for, and get. Ancillary businesses, like those of medical appliances, hospital construction, medical insurance, and paramedical manpower would get a boost, which would generate more employment and increase earning capacities to pay for better and more costly medical care.

All in all, a great way to lend direction to this important development in medicine, which can easily lose its way to the unscrupulous if not guided at this juncture. Or lose momentum by actions of self-proclaimed guardians of morality, if its positive energies are not harnessed.

2. Medicine as a Patient Welfare Centered Profession

Let us look at the contention of the second approach now.

If medicine has to remain a patient welfare centered profession, dedicated mainly to amelioration of suffering of humanity, and profits/positions/ prestige are only to be attractive perks not the main thing, then something real drastic will have to be set into motion right away. The medical man, and the academic researcher, will have to reign in his avarice. The pharmaceuticals will have to cut down on the pampering of the medics. The profit margins will have to be wholesome but not awesome. Genuine research will have to be forwarded, not spurious questionable activities that are on the

The medical man, and the academic researcher. will have to reign in his avarice. The pharmaceuticals will have to cut down on the pampering of the medics. The profit margins will have to be wholesome but not awesome. Genuine research will have to be forwarded, not spurious questionable activities that were on the upswing at the moment. Patient welfare will have to become paramount, regardless of profits.

He wants a clear distinction between the business of medicine. which industry follows, and the profession of medicine. which the practitioner/ medical researcher should. He regulatory mechanisms to be set in place for industry, and wanted that on a war footing. He also wants no interference in his work from industry, which wanted to involve him in questionable activities. He knows that the compulsions of academia/ practice and industry are essentially different. He wants each to respect the others' domain, and not infringe.

upswing at the moment. Patient welfare will have to paramount, regardless of profits. Diseases that afflict major populations will have to remain thrust areas regardless of the quantum of profits generated. And research itself, on the whole, will have to be guided by what is the need of the populace, rather than what is the fancy thing at present. Or what potentially raked in the dollars for the sponsor or the corporately run hospital.

The hallowed profession of medicine traces its lineage to the greats who sacrificed their lives working for disease amelioration. Medicine is a sacred and noble profession, and the suffering of a patient is its greatest challenge, regardless of what and how much it earned for the doctor concerned. No doubt he expects a reasonable life, with its comforts. But

he does not vie with, or envy, the businessman who could throw his money around. He has no need for such funds. Yes, he did need funds to support him, and his research. And he did need the funding agencies to make sufficient money to survive and sponsor medicine's onward march. But he is not to be a party to avarice and greed in the name of medicine, in himself or others. He is especially averse to cost escalations of drugs because of pampering of the medical man. He wants stringent procedures in place so that the compromised researcher, or industry major, could not manipulate results and take patients, and medicine itself for a ride, or lead it up the wrong alley.

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compulsions of academia/practice and industry are essentially different. He wants each to respect the others' domain, and not infringe. But he finds industry trying to influence, and modify, medicine to suit its ends. And finds pliant medical men ready to play game. And he finds that an alarming state of affairs.

He would not want money and grants to play as great a role as it does in medical practice and research today. The stilted growth of medical research towards what benefited the sponsors, while the whole mass of research and practices, which cries out for attention, remains conveniently neglected, is alarming. It has to be remedied on a war footing.

The number of lawsuits against industry indicate the patient was now awake and would not be taken for a ride. While this is heartening, the fallout of this could be a spoke in the momentum of medical advance, which he bemoanes. Moreover, malpractice suits against his colleagues maybe a manner to pull up the black sheep. But its increase is intimately related to how questionable business practices have entered medicine, and ruled the hearts, and minds, of the man whose primary work is to heal.

Hence, he would want the essential patient welfare thrust never to be lost. The medical man ever to remain dedicated to it. The medical ancillary industry, pharma sponsors included, to play second fiddle, and earn their millions as a result of, not while dictating, the way medical science had to progress. The patient is the boss, his welfare is the *mantra*, and the doctor and other paraphernalia are the means to

ensure it. In this profits are needed to forward the onward march of the boss' welfare, but it could never be at the cost of his welfare. This should be, and would always remain, the guiding force.

Doctors would have to rein in their avarice, which makes them play into the hands of industry. So would researchers. Industry would have to rein in its questionable methods to rake in profits. Patients would have to rein in their methods of intimidating both

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In other words, a massive movement to set priorities right by all the players concerned. And medicine once again to assume the role it was originally envisaged to play. To dedicate itself to disease amelioration; to dedicate itself wholly and solely to patient welfare. And to nothing else.

by flimsy lawsuits to claim huge compensations, which may get the money in and embarrass industry/medical men, but would ultimately result in cost escalation of medical services and defensive medical practice, both detrimental to his welfare.

In other words, a massive movement to set priorities right by all the players concerned. And medicine once again to assume the role it was originally envisaged to play. To dedicate itself to disease amelioration;

to dedicate itself wholly and solely to patient welfare. *And to nothing else*. And staunchly resist any moves from any quarter, howsoever mighty and howsoever tempting, to waylay it from this path.

The Choice

In other words, it is a choice between the expedient and the ideal. The choice is rather difficult. But it is better made now before circumstances force it on us when we are least prepared.

However, the problem is that the two approaches, both strongly convincing in their own way, leave us at a loss. Which to follow, which reject? And on what grounds?

The first one gives paramount importance to profits, but through the process of patient welfare. It appears attractive, and a worthy resolution of the problem. The second emphasizes patient welfare while not denying the value of commerce. It concentrates on medicine as it has been traditionally practiced.

Is it time to give up on the traditional and move on?

We think it is time to give up on neither, but to resolve issues with an eclectic approach based on a healthy resolution of these two. And move on.

Resolution: Medicine as a Patient Welfare Centered Professional Enterprise

No one can deny, or dispute, that the only justified reason the whole enterprise of medicine and its appendages can exist is patient welfare. Remove this one criterion and the whole system has to collapse. This applies as much to doctors as their ancillaries, including all the commercial establishments it has helped spawn. This ideal of patient welfare has been manipulated, sidelined, exploited, whatever. But no one can deny that this one criterion cannot be sidestepped. If any process seeks to deny this and yet exist, it cannot claim to do so on legitimate grounds.

Patient welfare is *necessary*, but not a *sufficient* enough criterion. For, to bring it about one needed the infrastructure and paraphernalia to ensure it. That requires funds. And running the enterprise of medicine as an efficient business could best generate it. Whoever decided to sanction anything and everything in the name of profit? Who has decided that business and profits necessarily involve malpractice? Why could ethics not play a role in business? For to brand every business as necessarily unethical, and therefore suspect, we applies a warped yard stick, and automatically sanctions every wrong doing in the name of business. For we must believe that sound business also involves an abiding commitment to values. As one of the most successful of businessmen in India today mentions:

While success is important, it can become enduring only if it is based on a strong foundation of values. Define what you stand for as early as possible, and do not compromise with it for any reason. You can't enjoy the fruits of success if you have to argue with your own conscience (Premji, 2004).

In other words, ethical guidelines are possible in business as well. In fact the whole field of business ethics seeks to forward precisely this. It is difficult, is prone to manipulation. And the majority, which cares two hoots at

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If the patients, clinician/researcher, along with infrastructure (including hospitals, pharmaceuticals, the distribution and training system involved) become the reactants, the products are patient welfare, profits and knowledge.

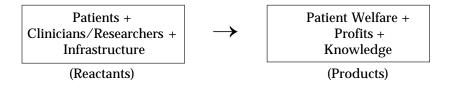
times, knocks it about. But it is implemental if we do not mentally sanction ulteriority as integral to business.

The whole point is how do we ensure that in profit making patient welfare is not compromised, and in patient welfare, profit making is ensured?

Let us take the example of a chemical reaction to clarify matters.

Reactants on the LHS. Products on the RHS.

If the patients, clinician/researcher, along with infrastructure (including hospitals, pharmaceuticals, the distribution and training system involved, previous knowledge) become the reactants, the products are patient welfare, profits and advanced knowledge.



Now, for ensuring the products that result are a wholesome mix, we must ensure on the LHS:

- 1. Patients are correctly identified, diagnosed according to evidence-based criteria, and handled with care, compassion and competence.
- 2. Clinicians/ researchers credentials are of impeccable standards, itself not a mean task:
- 3. Infrastructure updates itself periodically, and is tuned to react *positively* with the clinician/researcher. Again, something requiring quite an effort, especially the second part.

All those involved in formulating, regulating, modifying and evaluating procedures and processes to ensure quality check, control of reactants, and absence of pollutants have to be an ever-vigilant lot. And their procedures and processes have to be constantly updated.

Processes that ensure quality control of these two reactants have to be firmly in place. For that, all those involved in formulating, regulating, modifying and evaluating procedures and processes to ensure quality check, control of reactants, and absence of pollutants have to be an ever-vigilant lot. And their procedures and processes have to be constantly updated. Like your *Windows*, or the anti-virus installed in your computer.

That is one side of the story.

Equally important is it to ensure a healthy mix of the products (RHS). Of course ensuring quality control of reactants is one major step. And here weeding out unhealthy practices as well as encouraging wholesome ones is a must. But equally important is it to determine what is a healthy mix. What proportion of products ensure that the reaction had been successful? The products are optimal? And the gangue is minimal? And the corpus of knowledge that results is wholesome and patient welfare oriented?

We think a healthy proportion is patient welfare *with* profits, in that order. Such amount of patient welfare as also ensures profit, and such amount of profit as also ensures patient welfare. Because:

Profit, without patient welfare, is blind. Patient welfare, without profit, is lame.

That proportion of patient welfare which ensures profit is necessary. And that proportion of profits which never neglects patient welfare is as necessary. For to try to ensure patient welfare without profits is a lame exercise, and would always fail. Just as to ensure profits without patient welfare is a blind enterprise, and would always falter. So, if we do not wish to fail, or falter, the only resolution is that

proportion of patient welfare which also ensures profits, and that proportion of profits which also ensures patient welfare. Any compromise in this formulation and we know what it means.

Profit, without patient welfare, is blind. Patient welfare, without profit, is lame.

If patient welfare become the eyes, and profit become the legs, then they could complement each other. Lame patient welfare could ride on, and direct, blind profit, and both could reach their destination. Let us put it a little differently to clarify the issue further. Patient welfare, essentially, is lame. Lame meaning it cannot go far on its own. It needs to ride on something. Similarly, profit, essentially, is blind. It too cannot go ahead on its own because it lacks vision. It needs to be directed by something.

If patient welfare becomes the eyes, and profit becomes the legs, then they could complement each other. Lame patient welfare could ride on, and direct, blind profit, and both could reach their destination. In this both parties must know that none is superior to the other, both suffer from a disability, and both need the other to survive. It is as foolhardy for patient welfare to believe it can do without profit, as it is mischievous for profit to believe it can do without patient welfare. The recent spate of lawsuits should have made this amply clear to it.

Hence a lame patient welfare could climb the back of a blind profit, and both could complete the journey.

However, if the blind decided to chart the course and determine the destination, it would spell disaster. This was, in essence, what dishonest means of profit making by industry meant. And we know the fallout. Such means must be firmly resisted. Similarly, and equally important, if lame profit welfare want to complete the journey on its own, it would take a great amount of time. Besides, it may falter and fall, being unable to complete the journey on its own. This too has to be resisted. We know how without sufficient funds neither proper infrastructure nor further research can be forwarded.

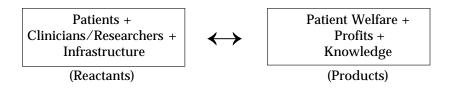
Similarly, a blind patient welfare and a lame profit would also spell chaos. Blind patient welfare manifested as fanatical proponents of patient welfare who could see no merit in profits. Such thinking is naïve and would receive only lip sympathy, if at all. Similarly, lame profit, which could not provide the funds for scientific research would be equally disastrous, and could be the result of a blind patient welfare.

It must be essentially lame patient welfare complemented by essentially blind profit. They have to coexist without switching roles, or usurping each other's domain. There is no option for both of them if they wish to survive in the long run, and resolve their conflicts amicably.

This would automatically ensure that the other product, knowledge, also remained gangue free. For vitiated patient welfare and vitiated profits also ensure a vitiated knowledge corpus.

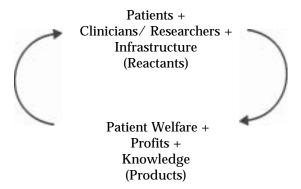
Let us go back to the chemical reaction formulation. Continuing from where we ended earlier:

If the patients, clinician/researcher, along with infrastructure (including hospitals, pharmaceuticals, the distribution, training system involved, and previous knowledge) become the reactants, the products were patient welfare and profits and new knowledge. What was worth noting was that it was a two way correspondence:

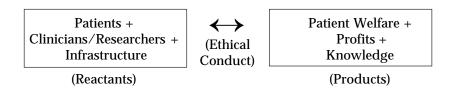


Research/clinical care combined with infrastructure working on patients lead to patient welfare with profits and advanced knowledge. Patient welfare with profits, combined with advanced knowledge, in its turn, lead to further development in research/clinical care with infrastructure and work on patients. This is the cycle that perpetuates itself to the benefit of all concerned:

It must be essentially lame patient welfare complemented by essentially blind profit. They have to coexist without switching roles, or usurping each other's domain. There is no option for both of them if they wish to survive in the long run, and resolve their conflicts amicably.



Moreover, we have to note that there has to be a catalyst in this process. One that speeds and regulates the reaction but does not itself take part or undergo any modification. This necessarily has to be ethical conduct by all parties concerned. The final revised reaction has to be as follows:



Summing Up: Medicine as a Patient Welfare Centered Professional Enterprise

In short, we think of *patient welfare* as the *center* around which everything revolves, and forsaking which nothing does. And we continue to believe medicine is a *profession*. Meaning thereby, it is bound by the rules of professional ethics, requiring certain essential

It is important that the profession of medicine should accept and allow for private enterprise in the field if it does not want nefarious activities to prosper clandestinely. Something like what it did for abortion.

Not allowing it caused so much illegal trafficking, allowing it with safeguards took the sting out of malevolence. Something similar would happen if we accept the enterprise of medicine as legitimate, but with the necessary condition of patient welfare not to be violated at any time.

qualifications as enshrined in regulations by certain statutory authorities. But it is also, though not equally, an *enterprise* wherein the profits that accrue from its practice can be considered legitimate if it does not forsake patient welfare at any stage of its planning and action.

It is important that the profession of medicine should accept and allow for private enterprise in the field if it does not want nefarious activities to prosper clandestinely. Something like what it did for abortion. Not allowing it caused so much illegal trafficking, allowing it with safeguards took the sting out of malevolence. Something similar would happen if we accept the *enterprise* of medicine as legitimate, but with the necessary condition of patient welfare not to be violated at any time.

Hence medicine becomes a *patient welfare centered professional enterprise.*

We think it appropriate to leave you here with this thought for your serious consideration.

Decide which side to be on

In this year, 2005, we have seen natural disasters like earthquakes, *tsunamis* and hurricanes vie with man made disasters like terrorist attacks devastate human life.

A hurricane of ominous proportions is building up in the background in the form of lawsuits against industry. And it will join with the *tsunamis* of consumer court cases against the man with the stethoscope, and working under the microscope. And the earthquake that follows will shake the very foundations of biomedical advance, medical care and patient welfare as we have always known and upheld as proper.

Disaster strikes. Be prepared. Decide which side you wish to be on.

Or be ready for the history of the Yadavas and the Romans to get repeated.

Concluding Remarks

- Cost of medicines escalate unreasonably because of increased R and D spending over 'me too' drugs, catering to the wants of the medical man which have multiplied beyond imagination, expenses over conferences, litigation, hype by the marketing departments, and keeping all those in power sufficiently satisfied to help push a drug from the laboratory shelf to the pharmacy one.
- 2. The cost of organizing conferences is no longer ever possible on delegate fees. The bottom-line is: Crores for a Conference, Millions for a Mid-Term. The problem is that the sponsor keeps a discreet but careful tab on docs. All in all, costs of medicines escalate, which means medical care becomes a luxury. The whole brunt of this movement is borne by the patient.
- 4. Companies like GlaxoSmithKline, Bayer, Pfizer, Bristol-Myers Squibb, AstraZeneca, Schering-Plough, Abbott Labs, TAP Pharmaceuticals, Wyeth and Merck have paid millions of dollars each as compensation in the last few years. The financial condition of many pharmaceutical majors is not buoyant either. Price deflation, increased R and D spending, and litigation costs are the main reasons.
- 5. In the future, the messy lawsuits situation will no longer be restricted to industry. It will involve academia and practicing doctors as well. Indian pharma industry captains, who are busy raking in the profits, will also come under the scanner. If nothing else, it means industry and docs would have to sit down and do some soul searching.
- 6. Both short and long-term measures will have to be put into place. Short-term measures involve reduced pharma spending over junkets and trinkets, hype over 'me too' drugs, manipulation of drug trials, avoiding getting pliant researchers into drug trials, manipulating Journal Editors to publish positive findings about

- their drug trials and launches; and for Indian Pharma, to conduct their own clinical drug trial of the latest blockbuster so projected in the West.
- 7. The long-term measures are related to the way biomedical advance has to be charted. To decide whether medicine is to be a corporate enterprise or a patient welfare centered profession.
- 8. Medicine as a corporate enterprise means ethical practices are to be followed, but those of a business, not of a profession. The basic difference between the two being that for the former it is profits with patient welfare, and for the latter it is patient welfare with profits. There were many advantages in this approach. However, there are four main hitches here. One is the massive cost escalation. Second hitch is neglect of disease conditions that afflict the socially disadvantaged. Third is how to curb the questionable business practices of the less scrupulous. Fourth hitch is how to tackle forces of the market place. Greater accountability, more transparency, and heightened efficiency are what the sick consumer can then ask for, and get.
- 9. Medicine as a Patient Welfare Centered Profession means patient welfare has to become paramount, regardless of profits. The profit margins have to be wholesome but not awesome. There has to be a clear distinction between the business of medicine, which industry follows, and the profession of medicine, which the medical practitioner/researcher should. The patient is the boss, his welfare is the *mantra*, and the doctor and other paraphernalia are the means to ensure it. In this profits are needed to forward the onward march of the boss' welfare, but it could never be at the cost of his welfare. This should be, and would always remain, the guiding force
- 10. A third approach involves an eclectic resolution of the two. Patient welfare is *necessary*, but not a *sufficient* enough criterion. We think a healthy proportion is patient welfare *with* profits, in that order. Such amount of patient welfare as also ensured profit, and such amount of profit as also ensured patient welfare. Because, *profit*, *without patient welfare*, *is blind*. *And patient welfare*, *without profit*, *is lame*. Hence medicine becomes a patient welfare centered professional *enterprise*. By an enterprise we mean here an activity

- wherein the profits that accrue from its practice can be considered legitimate if it does not forsake patient welfare at any stage of its planning and action.
- 11. However, if an essentially blind profit decides to chart the course and determine the destination, it would spell disaster. Similarly an essentially lame patient welfare would also falter. Also, a blind patient welfare and a lame profit would also mean chaos.
- 12. The resolution has to be the combination of an essentially lame patient welfare riding an essentially blind profit motive, so both can complete the journey.

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Questions that this monograph raises

- 1. How can the problem of price deflation, increased R and D spending and litigation costs of pharmaceuticals be solved?
- 2. How can conference costs be kept within such control that sponsors cannot exercise undue control over conference activities and participants?
- 3. Lawsuits against industry are on the increase. Lawsuits against doctors will rise as well. Any solutions come to mind?
- 4. Can medicine be acceptable as a commercial enterprise?
- 5. Will we be able to keep medicine patient welfare oriented? What measures would be necessary to ensure this?
- 6. Does it make sense to combine patient welfare with profit? What to do when the latter tries to dictate to the former?
- 7. If patient welfare is lame and profit is blind, the two handicapped are likely to deny their handicaps and blame the other for mishaps. What can be done to ensure that this is minimized?
- 8. What should Indian pharma do to establish its presence as a genuine world player, and not just a conduit for profit making in the name of new molecules launched in the west? How can genuine R and D efforts be enhanced in India?
- 9. Can doctors/researchers decide research agenda and minimize untoward industry influence over research, and how?
- 10. If we think of medicine as a patient welfare oriented professional enterprise, does it not amount to granting legitimacy to nefarious business influences through the back door?
- 11. Where do you think medicine is heading:
 - i) will become a business;
 - ii) will remain a profession;
 - iii) will combine the best of both
 - iv) professional standards will control business interests;
 - v) business interests will control professional standards;
 - vi) will combine the worst of both.
- 12. As a medical man, do you regret taking up medicine as a career? Will you encourage an ethical minded bright young person to take it up?

Call for poems in MSM Poems Section on Medicine, Health and Human Behaviour

We begin a Mens Sana Monographs Poems Section from this issue.

Interested poets may send their work for consideration. They may be in verse, but preferably in blank verse. A four-line write up on the poet with a photograph must accompany every submission. You may submit not more than three poems at one time.

While there cannot really be a restriction of any nature as to topics in poetry, poems dealing with medicine, health, delicate satire on human behaviour of various types, insighful reflections etc are more likely to be accepted for publication.

Poems may preferably be submitted in Word format by email and addressed to the Editor.

Acceptance, or otherwise, will be conveyed within four weeks of receipt of submission, if not earlier. We do not wish to increase the anguish of poets by making them wait further. That may lead to another distressed poetry because of us!

Poems for potential publication in Mens Sana Monographs Vol III, No 6, March-April 2006 ISSN 0973-1229 should reach the Editor in Microsoft Word format by 1st January 2006. All poems will be submitted for peer review and a decision of acceptance or otherwise will be conveyed to the authors by 1st Feb 2006.

Authors may contact the Editor, Mens Sana Monographs, for further details and clarification (email: mensanamonographs@yahoo.co.uk). They may also visit the website http://mensanamonographs.tripod.com for further information.

MSM Poems

Silences Parliament

Indeed. Yesterday

the crows gathered on our terrace

Silences for a meeting.

Allow whispers to There were at least five hundred

Travel of them long distances. if not more.

And,

And as they caw-cawed

and moved about animatedly

Whispers and argued Make silences and jostled

Come to life. and changed sides

and hung on to slender ropes

and made it all appear

Life itself very intense

Is a and

And

Whisper apparently purposeful

Between

Two silences. equally entertaining.

I remembered another

similar assembly.

Readers Respond

You can read here a response to the last issue of Mens Sana Monographs

Medical Practice, Psychiatry and the Pharmaceutical Industry: And Ever the Trio Shall Meet, Mens Sana Monographs, Mens Sana Research Foundation (2005), Vol II, No 6, Vol III, No 1-3, March - October 2005. ISSN 0973-1229.

Please allow me to congratulate you on bringing out Mens Sana 8th and 9th Monographs on Medical Practice, Psychiatry and the Pharmaceutical Industry. You and Shakuntala have obviously put in an enormous effort to study dozens of documents, articles and books to bring out such a comprehensive review of this topic with focus on important areas for debate in India. You deserve congratulations of all the readers of these Monographs.

Dr. Narendra N. Wig, Prof Emeritus Psychiatry, PGIMER, Chandigarh, India. 8th Sept, 2005.

Obituary

Dr. A. Venkoba Rao

I have to inform with great regret the sad demise of Dr Venkoba Rao, one of the senior most and highly esteemed psychiatrists this country has produced. His research work in psychiatry and medicine, as well as his work in philosophy and the human predicament, have been noteworthy indeed. He was a researcher and an academician of the highest order.

It was always a great pleasure interacting with him. Both juniors and his peers will remember him with great regard and equal fondness. He never made himself difficult to approach, and was open to all positive inputs, from whatever source.

He was highly appreciative of the work done by the Mens Sana Research Foundation too. I treasure the encouraging letter he wrote to us sometime back about the Mens Sana Monograph *Psychiatry, Science, Religion and Health,* of which here is an excerpt:

The articles in general are of high standard and are very readable...I must tell you that your monograph makes an enjoyable and informative reading and my personal congratulations to you on your achievement.

In fact, he was encouraging towards all efforts in the field of mental health.

His wide knowledge of philosophy and Indian thought, coupled with active research interest in mainstream psychiatry, made him a unique presence in the field.

His absence will be felt for a long long time indeed.

But I have lived, and have not lived in vain; My mind may lose its force, my blood its fire, And my frame perish even in conquering pain: But there is that within me which shall tire Torture and Time, and breathe when I expire; Something unearthly, which they deem not of, Like the remembered tone of a mute lyre...

Byron (Childe Harold)

On behalf of the Mens Sana Editorial Board, our subscribers, readers, as well as the Mensanamonographs group, I offer our deepest condolences to his bereaved family.

May his soul rest in peace.

Ajai Singh

Obituary

Dr. S. G. Mudgal

(11 Nov 1923-15 Aug 2005).

In the loss of Prof (Dr.) S.G. Mudgal, the world of philosophy has lost an eminent torch -bearer of the classical Indian tradition. His benign presence, stately bearing, and benevolent guidance to all his students and peers in the field was something to be experienced. Words are inadequate to describe such an experience. His anguish towards the neglect of the Indian tradition, and dismay at finding bright minds trying to stilt and distort the Indian philosophical corpus by viewing it through western methodology and approach was palpable. He was one of the finest of the committed proponents of that which was the best in ancient Indian thought. And he had no regrets proclaiming it. His knowledge of the classical western tradition was adequate for him to find the greatness therein, and find many comparative features, which fortified his abiding interest in the Indian one.

Lately he appeared in a hurry, probably realizing the end was near. In 2003 he published his 310 page book *The Bhagavad Gita* (Himalaya Publishing), a seminal work on the great treatise. This book is his understanding of the *Bhagavad Gita*, which, according to him, is theistic and realistic:

The world, according to the BG is real and not illusory, nor an illusion. The jivas are real. Bondage and attainment of Moksa are also real. Jnana and Bhakti are inclusive; ultimately it is Bhakti which leads to Mukti. Grace of Guru and God are emphasized. Bhakti continues even in the state of Moksa.

The Gita does not advocate the doctrine of Karma Sanyasa; but advocates the performance of Karma as worship, as dedication and an offering to God. Work thus done with a sense of dedication or worship, is liberating and not binding. (Back cover of the book)

Dr Mudgal had been a well known academician, erudite scholar, and an able and efficient administrator. He had been Principal of the well known Ruparel College, Mumbai, and Nowrojee Wadia College, Pune. He made a mark as Professor of Indian Philosophy and Comparative Religion. He studied all the schools of Indian Philosophy, especially the three schools of Vedanta, namely, Advaita, Visistadvaita and Dvaita. He had a great grasp over Mahayana Buddhism too.

A life immersed in Philosophy, welfare of students and society at large, and dedicated to prayer and ethical conduct. Every student who visited him came away blessed and transformed, with a desire to do good and work for society in his own way. Never ever even a trace of conceit or greed, never a blemish in an exemplary life lived according to principles of the highest moral order. It was difficult for this goodness not to rub off on all those whose life he touched.

We had numerous discussions with him for hours on end over various aspects of Philosophy. And it was a treat to listen to him expound tirelessly over a certain topic for hours, without once stopping to search for words, or even to drink a glass of water. And every time we came away feeling blessed to have met him and to work with greater dedication and commitment, irrespective of the decay of values all around.

He was one of the foremost subscribers of the Mens Sana Monographs, and was always very solicitous of its welfare.

We shall miss his kindly enquiries and his encouraging words. Just to think of him fills the mind with a great zest to persist on the right path regardless of consequences and oblivious of distractions.

He departed from us on Indian Independence Day 2005. Here are a few lines I (AS) wrote on him the very next day:

Independence day 2005

Independence day was special this time for another reason.

An individual soul having shed its kindly light over earthlings also shed its chains broke free and soared to prostrate at the feet of the Universal.

On behalf of the entire Mensanamonographs family , we offer our deepest condolences to the bereaved family.

May his soul rest in peace.

Ajai Singh , Shakuntala Singh

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