

The Academia-Industry Symposium

Medical Practice, Psychiatry and the Pharmaceutical Industry:
And Ever the Trio Shall Meet-I

The Connection Between Academia and Industry

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ABSTRACT

The growing commercialization of research with its effect on the ethical conduct of researchers, and the advancement of scientific knowledge with its effect on the welfare or otherwise of patients, are areas of pressing concern today and need a serious, thorough study. Biomedical research, and its forward march, is becoming increasingly dependent on industry-academia proximity, both commercial and geographic. A realization of the commercial value of academic biomedical research coupled with its rapid and efficient utilization by industry is the major propelling force here. A number of well-intentioned writers in the field look to the whole development with optimism. But this partnership is a double-edged sword, for it carries with it the potential of an exciting future as much as the prospect of misappropriation and malevolence. Moreover, such partnerships have sometimes eroded public trust in the research enterprise itself.

Connected to the growing clout of industry in institutions is concern about the commercialization of research and resolving the 'patient or product' loyalty.

There is ambivalence about industry funding and influence in academia, and a consequent 'approach-avoidance' conflict. If academia has to provide the patients and research talent, industry necessarily has to provide the finances and other facilities based on it. This is an invariable and essential agreement between the two parties that they can walk out of only at their own peril. The profound ethical concerns that industry funded research has brought center-stage need a close look, especially as they impact patients, research subjects, public trust, marketability of products, and research and professional credibility.

How can the intermediate goal of industry (patient welfare) serve the purpose of the final goal of academia is the basic struggle for conscientious research institutions/

associations. And how best the goal of maximizing profits can be best served, albeit suitably camouflaged as patient welfare throughout, is the concern of the pharmaceutical industry.

A very great potential conflict of interest lies in the fact that academia needs the sophisticated instruments that only big funding can provide, while at the same time resists the attempts of the fund provider to set the agenda of research, protocol, design, publication, the works. Conflicts arise at many steps and levels of functioning, and are related to the expectations, competing interests, and conflicting priorities of the different entities involved, whether they are the academic medical centers, the funding agencies, the patients and their families, or the investors and venture capitalists.

The public expects access to new treatments. Its appetite for innovation has been bolstered by the constant attention given by the press to new treatments and by the implicit promise from researchers of continuing advances. Similarly, patients demand privacy and control over information about themselves.

It makes greater sense for genuine researchers to associate with large long-term industry players who have a track record of genuine hard-core discoveries, even if the process is slow (maybe), and the funding less (may not be).

The element of control venture capitalists exert over the pharmaceutical industry is an under researched area for obvious reasons. But it needs further probing, for that will lay bare the pulls and pressures under which industry works.

It makes sense for ethically minded researchers and institutions not to fall in the trap of stocks and equity investments in industry, howsoever attractive they appear, and get rid of them as soon as possible if they have them. If at all they want, it makes more sense to own stocks of larger well established concerns, for the stock upheavals being less, the pressure of the market-place, and of venture sharks, is likely to be lower too.

While active participation by the researcher in the commercialization process may be greatly desired by industry, ostensibly in the name of creating value, academia must realize it is a bait it might find hard to swallow in the long run. It makes more sense for the researcher and institution to forego such temptations and/or walk out of such investments as soon as possible.

While mainstream medicine and research are booming, as is connected industry, concerns about professional commitment to patient welfare are growing too. Increasing corporate influence is challenging certain long held and fundamental values of patient care, which will have far reaching implications for biomedical care and the future progress of mainstream medicine.

KEY WORDS: *Academia, Pharmaceutical Industry, Academia-Industry Proximity, Biomedical Research, Commercialization of Research, Pharmaceutical Funding, Public Accountability and Academic Freedom of Universities, Commercial Value of Academic Innovations, Ethical Issues, Venture Capital, Stocks and Equity, Patients and Public Interests, Large and Small Pharmaceutical Firms*

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Introduction

A number of important areas of the connect between academia, the medical professional and the pharmaceutical industry have been highlighted by articles in the last decade, especially in the last five years, which have still to find place in textbooks of medicine or psychiatry. While this by itself can be considered alarming by some, for denial is a poor coping mechanism, if at all, what is of interest to us here is how the connect has

developed, what are the major areas of influence (and concern), what the remedies for the present, if any, and what the portents for the future. The growing commercialization of research with its effect on the ethical conduct of researchers, and the advancement of scientific knowledge with its effect on the welfare or otherwise of patients, are areas of pressing concern and need a serious, thorough study.

This monograph tries to address some of the issues in this connection.

Now it is possible to mentally resolve the issue for oneself rather well by the following argument. Academia-industry relationship is increasing and augurs well for the future growth of medical research and patient welfare. Well, there are some problems, as is inevitable with all such potentially controversial but useful relationships. Rather than concentrate on, and magnify, the faults, it makes more sense to accent the positive, and create an atmosphere whereby it continues to be maximized, while making the negative less attractive, and yet inevitable to an extent. There is negative fallout of everything. Instead of cribbing about it, we accept it and move on with optimizing the worthwhile.

This is a beautiful and useful rationalization, if the negative is to be put in its place and done away with. But it is a dangerous reasoning if it is meant to sweep certain ominous portents under the carpet. When it is the dust in our house that we have to take care of, we just brush it off right away, or sweep it under the carpet to be removed a little later. And do not bother any further. However, if the dust that flies is heralding an oncoming storm, we cannot brush it off, or sweep it under the carpet. For it retains the ability to sweep us off our feet, carpet and all. Here, damage control measures become mandatory, some after, but many more before, the storm erupts.

What is a saner option is to look at the dust today and prevent it from becoming a dust storm tomorrow. So, no glib rationalizations, only a serious look at the straws in the wind.

This monograph, and the ones that follow, looks at a bit of the dust raised and some of the straws floating around.

Academia - Industry Proximity

Biomedical research, and its forward march, is becoming increasingly dependent on academia-industry proximity, both commercial and geographic. A number of well-intentioned writers in the field look to the whole development with optimism:

We now have the potential to enter one of the most productive periods in biomedical research, the success of which will depend to no small degree on an increasingly close partnership between universities and industry (Nathan and Weatherall, 2002).

Economic partnerships between industry and academia accelerate medical innovation and enhance patient access to medical advances (Johns, Barnes and Florencio, 2003).

Most clinical studies that bring new drugs from bench to bedside are financed by pharmaceutical companies. Many of these drug trials are rigorously designed, employing the skills of outstanding clinical researchers at leading academic institutions (Bodenheimer, 2000).

Within many hundred years' time when people will reflect on history, the 19th century might well be written as the century of industry, the 20th century as the century of information and technology, and the 21st century as the century of biomedicines and healthcare (EFPIA, 2005).

Industry funding is supposed to help disease prevention and treatment, improve clinical practice and result in useful products for patients. In this the profit motive acts as a spur:

Without industry funding, important advances in disease prevention and treatment would not have occurred. In the words of Lee Goldman, chairman of the Department of Medicine, University of California at San Francisco, "companies translate biologic advances into useable products for patients. They do it for a profit motive, but they do it, and it needs to be done." ... many collaborations with pharmaceutical companies were conducted on a high professional level... The infusion of industry dollars into an industry-investigator partnership has clearly improved clinical practice (Bodenheimer, 2000).

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Already alarming portents from the activities of the recent past point to a rather roller-coaster ride for the academia - industry relationship, like the uneasy alliance or marriage of convenience it often turns out to be.

But this partnership is a double-edged sword, for it carries with it the potential of an exciting future as much as the prospect of misappropriation and malevolence. Moreover, such partnerships have sometimes eroded public trust in the research enterprise (Johns, Barnes and Florencio, 2003). Links between academia and industry are of increasing concern to academics and to

society at large and the sectors involved must review and revise their policies in order to sustain the public accountability and academic freedom of universities (Nature, 2001). For, the selection of research topics, the freedom of the research process, the public perception of researchers' role and gains, and the extent of exploitation that industry can carry out of institutions and researchers—all these have come under close scrutiny that will increase in the years to come.

Already alarming portents from the activities of the recent past point to a rather roller-coaster ride for the academia-industry relationship, like the uneasy alliance or marriage of convenience it often turns out to be. Moreover, universities will have to decide on the extent to which they wish to become commercialized and will have to monitor the effect that such commercialization has on the pattern of their research, on public confidence in research, and on academic freedom (Nathan and Weatherall, 2002).

Writing an editorial in the NEJM, Angell (2000) makes the point rather piquantly:

What is wrong with the current situation? Why shouldn't clinical researchers have close ties to industry? One obvious concern is that these ties will bias research, both the kind of work that is done and the way it is reported. Researchers might undertake studies on the basis of whether they can get industry funding, not whether the studies are scientifically important. That would mean more research on drugs and devices and less designed to gain insights into the causes and mechanisms of disease. It would also skew research toward finding trivial differences between drugs, because those differences can be exploited for marketing. Of even greater concern is the possibility that financial ties may influence the outcome of research studies.

Increasing Connection

The connection between academic institutions/research centers and private companies/pharmaceuticals is increasing for obvious reasons. A realization of the commercial value of academic biomedical research coupled with its rapid and efficient utilization by industry is the major propelling force here. An interesting offshoot of this is the close proximity of new major

laboratories to academic institutions all over the world. It makes sound business sense to have laboratories where academia can be easily accessed, and it makes equally sound business sense for academia to make itself accessible:

The decision of several large pharmaceutical companies, and many biotechnology companies, to build major new laboratories near U.S., European, and Asian universities is just one example of the growing commercial value of academic innovation in biomedicine and the talent that produces it (Moses, Braunwald, Martin and Their, 2002).

We may feel happy that this will add to the commercial value of academic innovations, and help sustain it in the long run, as well as provide great windows of opportunity to talent coming out of academia. But what we perhaps ignore is that the constant lure commercial interests provide may take away interest in any but such research as promotes industry's interest. While industry may innocently ask, 'So what's wrong with that', we all know precisely what's wrong with it, though may find it inconvenient to verbalize: namely, that so much that can be of patient welfare may not necessarily suit commercial interests of industry, and vice versa. And only that which can serve the latter will become research worthy in institutions. In other words, the research agenda will not be decided by academia, but by industry. More so in the future, if the present is any indication of portents. The wider and long-term implications of this process should be clearly understood, and agreed to only if found justified, not acquiesced in out of sheer ignorance, for inducement of profits, or other inappropriate gain.

'Patient or Product' Loyalty

Connected to the growing clout of industry in institutions is concern about the commercialization of research and resolving the 'patient or product' loyalty:

One of the major questions now is how to address potential conflicts of interest or commitment surrounding the commercialization of research — how to strike a balance between the need for investigators to act in the best interests of patients and their desire to serve the interests of the product they are developing (Kelch, 2002).

This is what Kelch starts his paper with. But his conclusion is quite categorical:

One cannot work simultaneously as an inventor-entrepreneur and a physician or other health care provider and maintain the trust of patients and the public. To attempt to do so is to challenge the primacy of the doctor-patient

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There is the other belief that academia-industry proximity aids technology transfer beneficial to academia. But this claim is somewhat sustainable in basic research, though greatly exaggerated in clinical research, which is the mainstay of their proximity:

covenant. On the other hand, the system must allow enough flexibility for promising new approaches to be tested (Kelch, 2002).

Which means the inventor-entrepreneur cannot also play the role of a treating physician, much though he may so desire, or feel competent about. At the same time, the system must continue to allow for him to prosper too, in so far as he demonstrates promise vis-à-vis patient welfare; and provide him an atmosphere whereby his experimental

approaches can be tested on research subjects supplied by academia.

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I believe the claim that extensive ties between academic researchers and industry are necessary for technology transfer is greatly exaggerated, particularly with regard to clinical research. There may be some merit to the claim for basic research, but in most clinical research, including clinical trials, the “technology” is essentially already developed. Researchers are simply testing it. Furthermore, whether financial arrangements facilitate technology transfer depends crucially on what those arrangements are. Certainly grant support is constructive, if administered properly. But it is highly doubtful whether many of the other financial arrangements facilitate technology transfer or confer any other social benefit (Angell, 2000).

In other words, grants facilitate technology transfer, other financial arrangements do not. We will have occasion to look into other financial arrangements when we study the effect of venture capital, stocks and equity, the pseudo-educational dollar etc. on the academia-industry connect.

Ambivalence About Industry Funding

The discussion up till this point makes it very clear that there is ambivalence about industry funding and influence in academia, and the ‘approach-avoidance’ conflict is well summed up in the response of one of them quoted below:

The infusion of industry dollars into an industry-investigator partnership has clearly improved clinical practice. Yet the medical literature contains many articles expressing concern about industrial funding of clinical research (Bodenheimer, 2000).

And then he goes on to list a number of studies that voice this concern:

Stelfox et al. (Stelfox, Chua, O'Rourke and Detsky, 1998) found that authors whose work supported the safety of calcium-channel antagonists had a higher frequency of financial relationships with the drugs' manufacturers than authors whose work did not support the safety of these medications. Davidson (1986) reported that results favoring a new therapy over a traditional one were more likely if the study was funded by the new therapy's manufacturer. Cho and Bero (1996) demonstrated that articles from symposiums sponsored by a single drug company were more likely than articles without company support to have outcomes favorable to the sponsor's drugs. Friedberg et al. (Friedberg, Saffran, Stinson, Nelson and Bennett, 1999) reported that 5 percent of industry-sponsored pharmacoeconomic studies of cancer drugs reached unfavorable conclusions about the company's products, as compared with 38 percent of studies with nonprofit funding that reached similar conclusions (Bodenheimer, 2000; parenthesis added)

Financial support to research favours industry as regards safety and effectiveness of drugs, and favourable outcome of trials. Researchers, in other words, are not immune to financial considerations and extra-scientific considerations while pursuing so-called scientific goals.

In the case of the academia-industry connect, we are at a stage at which psychiatry was some decades ago. It had reams and reams written on psychopathology, with little to offer as treatment. Or medicine was half a century ago, when it, similarly, had volumes on signs and symptoms but little to offer as treatment (remember the sanatoria phase for tuberculosis?). Similarly, even here we have reams upon reams written about the desirability-undesirability of the academia-industry connect, but little about the methods to remedy it. Hopefully, this will change as more concerned with the long-term welfare of biomedical advance get conversant with the magnitude of the problem and girdle their loins to do something about it. As happened with medicine in this last fifty years. Or with psychiatry as a branch in the last two decades. Maybe the next two decades will see greater efforts at remedying this situation with regard to the academia-industry connect. A major step forward would be taken if the ambivalence could be taken care of, and more clarity and firmness demonstrated on both sides, whether academia or industry. In any case, events and activists will ensure this occurs, if the concerned parties continue to remain complacent. Which may not be a very pleasant state of affairs to be in for sure.

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The need for large funds is, moreover, coupled with the desire to acquire it without making a dent in one's own pockets. The easiest way that can happen is getting an interested party to fund it, which has a big stake in the success of the entire venture. Hence, the pharmaceutical industry becomes a willing partner in the whole enterprise.

Funds, Research Agendas, and Profit Maximization

Where is the money coming from in medical research and related activities today? The reality is that academic institutions are becoming more and more dependent on pharmaceutical funding, as are the medical associations and conference organisers. The main reason for this is the need for large funds in the medical institutions and associations. This is no longer available to a significant degree from governmental agencies, or philanthropic foundations, except for a

fortunate few. This is from a May 2005 paper comparing industry and NIH funding in the US for psychotropic and other drugs:

Clinical psychopharmacology has been and likely will remain heavily influenced, if not dominated by, the pharmaceutical industry, especially for compounds early in the product development sequence. Industry funding for clinical trials is many times larger than NIH (extramural, including NIMH) funding: \$4.1 billion, compared to \$850 million in 2000 (March, Silva, Compton, Shapiro, Califf and Krishnan, 2005).

Even in 2003, Moynihan found:

More than half the biomedical research being done in the United States is now privately funded, with sponsors able to set the research agenda (Moynihan, 2003).

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Now, this is fine as it goes, and academia may consider the issue beautifully resolved. The only spanner in the works is industry and its aspirations, which are not any idealized notions of research for patient welfare, but to run a profit making concern. And why not, if it cannot make the profits, it cannot survive. And if it cannot provide the funds that flow only if profitability is ensured, and maintained down the years, no academic institution would want to associate with it anyway.

The question we can ask is: why can patient welfare not maximize profit? To that the answer is the perpetual gap between *is* and *ought*. Patient welfare ought to optimize profit, however shrewd marketing in the name of

patient welfare does. Patient welfare is good to espouse and mouth, but profit is the name of the game for industry. So, profit always: if possible with, if necessary without, patient welfare. For academia, it ought to be patient welfare always: if possible with, if necessary without, industry sponsorship. Unfortunately, the reality seems to have gravitated to industry sponsorship always: if possible with, if necessary without, patient welfare.

So, if academia has to provide the patients and research talent, industry necessarily has to provide the finances and other facilities based on it. This is an invariable and essential agreement between the two parties that they can walk out of only at their own peril. What academia must continue to provide is necessarily a mass of compliant patients and a crop of compliant researchers and administrators to further industry goals. What industry must continue to provide is the ready finances to fund it all. Now, the issue fundamentally is that research has to continue, for so much is at stake for researchers, institutions, and even patients' expectations in it. The only way it can continue in the present scenario, so it seems, is by industry funding, and the only way that can be ensured is by research agendas maximizing industry profits. If anyone can suggest another way, well, we would all rise in our seats and applaud him. Well, actually Schafer (2004) does, when he boldly suggests doing away with industry support altogether, but one wonders whether he finds willing supporters amongst academia and researchers.

R and D in Pharmaceutical Companies

While we present the flip side of industry funding, we must also note the way pharmaceuticals function with regard to research and development. It is not enough just to make them the whipping boys, and present academia as the holy cow led astray.

We must note that medicine costing is not only inclusive of R and D, marketing, infrastructure, raw material, manufacturing, regulatory authorities, trials and profits. Every new medicine carries the inbuilt cost of producing the next new medicine:

Since the price of a new medicine carries within it a contribution towards the cost of discovering the next, the mainstay of the European pharmaceutical industry's long-term competitiveness is its ability to pay for research and development of future medicines (EFPIA, 2005).

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Out of 5000-10000 products studied, only one reaches the pharmacy shelf, and that too after 12-13 years, at a cost of approximately euro 895 million per product.

Every new medicine is caught in an inevitable upward price spiral. Apart from other costs, it must pay for the development of the next new medicine. The pharmaceutical industry has to bear this in mind if it has to survive, and prosper, in the long run. So have the patients, and the medicine prescribers.

How can they expect newer medicines to come to them that are cheaper than the previous? Unless, of course, raw material is cheaper, and manufacturing/approval cost is lower? In other words, it is one thing to want new drugs, it is quite another to expect them to be cost effective. Activists and academia have to take note of this.

Pharmaceutical companies can take justified pride in the fact that many research-oriented pharmaceuticals spend more on R and D than most other industry sectors:

Research-driven pharmaceutical companies invest about 20 % of their sales in R&D, which represents a higher percentage than any other industrial sector (incl. high-tech industries such as electronics, aerospace or automobiles) (EFPIA, 2005).

However, money so invested needs to be recovered, if possible by patient welfare, if necessary without. It is absolutely necessary that recovery be ensured. Like the loan financing concerns run as much on how much they can finance as on how much is the recovery, you can trust the pharmaceuticals to go all out to recover their monumental investments. Being greater pals with prescribers and passing on the cost to the consumer are inevitable.

The next point is equally noteworthy here. We must know the difficulty of the pharmaceuticals to understand how they need to balance finance with patient welfare. Out of 5000-10000 products studied, only one reaches the pharmacy shelf, and that too after 12-13 years, at a cost of approximately euro 895 million per product:

...it takes an average of 12 to 13 years to bring a new medicine from the laboratory to the pharmacy shelf... (And) on average, only one out of 5,000 to 10,000 promising substances will survive extensive testing in the R&D phase to become approved as a quality, safe and efficient marketable product. (Also) several studies put the cost of researching and developing a new chemical entity (NCE) at euro 895 million (EFPIA, 2005; 'And', 'Also' added in parenthesis).

Hence, while costs are soaring, and pressures to reduce prices is on, individual companies find it difficult to survive, and are undergoing mergers and acquisitions so that overheads can reduce and profitability can be maximized:

Soaring R&D costs - combined with downward pressure on prices - are making it harder and harder for many pharmaceutical companies to recoup their R&D expenditure before patents expire. Individual companies are therefore becoming highly vulnerable and are striving to consolidate their positions and to achieve critical mass, through an ongoing process of mergers and acquisitions (EFPIA, 2005).

The greater pressures of soaring research and infrastructure costs, and added physician hospitality of various types, together with maintaining the great profitability of the pharmaceutical industry (one of the best amongst commercial enterprises today), and added litigation costs which are increasing and will increase in the future- all these point to a major cost escalation in the biomedical field, for which the already financially compromised patient will pay higher and higher sums, whether as actual sums or as insurance premium. Hence we can expect greater corporatisation of medicine in the future, and medicine becoming a business is a distinct possibility, if it is not already. However, there is a silver lining to it too. This is a fertile ground for greater preventive medicine, as also for complementary and alternative medicine (CAM). While some may have reservations about the latter, none can about the former. It also becomes clear why there is a greater thrust towards CAM we witness all over.

It makes sense for the critics of the academia-industry connect, as well as its proponents, to study the mechanics and compulsions of industry very closely if they wish to devise measures to remedy the ills that plague the relationship today, some of which we shall look into below. But it is equally important industry also carry out remedial measures to correct the anomaly at its end to ensure the future profitability of its enterprise, and justification for its continued presence.

Ethical Concerns and the Pseudo-Educational Dollar

The profound ethical concerns that industry funded research has brought center-stage need a close look, especially as they impact patients, research subjects, public trust, marketability of products, and research and professional credibility. Here is what Boyd, Cho and Bero (2003) have to say:

Clinical research involving human subjects and potentially marketable products carries with it unique ethical considerations. Human research subjects, the medical profession, and the public rely on clinical

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investigators to make decisions based solely on professional judgment, without regard for personal gain (Blumenthal, 1996; Relman, 1989). However, growing evidence suggests that close financial ties between industry sponsors and clinical investigators may influence the quality and outcome of clinical studies (Bero and Rennie, 1996; Bodenheimer, 2000). Furthermore, these relationships may undermine the public's trust of clinical research (Weiss and Nelson, 2000; Angell, 2000.) (Boyd, Cho and Bero, 2003.

Parenthesis added.)

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Moreover, there is evidence that drug-marketing techniques affect doctors' prescribing practices. This has ethical implications for doctors, as it affects the trust required in the doctor-patient relationship. Doctors need to recognise they are affected by drug marketing, and take steps to maintain their independence from the pharmaceutical industry (Breen, 2004). Some of the available evidence about doctors' prescribing habits points out that 80%–95% of doctors see industry representatives regularly (Moynihan, 2003). However that would not be a problem by itself without the other finding: more frequent contact is linked with unnecessary prescribing and increased use of new drugs (Wazana, 2000; Watkins, Moore and Harvey *et al*, 2003).

What is the evidence of the influence of attending sponsored conferences? Well, attendance at sponsored conferences is associated with increased prescribing of the sponsor's product. This increase can be seen for the next 6 months (Watkins, Moore and Harvey *et al*, 2003). And how much does the drug industry spend per physician? Hold your breath: it is estimated that industry spends about \$21 000 per year per practicing doctor on drug promotion (Jureidini and Mansfield, 2001) (See also Breen, 2004).

\$ 21,000 per year per practising physician? What are doctors? Some old time feudal lords who need to wallow in luxury?

Of course there are suggestions to reduce the impact of the industry dollar—by increasing government spending. In a letter as response to the Breen (2004) paper above, Woodruff (2004a), for example, suggests:

...I suggest that the pharmaceutical pseudo-educational dollar be bypassed by a major expansion in government funding (Woodruff, 2004b). The provision of

regularly updated, easily accessible treatment guidelines integrated into prescribing software (which most general practitioners use daily) would go a long way to decreasing our reliance on the drug dollar for information on appropriate treatment. This requires government investment and professional college cooperation, but would lead to recurrent savings to the Pharmaceutical Benefits Scheme and better treatment (Woodruff, 2004a).

Note the author considers the pharmaceutical financial support to be a pseudo-educational dollar. The suggestion of regularly updated easily accessible treatment guidelines is noteworthy, but who makes the treatment guidelines is very important. There is emerging proof of the influence of funding even there. We shall deal with this in the next monograph. (Nov. 2005-Feb2006).

He further points out:

Currently, the federal government spends \$21 million on drug information to doctors (National Prescribing Service Limited, 2002–03), while the drug industry spends \$1 billion on marketing (Spending on drug promotion, July 2004). To partially redress this imbalance would, however, require both political will and pressure from the profession (Woodruff, 2004a; parenthesis added).

The political will can be easily turned around, if it is not already. The professional will is already firmly turned towards the industry dollar. How practical Woodruff's approach will turn out to be only time can tell. But trust the well entrenched to resist it to the utmost, and do so in very persuasive ways. Well, if this sounds cynical, so be it. How can one hide the obvious?

But we would be most pleased to be proved wrong by events that follow.

Negative Implications of this Trend

Many negative implications of this trend (the association between academic institutions and private companies) have been recognized. Concern of priority shift from public to corporate welfare and violation of the hallowed doctor-patient relationship is mounting:

Articles in the popular and scientific press have discussed concerns about patient safety in clinical trials, issues related to privacy, conflicts of interest on the part of researchers and their institutions, a shift of priorities in academic research from the public good to

Many negative implications of this trend (the association between academic institutions and private companies) have been recognized. Concern of priority shift from public to corporate welfare and violation of the hallowed doctor-patient relationship is mounting.

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private commercial gain, and the potential for disruption of the historical compact between physicians and their patients (Kelch, 2002)(Moses, Braunwald, Martin and Their, 2002).

Concerns about patient safety, privacy, conflict of interest, and a shift of priorities in academic institutions are likely to be voiced all right, but essentially it is a losing battle for the institutions and associations as things stand today. This is because there is a fundamental dichotomy between the institutions/associations' professed principals and the pharmaceutical industry's goals and

objectives. While the former profess research for the sake of patient welfare and make their existence dependent on it, the latter researches for the sake of profits, patient welfare being only an intermediate goal. How can the intermediate goal of industry serve the purpose of the final goal of academia is the basic struggle for conscientious research institutions/associations. And how best the goal of maximizing profits can be best served, albeit suitably camouflaged as patient welfare throughout, is the concern of the pharmaceutical industry.

In this cat and mouse game, institutions/ associations may feel they are smart enough to utilize pharmaceutical industry for patient welfare, but often the case is otherwise. The pharmaceutical industry utilizes patients and willing doctors/researchers as accomplices, often without their awareness but sometimes as willing recruits, in their goal to maximize profits. And they are smart enough to do so with a massive ego-massage of the doctors/researchers concerned. And often the doctors/researchers concerned do not even realize it. Or even if they do, may continue to acquiesce in it.

If that is a tragedy according to you, well, it is one of epic proportions, and to which we see little hope of redress as things are proceeding at present.

Rationalizations abound

The response of investigators to the influence of industry is pretty complex, and rationalizations abound. Investigators find many compelling reasons to continue accepting industry sponsorship. One of the most compelling is the belief that although the system can be abused, I am not one to do so, or one whom industry can manipulate.

According to one Stanford University researcher (Boyd, Cho and Bero, 2003), for example:

It's a delicate thing. You have to decide for yourself. For example, I'm getting money from [a large pharmaceutical company] for a study I'm working on. They also have me on speakers' bureau. I feel comfortable with this arrangement as long as the slides I use are my own, and I'm speaking about my own research and opinions. I don't think the information I present has anything to do with what [the company] wants me to say. This system can be, and is, abused. Some people do give canned talks prepared by the companies that are paying them.

"I don't think the information I present has anything to do with what [the company] wants me to say". Great. Will you be able to speak publicly about your negative findings of the sponsored research you are presently working on? Will you be able to say the drug is hopeless? Would you speak about the ill effects, or no effects, of the drugs your sponsor company is busy promoting all around? Or in the slides that you prepare? Those are the questions that need honest answers. It is not just a matter of not giving canned talks. It is a matter of loyalty to sponsors for future prospects.

Another rationalization is equally smart, and convenient too. For example, another Stanford University investigator (Boyd, Cho and Bero, 2003) stated:

Obviously there is the potential for bad science, but I think that exists regardless of whether or not industry is involved. The issue fundamentally boils down to the sense of responsibility of individual investigators.

Bad science existing regardless of industry is not the same as bad science existing because of industry involvement. The question is: is it there or not? And to leave it to individual investigators is fine. But it should not become a ploy to do nothing, lay down no parameters, offer no guidelines, and have no regulatory or redressal mechanisms in place.

Although the effectiveness of regulatory mechanisms in ensuring the ethical conduct of clinical research is limited (Miller, Rosenstein and DeRenzo, 1998), which means regulatory mechanisms may work poorly, if at all, it does not mean they are useless. All it means is they are being unheeded, or worked around. The situation can potentially change with greater awareness in all concerned.

Bad science existing regardless of industry is not the same as bad science existing because of industry involvement. The question is: is it there or not? And to leave it to individual investigators is fine. But it should not become a ploy to do nothing, lay down no parameters, offer no guidelines, and have no regulatory or redressal mechanisms in place.

The academic biomedical and the industrial biomedical do not have similar needs. Their needs coincide only in so far as they both may need research fellows to work and senior investigators to guide. However, how the services of these research fellows and senior investigators have to be utilized is very different in both.

Whether others work or not, one regulatory mechanism works for sure. The regulatory mechanism of the research career upswing - industry profit combine, and will continue to guide present and future efforts.

If you differ, we admire your feelings, but let us have proof that it is not so.

Needs of Academia and Industry

Let us now take up the related issue of the needs of academia and industry.

Some researchers feel:

Academic biomedical research and industrial biomedical research have similar needs. Both require ready access to specialized talent, from senior investigators through postdoctoral fellows (Moses, Braunwald, Martin and Their, 2002).

This is one example of the naïve thinking so prevalent in academia, for which an antidote is urgently needed but will not be accepted as easily. The academic biomedical and the industrial biomedical do not have similar needs. Their needs coincide only in so far as they both may need research fellows to work and senior investigators to guide. However, how the services of these research fellows and senior investigators have to be utilized is very different in both. While the academic biomedical research professes to do so for patient welfare, the industrial one has to consider that only an intermediate goal in the ultimate one to maximize profits. This difference must be clearly understood and articulated, and academia has to seriously debate its ethical-pragmatic implications.

An important related issue is what researchers, both in academia and industry, seek, and how it is at variance with what industry and its needs can provide. Moses, Braunwald, Martin and Their (2002) believe:

Researchers from both environments seek interactive, bidirectional relationships that involve the exchange of ideas, materials, and expertise, rather than relationships according to the terms dictated by corporate and university technology-transfer agreements, which emphasize confidentiality, ownership, and valuation of intellectual property.

Indeed, and to good reason, and purpose, for they can survive, and prosper, only when they exchange ideas, materials and expertise, for those are their lifelines. And they are likely to see agreements as hindrances and irksome roadblocks in so doing. But their worth is immediately realized

when there are conflicts that need to be legally resolved, as happened in the recent Nancy Olivieri case (Downie, Thompson and Baird, 2001; Baylis, 2004; Schafer, 2004; Faunce, Bolsin and Chan, 2004) which we shall have occasion to discuss in a subsequent monograph (p53-55).

While, “Both groups of scientists often view the university’s technology-transfer office and the company’s legal staff as barriers to, rather than facilitators of, progress” (Moses, Braunwald, Martin and Their 2002), it maybe better for both sides to consider these as necessary processes, for the medical institution side to be careful about what it is going in for, and what are its rights if the whole project does not work out. As they say, a carefully worded and well-understood Dissolution Clause in any agreement is a necessary evil to prevent so much of potential bad blood entering in later, as did occur in the Olivieri case, for example (read a detailed exposition of the Olivieri case in Schafer, 2004). The need for full access to data, right to publish contrary findings, and ironclad protection for the researcher if the research contract between academia and industry goes bust is imperative. Moreover, institution and its researcher may have conflicting interests too, and that can be equally embarrassing to handle. As Drazen (2002) points out:

Research performed under a contract that gives the investigators full access to the data and the right to publish their findings, without interference from the sponsor, lets the peer-review system and the scientific process of replication eventually get to the truth. Had Olivieri’s research been performed under such a contract, it is likely that the entire crisis could have been averted. Particular problems can arise when the contracting party — the institution — is both in a position to profit from the sale of the drug or device under study and the employer of the scientist doing the work. In such a case, there is even greater need for ironclad contractual protection for the investigator.

Growing Scale of Research

Another related and equally important issue is the growing scale of research, the sophisticated techniques and complex equipment needed for modern research, the high costs involved, and therefore the greater need for industry funding and collaboration:

The growing scale of research is another important factor that favors collaboration. Basic research in normal biology and disease mechanisms is growing increasingly dependent on sophisticated techniques and complex equipment with high initial costs and high maintenance costs. These expenses are a substantial obstacle for many universities and make industry support or collaboration

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A realization of the differences in goals and motivations of academia and industry is an important step in increasing the ethical connectedness and reducing the ulteriority, while accepting that the connection has indeed been quite fruitful in some ways.

desirable (Moses, Braunwald, Martin and Their, 2002).

But academia has something important to offer as well in the form of patients and controls, and the other backup material on which research can work:

On the other hand, the critical task of genotype–phenotype correlation, on which pharmacogenomics, disease-predisposition testing, and early interventions depend,

requires access to well-characterized clinical populations and biologic material from normal and affected persons, as well as depth in bioinformatics and computational biology — resources that are the strength of the academic medical center (Moses, Braunwald, Martin and Their, 2002).

So there is so much to complement in both these institutions that has the potential both for research maximization and exploitation:

These complementary forces enhance the interdependence of industry and academic laboratories but also add to difficulties with regard to disclosure, ownership of intellectual property, and the interchange of researchers, information, and biologic materials (Moses, Braunwald, Martin and Their, 2002).

A very great potential conflict of interest lies in the fact that academia needs the sophisticated instruments that only big funding can provide, while at the same time resists the attempts of the fund provider to set the agenda of research, protocol, design, publication, the works. The fund provider, similarly, has a conflict of interest insofar as he provides the funds ostensibly for research and patient welfare, but all the time seeks to maximize his commercial interests. And when there is a conflict between the two, he must firmly cater to the latter, if possible with academia's cooperation, if necessary with the courts'.

No clear-cut or worthwhile resolution of this situation appears in sight as yet. Which, in essence, means the academia-industry relationship is wide open to ulterior motivations as much as to ethical connectedness. However, a realization of the differences in goals and motivations of academia and industry is an important step in increasing the ethical connectedness and reducing the ulteriority, while accepting that the connection has indeed been quite fruitful in some ways:

All of this is not to gainsay the importance of the spectacular advances in therapy and diagnosis made possible by new drugs and devices. Nor is it to deny the value of cooperation between academia and industry. But that cooperation should

be at arm's length, with both sides maintaining their own standards and ethical norms. The incentives of the marketplace should not become woven into the fabric of academic medicine. We need to remember that for-profit businesses are pledged to increase the value of their investors' stock. That is a very different goal from the mission of medical schools (Angell, 2000).

Is academia ready to cooperate but at arm's length? Is it ready to forego incentives of the market place? Is it ready to maintain its own standards and ethical norms? Is it ready to understand that the mission of medical schools is very different from the values of for-profit businesses?

Let academia make up its mind. It talks of getting 'informed consent' from patients. Let it make a 'informed choice' here and then give an 'informed consent' if found appropriate. Or walk out of the procedure.

Conflict in Expectations, Competing Interests and Priorities

Conflicts arise at many steps and levels of functioning, and they are related to the expectations, competing interests, and conflicting priorities of the different entities involved, whether they are the academic medical centers, the funding agencies, the patients and their families, or the investors and venture capitalists. Let us take up some of them here.

1. The Public

The public expects access to new treatments. Its appetite for innovation has been bolstered by the constant attention given by the press to new treatments and by the implicit promise from researchers of continuing advances. Direct-to-consumer advertising of drugs has increased the public's awareness of new developments in medicine, especially with respect to the treatment of common conditions, with the secondary effect of raising expectations (and health care spending) still further (Moses, Braunwald, Martin and Their, 2002).

New treatments being continuously discussed in the media adds to the appetite, and expectations, of a novelty hungry public. And a whole mass of lip smacking industry and opportunistic academia may latch on to this want with glee. How best to articulate genuine aspirations and eschew ulterior motives is the prime intellectual task of concerned academia as much as of serious pharmaceutical players. For, even the latter, if they have to remain long term in

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the field, will have to lay down certain ethical parameters that sustain their growth without hampering patient welfare. If they do otherwise, they may survive for a while, but will continuously be the target of justified malpractice suits and negative publicity, along with greater checks and balances being put in by governmental authorities and demanded by patient rights advocates, and a consumer-welfare aware, if sensation seeking, media.

Hardly a situation that fuels growth.

2. The Patients

Patients demand privacy and control over information about themselves. Information about genetic predisposition is especially troublesome to patient groups and privacy advocates, not only because of the unknown implications for patients and their families, but also because of the fear that once the information proves to be commercially valuable, it will become more difficult to control. These issues led in part to the passage of such legislation as the Health Information Portability and Accountability Act of 1995 and weighed heavily as the act was subsequently modified (Kulynych and Korn, 2002) (Moses, Braunwald, Martin and Their, 2002).

Genetic predisposition information as collected in research protocols is a real dilemma. Whilst knowing it is essential to enhance patients' interest, the advocacy groups nurse an apprehension not knowing how the information maybe utilized. How much of it will be considered and how much suppressed, especially when a commercially viable drug is at hand which can dramatically alter company balance sheets? Legislation is a necessary but often poor remedy. A clear protocol to reveal details of whether genetic predisposition impacts a certain drug is essential as a declaration in all drug research publications, just as conflict of interest at present is.

Related also is the integration of roles that a researcher must carry out to minimize potential conflict between competing loyalties that may hamper optimal care of patients volunteering for research. The roles of clinician and scientist must be integrated to manage conscientiously the ethical complexity, ambiguity, and tensions between the potentially competing loyalties of science and care of volunteer patients (Miller, Rosenstein and DeRenzo, 1998).

A healthy skepticism of the scientists' findings by the clinician, and a healthy respect for the needs of the practicing physician in the scientist may go a long way to bridge the gap, and increase connectedness all around.

3. Companies, large and small

A thought provoking insight into the way the size of a company affects its objectives in relation to academia is offered here:

The objectives of companies in their relationships to academia often vary according to the size of the company. Large pharmaceutical companies see great value in access to academic talent, ideas, and research tools and de-emphasize the importance of discrete inventions and patentable discoveries. In contrast, smaller companies, especially those that develop devices and diagnostic techniques, see greater value in obtaining late-stage technology (i.e., products that are near clinical trial) that are closer to market. These companies derive considerable value from their association with reputable institutions and investigators, which validates their efforts to raise venture capital and the potential value of the company and its product (Moses, Braunwald, Martin and Their, 2002).

This is an interesting observation about the differences in ways of functioning of large and small pharmaceutical companies. That the larger ones give greater value to continued access to academic talent, ideas, and research tools means they believe in long-term associations that sustain (probably ethically) over a longer period of time. That they de-emphasize the importance of discrete inventions and patentable discoveries means they may seek but are not obsessed with short term gains, which is but appropriate for long term players if they wish to sustain themselves over time. However, the smaller companies seek late-stage technology, and with ample justification. They are small players with limited capital, but an obsession to grow big and fast. That is possible only by palpable profits pouring in quickly, which late-stage technology provides very well indeed. Such companies woo venture capital armed with this technology, and understandably so. That they also woo researchers who have made a name for themselves to be part of their set-up in advisory/consultative capacity is equally understandable, for they have to continuously prove their credentials to others, as much as to themselves.

In this process, the Davids may make a killing at the expense of Goliaths of the pharmaceutical industry. It makes greater sense, therefore, for genuine researchers to associate with large long-term players who have a track record of genuine hard-core discoveries, even if the process is slow (maybe), and the funding less (may not be). Of course, if the researcher wants to grow fast, as much in wealth as in reach, he should know whom to approach, though be ready to be manipulated by

However, the smaller companies seek late-stage technology, and with ample justification. They are small players with limited capital, but an obsession to grow big and fast. That is possible only by palpable profits pouring in quickly, which late-stage technology provides very well indeed.

The element of control venture capitalists exert over the pharmaceutical industry is an under researched area for obvious reasons. But it needs further probing, for that will lay bare the pulls and pressures under which industry works.

market forces and shady operators in such companies who will maximize profits by side tracking him when it suits them, no explanations given. This is of course no guarantee that the large operators would not do likewise, but the risk is lesser, as is the frequency of such happenings. For they are used to a certain approach, and have a certain strong credibility to protect, and are hardly likely to indulge in petty deeds as a norm unless

someone treads too sharply on their toes. The smaller ones would have no qualms of taking such action. This, of course, does not mean exceptions do not exist in both categories.

4. Venture capital

The venture capitalists, especially in smaller companies, are the people who are in it mainly for profits. The pharmaceutical company, howsoever small, can be expected to have some qualms. Since they have to continuously interact with the medical profession, practicing doctors researchers or academia, they have to maintain at least a semblance of accountability to patient welfare. The venture capitalists, on the other hand, need have no such qualms at all. They can lay down their terms and conditions, and enforce them pretty ruthlessly. Their greater presence in industry is a new challenge to academia, to which an appropriate response is needed:

Venture investors in these entities reinforce the importance of establishing the investigators' full commitment and making it public and visible (Moses, Braunwald, Martin and Their, 2002).

Indeed, for any nexus between investigators and investors should be exposed, and any blurring of boundaries firmly resisted. But the presence of venture capital can become a good ploy to increase profitability for the pharmaceutical companies that depend on them, citing the former's pressures to suit their own profit motives too. In this whole game, if patient welfare can be served, great. If not, well, sorry, but that's the name of the game. Such games playing can also occur, which researchers and academia need to be aware of.

The element of control venture capitalists exert over the pharmaceutical industry is an under researched area for obvious reasons. But it needs further probing, for that will lay bare the pulls and pressures under which industry works. If there used to be a 'investor's lobby' in real estate which controlled the builders and the market rates, there seems to be a parallel

phenomena in pharmaceuticals which controls the manufacturers and the areas of research too. Some more probing in this area would make many skeletons tumble out of industry cupboards.

That venture capitalists should insist on researchers making financial stakes in their funded concerns is but plausible, for that ensures for them the researchers' total commitment to maximizing profit, even at the cost of ethical or patient considerations if need be. Hence, the insistence that researchers declare their financial stakes in companies whose products they research, as they do other data to declare conflict of interest, is an eminently worthy idea to implement.

5. Stocks and Equity

Let us also look at the other manner commitment to profits is ensured by industry:

The most common vehicle used to assure such commitment is equity or stock options assigned to the investigator and, with increasing frequency, to the institution where the work is performed (Moses, Braunwald, Martin and Their, 2002).

That investigators and even institutions should consider equity/stock options an attractive investment, especially as they have what could be considered 'insider-information', and maybe offered such options free or at substantially discounted rates, makes for potentially dangerous portents. While all may be fine if the products are really worthy, the problem comes if they bomb, or are found to have serious side-effects, or involve multiple legal cases or public interest litigations (PILs). In which case the company bottom-lines can go hopelessly in the red, especially if they are small companies mainly dependent on venture capitalists. Here researchers may be forced to toe the PRO line of the company involved.

In other words, it makes sense for ethically minded researchers and institutions not to fall in the trap of such investments, howsoever attractive they appear, and get rid of such stocks as soon as possible if they have them. If at all they want, it makes more sense to own stocks of larger well established concerns, for the stock upheavals being less, the pressure of the market-place, and of venture sharks, is likely to be lower too. They may also seriously consider whether owning stocks as a part of, or consequent to, research funding should be forsaken for long-term

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While active participation by the researcher in the commercialization process may be greatly desired by industry, ostensibly in the name of creating value, academia must realize it is a bait it might find hard to swallow in the long run.

peace of mind. In any case, there is no social benefit attached to researchers owning stocks:

But it is highly doubtful whether many of the other financial arrangements facilitate technology transfer or confer any other social benefit. For example, there is no conceivable social benefit in researchers' having equity interest in companies whose products they are studying (Angell, 2000).

As far as stocks of young companies go:

Stock or options in young companies are relatively affordable, since they become valuable only if the company and product become successful. Active participation by the investigator in the commercialization process is viewed as essential in creating value. This engenders a powerful but controversial incentive for the investigator and has proved to be one of the most difficult issues for academic centers to manage (Moses, Braunwald, Martin and Their, 2002).

While active participation by the researcher in the commercialization process may be greatly desired by industry, ostensibly in the name of creating value, academia must realize it is a bait it might find hard to swallow in the long run. It makes more sense for the researcher and institution to forego such temptations and/or walk out of such investments as soon as possible:

Institutions and institutional decision makers should fully disclose industry-related financial interests and relationships. Without legitimate justification for such interests, individuals should divest themselves from these interests (Johns, Barnes and Florencio, 2003).

However, considering the realities of the market place this may be easier said than done, especially for those investigators who depend on small/medium enterprises which themselves depend on venture capitalists, or heavily borrowed capital.

The intricacies of how economics plays a strong role in the whole process of research investigation is highly complex, and need detailed study on their own. Although one often feels one is better off being blissfully unaware of its intricacies. Which is probably the reason it is under probed, and may so remain. Both manifestations of our denial, which may prove costly in the long run.

A survey of the scenario yields certain mixed portents. While mainstream medicine and research are booming, as is connected industry, concerns about professional commitment to patient welfare are growing too. Increasing corporate influence is challenging certain long held and

fundamental values of patient care, which will have far reaching implications for biomedical care and the future progress of mainstream medicine. Events in the next two-three decades will decide the fate of modern medicine and connected industry.

The tug of war between commercial interests and ethical concerns promises to be a roller coaster one. Hold on to your seats, gentlemen.*

Increasing corporate influence is challenging certain long held and fundamental values of patient care, which will have far reaching implications for biomedical care and the future progress of mainstream medicine.

Concluding Remarks

1. Biomedical research, and its forward march, is becoming increasingly dependent on industry-academia proximity, both commercial and geographic. A realization of the commercial value of academic biomedical research coupled with its rapid and efficient utilization by industry is the major propelling force here.
2. Strengthening relationship between academic institutions and private companies has given rise to its fair share of problems.
3. Concerns about patient safety, privacy, conflict of interest, and shift of priorities in academic institutions are issues that need urgent redress.
4. Connected to the growing clout of industry in institutions is concern about the commercialization of research and resolving the 'patient or product' loyalty.
5. Academia needs sophisticated instruments/appliances that only big funding can provide, while at the same time resists the attempts of the fund provider to set the agenda of research, protocol, publication, the works.
6. Conflicts arise at many steps and levels of functioning, and are related to the expectations, competing interests, and conflicting priorities of the different entities involved, whether the academic medical centers, the funding agency, the patients and their families, or the investors or venture capitalists.
7. The profound ethical concerns that industry funded research has brought center-stage need a close look, especially as it impacts patients, research subjects, public trust, marketability of products, and research and professional credibility.

*Provided of course your seats remain, and you can still hold on to the rope.

8. How can the intermediate goal of industry (patient welfare) serve the purpose of the final goal of academia is the basic struggle for conscientious research institutions/associations. And how the goal of maximizing profits can be best served, albeit suitably camouflaged as patient welfare throughout, is the concern of the pharmaceutical industry
9. It makes greater sense for genuine researchers to associate with large long-term industry players who have a track record of genuine hard-core discoveries, even if the process is slow (maybe), and the funding less (may not be).
10. The element of control venture capitalists exert over the pharmaceutical industry is an under researched area for obvious reasons. But it needs further probing,
11. It makes sense for ethically minded researchers and institutions not to fall in the trap of stock and equity investments in industry, howsoever attractive they appear, and get rid of them as soon as possible if they have them.
12. The intricacies of how economics plays a strong role in the whole process of research investigation is highly complex, and need detailed study on their own.
13. While mainstream medicine and research are booming, as is connected industry, concerns about professional commitment to patient welfare are growing too. Increasing corporate influence is challenging certain long held and fundamental values of patient care, which will have far reaching implications for biomedical care and the future progress of mainstream medicine.

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Questions that this monograph raises

1. Is the connection between academia and industry desirable?
2. Do we need the financial sponsorship to medical research on such a large scale?
3. Can medical conferences and associations work without industry sponsorship?
4. Is conflict of interest invariable in every academia-industry relationship? Can it be resolved?
5. Have you faced ethical problems in industry relationships, and how did you tackle it?
6. Do large and small pharmaceuticals really differ in their approach to research?
7. Can patient welfare be the final goal even of industry?
8. Does patient welfare guide medical research any longer, or has research become a handmaiden of commercial interests?
9. Is doing away with industry sponsorship a practical proposition?
10. Is industry sponsorship really the villain, or are smart operators in academia just painting it as such to carry on with their own questionable activities?
11. Is the academia-industry ethical problem unique, or only a manifestation of a wider malaise that afflicts society?
12. Where do we go from here?

Readers Respond

*(You can read here some responses to the last issue of Mens Sana Monographs: Resolution of the Polarisation of Ideologies and Approaches in Psychiatry, Mens Sana Monographs, Mens Sana Research Foundation, 2004-2005, Vol II, No 4-5, Nov 2004- Feb 2005, ISSN 0973-1229.)**

1. I read with interest and appreciation your Monograph *Resolution of the Polarisation of Ideologies and Approaches in Psychiatry*. When I was a medical student in CMC, Vellore, Dr. Stafford Clark from UK visited us and gave a public lecture. The main message was that all diseases are psychosomatic, in the sense that emotions are involved in all diseases, either in the causation or in the perpetuation. This is all the more true in Psychiatry. The so-called polarisation into biological and dynamic psychiatry is artificial and misleading. In all psychiatric conditions, both genetic and environmental factors are involved. The only difference is in the degree of involvement. In psychoses, genetic factors are more important than environmental factors and in neurotic and personality disorders, environmental factors are more important. We have to advocate integration and not polarisation. There should be only one school of psychiatry—biopsychosocial model as proposed by Engel.

Dr. Abraham Verghese, Retd. Prof. of Psychiatry CMC, Vellore

2. The Monograph *Resolution of the Polarisation of Ideologies and Approaches in Psychiatry* is thought provoking. It has come out very well.

Dr. J.K.Trivedi, Immediate Past President, Indian Psychiatric Society

* This monograph has been listed for review by JAMA, May 18, 2005, 293, p2417 -2418. You may review it for the journal if you desire.

Psychiatry, Science, Religion and Health, our Annual 2004 issue, is also listed in JAMA, 20th July, 2005; 294,p377-378.