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MK Bhan: Biotech is not a business, its a societal tool

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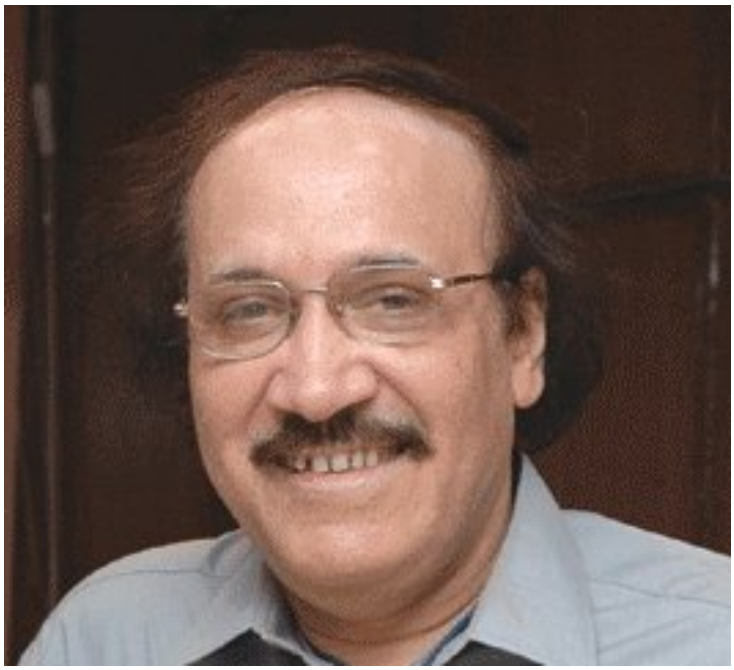

Dr Maharaj Kishan Bhan, former secretary of India's nodal biotechnology agency, is an eminent pediatrician and clinical scientist par excellence. His research in the area of diarrhoeal diseases and child nutrition is globally recognized. He has been the brain behind a Rota viral vaccine, which has not only created a new paradigm on health and international interaction, but also put India on the path of novel vaccine development.

During his decade long stint at DBT, he has brought in new thinking and dynamism to the area of biotechnology. It was no different when *BioSpectrum* recently caught up with him in the late evening at his office which was still abuzz with calls and visitors. In an exclusive interview, Dr Bhan talked at length about various issues pertaining to Indian biotechnology sector. Excerpts from the interview.

Does the growth of biotech industry in recent years match upto your forecast? How does the future of biotech in this country look like?
During last couple of years, the industry at an average has witnessed twenty percent growth. And at the moment even with the lower denominator, we must be happy as it is the time to recognize that global economies are not doing well. It is important to foresee that we are investing resources in a way that in future, the pipeline of export oriented products be the only parameter. For example how many new molecules are entering clinical trials. With the science growing deeper and broad based, pumping money into multi-disciplinary fields is a must to do.

My concern really is that science should become more inventive. I think that worries me more than anything else. As long as we keep working on the way scientific questions are asked, the inventiveness of science and the ability to grow translational capacity in a way whether it is through PPP or purely through industry or public transfers will be critical. The government is expanding health spending with thirty percent increase in government hospitals, and medical admissions.

It plans to open another thirty world class medical colleges. Moreover, there are tremendous opportunities in the other areas as well. Therefore, we should be doing lot of things to prepare for the time when the market is much bigger. We should not be hesitant in investing for future. That is how I see twenty years down the lane. The question should not be how big we will be in five years but how strong we will be in twenty years.

What about the demand and supply? How can the growth assessment be done?
Growth is about demand and not only about science. For example, non-generic drug industry requires ample demand. That is essential, as its absence will hamper investments into research and purposeful output. What is required is the technology driven by innovation landscape together with promotion of entrepreneurship and industry-academia interaction. My confidence arises from the government policy for expansion of the health sector. It is the demand push and users of medical technologies that will drive the industry. Above all we must take a long term view of biotechnology.

One thing that I have learnt over past five to six years is that biotech output must be measured only through societal transformation. I think it is a mistake to look at biotech as a business as there are as other much easier ways of making money. When you look only at the percentage type growth assessment, it makes the whole process meaningless. The correct way is the measurement of impact created by biotechnologies on meeting healthcare and other needs.

What are your views on the regulatory approval process in the country and the latest developments on the proposed Biotechnology Regulatory Authority of India (BRAI)?
We are currently going through the host of issues. Human greed is creating havoc with the system. Apart from that, mounting energy requirements too is a reality. The only way out is science and technology. Therefore we have to be nimble for the future.. I always believe that our regulatory system has matured a lot and is well capable of handling issues except at the level of commercial release of the product. BRAI was meant to streamline the efforts in this direction. We are experiencing difficulties for long in passage of the bill in the parliament because of concerns that can be readily removed.

For example if there are concerns on upmanship of one ministry, then chief secretary can function as a nodal person for all the ministries. The authority can have a chairman of high stature and management followed in a way that best practices are followed with respect to training, standardization but also enough number of people. One thing is very clear and that is everybody to understand that nothing can be gained by opposing BRAI.

For me regulation is in two steps. One is scientific evaluation that requires best scientists and processes that match the opposition with best practices in world. Well at the same time, this is also a reality that we can't have every Indian on it but what is important is that it has the most stringent regulations to satisfaction of all. The second part is that of commercialization and that involves state governments, central government and civil society.

These are issues of policy. We haven't stopped manufacturing drugs because these are expensive. We have an essential drug pricing strategy and same can be applied to agriculture. Scientific committees cannot be decision makers. After all a scientist is not going to tell you what to eat or not. However, I believe that we should separate the assessment of risk from the commercialization part. After all this is a democratic country and even after all the debates, I think the consumer must be the final authority to choose and decide. So let the benefits of technology reach them and either they will take it or just ignore it.

Recently you had said that diagnostics will be the next big focus of DBT. What are the steps taken in that direction? Which are the other priority areas?
There are tremendous opportunities in the areas of detection, prognosis and surrogate markers. The best way to look at it is through problem. We do an analysis and we come to know that diagnosis can play an important role in clinical trials management practices. Likewise in agriculture, animal husbandry and diagnostics sector, we need to create this central innovation system. We can then have well defined opportunities. Then they start asking what are the tools we can use for business opportunities.

Diagnosis along with new therapeutics can become the foundation of modern medical care. In chronic diseases, testing precautions are being exercised . That means if you meet requirements of million diabetics, we can make their life better on to better. And makers of progress or lack of it. It requires information technology and telecommunication to be used. It

requires reworking of system when patients and facilities can self monitor. For all other disease, it can be what biomarkers can do to the process of drug development. I think there are fantastic opportunities in the areas of diagnostics, vaccines, cytology, pathology and others.

Given the deadlock on Bt crops in the country, what according to you are the steps required to create awareness and connect with the common man on the issue?
My only concern is the hindered agricultural growth. We have to address wherever there are concerns. One way is that we effectively explain the technical as well as social dimensions of the agri-biotech.. When we say technology, the question is for whom. We have rich farmers and marginal farmers. To provide for both, there is a special policy issue. Again the technology renewal after a decade because of development of resistance due to abiotic stress.

If we concentrate on things that are in public area and are of huge importance to public such as rice, wheat, legumes etc, it can lead us to extremely important results. Secondly, we must have a strategy for small farmers. So that hybrids in variation must be pushed concurrently. And it also means now that we really augment our institutional capacity in genomics, bioinformatics and breeding. There is a capacity enhancing challenge and then its up to them to decide.
However, I don't think we must withdraw because of current difficulties in transgenics. The R&D must continue despite the commercial release getting delayed.

What about the arguments going on about choosing certain crops of interest for transgenics ? Is it demoralizing the effect for the industry in the long run and where does it lead us?
We should use transgenics where there is no option. The strategy must be to focus on big need rather than small one. For that the approach, one should not ask which technology but choose the right technology. Its the tenacity of efforts to win public opinion. We must work on a basket of technologies and not just the easier ones. We have traditional technologies such as MAS, and hybrids and simultaneously look for more transformable technologies. For those such as RNAi and others that are in nascent stage, we must continue to evolve. My whole feeling is that in case of any disruptive technology, there will always be challenges of acceptability and clarity.

I would say that this is not a mature way in twenty first century to handle such a complex issue. We should have courage to say we don't want to use it but we can't just destroy the regulatory system. Lack of clarity in assessment of risk and decision making for commercialization because there is no proper system in place for that. A particular state government might say that they don't want it but others who are interested can't be stopped from availing the benefits.

We must surely ask the questions that are legitimate enough but not at the cost of weakening the regulatory system. This is the country of Mahatma Gandhi. You can't use unfair measures for a purpose you believe is right. It is strange that few people doubt the quality of our products even though approved by RCGM. And that too after statistics show that 60% of these are being exported. I don't think these worries and negativism are justified when the available data suggests otherwise. Apart from various committees that surely require a full time chairman, there could be a committee of secretaries of ministers for discussing joint proposals at length to weed out any doubts that might crop up later. The agriculture ministry too can create the unique commercial set up for societal assessment of products.

Are you satisfied with the outcome on various projects for boosting R&D and PPP in biotech industry? How do you view relevance of bioclusters for the future?
I think the programs like BIPP and SBIRI have really helped to foster innovation and promote the industry. The Biotechnology Industry Research Assistance Council (BIRAC) is a right step in taking that further. There has been substantial progress but the glass is still half full. Would love to see the increased biomedical capacities, new diagnostics tools, affordable agricultural techniques among other various things. Scaling up of existing technologies through collaborations within the industry and also academia too is highly relevant for the sector to make an impact on the society in the long run.

The bioclusters are a step towards deeper scientific and business collaboration. We need enough such clusters and knowledge cities to promote innovation in the sector. Currently the development of three clusters at Mohali, Faridabad and Bangalore is underway. Redesigning the strategy consistently is very important for the industry, academia and policymakers to sustain the industry.