Ethical issues in health care sector in India

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Abstract The issue of ethics and economic efficiency in the provisioning and delivery of services becomes complex in the Indian context where health indicators are poor. In an attempt to explore this issue, this round table article first provides an overview of the field of ethics in health care, the health care sector in India and its facilities, the key institutional actors and finally, the key ethical issues concerning the different players in health care—the physician, the bio-pharmaceutical industry, and the chemist. In its second part, the article reports on a discussion of the issues with a panel of experts across geographic and organizational settings.

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Academic perspective

Health care institutions across the world are facing challenges in the delivery and provisioning of services with financial solvency. Patient care now competes with the financial solvency of the health care institutions (Silverman, 2000), and the issue of ethics has become more relevant than at any other point in time. Health care services have a special moral quality. The purposes of health care services include saving lives, preventing or relieving suffering, preventing and curing disease and disability, and ameliorating the consequences of disease when it cannot be prevented or cured. Few people can be morally comfortable with the idea that some people should be denied access to health care that might relieve their suffering or save their lives because they cannot pay for it (Enthoven, 1993). In the Indian context, where health indicators of the country are poor, the discourse on ethics assumes greater complexity and requires a more nuanced understanding and appreciation of the contextual elements. This note attempts to provide a brief overview of the field of ethics in health care, the status of the health care sector in India, the key institutional actors and finally, the key ethical issues arising out of the interactions across the various actors.

Ethics and health care

The field of medical ethics has long existed, arising from the Hippocrates oath, and tenets of the early religious healing traditions of the West. Several Asian traditions have also had ethical tenets governing the physician—patient relationship (Tsai, 1999; Desai, 1988). In the field of contemporary medical ethics, the doctors in the USA were the first to develop a modern code of ethics. At the first meeting of the American Medical Association (AMA) in 1846,
a committee was appointed to report on a code of ethics for the organisation. Modern medical codes of ethics are based on the works of Thomas Percival, a British Physician credited with giving much thought to the future of the profession. The International Code of the World Medical Association, an organisation representing physicians founded in 1947, ensures that physicians strive for the highest possible standards of ethical behaviour and care at all times (Backof & Martin, 1991).

In the 1970s, traditional medical ethics changed into an interdisciplinary field involving theologians, lawyers, philosophers, social scientists, and historians, as well as physicians and other health professionals (Veatch, 2006). The reason for this was the increasing impact of science and technology, the growth of specialisation in the field of medicine, public expectations from new medicines and surgical techniques, changes in the financing and delivery of health care, and the transformation of medical schools into large medical centres in the West. The field of medical ethics which focused on the moral responsibility of a physician to a patient was not adequate to address the ethical aspects emerging out of the changed context. With more stakeholders, such as medical devices companies, pharmaceutical companies, diagnostic clinics, insurance companies, clinical trial organisations, and other service providers entering the field, there was a need to expand the scope of the definition of ethics within the field of medicine. In recent years, the terms "bio-medical ethics", "bio-pharmaceutical ethics", and "health care ethics" are gaining importance. The term bio-medical ethics includes the issues related to reproductive biology, such as stem cell research and human cloning and the ethical dimensions arising out of these changes. The term bio-pharmaceutical ethics refers to the ethics associated with the discovery and development of the products. The term health care ethics is increasingly being used as an umbrella term to encompass ethical aspects previously included in medical-, bio-medical-, bio-pharmaceutical- and also organisational- and business ethics of different stakeholders involved in the provisioning and delivery of health care services. It is this broad definition of health care ethics that is being used in this note and the round table discussion that follows the note.

**Indian health care sector**

The health indicators of India have consistently lagged behind the economic development that has been witnessed over the last decade and the need for increased investment in health care has been acknowledged. The public expenditure on health in India remained at about 1.1% of GDP in 2010 (Ministry of Health and Family Welfare, GOI). Public health care delivery is done through a network of over 146,036 health sub-centres, 23,458 Primary Health Centres (PHCs) and 4276 Community Health Centres (CHCs). There is a 150-bed civil hospital at the district level to provide tertiary care. Only 23.5% of urban population and 30.6% of the rural people choose government facilities, thus reflecting the widespread lack of confidence in the public health care system (Central Bureau of Health Intelligence, 2010).

Studies have acknowledged that India ranks among the top 20 countries in the world in its private health care funding and that 82% of the total medical expense in India is paid for through personal funds (Sengupta & Nandy, 2005). According to the Central Bureau of Health Intelligence, majority of Indians trust and visit private health care despite the fact that cost of treatment in private treatment is significantly higher than public facilities (Table 1).

Private sector health care is highly fragmented with over 90% of private health care being serviced by the unorganised sector. Eighty percent of the private hospitals are small clinics and nursing homes (less than 30 beds). Six to seven percent are 100–200 bed size hospitals and only 2–3% of hospitals are 200- plus bed (Table 2). Most of the large hospitals are located in the urban areas.

The sector however has attracted considerable private investments and it appears that the participation of the private sector in this field is likely to continue in the near future. The conflict between the financial solvency of the private sector players to the need for affordable quality health care services in ways that enhance the health and well-being of citizens is an immediate and visible area of ethical conflict in the sector.

**Disease burden and adequacy of facilities**

In the course of development, countries undergo an "epidemiologic transition". Initially the developing nations have high morbidity and mortality due to communicable diseases and maternal and child mortality. As economic development occurs, these morbidities decline significantly and there is an upsurge of diseases of the affluent class, that is, non-communicable diseases, injuries and geriatric problems. India, however, faces a dual burden of high incidence of infectious diseases (Tables 3 and 4) and a rising epidemic of non-communicable diseases. The trend of dual burden is consistent across urban and rural areas with a slightly higher proportion of non-communicable diseases in urban areas (Table 5). With the changing trends in the communicable diseases, changing demographics, increasing urbanisation, and increased lifespan, the burden of disease is likely to increase further, putting a burden on an already insufficient health care system.

Given the cost of treatment, disease burden, and the poor public health care facilities, the moral and ethical discussion on the "right to live" assumes a greater significance in India. In the next section, we introduce the typical experiences of an imaginary patient in the health care system in India.

**An imaginary patient**

This section outlines the trajectory for an imaginary patient (Patient X) traversing through the value chain in Indian health care. Patient X might be a poor farmer, an entrepreneur, or

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Average cost (in rupees) of a typical illness episode in public and private sector.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Public facilities</td>
</tr>
<tr>
<td>Cost of an out-patient episode</td>
<td>242</td>
</tr>
<tr>
<td>Cost of an in-patient episode</td>
<td>859</td>
</tr>
</tbody>
</table>

Source: Selvaraj & Karan, 2009
a settled professional. Patient X visits a general physician, who advises diagnostic tests, and cautionary medicines and could also refer X to a specialist. Patient X has bills to pay and the following options of payment: if Patient X has been treated at a public hospital she may have the option of not paying any of the bills; Patient X could approach her insurance provider if she is employed in a big company and has employer-provided insurance; Patient X could approach her insurance provider from the state if she comes from below-the-poverty-line and has state provided insurance. Despite the options, it is an arduous journey, and one hopes, without serious implications.

The above anecdote is educative of how as a patient or a consumer, one is dependant on so many stakeholders across the value chain in the Indian health care industry. There are the doctors – the generalists and the specialists, the medicine-makers, local firms and multinational corporations (MNCs), and the diagnostic device producers – domestic and multinational – supplying their equipment to the hospitals who can afford them. Finally there is the concerned insurance provider to turn to for settling the bills, provided one is among the privileged few in society to have insurance support.

A brief overview of the key stakeholders in the value chain is provided in Fig. 1. It must be noted that several private and public actors are present in different parts of the value chain. Therefore, the inter-relationships across the actors are complex and raise several issues pertaining to conflicts of interest.

### Table 2  
Classification of hospitals in India.

<table>
<thead>
<tr>
<th>Types of hospitals in India</th>
<th>Government</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care centres, district hospitals and general hospitals</td>
<td>Nursing homes</td>
<td>Mid tier</td>
</tr>
<tr>
<td>Variable: based on types</td>
<td>Primarily nursing homes and recovery rooms with adequate infrastructure</td>
<td>Corporate hospitals with in house staff and consulting physicians</td>
</tr>
<tr>
<td>Variable: based on types</td>
<td>&lt;30 beds</td>
<td>30-100 beds</td>
</tr>
</tbody>
</table>


Health care is a key aspect of any developing nation and the need for quality, accessible and affordable health care is a necessity. A particularly central role in health care delivery in modern societies is that of the physician. Francis Moore the respected American physician noted, that “the surgical investigator must be a bridge tender, channelling knowledge from biological science to the patient’s bedside and back again”, adding also that the surgical investigator was open to the charge of not being a very good scientist from one end of the bridge and of not spending enough time in the operating room, from the other (Murray & Moore, 2002). In contexts like India, the role of the physician is more nuanced and tricky, especially since physicians have been historically revered in the society and their decision-making powers are further enhanced. But such a role also brings along with it responsibility. It is arguable if the two key nodal organisations of physicians in the country, the Medical Council of India (MCI) and the Indian Medical Association (IMA) have been able to live up to that responsibility in recent times.

### Institutional structures and ethics

The IMA, organised in 1928, was the result of efforts in Calcutta to form an association of doctors in pre-independence India. It currently has over 178,000 members with about 1700 local branches. With antecedents that can be traced to the Bengal Medical Association, IMA has historically seen respected doctors as its president. A key name in this regard is Dr. B C Roy in 1929–1930 who later on became the Chief Minister of West Bengal. (However, in recent times, the reputation of the presiding doctors has been in question.) It is also important to note that the IMA has played a global role in setting the medical standards and norms across the world.

### Table 3  
Pattern of communicable diseases.

<table>
<thead>
<tr>
<th>Trends of communicable diseases in India</th>
<th>Diseases showing increasing trends</th>
<th>Diseases showing decreasing trends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dengue, chikungunya</td>
<td>Poliomyelitis</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>HIV-TB co-infection</td>
<td>Neonatal tetanus</td>
<td>Measles</td>
</tr>
<tr>
<td>Cholera O139</td>
<td></td>
<td>HIV/AIDS</td>
</tr>
<tr>
<td>Japanese encephalitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leptospirosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novel H1N1 infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eradicated: smallpox, guinea worm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eliminated: yaws, leprosy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


### Table 4  
Burden of communicable diseases.

<table>
<thead>
<tr>
<th>Communicable diseases</th>
<th>Magnitude of the burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB</td>
<td>283 cases per lakh population in 2007</td>
</tr>
<tr>
<td>HIV</td>
<td>2.27 million HIV-positive persons in 2008</td>
</tr>
<tr>
<td>Malaria</td>
<td>2 million deaths per year</td>
</tr>
<tr>
<td>Leprosy</td>
<td>130,000 affected people</td>
</tr>
</tbody>
</table>

too; some of its members were earlier members of the British Medical Association and IMA members were also influential in the setting up of the World Medical Association in 1962. At around the time of IMA’s formation, the Medical Council of India (MCI) was established in 1934 under the Indian Medical Council Act, 1933. The Council was later reconstituted under the Indian Medical Council Act, 1956 that replaced the earlier Act. The main functions of the MCI are the following: establishment and maintenance of uniform standards for undergraduate medical education; regulation of postgraduate medical education in medical colleges accredited by it (The National Board of Examinations is another statutory body for postgraduate medical education in India); recognition of medical qualifications granted by medical institutions in India; recognition of foreign medical qualifications in India; accreditation of medical colleges; registration of doctors with recognised medical qualifications; and maintaining a directory of all registered doctors (called the Indian Medical Register). Finally, registration of doctors and their qualifications is usually done by state medical councils.

On 25th June 2012, the nation witnessed an unprecedented one-day strike by the IMA which contested the proposed promulgation of the Clinical Establishments Act and the formation of the National Council for Human Resources in Health (NCHRHH) by the Government of India. Physicians across the country affiliated to IMA could foresee through these developments, a diminishing role of IMA in Indian society. This event followed Bollywood actor Aamir Khan’s show on national television channels highlighting the controversial roles of doctors around the country. These events were not in isolation — coming after the arrest of the MCI president Dr. Ketan Desai by the Central Bureau of Investigation for allegedly accepting a bribe to permit Patiala-based Gyan Sagar Medical College to recruit a fresh batch of students without having adequate infrastructure. Subsequent to this, MCI was superseded by the President of India and its functions entrusted to a Board of Governors. The present Board of Governors was notified on 13 May 2011.

It is clear that while doctors have a bridging role to play as alluded to by Francis Moore — their position is particularly under the radar today in India. A recent article effectively points to this, highlighting the role of “doctors in entrepreneurial gowns”, and pointing to how various private-sector physicians are also holding a conflicting position with the IMA and are breeding industries such as in the “treatment of obesity” (Nagral, 2012).

At various points in this round table discussion, we come back to the key role of physicians and doctors in our lives. While we certainly try to outline the role of firm-level instruments and address issues for pharmaceutical firms, domestic and multinational, and further discuss issues about harmonisation of various regulatory bodies, physicians — being central to the act of health care delivery — have a key role to play in the context of ethical behaviour in health care markets. They form a key component of our discussion.

**Table 5** The causes of death.

<table>
<thead>
<tr>
<th>Causes of death</th>
<th>Overall</th>
<th>Rural areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable diseases, maternal,</td>
<td>38%</td>
<td>41%</td>
</tr>
<tr>
<td>peri-natal and nutritional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-communicable diseases</td>
<td>42%</td>
<td>40%</td>
</tr>
<tr>
<td>Injuries</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Ill-defined causes</td>
<td>10%</td>
<td>9%</td>
</tr>
</tbody>
</table>


**Figure 1** Health care value chain in India. Source: (Chandwani, Devare & Srinivasan, 2011)
Dr. Richard Manning begins the round table discussion by underlining the issue of ethics and efficiency as they relate to health care markets. This is a particularly salient guiding framework since it is important to note that what might be ethical might not necessarily be efficient and with the particular case of health care markets this problem might be aggravated. Andrew Shleifer (2004) discusses this trade-off, pointing out that: “When unethical behavior cuts costs, competition drives down prices and entrepreneurs’ incomes, and thereby reduces their willingness to pay for ethical conduct. However competition might be good for ethical behavior in the long run, because it promotes growth and raises incomes. Higher incomes raise the willingness to pay for ethical behavior, but may also change what people believe to be ethical for the better.” With regard to child labour, Shleifer points out that in many parts of the developing world, without good access to capital markets and educational opportunities, the alternative to child labour could well be malnutrition and disease.

Thus the overlying issue of ethics and efficiency is important and among other elements can be guided by two key firm-level instruments that Dr. Manning outlines. Both of these instruments could enhance or destroy social welfare depending on how they are used and relate to pricing and marketing methods used by pharmaceutical firms. In the context of India this is particularly pertinent with a large section of the population having inadequate access to medicines, more so patented ones sold by multinationals at prices far beyond their reach. Dr. Manning raises the possibility of an important policy lever of differential pricing and wonders whether it might have the potential to address this problem. Theoretically speaking, marketing and promotional activities might have an informational contribution about products such as medicines. Dr. Manning alludes to them, but in the context of India this is again salient since it might not be used by firms as a social good. The Indian Medical Association is currently considering this particular area in careful detail and contemplating regulations to be put in place for implementing checks on marketing and promotion activities of firms; it is but pertinent that Dr. Manning’s thoughts would ring a bell in that policy discussion.

The next speaker at the round table, Mr. Rijit Sengupta extends Dr. Manning’s thoughts. An overarching theme of Mr. Sengupta’s views is the role of non-market mechanisms in ensuring ethical behaviour within the context of Indian health care markets. He terms these as the twin roles of co-regulation and self-regulation, his thoughts falling broadly under three key aspects that economists have earlier pointed to in their efforts to raise the willingness to pay for ethical conduct: those of long run market pressures, moral suasion, and governmental regulation.

Carrying forward Mr. Sengupta’s thoughts, Mr. Deepak Sapra from Dr. Reddy’s Laboratories points out to issues around “wellness” for an emerging economy like India. Several of Mr. Sapra’s thoughts ring a bell with issues highlighted earlier by Dr. Manning or Mr. Sengupta; in particular with the role of pricing, drug discovery, and research in neglected diseases. As an alumnus of IIM Bangalore it is also heartening to notice Mr. Sapra pointing to the game-changing role that digitisation and information technology can play in reducing uncertainty of the nature that Arrow (1963) has highlighted as historically prevailing in health care markets around the world, more so in India.

Mr. Sapra’s thoughts are given logical completion by Dr. Ravikumar Banda, Founder and Managing Director of Xcytis Diagnostics. Dr. Banda an erstwhile physician and now an entrepreneur starts off by highlighting the “physician-centricity” of health care markets, more so in contexts like India. Dr. Banda’s thoughts particularly are contextual in relation to the role of the MCI and the IMA, the two key nodal bodies of physicians in the country. Dr. Banda touches upon various aspects where society and these institutions need to buckle up and raise their voices when it comes to how physician behaviour affects the ordinary Indian citizen’s life. Dr. Banda also brings out in his discussion the pivotal role of the Central Drug Controller General of India in installing formal regulatory systems to promote ethical behaviour in Indian health care markets.

We highlight in Box 1, the key issues that get covered in the round table. The area is vast and there are several

<table>
<thead>
<tr>
<th>Box 1. Key issues covered in the round table.</th>
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<tbody>
<tr>
<td><strong>The bio-pharmaceutical industry</strong></td>
</tr>
<tr>
<td>a. Pricing of drugs (brand vs. generic)</td>
</tr>
<tr>
<td>b. Investments of MNCs in tropical disease drug discovery to life style</td>
</tr>
<tr>
<td>c. Advertising — information disclosure in ads; doctor-pharmaceutical firm nexus to promote certain drugs over others through samples, sponsorship and other practices, with little attention to quality</td>
</tr>
<tr>
<td>d. Availability of banned drugs and counterfeits.</td>
</tr>
<tr>
<td>e. Disregard of regulations in sponsoring clinical trials</td>
</tr>
<tr>
<td>f. Private health care providers and the issue of “inappropriate care”.</td>
</tr>
<tr>
<td><strong>Physician</strong></td>
</tr>
<tr>
<td>a. Irrational prescription of drugs</td>
</tr>
<tr>
<td>b. Prescription by brand names instead of equivalent generics</td>
</tr>
<tr>
<td>c. Commission received for referrals to diagnostic centres</td>
</tr>
<tr>
<td>d. Prescription of non-essential drugs</td>
</tr>
<tr>
<td>e. Monitoring of the Medical Council of India and its code-of-conduct.</td>
</tr>
<tr>
<td><strong>Pharmacy/chemist</strong></td>
</tr>
<tr>
<td>a. Use of the MRP as the price</td>
</tr>
<tr>
<td>b. Collusion by pharmacists on price</td>
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</table>
issues around ethical behaviour in the context of health care markets in India that merit attention. With the presence of international and domestic participants, experts from consulting and not-for-profit institutions, the pharmaceutical industry and a physician — we have attempted in the discussion, to make a fair representation of all issues under the overarching theme.

Ethical issues in health care sector in India: discussion

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Rijit Sengupta: Director, Consumer Unity and Trust Society (CUTS) International. rgs@cuts.org

Chirantan Chatterjee

The theme of this round table is ethical issues in the Indian health care sector and we have speakers from different parts of the value chain to get practitioner inputs on ethical behaviour in health care. I will start by alluding to Nobel Prize winning economist Kenneth Arrow’s seminal paper from 1963, where he first talks about the curious nature of ‘uncertainty’ in health care markets that engenders particular problems of adverse selection and moral hazard. Arrow also focused on the physician-centricity of health care markets, where the final consumer and the provider are almost always intermediated by an agent in-between, the physician concerned in most cases. Since the area is vast what we will try today is to cover various issues with Professor Arrow’s thoughts in the background. It is also a pleasure to bring in Richard, Ravi, Deepak, and Rijit in the ambit of this discussion. They come from various parts of the value chain in the industry and their thoughts potentially will cover the entire gamut of issues relevant to health care markets and ethical behaviour. Over to you Richard.

Richard Manning

Ethics in health care

Given my background, it is natural for me to think about things in terms of efficiency and markets. My view is that a discussion of ethics needs to be grounded in a recognition that people will tend to act in ways that they perceive to be in their own best interest. When society has in place appropriate structures and protections, individuals acting in their own interest often lead to outcomes that leave others better off as well. Not to be trite, but my view is that Adam Smith was keenfully insightful when he described the power of the “invisible hand.” Economic growth and development have done a great deal to lift individuals out of poverty and to foster prosperity in societies. There is a great deal of overlap between the search for economic efficiency and the betterment of mankind, which is to me a key standard by which ethical behaviour ought to be measured. As economies, particularly the emerging economies, continue to grow, individuals will desire more and better quality of life. Health care can be a major component of that improved quality of life and can be an important factor in enabling continued economic growth and development.

In short, the ethical responsibilities held by both governments and biopharmaceutical companies have to do with allowing/helping individuals achieve their goals with respect to quality of life. As economies grow, individuals will naturally desire better quality of health care for themselves and those they care about. The rules governments put in place can either foster or retard that progress.

Two key issues in ethics: pricing and marketing

Pricing

Relative to the pharmaceutical industry, no issue raises more ethical considerations in the emerging markets (or in the developed ones) than pricing.

Ethical issues in pricing cluster around two poles: 1) providing access to existing medicines for those that cannot pay and 2) maintaining the incentive to continue to develop medicines that address unmet needs. Essentially these problems come down to caring for the needs of present patients as opposed to caring for the needs of future patients. Critics of the pharmaceutical industry sometimes appear to give too little attention to the latter; the industry sometimes appears to give too little attention to the former. In fact, a wholly ethical approach to the problem of pricing must consider both current and future needs.

Some argue that the developed world is a sufficiently large and wealthy market to bring forth innovation in medicines and that ignoring the property rights of companies in lower income countries through compulsory licensing, voiding of patents, strict price controls, or whatever mechanism can do no meaningful harm to the future flow of medicines. For medicines that treat conditions prevalent in both developed and emerging markets, it is almost certainly true that the lost sales from “free riding” in low income countries are not a large deterrent to innovation at least in the near term. However, such static effects are not the only ethical consideration.

Companies that might start selling at very low prices in lower income markets have a natural interest in moving into higher income markets, and products sold at low prices in low income countries will naturally tend to flow into higher income markets whether through legitimate channels or...
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otherwise. Additionally, generics manufacturers seeing opportunities to challenge patents in developed countries have an incentive to turn their attention to those markets as well. Both these forces threaten to leave those with low incomes without the supply they need.

Additionally, as the emerging markets countries to grow, they become meaningful markets and larger and larger segments of their populations will have the capacity to pay for innovative medicines. Should they not? Is there no ethical responsibility for people who can afford to pay for innovative products to do so regardless of where they live?

A key example of this tension, and the need to solve it, is HIV. Thanks to innovation in medicines, access to appropriate medications can turn this disease into a manageable health challenge. Without access, it remains a nearly certain death sentence. The gains to treatment are exceptionally large as it allows people to remain productive in the most productive years of their lives. Although more remains to be done, great progress has been made to foster access to HIV therapies and to bring down their cost to those that cannot pay.

Philipson and Jena demonstrated that despite the relatively high perceived prices for the medicines, the companies that developed HIV therapies captured only about 5% of the value of their innovation. In short, prices could easily have been much higher and patients would still have captured the bulk of the gains from the new therapies.

To current beneficiaries this is obviously good. However, trouble looms due to dynamic factors. The HIV virus mutates over time and the medicines that currently keep it at bay will probably not always do so. Short of eradicating the virus, which is most likely impossible, there will be a continuing need for new HIV therapies over time. Who will develop those? As prices are driven down naturally by patent expiration and perhaps less naturally through political pressure, the potential reward to the innovator that brings new HIV therapies to market become small. Today there are relatively few HIV research programmes under way. Without an incentive to continue the search for cures, the gains of the present are coming at the expense of the gains in the future.

The challenge in HIV and other therapeutic areas is to make products available for people that are unable to pay while not destroying the markets for those that are able. That is no simple task as it pits the interest of the present against the interests of the future.

One potential solution to the dynamic efficiency problem is fostering differential pricing through partnerships among private companies, NGOs and governments. In a functioning differential pricing system, individuals or population segments that can afford to pay only nominal prices (or perhaps no price at all) would have drug supplies segregated to allow them access while not threatening existing commercial markets. While simple in concept, the application is extremely difficult. Efforts have been made to develop differential pricing schemes, but the alignment of interests is very challenging. Making real progress will require the commitment of various parties to ignore strong immediate interests. Exactly how to obtain that commitment is unclear.

Finally, although private companies have demonstrated a willingness to invest in treatments for neglected diseases, those efforts have not and cannot be central to their mission. While economic growth and development will go a long way towards lessening the burden of those diseases, many scholars agree that some non-market mechanisms will be necessary to address those issues. While these ideas have resulted in some successes, meaningful progress has not yet been achieved.

An interesting question in this realm is who has the ethical responsibility to bear the burden for research into treatments for neglected diseases? No doubt, because the infrastructure of discovery and development that already resides in the private biopharmaceutical companies conveys on them a cost advantage in the search for new cures, they will play a role. Exactly what the dimensions of that role should be seems less obvious. Certainly those companies have financial resources, but that alone should not lead them to bear the burden alone.

On the one hand, recent market developments have knocked the innovative industry down the ranks of most profitable companies in the world. Both in the US and on a global scale, companies with the largest market value and income reside largely in the oil and finance industries or in information technology. If ethical responsibility is apportioned according to ability to pay, certainly a wider set of contributors than the biopharmaceutical companies would be identified. Additionally, why is it that shareholders of private companies should support this cause? Are they the disproportionate beneficiaries? The answer to the question is not obvious. Who should pay for the benefit of others is not something about which economics typically has a lot to offer. It only seems clear that the answer is unclear.

Ethics and marketing

A second key issue involving ethics in health care is the marketing of prescription drugs. As in any industry, there are legitimate concerns about the incentives the seller of a good might have to distort information conveyed about their product. In health care, this concern is heightened by the fact that the ultimate consumer, the patient, is typically somewhat disconnected from the choice of medical approach to use. When the physician acts in the patient’s best interest, the ethical concern about marketing is less serious. So a first step in thinking about the ethical challenge in marketing pharmaceuticals might be to consider the incentives facing the care-giving physician. When patients have the ability and freedom to compare and select a physician based on how well he or she represents the patient’s interest, the concern that the physician might be unduly swayed by marketing efforts of the pharmaceutical company is diminished.

It is also important to recognise that marketing activities are a means of providing information to people as they make economic choices. Information is costly to acquire and process. Brands and trademarks exist because they convey information to consumers about characteristics of a good or service at a relatively low cost. Advertisers remind people of their goods and service offerings because people have many things to pay attention to and reminders can help sort through information to help people decide what to do with scarce time and resources.
Likewise, physicians are more able to make appropriate therapeutic recommendations to patients when they know more about the products they prescribe. Although in a perfect world, it might seem desirable for physicians and patients to learn all they need to know from completely disinterested parties, the reality is that pharmaceutical companies know more about their products than anyone else, and absolutely independent sources of information are costly to acquire. In modern health care systems, a physician’s time is scarce. Although academic publications provide an important source of new information, the cost of staying on top of the latest advances is not small.

Hence, allowing companies to provide information to patients and physicians can be an important component of improved quality of care. It is common among economists to argue that the best solution to concerns about biases in the provision of information is the provision of more information. When competitors each convey information to physicians, they are able to determine credibility of various sources and filter out better from worse.

Of course, inappropriate inducements to prescribe specific products should not be allowed, but it is easy to go too far and forget that the provision of information is a complicated, costly, and valuable exercise. Sometimes combining lunch or dinner with information about medical treatment may be a problem, but sometimes it may be the best way to lower the cost of the physician obtaining that information. Limiting contact between physicians and marketing professionals can have unintended consequences.

A recently published article examined the impact of access to sales representatives in the US on prescribing patterns of physicians treating cardiovascular and diabetes patients. Perhaps not surprisingly, the study found that physicians working in settings with greater access to pharmaceutical company representatives had more rapid adoption of new medicines than those working in settings with restricted access to sales representatives. One can argue about the merits of rapid response to the launch of a new medicine. Certainly, however, delaying treatment in cases where a new medicine would provide a substantial benefit to patients presents an ethical problem.

A more obvious ethical problem would be continuing to expose patients to a newly discovered risk. Importantly, Chressanthis and his colleagues found evidence that this was an unintended consequence of restricting interactions between physicians and sales professionals. Physicians in their sample that had low access to sales reps took significantly longer to reduce prescribing in response to a newly discovered risk than those with high access to sales professionals.

Of course, the applicability of these specific findings to India or other emerging markets with different information structures, different regulatory environments and different education levels is not obvious, but the reality that information is costly and that providing more information allows people to make better decisions is universal. Allowing manufacturers to provide information to professionals and perhaps to patients as well is a fundamental step along the ethical course. Any structure that dictates the conditions on which information can flow should account for the potential gains from having more and better information in the hands of prescribers and patients.

Rijit Sengupta

Regulation in the health sector and the realities of implementation

Ethics and health care
I have recently published my presentation on regulation in the health sector into six sub-points. The first point is a comment on the topic itself. There are two leading words in the topic: one is “ethics” and the other is “health care”. As far as ethics is concerned, we now have the National Voluntary Guidelines (NVG) on Social, Environmental, Economic Responsibilities of Business, which was adopted by the Government of India, Ministry of Corporate Affairs. The NVG tries to define responsible business conduct and it presents a framework consisting of nine principles with certain core elements to actualise each of the principles. We can use principle one of the NVG to lay out broadly what we mean by ethics in business and apply that specifically in the health care sector. Principle one, which states that businesses should conduct and govern themselves with ethics, transparency and accountability, emphasises that ethical conduct in all its functions and processes is the cornerstone of responsible business. There is an emphasis on the accepted or written and non-written codes, and principles and values which define ethical behaviour. It emphasises transparent communication and a culture of integrity. It asserts that businesses should refrain from indulging in corrupt practices and honestly discharge their responsibility on financial and other areas pertaining to mandatory disclosures.

Health care market
What do we understand by the term “health care market” and what are its salient features in the context of this discussion? First, the health care market is an extremely diverse market as far as the states are concerned, given that health care is a state subject. Second, it is characterised by considerable information asymmetry. Third, it is driven by a weak market regulatory framework which does not have a very satisfactory implementation record. As far as the topic is concerned, when you talk about health care from a holistic perspective, it is different to separate practices in the pharmaceutical sub-sector from the health care sub-sector. The pharmaceutical sector is extremely heterogeneous and has been undergoing considerable consolidation through mergers and acquisitions recently. This is going to change the topography of the pharmaceutical sector as far as the nature and kind of players are concerned. The health care sector is equally heterogeneous, an extremely dispersed and unregulated market. It is often difficult to identify the scope/borders of this market.

Regulation of the health care/pharma sector
My next point is about regulation in the health care sector and I will enumerate certain issues related to the experience of regulatory enforcement in this sector. The first is about pharmaceutical pricing. The National Pharmaceutical Pricing Authority (NPPA) which is the regulator for prices in the pharmaceutical market is located under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceuticals which is situated under the Department of Pharmaceutical...
Ministry of Chemicals and Fertilizers. We are talking about health care here and the Ministry of Health and Family Welfare should have been the ministry or the custodian of the drug regulator in this case. The NPPA’s motto is to serve the consumers while encouraging the pharmaceutical manufacturers to produce adequate quality of products to meet the rising demand. However, we know from experience that often protecting the interests of the industry becomes a priority over protecting the interests of the consumers. For instance, if you look at the list of essential medicines, there has been a considerable reduction in the number of medicines which are covered in the National List of Essential Medicines (NLEM) over time. While at the same time more and more private companies have been given licenses to produce drugs in our country.

The second point about regulatory enforcement is about the quality of the drugs which are available in the market and what the regulator has done in order to ensure that quality is maintained. The Central Drug Standard Control Organisation (CDSCO) which controls the in-flow of drugs into the country and oversees clinical trials, is placed under the Ministry of Health and Family welfare. However, if you discuss issues with them, they say that their sole responsibility is to ensure that they provide licenses to international firms entering the market. The license for domestic drug firms is provided by the state drug controllers, who are also responsible for monitoring the performance of these firms in the market with regard to availability and quality of the drugs they produce. Having worked in this sector for the last few years, CUTS feels that if the enforcement of such regulatory responsibility (of availability and quality of drugs in the market) is left with the state, it might be counter-productive. There is a large variation in the capacity of the state drug controller and also in factors that determine the market at state-level. In one of our recent projects for state drug controller and also in factors that determine the productive. There is a large variation in the capacity of the market) is left with the state, it might be counter-

The third issue concerns marketing. Under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, pharmaceutical companies are not supposed to influence the behaviour of doctors by offering gifts/commissions. But evidence suggests otherwise, going by the large number of complaints which have been received by the MCI about such practices. Recently there has been an attempt by the Health Ministry to come up with a Uniform Code of Pharmaceutical Marketing Practices (UCPMP). It is a voluntary guideline but the ministry is very keen to enforce it given the prevailing concerns related to marketing of drugs in the country.

The fourth and the last point pertaining to experiences in regulation is registration of health care institutions. The Clinical Establishment Act, 2010, which was notified earlier in May 2012, still remains a model law and is yet to be adopted and adapted across most of the states. Only seven states have adopted this Act to date, namely, Arunachal Pradesh, Himachal Pradesh, Uttarakhand, Rajasthan, Jharkhand, Mizoram, and Sikkim, and the Union Territories. There is still a lot of resistance from the states in adopting the Clinical Establishment Act. Related to this, in terms of the performance of the health care institutions, according to the National Antibiotic Policy of 2010, the government has been toying with the idea of prescription audit to assess adherence to “rational use of drugs” (RuD) by the doctors and health care institutions. But there has been resistance to this suggestion, especially from the Drug Traders Associations in the country.

Recently, there were reports in the media about continuing friction between the Planning Commission (Government of India) and the Ministry of Health and Family Welfare regarding recommendations made by the High Level Expert Group on Universal Health Care headed by Dr. Srinivas Reddy. If one looks at the chapter on Health in the Five Year Plan (2012—17), it talks more about managed care which has not gone down well with the Ministry of Health and Family Welfare for obvious reasons. The Health Ministry had hoped to receive greater financial support for enhancing the capacity of the sector to provide better health services, especially to the poor.

It is appalling that our country still doesn’t have a National Health Policy. A draft has been lingering for a long time. There is a lack of political will in supporting and streamlining the health care sector as far as regulations are concerned, which has had major implications for a majority of our fellow citizens. The first is the high cost of health care, and according to a World Bank estimate based on 2004 data, several million households fall into poverty in our country due to high health care expenses in India.

Private health care
The next concern is about private health care expenditures in our country and implications for the economically disadvantaged. According to a report, private expenses in health care constitute 80% of the total health care expenses in India, which is very high as compared to other developing countries. The issue which is of even more concern is that expenditure on drugs comprises 72% of the total out-of-pocket expenses in our country. A third issue on which we have done some work is the nexus between various health care providers in the country. In our report prepared on the basis of primary information gathered from the two states — Assam and Chhattisgarh — what we saw was that the pharmaceutical companies were continuing to influence doctors through promises of foreign visits and continued medical education. The job of the medical representatives too has become part of this loop.

Another thing that we need to think about is the size of the pharmaceutical industry in the country — do we need so many pharmaceutical companies/drugs in the market? The nexus between the doctor and the diagnostic clinic is considered as “usual practice” and operationalised through “cuts and commissions” even though this is prevented
under the MCI Regulations. It is not private health care alone that is affected by these kinds of practices. Even in public health care, we have evidence to suggest deliberate suppression of medicine supply in public hospitals, of consumers being forced to go outside public hospitals for medicines which were otherwise available at low cost (or no cost) from the medical store within the public hospitals. We need to deliberate on the kind of regulations that we are looking at and looking for.

Co-regulation and self-regulation
There has been a considerable amount of stress on public regulation and we have ignored the two other extremely important types of regulation: the first being co-regulation, and the other, voluntary self-regulation. Co-regulation sees the government regulating through the sectoral association (i.e., the pharmaceutical association in the pharmaceutical sector and hospital association in the health care sector). We have seen that sectoral associations have remained extremely meek in monitoring the behaviour of their members. We need to find ways in which the government can work hand in hand with sectoral associations and empower them. The sectoral associations must become more active and penalise members who are indulging in malpractices and/or not complying with applicable rules that have implications on their behaviour.

The most appropriate analogy that I was able to draw was of a school where you have a teacher who disciplines the class; she can be equated with the public regulator/government. Yet you also have a monitor who is elected from within the class but is accountable to the teacher. This is the role that sectoral association should carry out, and remain accountable to the government. This is probably the kind of model we need to explore for the pharmaceutical and health care sectors. It is time to see how that can be done. It is also necessary to assess the catalytic forces for self-regulation, and promote them in the sector.

Role of CUTS
Finally, I would like to inform you about our organisation and what we are doing to deal with this situation as a consumer protection organisation. Firstly, we are trying to gather some of the evidence that is otherwise difficult to get and use that to raise a debate on the need for reviewing the regulatory framework for the sector. Secondly, we are trying to push the agenda that the main objective of the pharmaceutical or the health care sector is to promote consumer interest. Unlike in any other purely economic sector such as steel, retail, apparel or automobile — consumer/public interest issues are of prime interest in the pharmaceutical and health care sectors. Therefore, the geography and the framework for regulation are different and have to be resolved by the government, both at the central and the state level.

We have to see how we can promote the NVG to effect a more responsible pharmaceutical, medical or health care sector in India — such discussions/processes should not be restricted to the national level but should take place across the states.

There has to be a consistent process or forum to ensure transparency across implementation of public regulation at the level of the state. Even with co-regulatory activities, for e.g. the sectoral regulation, much depends on the nature of the market and that requires some thought. We have also been lobbying for the adoption of the national competition policy in India, looking into the policy impediments that have hindered a level playing field in the pharmaceutical sector, and affected entry and operations of pharma firms in the country. We try to balance both: as a consumer organisation we try to enforce the agenda of consumer protection on the one hand, while on the other we try to assess what is good for the industry.

Deepak Sapra

Ethics in health care

My starting point for any discussion on health care ethics is the fact that it is imperative for a society to have healthy citizens and therefore provision of universal, affordable health care should be a core objective.

The other fundamental premise is that health care is an important aspect of our life and part of the society we live in. So any discussion on ethics in health care cannot be in isolation of ethics in society.

I want to list out some of the major issues that I see around health care and especially pharmaceuticals where the question of ethics comes in and there are several grey areas.

We use terms like health “care”, and pharmaceutical “industry”, and pharmaceutical “market”. While these are seemingly just definitions, the words used in these terms appear to be at odds with each other — “care” and “industry”, “care” and “market”. The question is whether we can reconcile these intended outcomes in a manner that is win-win.

Some of the issues I wish to point out are

- Drug pricing — Are drugs priced in a manner that they can serve the needs of people who need them? Can pricing improve access? To what extent do market forces help in shaping pricing and impacting accessibility.

- How does pricing link to who the payer is, i.e. whether it is out of pocket, insurance company, or the state?

- Drug discovery — are the efforts towards research targeted to those segments where there are glaring health care gaps?

- Influencing doctors and other health care service providers in order to generate prescriptions. What kind of influence is acceptable — scientific, medical, academic, commercial.

Where do the lines get blurred?

- Pharmaceutical research and clinical trials (CTs) — How much of it is ethical and to what extent do we go?

Drug pricing

I would like to share some specific examples. Let me start with the example of AIDS which is prevalent in several parts of the world, including some of its most disadvantaged
parts, especially sub-Saharan Africa, parts of Latin America, and Southeast Asia. Typically the cost of first line therapy for an individual afflicted with AIDS used to be $50–60$ per day irrespective of which part of the world the individual lived in. As a consequence, many people were denied access because the drugs were simply unaffordable, especially so as several patients were living at below $1$ a day. With genericisation and competition, several players came in, providing cheaper versions of the same therapy which led to costs coming down to $1$ a day. My next example is of Rituximab, a monoclonal antibody, the biosimilar version of which is manufactured by Dr Reddy’s, the company I work for. The number of patients in India who were deriving the benefit of this therapy was a handful, a few thousand, when the product was being sold only by Company X, the innovator. Enter the biosimilar version, at a price point that was about 50% lower, and the number of patients getting benefitted expanded dramatically to several fold. Thus, for the right kind of price and the right kind of free market play, there can be a substantial impact on the number of beneficiaries. This can be especially effective in scenarios where the payer pays from the pocket, in countries such as India, Brazil, Latin America, Africa, and other parts of Southeast Asia. The coming in of competition immensely increases affordability. While these kinds of drugs are still very expensive for several patients, the coverage increases disproportionately with the fall in price.

This is one of the most important issues around ethics and health care. It should be possible for someone to access an intervention/drug at the right time and in a manner that doesn’t cripple him/her financially. This is a very important issue that generic companies and competition in the pharmaceutical space have been able to address. I feel happy and proud to be a part of this sector in India especially because we are making a tremendous impact towards improving the affordability of drugs, in every part of the world.

Drug discovery

Drug development is a high risk, high investment and resource intensive game. It takes 10–12 years to get a drug to the market; it costs anywhere between USD 800 mn to a billion. If companies cannot recoup the money, as corporations they will find it difficult to invest in specific areas. This determines choice of areas to invest in, and commercial attractiveness often scores over public health concerns. This is one reason we see so many new drugs in the neuropsychiatry space and so little, for example, in tuberculosis.

As a synthesis, we must harness and leverage the power of free markets with the benefits of collaboration, especially on research in areas of public health concerns. Technology is an enabler and the more we use it to impact how drugs are researched and manufactured, and how diseases are diagnosed, the easier it will be for new drugs to get to the market.

Investments in research also have to be a collaborative effort between the public and private sectors with higher funding for non-profitable drugs. Several old diseases, for example malaria, are coming back with a vengeance and there are no drugs targeting such resurgence. We must provide incentives and funding for the right kind of research.

Influencing doctors

The third issue is around influencing doctors and others in the industry on the drugs that are prescribed. Many pharmaceutical companies have been questioned or criticised for the way they achieve their financial targets, and the financial metrics that they adopt, for example, categorising doctors by the value of prescriptions they generate, and the methods used to influence doctors and generate prescriptions. Even with regard to unbranded generics, concerns have been raised in the US about influence over another set of players in the value chain — the pharmacy chains, aggregators, and super markets, who are customers and influence drug usage.

Clinical trials

Clinical trials are performed while establishing the safety and efficacy of drugs intended for use on human beings. There are a series of tests which need to be undertaken, on healthy volunteers as well as patients. One of the most controversial ones is the issue of trials on human beings. Are we treating patients in the right manner? Are they aware of what is happening? Are we providing the right kind of post-trial support to volunteers? This impacts us in India a lot, as India is a preferred CT destination owing to lower costs. One estimate put the comparative cost of CTs in the ratio 1:4; that is if it costs $10M in India, then it will cost $40M in the US. The important thing to note here is that there is a need for transparency and this is not a very strongly established system in India. Concerns have been cited about the medical, ethical and financial treatment of volunteers and subjects. A pharma report suggests that in 2012, more than 200 people have died as a result of clinical trials in India. This brings us to the question whether all was fair and square, and whether the subjects were made fully cognisant of the issues around enrolment and subsequent medical attention. So, how do we create health care ethically and legally?

There is debate around reducing clinical trials on humans, wherever possible. Can we use more of technology and IT? Can we use more statistical tools and be accepting of them? Can we do more predictive in vitro experiments to reduce in vivo activity? Can we formalise authorities’ responses, so that there is mutual recognition of each other’s approvals? Some of these questions could show us the way.

Ravikumar Banda

Perspective on Indian health care

My perspective is likely to be different from that of the other panellists on this subject. Let me tell you where I come from. I have done my medicine, post-graduation in psychiatry and I practised for some time. I then worked with Astra Zeneca research foundation after which I started my own company. So I have seen the industry from within, plus I know what a medical practitioner feels.
Paradox of health care industry

Health care is a very peculiar industry in that the consumer has no rights. The consumer is completely governed by a middleman who doesn’t pay for it, and that is the doctor. In this situation, there is one thing that is quite frightening: a clinician crossing ethical borders can cause lot more damage than the pharmaceutical industry crossing the legal borders. So we require phenomenal ethical regulation which includes both the doctors and the other people concerned within the same framework. To enable this, we have one organisation, the MCI. While MCI is an august body in this country, it has zero capability of enforcing regulations or taking anybody to task. They do not have recourse to legal aid that can help them to take action if something goes wrong. Even when legalities have been breached by clinicians it is very difficult for MCI to intervene and do something about it when somebody complains to them. They have to seek justice through the courts.

We have a paradoxical situation in this country, where we have a huge disease burden when compared to the Western world, but we are doing little to effectively manage the abundant sickness. We have a lot of plans but I don’t think we are implementing any of them.

The need for innovative health care delivery

What we require is two things, namely, inventions to tackle some of these problems, and innovation in delivering the solution to the last man in the remotest village. We lack innovative health care delivery. Quite often, we blame the person who invented the solution for the disease. We, the government and society have been opportunistic. While many people have been benefited by making some drug generic we have killed innovation in the process. We don’t see how we can keep the person still interested in the solution, in going further. At the end of the day, the pipeline will dry up. Patent and patent protection is not a problem. The problem lies in intellectual property rights (IPR) management, the pricing of the new drug, negotiating with a company when a new innovation has been made in making that available to people, and so on. There we don’t have solutions and we require a lot of inventions in that space.

However, we have the problem of poor performance with regard to inventions, ethically as well as on the management side. Big corporations are scared of investing in inventions and SMEs are enthusiastic in niche areas, they think that it can give them a unique position if they have a new invention but they don’t have the money to see the problem through. There are government initiatives such as New Millennium Indian Tecnological Leadership initiative (NMITLI), Biotechnology Industry Research Assistance Programme (BIRAP), where part of the funding comes from private initiatives. However, we have ethical issues when it comes to supporting inventions in this country or supporting funding. We have committees which look at public–private partnerships and they are worried that at the end of the day, there is public money coming into a project that ultimately can be taken up as a product in the private sector. Though one may have price controls, it is the company that makes a profit. They feel that the private investors in the company have been made rich by expenditure at the public’s expense. Amidst these confusions and ethical dilemmas we forget that they there could be a public good at the end of the process, and we lack the confidence that a private company could make medicines affordable to people. Since the product has come with peer-funding, it comes with fewer problems, so the company could make it more affordable.

They do not also understand the issues connected with commercialisation of a product. Let me give you the example of a company X that came up with a medical diagnostic device that could be plugged into the Internet and would provide excellent tele-medicine services, connecting doctors and patients in remote villages. But that product has gone nowhere because of the insistence that the price should be kept very low and within that pricing, there was no distribution margin for 2–3 levels as required. We need to think through the whole distribution chain and incentivise the whole system, if not it won’t reach the last man.

Ethical practices and positions

I now come to a problem that Rijit alluded to: the cuts taken by doctors. It’s a huge problem in our diagnostics industry. Where did the cuts get created? The doctors blame it on pharmaceutical industry; I completely blame the doctors. We need to have highest ethical practices with diagnostics and drugs as the cuts and incentives add to the patient’s burden. The doctors within their own fraternity, and with the MCI and all the others concerned, need to get together and see that the highest ethical standards are maintained.

Let me demonstrate what I mean by unethical practice. As a diagnostic provider let us say that I sell an HIV test kit at a price between Rs. 17 and Rs. 25 depending on the tax structure of that state to the hospital but the hospital in turn charges the patient anywhere from Rs. 325 onwards. Is there so much of value addition in the hospital on this diagnostic kit? Definitely not. The charges are arbitrary and this is largely an unethical practice. Hospitals are built at a certain cost and they generally want to earn their costs back on everything that goes through that hospital and that’s where everything gets overcharged. I don’t know who will control it, but it’s a huge problem in making health care affordable in this country. Whatever the manufacturer does, it does not reach the people because the hospital will hike up the price.

Coming to the regulatory hurdles, we have a Central Drugs Controller General of India (DCGI) who reports to the Union Health Minister. Each state has a drug controller who runs the day to day business of regulating, inspecting and prosecuting. This is under each state government separately and it is a very confusing situation for the industry and it needs to be rectified. The second problem in this area is the lack of a clearly defined work ethic. Even if we put aside things like corruption, delay in issuing license — sometimes for years together, is an unethical practice which is not punished. On the other hand, if a drug is granted a license and is used effectively for four years, and in the fifth year there is a problem, the manufacturer will be punished severely and the Drug Controller gets a black mark. So many people feel that inaction is the best way. This is how it is all over the world, not only in India. However, the US FDI says there are ethics within that. If a new drug is going to improve health care by even 5% or 2%
more than what the current drug is doing then it is your ethical duty to see that the drug reaches society in the shortest time. This is lacking in India. We have not ever stated the ethical position, that it is also the duty of the government to see that a drug reaches the people within a stipulated time. Therefore, some ethics has to be brought into the regulatory process. One important point that everybody forgets, including the health ministry, is that if we delay a drug then the cost of this delay is loaded on to the price of the drug. We have to think through every delay and include it in the process.

Public-private partnership

Next, I would like to continue what Deepak brought up — about public-private partnership and the point of trust and I will say that trust is lacking on both sides. Both the industry and the bureaucracy are culpable in their own way but if we keep blaming each other and carry on a game of one-upmanship, this will go nowhere. At some point we need to say stop and restore the ethical balance. The most important aspect of this is, what is the effect on the ethics of the whole society. We need to be responsible as a society on many of these issues.

Let me give you an example from clinical trials. There have been instances where committees working under the Drugs Controller General of India (DCGI) have given opposite decisions in similar situations. Very often committee members though academically qualified do not understand the ground realities of public health, and they take decisions based on convenience.

It is a clinical trial which costs the maximum while developing a drug. If we want to develop generic drugs, which are important for the common man, we would probably have the following situation. An anti-tuberculosis drug was developed by a company in India, which went through toxicology successfully, and through phase one of the clinical trials, after which nothing further was heard about the drug. Do you know why? The next step is a big trial that would cost about S750M. The company is in a dilemma whether to proceed or not because when this product is successful, every country poor or rich will want to procure it. It would be the governments of countries who would want to procure it and they would negotiate over the price. But who will finally pay for this S750M worth of clinical trials? This dilemma could prevent the drug from seeing the light of day because if this question is not settled, the company could cap the drug indefinitely. This is where public-private partnership can come into play. Maybe the Government of India should permit the company to conduct the clinical trial in India and negotiate for a differential price in India. But nobody is doing that. Everybody is willing to do what is called open source drug discovery platform in which first discovery costs $100M or less. That part they want to subsidise. But nobody is talking about the remaining $650M. We need that kind of public–private partnership if you want to take the new drugs which are invented elsewhere to the masses; you are required to support them too and their inventions, otherwise you will have a big problem of demoralising the inventive companies.

The foremost point is we need to think about how to bring ethics back into medical community back.

Discussion

Vasanthi Srinivasan: Thank you. You have laid out the range of issues on the subject of ethics in health care quite comprehensively. The issues discussed reflect the complexity of the sector, the multiple stakeholders involved, the different interests of each of these stakeholders, the weak regulatory framework, and the question of self-regulation at the level of medical professionals and organisations.

What would be the three recommendations or suggestions that each of you has to any of the stakeholders that would contribute to building a more ethical health care systems?

Rijit Sengupta: A critical issue, which was raised by Ravi as well, is the role of the drug controller (DCGI) both at the centre and at the state level. The Ministry of Health and Family Welfare must develop a mechanism that promotes co-operation and consistency across the drug controller functions in the states.

Most of the services in this country have a dedicated sector regulator but the private health care sector (private hospitals and clinics) neither has a regulatory framework nor a regulator. The government must articulate its position in terms of regulating the private health care sector, given the proliferation of private providers in this sector which is only going to increase. The third thing would be with regard to the marketing of drugs. The government must move from developing voluntary guidelines to stricter regulatory norms as far as marketing and distribution of drugs is concerned. These are my key recommendations.

Deepak Sapra: The core of my argument is based around affordability and I have a few recommendations on that. In the Indian context, one aspect that really impacts affordability is the time it takes for drugs to get approval – this aspect was pointed out by Ravi in his presentation. It would be a very important aspect in health care overall. In order to increase affordability we would have to reduce the time it takes to get approval for various kinds of drugs and we have to make sure of getting more people into the market as early as possible. Another aspect, on the same point, concerns the affordability of drugs which are still governed by patent. On this my recommendation is that we must look at compulsory licensing not just from the perspective of patent protection but also from the perspective of number of patients it is likely to impact. To my mind, compulsory licensing could be one way, especially in certain critical diseases where alternatives are not available. This could get more drugs into the market in a manner that is affordable to a wider mass of people in a country like India.

I am conscious that it is a very dangerous argument, because it could open the flood gates and therefore you need to be very careful. It needs to be selectively done in the case of those products where there are no substitutes available and where there is a real case for public health or where a large number of patients are not being able to gain the benefits of that medication.

My third point draws upon the emerging thinking around innovation, which Ravi and Rijit also spoke of. I agree that the scope for innovation in this sector is phenomenally high at the moment because of the various kinds of possibilities
that exist in the value chain. My recommendation to venture capitalists would be to be consciously on the lookout for the models which incorporate innovation in the health care industry, especially around delivery, and to start in places which are not conventionally considered important markets or important customer segments. There is a lot of value at the bottom of the pyramid and there is a lot of value in taking it forward. There are various innovative approaches that people are trying out and people have done it in different parts of the world. We should be able to encourage innovation and get it into the Indian scenario. Another aspect I would like to draw attention to is that there is tremendous potential to leverage technology to reduce many of the barriers that exist, especially around information asymmetry. We could collaborate with the leaders in the field over this.

**Vasanthi Srinivasan:** I have a PhD student who is researching on scaling up of health care services and one of his areas of interest has been telemedicine. Many telemedicine initiatives have been announced in the public-private partnership mode but the incentive structures that are built in are unclear. What is likely to be the future of telemedicine given that it could enable affordable access to health care in rural areas?

**Deepak Sapra:** For this, we would have to look at collaboration with different players in the value chain.

**Ravikumar Banda:** Telemedicine is a subject close to my heart. There are all sorts of problems around it and I have seen companies struggle. The point in telemedicine is taking the product to the end customer. How do you reach it and how do you make the whole path smooth? It’s like this: People say if you have a small margin and large volume, it’s a great business to do in health care. But reaching a large volume of people requires hectic marketing and that’s a hugely expensive proposition. In order to aim at very big markets, you should be able to reach a large volume of people and that gap has to be first looked at. There we need to think how to reach a large sector of people without going through the classical pharmaceutical marketing method, which is a very expensive proposition. Only if we bridge that gap, I think more and more innovations will occur which will simplify telemedicine. People forget that if a farmer can be saved a trip from his village to his city for medical consultation, he is willing to pay for the telemedicine service. So we must think of how we can cost telemedicine cleverly to make it accessible to the end user.

To reply to Vasanthi’s question, my three suggestions would be: Firstly we need to integrate MIC with the enforcement agency. We need to have MCI tie up with IMAs and time lines in executing these regulations, be transparent and evolve guidelines by involving the pharmaceutical marketing method, which is a very expensive proposition. Only if we bridge that gap, I think more and more innovations will occur which will simplify telemedicine. People forget that if a farmer can be saved a trip from his village to his city for medical consultation, he is willing to pay for the telemedicine service. So we must think of how we can cost telemedicine cleverly to make it accessible to the end user.

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