

Bottle of Lies, Cabinet of Neglect

It is because India’s drugs authorities have been so lax that Ranbaxy-type frauds happen, poor quality persists

UNDER NORMAL CIRCUMSTANCES, US-based investigative journalist Katherine Eban’s *Bottle of Lies*, primarily based on the fraud in Ranbaxy, may not have created the stir it did. After all, frightening as the faking of data at Ranbaxy was, much of this is well known; and though Wockhardt, Mylan, GVK Biosciences, Zydus, Dr Reddy’s feature in the book in varying degrees, the book is really about Ranbaxy. What makes the book’s subject more worrying is the number of US FDA actions on various Indian pharmaceuticals firms. Just earlier this month, the FDA pointed to the destruction of quality-control paperwork and scant documentation of safety tests at the Strides Pharma’s plant in Puducherry and said that this raises questions about quality control at Strides and the ‘integrity and accuracy’ of its data. Last month, the US regulator had warned Aurobindo Pharma for ignoring impurities in valsartan, the anti-hypertension drug it produces. The FDA has issued 209 warning letters so far, of which nine are to Indian Pharma companies, versus eight out of 419 in 2018.

It is, of course, possible to allege a bias in such reporting; Eban, after all, nudges readers to trust top brands, from patent-holders, over generics. And the well-known revolving door that allows FDA officials to move to US pharma firms does put a bit of a question mark over the findings, more so since Indian generics are making inroads into US markets. But if, after all this, people are willing to believe Eban, it is due to a colossal failure of Indian authorities to regulate; this is made worse by the desire to understate the extent of the problem. India’s drug regulator, the Central Drug Standards Control Organisation, for instance, is woefully understaffed; against a recommended 4,200 drug inspectors (based on the Mashelkar Committee formula), the total number of sanctioned posts in the states and UTs, as of April 2018, was 1,600 and just 1,200 were actually filled. Similarly, in January 2019, there were just 224 inspectors with the CDSCO against a sanctioned 510. This is compounded by varying regulatory regimes in states; as a result, drugs declared to be sub-standard in one state may still get sold in another before the regulator of the latter catches up. India may not, unlike Ranbaxy-whistleblower Dinesh Thakur argues, have two standards for drugs manufacture—a superior one at FDA-approved labs and an inferior one for the local population, but various studies from time to time report poor quality drugs. A few years ago, the CAG reported that 15-31% of the drugs drawn from different Armed Forces Medical Stores Depots were not of standard quality. And yet, most official studies point to very low levels of spurious drugs in the country even though most in the industry cite numbers ranging from 25-40%; government controls on prices that leave wafer-thin margins are another reason for the proliferation of spurious drugs.

Rather than trying to shout down those who talk of a problem in India’s drugs production and regulatory regime, and a bias in the writings of those like Eban, India would be better served by strengthening its regulatory regime. It is a sad day when both drug manufacturers and government officials boast of how many FDA-certified production facilities India has instead of talking of how strict Indian quality control is; that is the surest proof of the fact that the Indian regulatory system is all but non-existent.

No country for girls

Male child preference is back, with a vengeance

INDIA’S DECLINING TOTAL fertility ratio (TFR), in both rural and urban areas, may be good news, but read along with the sex-ratio at birth (SRB), the country may be headed towards a demographic disaster. Thanks to many factors, such as the improvement in education levels, especially among women, and access to healthcare and contraception for women, the TFR fell to 2.2 in 2017—just above the WHO recommended replacement level of 2.1. The SRB, as per the Sample Registration System (SRS) data, however, fell to an all-time low of 896 in FY17. As per a *Times of India* analysis, this means 117 lakh girls are missing in the country. This is unfortunate since the SRB had been improving over the past few years; it was 909 females for every 1,000 men in the three years ending 2013. More worrying, the SRB is lower in urban areas; at 890, it is much lower than the 898 in rural areas. And, while the SRB rose in states like Uttar Pradesh, Bihar, Maharashtra and Gujarat that were traditionally seen as laggards, a state like Kerala that had a high SBR traditionally saw a big dip, from 974 to 948.

While the fall in fertility rate is welcome, combined with the decline in the SBR, this means India is likely to continue to see a fall in fertility rates; over the next couple of decades, India could be looking at a big dependency problem. The sex ratio skew hints at illegal sex determination and related termination of pregnancy thriving despite the laws to crack down on this. A crackdown in Punjab—a state with one of the worst SBRs in the country—resulted in, so far this year, 60 sex-determination centres being caught. Factor in the advances in assisted reproductive technologies, and the fact that India’s IVF market is booming, and sex selection becomes a formidable beast to defeat. Given how the existing laws banning sex selection have not been able to prevent it from happening illegally, the Indian Medical Association had demanded the repeal of the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act earlier this year, saying that the law unfairly puts the onus of stalling sex selection also on the medical and para-medical fraternity. However, against the backdrop that the SRS paints, such a demand is not only unsound, it is harmful too. For its part, the government must realise that its *Beti Bachao, Beti Padhao* needs to be re-tar-getted—it is focussed primarily on the poor and in rural areas whereas the problem is equally large in urban areas and among the not-so-poor.

AidsFALL

UNAIDS says, for the first time, there is a shortage of funds to tackle HIV/AIDS

THE UNAIDS’S GLOBAL AIDS Update, *Communities at the Centre* report, highlights the lack of funding for tackling HIV and AIDS globally. The report notes that for the first time, global funds for tackling AIDS and HIV have fallen by almost \$1 billion. The report also shows that there has been disparate progress both regionally and amongst focus groups in tackling HIV/AIDS. AIDS-related deaths have declined by 33% since 2010, to 770,000 in 2018—but this progress has been different across regions. The report shows that since 2010, AIDS-related deaths have increased by 5% in Eastern Europe and Central Asia and by 9% in Middle East and North Africa. While the report acknowledges the progress in terms of curbing and tackling HIV and AIDS-related deaths, this progress has been unequal, with high-risk groups—gay men, transgender people, sex worker, intravenous drug users and prisoners—still excluded. In 2018, 95% of new HIV infections in the aforementioned regions have been from these groups. And, less than 50% of the high-risk groups were reached out to with HIV prevention services in more than half of the countries. How big a miss that has proved to be is evident in the fact that these groups account for 54% of the new HIV infections globally.

The shortage of funds is due to a global fund crunch and domestic efforts lagging the scale required. As of 2018, \$19 billion was available for AIDS response—\$7.2 billion less than the required \$26.2 billion needed to be raised by 2020. The UN has called for donors to give at least \$14 billion to the Global Fund to Fight AIDS, TB and Malaria. If donors and political leadership of developed countries don’t take the lead in replenishing AIDS funding, realising the Sustainable Development Goal on health will be difficult—curbing HIV/AIDS to the desired level might take longer than 2030, leading to a higher burden from the infection.

● TAX TERRORISM

TAX DISPUTE DATA SHOW THAT NDA II HAS FAILED TO TACKLE TAX TERRORISM, AND THE LEGACY PROBLEMS OF HIGH-PITCH DEMANDS & LITIGATION DELAYS CONTINUE

Tax justice has broken down

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Views are personal



officers tell many corporates that they have a target, they know they are wrong, and then make the corporates pay taxes against high-pitch assessments, tell them to appeal while assuring the latter that they will get refunds in appeal. In some instances, they have even frozen corporates’ bank accounts to force them to pay advance tax! Look at the balance-sheets of the top 30 ethical companies in India. Contingent liabilities created because of tax disputes tell their own story. As per Receipt Budget FY20, in Reporting Year 2017-18, the corporation tax amount under dispute, at ₹3.99 lakh crore, is 5.8 times the corporation tax not under dispute (₹0.69 lakh crore). This ratio was lower, at 3.7, in Reporting Year 2013-14. What started in the UPA era has risen under NDA II—a failure of the political leadership! The political leadership seems to have become victims of tax officers and has lost sight of its duty to protect honest citizens from perverse assessments. Tax justice has broken down!

Tax officers needlessly pursue appeals at higher levels, regardless of the outcome, since there is no penalty on the I-T department and its officers. Resolution at CIT (Appeals) take about two years, 3-5 years at ITATs, 5-8 years at High Courts and about five years at the Supreme Court (SC). It is common

knowledge now that tax dispute in India normally takes 15-20 years from the time an assessment is completed to the time the SC possibly takes a decision. In some instances, even the SC decision is not given effect to urgently, and obviously, CBDT doesn’t seem to review or care!

The I-T department is the largest tax litigant in India. The 2018 Economic Survey states that, of the total number of direct tax cases pending, the department has initiated 88% of the litigation at ITATs and the SC, and 83% of the litigation pending at High Courts. The success rate of the taxman for both direct and indirect tax litigation at all levels is under 30%. The 2017 CAG report states that the I-T department loses 65% of its cases. Over a period of time, its success rate has only been declining. But our political leadership again has failed to protect taxpayers.

The CBDT, in July 2018, enhanced monetary limits for filing of appeals by the I-T department before the ITATs (₹20 lakh), HCs (₹50 lakh) and SC (₹1 crore). These would prevent tax officers from routinely filing frivolous cases and enable a judicial focus on high-value litigations. Even while these limits are per se very low for a meaningful impact, the CBDT has to repeatedly urge its officers to with-

draw all pending appeals before a certain period. Even the CBDT writ does not seem to work!

A perusal of all the above makes one come to the inescapable conclusion that NDA II was not successful in keeping its promise of ending tax terrorism. On the ground, not much impact has been felt even though processes and technology seem to have been improved. Tax disputes remain as high as before. When NDA II came to power, the amount of tax dispute in March 2014 was ₹4.10 lakh crore as per Receipt Budget 2015-16—it was up by 50% to ₹6.24 lakh crore in March 2018, as per Receipt Budget 2019-20. Jaitley, in his 2016 Budget speech stated, “Litigation is a scourge for a tax-friendly regime and creates an environment of distrust in addition to increasing the compliance cost of the tax payers and administrative cost for the Government.” He made many such statements, but seems to have promptly forgotten them.

The government has failed to protect citizens and business from a tax system that has run amok with a broken assessment system and a broken appeal system! No major country has both broken. Tax officials seem to think of everybody as evaders and themselves as vigilantes! We have filed returns in over 30 countries, but no country treats taxpayers as badly as India does. There can’t be ease of doing business unless the taxation system is fair and effective. Several committees, from the Kelkar committee to the Shome committee, have suggested solutions, but these have been given scant regard. The government must decide on implementing the panels’ suggestions and treat taxpayers fairly. The NDA thanks the tax payers in the budget—never the case with the UPA—but the rest of the treatment remains almost the same.

The PM is committed to improving Ease of Doing Business. But the most significant ease would come from fair, equitable tax assessment with no high-pitched demands and appeals decided in 3-4 years. We hope the PM and the new FM tackle the biggest impediment to Indian business becoming globally competitive, and India being respected globally for a fair tax system.

LETTERS TO THE EDITOR

Nationalisation of banks in India

Appropos of ‘Indira Gandhi killed banks, no one there to fix her folly’ (July 17). Mrs. Gandhi nationalised 14 banks in 1969 and six more in 1980, ostensibly to help the poor get loans on easy terms. However, the real beneficiaries turned out to be her own party men and industrialists favourable to her, who availed huge loans from these banks that were never repaid. Even the loans *melas* that were regularly held at these banks only benefited the brokers and middlemen of the Congress party, with only a small portion of the distributed (!) loans reaching the actual beneficiaries. Soon after the first round of nationalisation, one got a taste of the shape of things to come in May 1971, when the infamous Nagar-wala case played out at SBI, Parliament Street Branch, the full facts of which are not known even today. Far bigger scandals and frauds have since happened in the state owned banks, leaving them saddled with huge non performing loans that have been written off at periodic intervals, resulting in their capital erosion, followed by recapitalisation with taxpayers’ money. Nobody expects the BJP government to privatise the public sector banks (PSBs). All said, they are needed for implementing the government sponsored schemes and projects, if for no other reason. But the least that the Modi government could do is to merge the weak banks into the strong and ensure that they are run professionally. If this is not done even during the second term of Modi Rajya, there is no hope for the PSBs to ever be reformed.

— V Jayaraman, Chennai

● Write to us at feletters@expressindia.com

Screen weak pills to save drug costs

It is easy to assume once we’re taking a drug that we would have been sicker, or dead, if we weren’t taking it. But in some cases, we would have been fine—or better off

MANY OF THE prescription drugs Americans struggle to pay for don’t work very well, and if we were better informed, we might not consider them worth the risk of side effects. Buried among the mediocre drugs are a few that do add years of life or alleviate significant suffering. Clarifying which ones really are lifesavers—such as insulin, drugs for HIV and hepatitis C—would help get those drugs to the people who need them, and help spare everyone from unnecessary medication.

Medical costs, especially drug costs, have rightly taken centre stage in political debates as prices continue to rise and surveys indicate that cost deters many people from filling prescriptions. The problem has needlessly spread: The number of prescriptions being written has tripled in the last 15 years, but this has not been matched by a tripling of the number of miracle cures and magic bullets.

How are we consumers to know which drugs we really need? Drug companies skew statistics and market heavily to make their products sound much safer and more effective than they really are. Philosopher Jacob Stegenga argues in “Medical Nihilism” that we’re all assuming medicine has much more power to heal than it actually does. Which makes sense: Many products that are heavily advertised are overrated. The drug industry spends approximately \$30 billion a year on marketing.

Ad campaigns can “raise public awareness” of problems that were

essentially invented to sell drugs. Consider the blockbuster eye drop Restasis, which has very little effect on anyone’s eyes. Ad campaigns scared people into thinking they had “dry eye syndrome” and risked permanent damage without treatment. Another popular campaign convinced healthy men to take testosterone by raising awareness of “Low-T of aging,” though the risks of taking the drug are likely to outweigh benefits for those without certain health conditions.

Some of that \$30 billion marketing money goes to influencing physicians. Many receive generous speaking fees, are taken on junkets, or are named “influencers” and treated to fancy dinners and luxurious hotels. Psychologists who study conflicts of interest have shown how this has an insidious effect: Doctors think they are not being influenced by their industry benefactors, but they do prescribe more of those companies’ drugs.

The press can also boost marketing by parroting statistics put out by industry press releases, some of which are true but misleading. In “Doctoring Data,” physician Malcolm Kendrick shows how a study can be spun to suggest a drug will save 50,000 lives, but the same data can be read to say that of 200 people taking the drug, 199 will get no benefit and the other one will live only several months longer.

The more impressive number of “saved” lives is derived from assuming that millions of people will take the drug and that a couple of extra months

FAYE FLAM

Bloomberg



KISAN SATYAGRAHA

The gene is out of the bottle

The Kisan Satyagraha shows that Indian farmers understand their needs, and are willing to seize the opportunities that come their way, in the form of new technologies and new markets. The Bt experience reconfirms that farmers' grasp of the ground reality is far better than that of the political leaders who claim to protect them, or the many social activists who claim to care for them

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OVER THE PAST one month, the Kisan Satyagraha in Maharashtra has firmly placed the issue of genetically modified (GM) crops from farmers' fields onto the political agenda. The only question that remains is whether these crops will enter the market legally, safely and profitably? Or will GM seeds enter our markets illegally, without any security or safety, and leave in its wake windfall profits for the unscrupulous producers of seed, while many honest farmers and businesses face the prospect of ruin due to uncertain quality of seeds.

The saga of HTBt cotton

The herbicide tolerant (HT) Bt cotton seeds are not approved by the regulatory agencies in India. Yet, in 2017, a team from the Department of Biotechnology found that around 15% of the cotton being grown in Andhra Pradesh, Gujarat, Maharashtra and Telangana had the HT gene. At least a few lakh farmers have surreptitiously tried out the unapproved HTBt cotton. They have even named it to be "chor Bt"! This is the largest field trial of a GM crop possible.

Bt cotton incorporates a gene from a naturally occurring soil bacterium that makes the plant resistant to bollworm. Traditionally, cotton fields, including Bt cotton, require weeding, which is a labour-intensive, time-consuming and a costly exercise. The new HT characteristic makes the plant tolerant to herbicides, enabling farmers to spray herbi-

cides to quickly and cheaply eliminate the weeds that compete with the plants for soil nutrients and moisture.

The satyagraha

The Kisan Satyagraha was launched in Akoli Jahangir, a remote village in the Akot taluka of Akola district, Maharashtra. A farmer, Lalit Patil Bahale, symbolically sowed the seeds of HTBt cotton on a two-acre field in his own farm, on June 10, 2019.

Lalit Bahale decided to publicly sow the seeds of his own choice on his own field, and at his own risk, despite the uncertain origins of HTBt seeds. Lalit wanted to turn "chor Bt" into "hakkache Bt," underscoring farmers' "right to Bt."

It was a brave act of a lone farmer, born out of utter frustration at the stranglehold of regulations that have tied up Indian farmers and restricted his access not just to seeds, but denied access to new technologies and the wider markets as well. The thousand-odd farmers gathered in Akoli Jahangir village shared Lalit's frustration.

It has turned out to be Indian farmers coming out party! With the monsoon finally arriving, the instances of a similar satyagraha by farmers have spread rapidly.

History repeats itself

Lalit Bahale is an activist of the Shetkari Sanghatana, and also its national spokesperson. His family farms about 60 acres of land, and they have not grown cotton for quite a few years now

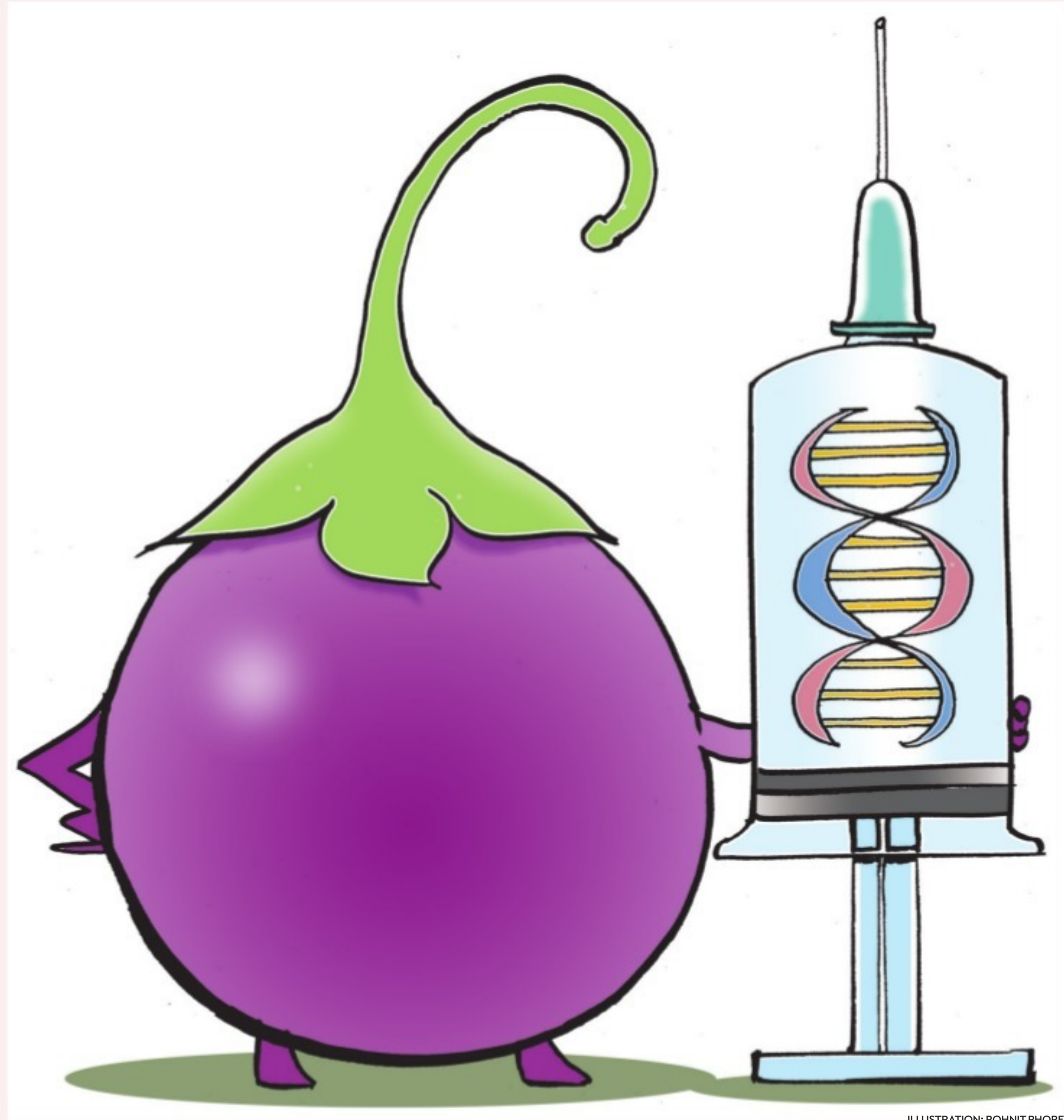


ILLUSTRATION: ROHINI PHORE

because of rising labour costs, having shifted their emphasis from field crops to orchards.

Shetkari Sanghatana is the farmers' organisation founded by late Sharad Anantao Joshi in 1979. Between 2000 and 2002, Joshi led the farmers to a heroic struggle for the first and only GM crop so far approved in India, Bt cotton. Lalit Bahale was among the thou-

sands of volunteers from Maharashtra who had gone to defend their fellow farmers in Gujarat who had been planting the then unapproved Bt cotton. The government had ordered the illegal crops to be destroyed, but the prospect of large-scale civil disobedience deterred the state from taking any action. Within months, Bt cotton was approved at the end of March 2002, and

the rest is history. Today, well over 90% of cotton in India is genetically modified, with the Bt gene being incorporated into hundreds of varieties that are locally relevant.

The regulatory maze

Powered by Bt cotton, over the past decade, India has emerged among the world's top producers, and exporters. In

fact, cotton is the most successful crop in India, since the Green Revolution.

Across the world, a dozen GM crops have been approved, and hundreds of millions of people, including Indians, have been eating these for a decade or two, without any adverse impact on human or animal health. In fact, millions of cattle in India feed on seeds from GM cotton, which have proved beneficial for dairy animals.

Yet, 20 years later, the mindset of the government in India and the regulatory environment has remained unchanged. For ten years, two successive governments—irrespective of political ideology—have failed to approve any new generation of Bt cotton. While Indian farmers are stuck with the second-generation Bt cotton approved in 2006—and its yield stagnating in the recent years—the world has moved on to the fourth- and fifth-generation Bt cotton. Today, 60% of the cotton grown in the world is estimated to be HTBt.

Despite being the same protein Cry1Ac used in Bt cotton and Bt brinjal, Indian regulators have attempted to reinvent the wheel. The Bt gene has also been used in other edible crops such as soya and maize, in the US and other countries, for over a decade. Yet Bt brinjal in India became perhaps the most rigorously tested vegetable ever. And even after it was recommended by the regulatory body, the Genetic Engineering Appraisal Committee (GEAC), in 2009, the political leadership has continued to abdicate its responsibility and imposed an indefinite moratorium.

However, Bangladesh approved the same Bt brinjal in 2013, and around 50,000 farmers have adopted it so far. Last year, the GEAC asked Bangladesh for data on the performance of Bt brinjal in their country. Bt protein has proved to be an effective defence against the fruit and shoot borer, which poses a very serious threat to the brinjal crop. But there are other sucking pests as well, for which farmers still need to use some pesticides, and adopt other practices.

The gene is out of the bottle

The Kisan Satyagraha shows that Indian farmers understand their needs, and are willing to seize the opportunities that come their way, in the form of new technologies and new markets. The experience reconfirms that farmers' grasp of the ground reality is far better than that of the political leaders who claim to protect them, or the many social activists who claim to care for them.

The genie is out of the bottle! Farmers want to enjoy the same freedom to choose the gene in their crops, just as every other sector of the economy chooses the technology of its choice.

(This is the first of a two-part series.)

DATA DRIVE

Motown enters slow lane

SALES OF PASSENGER cars and two-wheelers are going through a prolonged downturn as economic growth has slipped to a five-year low, income growth has slowed down, rural demand is weak, and lending institutions, especially the non-banking financial companies (NBFCs), are facing liquidity crunch. Passenger car sales fell for the 12th consecutive month in June, barring October last year, and two-wheeler sales collapsed for seven months in a row, data from SIAM show.

Even vehicle registration tracked by the Federation of Automobile Dealers Associations, a better indicator of retail vehicle sales, fell 6% across segments in the three months to June this year. The dealer association underlined that while the passenger vehicle inventory has eased slightly, commercial vehicle and two-wheelers' inventory has risen.

Liquidity is one of the important factors impacting auto sales as all commercial vehicles, eight out of 10 passenger vehicles, and around half all two-wheelers are financed by banks and NBFCs. Vehicle loan growth in May slowed to 5.7% y-o-y from 10.4% last year as lenders have become cautious in both retail and dealer financing.

Over the past five years, the size of pre-owned market has expanded significantly, with higher share of organised players. Higher growth in pre-owned cars over the past two years is a reflection of rising consumer interest in this segment, which is also impacting sales of new vehicles.

Auto industry faces prolonged downturn

Domestic sales, % chg, y-o-y

Passenger vehicles

Two-wheelers

33.4

23.8

18.4

16.9

19.7

9.2

22.3

37.5

8.2

2.9

4.1

17.2

7.2

-0.4

-1.9

-1.1

-3

-16.4

-17.1

-20.6

-11.7

-17.5

June 2019

Source: SIAM

Vehicle registration slumps across all categories

% chg, y-o-y

March

April

May

June 2019

Passenger vehicles

Two-wheelers

Commercial vehicles

Three-wheelers

Total

-10

-2

-1

-4.6

-7

-9

-8.6

-5

-12

-16

-19.3

-6

-4

-2.8

-8

-8

-7.5

-5.4

Source: FADA

Growth slowdown reflected in auto sales

GDP, % chg, y-o-y

5.5

6.4

7.4

8

8.2

7.2

6.8

6.8

Source: CSO

Individuals put off high-value purchases as income remains muted

(Growth in salary bill of listed companies; % chg, y-o-y)

5.6

7.3

8.3

12.2

12.8

12.2

13.8

7.4

Source: Capitaline

RBI's Consumer Confidence Index dips again

Future expectations index

Current situation index

128.4

97.3

Mar 2014

May 2019

Source: RBI

Growth of bank credit for vehicles slows down

% chg, y-o-y

19.2

12

10.4

5.7

May 2016

May 2017

May 2018

May 2019

Source: RBI

Finance from banks/NBFC drives sales

100%

for commercial vehicles

80%

for passenger vehicles

45-50%

two-wheelers

Pre-owned car sales outpacing new car sales

(in %)

Used car sales

New car sales

12

10

8

6

4

2

FY17

FY18

FY19

Source: Edelweiss