THE HINDU Business Line

‘Pharma industry has a deep culture of corruption’

Chirantan Chatterjee

Dinesh Thakur

Dinesh Thakur, who blew the whistle on Ranbaxy’s compromises with quality, discusses Indian pharma's ills.

Circumventing 56 patents protecting a medicine to re-invent a novel process and procure a 57th one for Eli Lilly’s drug Cefaclor had been Ranbaxy’s biggest claim to fame in the last couple of decades. But in 2013, the situation flipped in what can be termed as its summer of ‘dirty medicine’.

Now widely reported by international press, **Ranbaxy**, the maker of generic Lipitor to millions of Americans and pioneer in India’s generic medicines revolution, paid damages to the tune of $500 million to settle on corporate fraud related to unethical production of medicines that compromised on quality. These transgressions by Ranbaxy would not have surfaced had it not been for a certain gentleman, **Dinesh Thakur**, who was the insider and the **whistleblower** in this case. Thakur, who subsequently was rewarded for revealing the truth, discusses in this **conversation** with **Prof Chirantan Chatterjee**, IIM Bangalore, the future of **‘Quality Medicine’** coming from the Indian generics pharmaceutical industry.

Whistleblowers, much like Thakur, have earlier received plush incentives for their job well done; but this conversation also reveals a man who deeply cares about public health, corporate fraud and quality medicines coming from India, the pharmacy of the world.

I will start off by asking how you view the Indian drug-quality situation has impacted ‘Brand India’ in export markets? Clearly, pharmaceuticals is a great story for the brand outside but how do you think this brand will suffer abroad/is suffering abroad and what concrete steps can be taken to redeem that situation?

Let’s begin by understanding what “Brand India” represents. Two of the storied industries from India are IT Services and Generic Pharmaceuticals. In both cases, the brand represents “low cost” at its core. Offshore IT-enabled services are based on the labour cost arbitrage between India and the west. Likewise, lower manufacturing costs, coupled with a protective patent enforcement environment for over 25 years, allowed Indian generic manufacturers to develop competencies in producing low-cost generic drugs. So the focus has always been on “the cost”, often at the expense of quality. Otherwise, how do you explain the overwhelming desire of the Indian consumer who prefers “foreign” manufactured goods, from consumer electronics to automobiles, often at a premium price?

Now that we have defined what “Brand India” stands for, let’s address the question you asked. Has it taken a beating abroad? The answer is not yet. Even though the case with Ranbaxy was so egregious, it’s still one instance. Although we have seen the beginning of the domino effect with Wockhardt, Strides Arcolab, RPG Life Sciences and many more, Ranbaxy stands as a singular instance of wrongdoing of epic proportions (seven criminal felony pleas). Fortunately, generic drug manufacturers are not a household name like their innovator counterparts in the west; so despite being in the news, consumers haven’t fully connected them with the wrongdoing. However, if this trend continues with other generic drug manufacturers based in India, then it is clear that the brand will take a beating.

There are three things that can be done immediately to alleviate this problem. First, make public health a priority for the country. For a country of over a billion people, we do a terrible job of ensuring safety and effective services in public health. Second, fix the regulatory mess. Institute a proper regulatory system within India and install competent authorities to implement the rules; get rid of the bureaucracy that stifles this industry. Third, change the focus from “low cost” generics to “high quality” generics. Implement a system of quality controls and incentivised integrity programmes to ensure compliance. As Will Rogers once said, you never get a second chance to make a first impression.

Let's not ruin the opportunity we have and make the right impression for "Brand India".

In a recent article you have noted that India's main problem in drug regulation is that "nationalism has replaced health protection as the guiding principle of drug regulation". Can you elaborate on that? How do you view that to evolve especially since 'nationalism' has always been a key reason why countries engender a strong domestic pharmaceutical industry? Are there junctures where industries need to evolve from such a view of pharmaceutical industrial development?

The reaction to what happened at Ranbaxy after my case became public in India is symptomatic of the myopic view of the industry and the regulators in India. It is a well-known fact that there are two standards of manufacturing medicines in India, one for what are called "regulated markets", which include the US and Western Europe and the other for what are called "less regulated markets", which include India among others. The standards for product quality at locations that cater to the "less regulated markets" are several notches below those implemented at facilities that manufacture drugs for the US, for example, even among large companies. This is a well-known fact in the industry.

Of the several hundreds (or perhaps thousands) of companies that make products for the Indian market, only a small percentage supply the US market; and hence have the technical know-how and expertise to comply with a higher standard of quality. Given all this, how do you explain the response from the Ministry of Commerce, Ministry of Health, the industry itself and the Indian Regulator which have yet to find one quality related violation at any of Ranbaxy's manufacturing facilities? I am quite sure that patients in India wouldn't like to take drugs which are made in a facility that has urinals lacking running water for employees to wash their hands after using the toilet. This was an observation in a recent US FDA inspection report. How is it that the inspectors from the Indian regulator did not find this objectionable, let alone all the rest of violations in the manufacturing process, which are far more egregious? In an effort to buttress the image of the Indian pharma industry, we are beginning to lose credibility if we keep asserting sabotage from foreign competition.

India cannot be afraid to look at what is wrong. If we hope to compete in the international marketplace, whether it is medicines, food, IT services or automobiles, we have to be able to reliably deliver a quality product. Nationalism is not at odds with sound business practices. India developed a strong domestic pharma industry because the policies we have had for 30 years were nationalistic. Today, the industry makes more money from selling its products to the west than it does in India. Rather than introspect on what went wrong, the reaction is to blame everyone but us. Pride is a dangerous thing, especially if it prevents people and nations from taking an honest inventory. A true patriot says "we can do better"; a false patriot on the other hand says "we are good enough". As we have begun to see, our problems are not limited to just one company; they are industry-wide. We better address them before we lose our standing in the international marketplace.

Big Pharma has been much maligned earlier and quality crisis is nothing new in this sector globally. In fact it was only last year that Grunenthal issued an apology for the 'Thalidomide Crisis' — 50 years after the actual crisis happened and changed the face of drug regulation. Your take on whether the Ranbaxy case is different from past ethical violations that have manifested in the pharmaceutical world globally? And if yes, how is it different?

You are comparing apples to oranges. The makers of Thalidomide did not intentionally set out to poison women and children; they were ignorant and did not think a drug taken by a pregnant woman could pass along the placental barrier. The regulations that govern the approval of drugs today, the extent of testing required are a direct consequence of the Thalidomide tragedy. What happened at Ranbaxy was not an accident caused by ignorance. People in positions of decision-making authority knew full well what the impact of their actions would be. This was callous indifference to human life; a devil's deal to put profits before patients and risk the lives of the unseen for the personal profit of a few. But yes, if your point is that the pharma industry seems to have a deep culture of corruption, I wouldn't disagree. But I am not sure the Thalidomide case is an example of that, however.

A couple of decades ago, in 1993, Harvard and Chicago economists Andrei Schleifer and Robert Vishy, in a pioneering article titled "Corruption" in the "Quarterly Journal of Economics," posit two hypotheses about corruption: (1) the structure of government institutions and of the political process are very important determinants of the level of corruption. In particular, weak governments that do not control their agencies experience very high corruption levels. (2) the illegality of corruption and the need for secrecy make it much more distortionary and costly than its sister activity, taxation. Which among these two views applies more to India's corporate drug regulation issues in general? Any thoughts on how to remedy the situation?

The annual budget for the CDSCO until recently for a country this large was less than $7 million. Are you surprised then that the bureaucrats are cosying up to the industry, that they cannot locate approvals (secrecy) that they gave to the industry to conduct clinical studies? When was the last time we had a person qualified in public health head the CDSCO?

Given the scathing reports in Parliament, the remedy now seems to be to appoint an appellate board consisting of more bureaucrats and a few functional experts (medical doctors) to oversee the regulatory body. What do we expect to accomplish with this new structure? Efficiency or transparency? Why is it acceptable for us to have a very qualified and extremely competent Governor of the Reserve Bank of India, an institution that oversees monetary policy and not for the institution that is responsible for public health of a country of over a billion people? Is public health not half as important as fiscal health for us? Compare the transparency in the processes of the RBI to those of the CDSCO; is there

a comparison at all? So it's true in this case that the structure of the institution and of the political processes are a key determinant of the state we find ourselves in today.

Plants grow stronger and faster when they are watered; likewise, as a society, we get more of what we incentivise. There are parallels in other democracies which work; they have worked for hundreds of years now. Laws like the False Claims Act have worked in the US in prosecuting corporate fraud in many situations, from healthcare to defence, from stock swindles to oil and gas price-gouging. People speak of incentivised integrity as a "bounty programme"; honestly, in the real world, if you want to get rid of a big fierce animal that is predating on the community, a bounty programme works very well.

I want to draw your attention to an emerging view in the strategy literature. Some strategy scholars have recently argued that it's not industry structure (inspired by Porter's 5 forces) or the resources (inspired by the resource based view and competencies of firms) that determine long-run competitive advantage of firms. It might be what some are calling it 'influence rents' — the rents certain firms over others are differentially able to extract from institutions — that might be determining success for a firm. One test of the fact that 'influence rents' exist comes from the existence of the lobbying industry, whether in Washington DC or Delhi. However, one wonders if this is a tenable argument for firms at large, more so Indian pharmaceutical companies and for brand-India in the long run. What are your thoughts on 'influence rents' and an institutional-based view of the firm for other competitor clusters of bio-pharmaceutical activity like in China?

Politicians, to some degree, run on payment, payola and "influence rents" all over the world. That is why law enforcement and regulation tends to be relatively weak the world over, and why some companies and sectors get bigger tax breaks or more support than others. From the honesty and quality control side, the fact that enforcement resources are always too small means whistleblowers are especially critical. In a world of small government, the whistleblower and his or her lawyer work as "force multipliers" for good government, while a private right of action means even if the government does not act, the case can still go to court and be seen in the full light of day. Will liars, cheats and thieves oppose such laws? Of course, that is natural.

Having said that, "influence rents" work only if you have a good case supporting your goal. For example, let's look at the policy for price control within India. Clearly, there is a very strong lobby representing OPPI which has significant say over the structure of the policy. However, if you acknowledge that these controls inhibit investments in innovation, and that a business has to make a profit to survive, how does limiting innovation to just "Indian innovation" help the public health system in the country?

I know you are legally obligated not to talk about the Ranbaxy case. But could you share some intuition on how Ranbaxy's actions could have micro-level implications? In terms of what employees develop as skill-sets, what it does to their motivations, and what might be the implication if Ranbaxy has seeded many employees in the industry in other spin-off firms. In fact, some research based on data from LinkedIn shows that Ranbaxy is amongst the highest seeding firms in the industry. So one wonders if there are micro-employee level implications coming out of the event in these days of nano-economics more than micro and macroeconomics — your thoughts?

There are some intrinsic challenges in succession planning and leadership development in India that I have noticed in my brief tenure at Ranbaxy and also at Sciformix, the company I co-founded and ran as its CEO for five years until last year. First, it's a very small group of people who rotate within the senior levels in the industry; successively reaching higher echelons of decision making with each transition. So your premise about seeding people across the industry is very valid. Second, in India especially, I have found that leaders have a real fear of developing their successors for a variety of reasons. There is a large gap by design between a Vice President who heads a function and his second tier, most often the second tier is a senior manager within the function. The hierarchical nature of organisations, especially in India, is designed to not empower middle management to make decisions; these decisions are almost always rolled up to the senior management. Third, there is a sense of entitlement among the employee base, they expect to be recognised/promoted by virtue of their tenure, not according to their accomplishments. This is true of generation X, many of whom have grown very rapidly over the last 10-12 years with a growing economy. Perhaps this is a remnant of the "administrative service" culture which became the core of the country until the early 1990s IT services revolution.

Culture plays a very important role in shaping people's perceptions and actions in terms of decision-making. I wrote an opinion piece in The Hindu where I argued that the much celebrated frugal-innovation, aka "jugaad" is the bane of our approach to quality. In organisations that largely remained hierarchical, fast growth came at the expense of building lasting institutional foundation, which is a hallmark of a sustaining organisation. People who worked for any length of time at Ranbaxy, who left to join other organisations subsequently, took their values and their managerial approach from the culture that they learned from. A good example would be to look at who is in leadership positions at other Indian pharma companies who have been pulled up for similar violations by regulators from the west after my case against Ranbaxy became public.

Now for some personal questions. I see that your Linkedin profile has a designation of you being a 'whistleblower.' Few know that the US has a long history of laws related to whistle-blowing. In fact if I am not wrong, Ralph Nader first coined the word and the constitution probably by law grants protection to the 'whistleblower', wiki tells me, from a legislation going back to 1778. In the context of emerging economies such as India, Brazil or China, i want to ask you if those kinds of protections will

help to unearth corporate frauds with a greater frequency in transitional and emerging economies? Or would it be contingent on the basic fabric of an individual wherever he/she is based in blowing the whistle, and will continue to be contingent on luck rather than on regulation?

The term whistleblower goes back to the British, when unarmed bobbies would blow a whistle to alert citizens and other bobbies in the area that a criminal was in flight. So, from the beginning, whistle-blowing has been about public-private partnership, with citizens and law enforcement working together for the community good. Some people will always come forward no matter what the cost, but they are rare. When you blow the whistle, the only thing you are guaranteed is that you will lose your job and possibly your career. If you happen to live in India, perhaps you lose your life as well; as has been documented in several cases.

Doing the right thing should not be a suicide plan, and that's what the incentivised integrity programmes in the US are about; if you report a big fraud, the government hits the company for treble damages and out of that sum they pay whistleblower awards, as well as the cost of lost interest, investigations and prosecutions. The fine has to be more than the cost of doing business, and sometimes it actually is. The system works and the government and taxpayers benefit.

Will incentivised whistleblower programmes work in India and China as well as the US? Of course, they will. People are the same all over the world. But for them to work, government has to prosecute wrong-doing and levy the fines, and there can be no sacred cows. These investigations are long and often very demanding. During such long, drawn-out investigations, the sanctity of the process and the secrecy of the information provided by the whistleblower have to be maintained. The legal justice system has to work, to protect the whistleblower while the allegations are investigated, and to guarantee the integrity of the investigation from compromise. These are pre-requisites of a functioning whistleblower framework. This is where the challenge is.

I want to go back to the topic of ethical production of drugs by the Indian pharmaceutical industry. They, after all, have had a big impact on welfare by supplying cheaper generic medicines across various therapeutic markets globally in the last two decades. What do you see as the way forward for this industry, especially in the light of higher regulatory burden coming from ethical adherence to quality? Will its success stories mellow or will one witness resilient push-back from firms in the sector — your sense?

It is true that the Indian generic pharmaceutical industry has had a significant impact on cost and availability of medicines in the third world. Markets in the US and western Europe are lucrative, but the Indian industry has made significant inroads into Africa and Latin America as well, which pale in comparison to the revenue that they generate from the west.

We have already discussed the existence of two sets of manufacturing standards within the Indian industry, one catering to the "regulated markets" and a different one catering to the so called "less regulated markets". The unfortunate issue is that there are no systems to assess the effectiveness and safety of these drugs that are made for the "less regulated" markets in those countries. Take India, for example, I was a part of the effort to devise a safety surveillance system which has now been implemented at a handful of centres across the country a few years ago. Until then, we did not have anything like this to collect and analyse information on the side-effects of drugs taken by patients across India.

In the west, the US FDA and the EMEA collect this kind of information which helps them establish the safety and efficacy of drugs in their respective geographies. In the absence of such systems in countries such as India, on what basis do we claim that our drugs have a material impact on public health? Do we have any data that tells us how many times a particular prescription has been changed because of drug-drug interactions? Many of our elderly take more than one drug today, perhaps one for controlling their blood pressure, another one to control their sugar levels and perhaps a third one for their arthritis. We have no data to assess how these formulations (remember, I am saying formulations, manufactured according to the standards for "less regulated" markets) behave in our patient population.

Let us also recognise that anyone can make generic drugs. We are not providing any secret information — all we have to offer is cheap labour, new factories, and good quality control. If the quality control is lacking, then it's all for nothing. Cheap labour will work for a while, but it's worth remembering how few workers it takes to run a light bulb factory in the west. We are not too far from completely automated generic drug factories; this is the natural evolution of the industry. The future is coming fast, and India would be well prepared if it puts quality first. Quality last will not cut it when it comes to prescription drugs.

Going to another key issue, the base of the pyramid markets, as it particularly pertains to people who don't have access to drugs, do you think drugs with less than sub-optimal efficacy is a welcome compromise to make? For example, daily dose wise — perhaps a doctor would want a 10 mg statin to be the optimal prescription for a poor patient anywhere in the world. But let's say this patient doesn't have insurance, and neither would he/she comply to RX-mandated daily dosage. In that case, how would/should pharmaceutical firms treat the issue? Is producing a 3 mg drug for this representative patient okay in your mind, for after all this patient will then get access in all senses (of course without compromising on bio-equivalence for sure)?

Medicines don't work in the way this question is posed. As a part of the testing process, innovator pharma companies establish what is called a "therapeutic dose". This is the dose that actually works to cure the symptom for which the drug is prescribed. So if the therapeutic dose is 10 mg, giving 3 mg of the same drug to a patient will not help. In fact, in

some areas, it is harmful to do so. For example, if you are diagnosed with a bacterial infection, taking a sub-potent drug will not only not cure your ailment, worse, it will engender drug-resistance bacteria. It is for this specific reason that the US laws define “adulterated” drugs as those which contain the active ingredient in quantities lower than approved by the US FDA.

How difficult has life been ever since 'Dirty Medicine'? How have your family and friends reacted to the situation? How are you planning to move forward in terms of creating awareness around corporate governance in Indian businesses? Any plans of writing a book or making a movie — a la Al Pacino’s Insider?

I am living life as it comes. I have a wonderful family and wonderful friends, and that helps a great deal. It is a comfort that it only takes a small candle to slay a lot of darkness. The world bends towards justice and integrity, and I believe that firmly. But no, I am not planning to star in a movie. I am thinking of how to help in the field of healthcare both in India and in the US. I have been given an opportunity to help, and providence says I must not squander it.

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