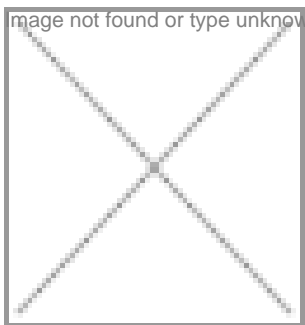


Risk-averse society to stunt biotech growth

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More biotech drugs than conventional products are getting approved in many nations than a decade ago. This does not however mean that the biotechnology industry will be on a roll in the coming decades. Some recent regulatory decisions against some promising products have put a rosy path for some time to come.

As I write this editorial from Washington DC while attending the annual Bio International Conference, came a devastating news. A panel of experts appointed by the US regulator, the Food and Drugs Administration (FDA), has recommended against the use of the world's largest selling anti-breast cancer drug.

Reluctantly approved in 2008 as a promising cure against breast cancer, Genentech's Avastin had zoomed to the top of the biotech sales chart quickly to garner global revenues of \$6.8 billion. The healthcare community and patient groups have been raging against each other over the efficacy of this drug which costs over \$88,000 for a year's treatment. The regulator decided to withdraw the drug in December but agreed to a wider review by experts. With the experts voting against the use of Avastin in the treatment of breast cancer, the FDA chief will have very little option but to implement the recommendation.

Of course, this does not mean the end of the road for Avastin which has been approved in the treatment of other types of cancers in combination with different sets of drugs. What about the fate of 17,500 women in the US and an equal number in other countries who had found some hope in Avastin treatment in the last two years? Most of them along with their families have made the informed choice to get Avastin treatment despite the enormous costs involved. Should these patients be denied the few extra months of life which the drug has given because of the fear of other side-effects.

It is easy to blame regulators. But regulators are not part of the problem. Biotech scientists are near unanimous that the regulators are only responding to the signals from the society which has become increasingly risk averse. Progress in science happens in stages and acceptable risks are part of the drug development process. But even as people revel in the marvels of modern science, risk aversion in every walk of modern life is percolating to healthcare too.

The evidence of this comes from other parts of the world too. Cucumbers have disappeared from kitchen all over Europe after the e.coli outbreak was traced to a batch of organic Spanish cucumbers. This is not the first outbreak linked to organic products. On the other hand, genetically modified (GM) food products are scientifically proven to be safer than organic products. Yet the advances of GM technologies are restricted to just a handful of nations. India's reluctance to allow the consumption of its first GM food, a transgenic brinjal variety, is an example of the risk aversion philosophy triumphing over science. In the US too, a politically motivated move has slowed the approval process of the world's first transgenic animal food, the GM salmon which could supplant the protein supply caused by the large scale depletion of natural salmon due to over fishing and environmental causes.

Biotech industry leaders have some more work to do outside their R&D centers to win public support for their work. The industry has not done a good job of this so far.

After the ranking of India's Top 20 biotech companies, it is time to do the same for key technology enablers who are an integral part of the biotechnology industry. The BioSuppliers industry has registered a 19 percent growth over the previous year's single-digit growth numbers. This segment with revenues of 4,600 or \$1 billion is an indicator of the status of the core biotech industry. Some credit should also go to companies like Spinco Biotech which has zoomed to the No.1 rank with an amazing growth of 80 percent. The vibrant tech enablers community is an integral part of the biotech ecosystem and their significant contribution is a booster for the industry.

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